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SYNCHRONOUS PRIMARY CANCERS OF THE RECTUM AND PROSTATE: MONOCENTRIC EXPERIENCE AND REVIEW OF THE LITERATURE

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Introduction: Prostate and rectal carcinomas are two of the most common cancers in males and both increase in incidence with age (1). There is a number of small case series but no large series of synchronous cancer treatment outcomes has been reported, when a synchronous diagnosis is made (2). We collected data from patients affected by prostate cancer who were admitted to our Department in the last 10 years, and thoroughly reviewed the literature in research of patients with synchronous primary carcinomas of the rectum and prostate (SCRP). *Materials and Methods:* From January 2005 to May 2016, a retrospective analysis of patients with synchronous diagnosis of adenocarcinoma of the prostate and rectum was performed. Management of synchronous cancers was discussed at combined multidisciplinary team. Moreover, in order to produce analytical results, we performed a review of the published literature in PubMed database, using "prostate cancer", "rectal cancer", "synchronous","simultaneous" and their combinations as key phrases. *Results:* 11 patients (mean age, 61.7±9.8) were diagnosed with rectal and prostate cancer. 7 patients had synchronous carcinoma of the prostate and the lower two thirds of the rectum. The remaining 4 patients had metachronous prostate and rectal cancers. In 5 patients rectal cancer was detected as a part of conventional screening for prostate cancer (PCa) with digital rectal examination (DRE). The presenting symptoms for rectal cancer were rectal bleeding (n:5), incomplete obstruction (n:1), tenesmus (n:2), and incidental diagnosis during imaging for PCa (n:3). 8 patients had no evidence of metastatic disease at presentation and were treated with curative intent. 3 patients had sites of metastases, and therapy was targeted towards symptom control: lung (n:2) and liver (n:1). 5 patients underwent a radical prostatectomy (RP), and subsequently received chemotherapy for rectal cancer and then had an anterior rectal resection. 2 patients received hormonal therapy for PCa and an abdominoperineal resection (APR) for rectal cancer. 1 patient received an APR and had expectant management for PCa. 3 patients required a palliative radiotherapy and chemotherapy. 3 patients died at mean follow-up of 9.7±3.1 months. *Discussion and Conclusion:* Our literature search showed a total of 92 cases with SCRP. The vast majority of patients (73%) presented with symptoms suggestive of a colorectal lesion, and a suspicion of a concurrent PCa occurred as a result of an abnormal DRE (19%) or during imaging for PCa (8%). 30% of patients underwent RP and low anterior resection depending on the tumor location, while 8% were submitted to pelvic exenteration (PEx) with formation of ileal conduit. Another option adopted was the utilization of chemo-radiotherapy with or without androgen deprivation. The role of curative surgery in treating PCa patients with rectal involvement has been controversial. Surgery is a wise approach in localized tumor cases, as well as informing the patient carefully regarding the major morbidity of bleeding, sepsis, impotence and incontinence. Urinary incontinence develops in almost a third of patients after rectal and prostate surgery, and combined urinary and faecal incontinence occurs in 14% of patients with normal pre-operative function (2). PEx was limited to palliative debilitating perineal pain and other local symptoms, such as haematuria. Radiotherapy has been described as an effective treatment for SCRP and may be more appropriate in less fit patients, as is the case with many hormonal therapies in combination with radiation (3). The interaction between rectal and PCa is uncommon, complex and worth keeping in mind as both tumors are amenable to cure whether presenting synchronous or in metachronous sequence. However, both cancers are detectable by screening methods and are readily amenable to curative treatment, especially when detected at an early stage. The long-term survival probability after 5 years exceeds 90% for locally staged.

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3

SAFETY OF TESTICULAR PROSTHESIS INSERTION AT THE TIME OF RADICAL ORCHIECTOMY FOR TESTIS CANCER IN PATIENTS UNDERGOING ADJUVANT THERAPIES

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Table I. *Summary of the complications reported by the different groups of patients.*

Complications	Patients who had ChT	Patients who had RT	Patients who had ChT+RT	Patients who had no adjuvant treatment	*p*-Value
Overall	6 (4.3%)	8 (6.2%)	0 (0%)	7 (5.1%)	$p>0.7$
Uncomfortable position of the prosthesis	3	3		4	
Pain	1	3	-	1	
Spontaneous extrusion	1	-	-	1	
Surgical removal or repositioning of the prostate	1	2	-	1	

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Introduction: Since the introduction of platinum-based chemotherapy (ChT) in the 1970s, long-term survival following testicular cancer (TC) is now the norm. Thus, issues like the quality of life after radical orchiectomy became of paramount importance, and the loss of a testis represents a traumatic experience in males of any age. Because of this, testicular prostheses have been used since 1941, when the first model composed of vitallium was described. Nowadays, silicon-gel filled, saline-filled and elastomer prostheses are available in small, medium and large sizes. The safety of the concurrent insertion of a testicular prosthesis in course of radical orchiectomy in terms peri-operative complications has already been assessed. Aim of this study was to assess if the insertion of a testicular prosthesis at the time of radical orchiectomy was related to a higher incidence of complications in patients undergoing adjuvant treatments such as ChT or ratiotherapy (RT) for TC. *Patients and Methods:* This was a retrospective study: we reviewed the records of all the patients who underwent radical orchiectomy with testicular prosthesis insertion at our Institution; we also retrieved the records of patients that underwent radical orchiectomy with testicular prosthesis insertion elsewhere and then had adjuvant treatment at our Institution since 1999. We recorded prosthesis-related complications of any kind. Statistical differences in the incidence of prosthesis-related complications in each group of patients were evaluated with the chi-square test. *Results:* We retrieved the records of 587 patients; of them, 393 had a testicular prosthesis positioned at the time of orchiectomy. 138 of these patients underwent adjuvant chemotherapy and 129 underwent radiotherapy. Median follow-up was 57,7 months. Of the 138 patients who had adjuvant chemotherapy, 6 (4.3%) reported complications, while, among 129 patients who had radiotherapy, 8 (6.2%) complained about the prosthesis. 10 patients had both chemo- and radiotherapy, with no prosthesis-related complications. 136 patients with testicular prosthesis did not undergo any kind of adjuvant treatment; 7 (5.1%) of them reported prosthesis-related complications. Complications occurred are shown in Table I. No differences were found in the incidence of prosthesis-related complications between patients who did not have adjuvant treatment *vs.* patients who had chemotherapy ($p=0.76$) or radiotherapy ($p=0.71$). *Discussion:* Under a psychological point of view, the loss of a testicle is felt to be a threat to masculinity by many patients, especially by younger ones. Furthermore, after unilateral orchiectomy for TC, men report more sexual dysfunction compared to men in age-matched group with other forms of cancer. Testicular prostheses have been shown to reduce the psychological impact resulting from the loss of a testicle. The rate of peri-operative complications following testicular prosthesis insertion is substantially the same as after inguinal orchiectomy itself, which is 8%. The most common complications reported following testicular prosthesis insertion are: extrusion (3-8%); scrotal contraction (3-5%); pain (1-3%); hematoma (0.3-3%); infection (0.6-2%). Our results showed that, in a sample of 393 patients, the rate of reported complications related to the insertion of a testicular prosthesis at the time of radical orchiectomy are low and similar in patients who had adjuvant treatment or not. *Conclusion:* Testicular prosthesis insertion at the time of radical orchiectomy confirmed to be a safe procedure even in patients undergoing adjuvant treatments for TC. Testicular prosthesis insertion should be offered to all patients candidate to radical orchiectomy despite the possible need for adjuvant treatment.

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INHIBITION OF AUTOPHAGY INCREASES THE RESPONSE TO SUNITINIB IN CCRCC CELL LINES

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Introduction: Renal cell carcinoma (RCC) represents about 3% of all cancers and is the kidney malignancy with the highest mortality rate of urinary neoplasms. The most common subtype of RCC is clear cell RCC (ccRCC) that accounts for 70-80% of RCC cases (1, 2). One third of cases presents metastasis at diagnosis with a 30% of disease recurrence for RCC patients undergoing surgery. Moreover, treatment with tyrosine kinase inhibitors in RCC subjects with advanced disease has not shown any advantage on overall survival (1). Therefore, research on new therapeutic targets focuses on molecules that can enhance therapy response. This is a crucial point to improve the management of RCC patient. The kidney cancer progression could be induced by the activation of autophagy, the biological process used by cancer cells to produce energy in hypoxic and acidic environment. Thus, the use of autophagy inhibitors could be considered as a novel antitumor therapy (3). In addition, there is emerging evidence that the use of autophagy inhibitors could sensitize cancer cells to anticancer drugs. Therefore, the combination of both tyrosine kinase and autophagy inhibitors could improve therapy response in ccRCC patients. *Materials and Methods:* Combined treatment with the autophagy inhibitor (Chloroquine) and anti-tyrosine kinase (Sunitinib) was performed in two different ccRCC cell lines (KJ29 and Caki-2). Cell growth was analyzed by Cell Tyter System (Promega, Madison, WI, USA), culturing cells in presence of both Chloroquine and Sunitinib for 24 and 48 h. Cell density after different treatments of ccRCC cells was evaluated by using a phase-contrast microscope at 10× magnification. Apoptosis was analyzed by the Hoechst method. Apoptotic nuclei were observed by a fluorescence microscope at 50× magnification after cell treatment with chloroquine and sunitinib. *Results and Discussion:* We observed that the up-regulation of miR501-5p in ccRCC tissues is associated with a poor prognosis for ccRCC patients (2). Moreover, the overexpression of this miR induced the activation of autophagy in ccRCC cells. Cancer cells might use autophagy to trap and destroy molecular drugs by lysosomal vesicles. Therefore, the inhibition of autophagy should restore drug response. Consistently, we have observed that pre-treatment with Chloroquine, an autophagy inhibitor, in KJ29 ccRCC cells potentiated the Sunitinib-induced inhibition of cell growth compared to Sunitinib used alone. This finding was confirmed treating Caki-2, another ccRCC cell line, with both Chloroquine and Sunitinib. Moreover, the double treatment with these molecules reduced cell density compared to Chloroquine or Sunitinib, individually applied. The reduction of cell proliferation induced by the inhibition of both autophagy and tyrosine kinase receptors is associated with stimulation of apoptosis. In fact, the formation of apoptotic nuclei in double treated ccRCC cells, compared to those treated with the single compound, was observed. These results show that the inhibition of autophagy increases the efficacy of Sunitinib by the activation of apoptosis in ccRCC cells. *Conclusion:* These data suggest that the double treatment with both autophagy and tyrosine kinase inhibitors could be considered as a new therapeutic approach for the treatment of ccRCC patients.

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SALVAGE IMAGE-GUIDED EXTERNAL-BEAM RE-IRRADIATION OF LOCAL RECURRENCE IN PROSTATE CANCER: CLINICAL OUTCOME AND DOSIMETRY

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Introduction: To assess the potential clinical and dosimetric benefits of external beam re-irradiation delivered to either the prostate or prostatic bed for local recurrence after radical or adjuvant/salvage radiotherapy. *Materials and Methods:* Between November 2009 and January 2016, 60 patients with local recurrence of prostatic cancer after radical or

adjuvant/salvage radiotherapy, were treated in the European Institute of Oncology. Median age was 63 years (range=47.1-81.7) and median prostate-specific antigen (PSA) at the time of relapse was 21.7 ng/ml (range=3.5-228.5). This retrospective analysis included 37 patients that received image-guided external beam reirradiation (re-EBRT) delivered with VERO® technology; of this, 18 patients were treated with a total dose of 30 Gy in 5 fractions (6 Gy/each) and in 19 patients 25 Gy were delivered in 5 fractions (5 Gy/each). Dosimetric data are provided in Table I. Patients with distant metastasis at the time of re-EBRT were excluded. Acute and chronic toxicity was assessed according to RTOG/EORTC criteria. A concomitant hormonal treatment was administered in 10 patients. Biochemical control was assessed according to Phoenix definition. *Results:* The mean and median follow-up were 20.7 and 17.1 months, respectively (range=2-65.5). Acute genitourinary (GU) toxicity included G1 and G3 events in 7 and one patient, respectively. Acute gastrointestinal (GI) toxicity included G1 event in 3 patients. Chronic GU toxicity was assessed in 4 patients and G1 was observed in 8 patients. Chronic G2 GI toxicity occurred in 2 patients. At the last follow-up 19 patients (51.4%) showed no evidence of disease, 16 (43.2%) are alive with biochemical or clinical disease and 2 patients (5.4%) died: 1 due to disease progression and 1 due to second cancer. *Conclusion:* Re-EBRT, using image guided approach, is a feasible option for local prostate cancer recurrence achieving tumor control at about 2 years in half of the patients (unselected series). No severe acute and chronic toxicity after re-EBRT was observed. Considering that currently there are no consistent data in literature regarding dosimetry in reirradiation of recurrent prostate cancer, we suggest that our promising results provide a benchmark to estimate the toxicity profile.

Table I. Description of the principal constraints reported.

Organ	Dosimetry	
	Mean total	Range
Bladder		
D30% (Gy)	3.03	(0.5-24.8)
Rectum		
D30% (Gy)	6.55	(0.8-15)
D60% (Gy)	2.95	(0.4-20.8)
Penile bulb		
V29Gy (%)	0.21	(0-1.5)
Posterior rectal wall		
Dmax (%)	38.78	(14.6-64.3)

D30%: Dose to 30% of volume; D60%: dose to the 60% of the volume; V29 Gy: volume receiving the dose of 29 Gy; Dmax (%): % of the maximum prescribed dose, reported in the volume.

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^{68}GA-PSMA: HIGH SENSIBILITY, SPECIFICITY AND DETECTION RATE TRACER EVEN WITH LOW PSA LEVEL: CASE REPORT

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Introduction: Prostate-specific membrane antigen (PSMA) is expressed ubiquitously on the membrane of most prostate tumors and its metastasis. Recently PSMA was introduced as a target for both radionuclide diagnostics and therapy in patients with prostate cancer. Because of the highly promising results in earlier studies, positron emission tomography (PET) imaging with radiolabels PSMA ligand is applied, especially in patients with biochemical recurrent after radical treatment. *Case Report:* A 63-year-old male with uneventful medical history, underwent radical prostatectomy and lymphadenectomy in June 2006 for prostate adenocarcinoma, Gleason score 8 (4+4) pT2cN0. Adjuvant androgen deprivation therapy (ADT) was prescribed for two years and it was well-tolerated. From October 2008 to October 2014 clinical follow-up was performed; the patient was asymptomatic and the prostate-specific antigen (PSA) was <0.01 ng/ml. In November 2015 the PSA was 0.3 ng/ml, and in May 2016 rised to 1 ng/ml. In July 2016 a ^{68}Ga-PSMA PET/CT (computed tomography) imaging was performed and it revealed multiple skeletal tracer uptake (T1 and L2 vertebra; Figure 1, left femur) as well as in right superior lung lobe (Figure 2). The patient had no symptoms. A total body CT was performed ant it confirmed bone lesions and a lung nodule in right superior lobe, 22 millimeters size, suspicious for lung cancer. In august 2016 ^{18}F-FDG PET/CT confirmed all these lesions. The patient started hormonal treatment with luteinizing hormone releasing hormone analogue (LHRH analogue). On the 13th of September the patient underwent pulmonary biopsy and the histopathology report described a metastasis from prostate adenocarcinoma. On 28 of September the PSA was <1 ng/ml. The patient remained asymptomatic. According to the performance status of the patient (ECOG 0), the age and the stage of the disease, on the basis of CHAARTED and STAMEDE studies results, chemotherapy with docetaxel at a dose of 75 mg/m^2 of body-surface area every three weeks for six cycles was prescribed in addition to ADT.

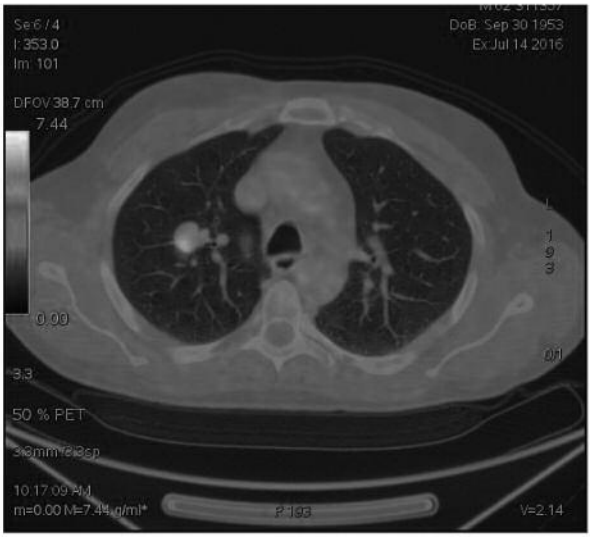

Figure 1. *the ^{68}Ga-PSMA PET/CT performed in July 2016 revealed tracer uptake in right lung.*

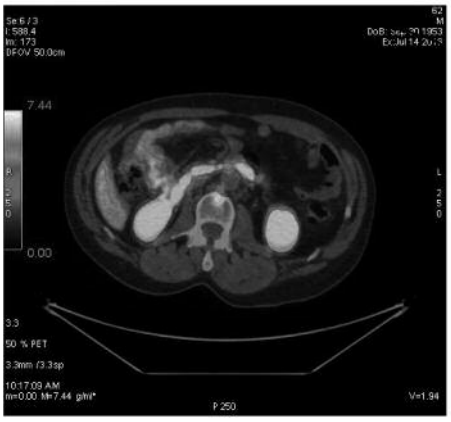

Figure 2. *the ^{68}Ga-PSMA PET/CT performed in July 2016 revealed tracer uptake in L2 vertebra.*

Conclusion: PSMA PET can be considered as a highly promising tool in prostate cancer imaging due to higher detection rates, especially at low PSA level. In some cases this imaging technique could become very useful because it could change clinical practice and medical treatment.

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IS IT POSSIBLE TO PREDICT THE EFFECTIVENESS OF ELECTIVE PELVIC RADIOTHERAPY IN CLINICALLY NODE-NEGATIVE PROSTATE CANCER PATIENTS? A LONG-TERM ANALYSIS

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Introduction: The role of the whole pelvic radiotherapy (WPRT) remains highly controversial. Randomized trials have failed to show a benefit for patients that received prophylactic irradiation (46-50 Gy) of the pelvic lymph nodes (PLN) in high-risk cases. Although there is not sufficient evidence to

advocate WPRT in intermediate, or even high-risk, localized prostate cancer patients, elective WPRT could be considered in high-risk patients, based on validated nomograms. In our institution, a retrospective analysis was published on a total of 358 prostate cancer patients (Pca) with intermediate- to high-risk features in order to evaluate the effect of WPRT in association with long-term (>1 year) ADT. With a median follow-up of 52 months, the results of that analysis supported the use of WPRT only for patients with a high risk of Limph-nodal Involvement (LNI) (>30%) assessed using the so-called "Roach equation" (1). Aim of this long-term analysis is to update data about biochemical Disease-free-survival (bDFS), disease-free survival (DFS), disease-specific survival (DSS) and overall survival (OS), in order to confirm 30% as threshold of LNI to select patients that can benefit of WPRT. *Patients and Methods:* Patients classified in high- and very high-risk groups, according to last NCCN stratification system (Stage T3 or T4 and/or GS 8-10 and/or PSA level >20 ng/mL) were analysed. The risk of LNI was assessed through Roach equation. RT was performed mainly with 3D technique after 2000. Prone or supine immobilization were used respectively in WPRT and Prostate Only RT(PORT). CTVs were: CTV1 prostate (total dose 7020/1.8 cGy fx until 1999 and 73.8/1.8 cGy fx afterwards), CTV2 seminal vesicles plus CTV1(total dose 55.8/1.8 cGy fx for cT1-T3a and 64.8/1.8 cGy fx for cT3bT4), CTV3 PLN, in WPRT (total dose 4500/180 cGy fx). PTVs derived from a common margin of 1 cm to corresponding CTV. Long-term androgen deprivation therapy (ADT) was prescribed. Late toxicity was graded according to the CTC v4.03 for WPRT and PORT group. Statistical analysis was performed using R statistical software 3.2.4. All outcomes were analyzed using the Kaplan-Meier method, univariate and multivariate Cox proportional hazard analysis. Kaplan-Meier curves were compared using Log-rank test. A linear cross correlation matrix (Pearson test) was used among statistically significant covariates ($p<0.05$), in order to select not-linearly correlated variables, and to include them in the multivariate analysis. To evaluate toxicity, a non-parametric Wilcoxon test was applied. *Results:* We selected 319 high-risks patients among the 358 patients enrolled between 1994 and 2007: 20 patients treated until 1999, by 2D RT, and 299, treated from 2000, by 3D RT; 147 (46.1%) treated with WPRT and 172 (53.9%) with PORT. Median age at diagnosis was 70 for WPRT (range=42-80 years) and 72 for PORT (range=56-83 years) group. The two groups were heterogeneous for age, with a statistically significant difference between them ($p=0.0017$). No other significant differences were found among patients treated with PORT or WPRT, including disease stage, Gleason score, or PSA level at diagnosis, also in patients younger than 70 years old. With a median follow-up of 128 months, the 10-year bDFS, DFS, DSS and OS rates for the whole high-risk patient population were respectively 64%, 75%, 91% and 83%, with a median overall survival of 127 months. Then, a subgroup analysis was performed, considering LNI risk, as assessed by the Roach formula, using different cut-off levels (15%, 20%, 25%, and 30%). The sub-group analysis confirmed no statistically significant differences between WPRT and PORT for each nodal risk group, either in terms of bDFS, DFS OS, age <70 years ($p=0.077$). Only OS curve showed a better prognosis for WPRT, statistically significant in 15% and 20% nodal-risk groups, but not confirmed by univariate analysis. Grade 3 late toxicity, either gastrointestinal (GI) or genitourinary (GU), was very low (0.63% and 0.94%, respectively). Grade 4 late GI toxicity was reported only in one patient, treated with WPRT. No grade 4 GU toxicity was reported. The comparison between WPRT *vs*. PORT group show any statistically significant difference, neither in terms of GU ($p=0.81$) or GI ($p=0.15$) toxicity. *Conclusion:* This long-term analysis failed to demonstrate a benefit for elective WPRT compared to PORTin the treatment of even high-risk clinically node-negative prostate cancer patients. Limitations of our analysis are related to the retrospective nature, small sample, long-time of accrual and, then, different doses and techniques used. The results of ongoing trials and new studies can help us create performing tools for patient selection.

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OUR EXPERIENCE WITH RETROPERITONEAL ROBOTIC LYMPHADENECTOMY DISSECTION FOR TESTICULAR CANCER RECURRENCE

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Introduction: The aim of our report is to describe the feasibility of robotic retroperitoneal lymph node dissection (Ra-RPLND) for non-seminal testicular cancer recurrence using the Robot Da Vinci Si. *Materials and Methods:* Between 2013 and 2015, 12 patients underwent primary R-RPLND at our centers. The patient was positioned in a lateral decubitus position, after pneumoperitoneum was performed using a Veress needle, a 12-mm camera port was placed at the umbilicus and four more trocars were used in the abdomen: two for robotic arms and two for the assistant robot; a modified template dissection was planned. Paraaortic

lymph nodes were dissected at the level of the common iliac artery to the root of the left renal artery along the lateral margin of the aorta. *Results:* The median operative time was 235min (214-258 min), estimated blood loss was 50 ml (IQR: 50-100 ml), node count was 26 (IQR: 18-32), and length of stay was 4 d. There was one intraoperative complication, two early post-operative complications (9%), no late complications, and the rate of antegrade ejaculation was 100%. Of the five patients with positive nodes (seven pN1and one pN2), five (62%) received adjuvant chemotherapy. *Discussion:* The advantages of the Ra-RPLND technique are reduced blood loss and rapid patient recovery. *Conclusion:* The robot system offers precise and secure dissection of lymph nodes and remnant masses. Based upon our experience, Ra-RPLND offers an optimal oncologic and functional outcome with excellent cosmetic benefits.

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SALVAGE RADIOTHERAPY IN LOCOREGIONAL MACROSCOPICALLY-RELAPSED PROSTATE CANCER: RETROSPECTIVE ANALYSIS OF CLINICAL OUTCOMES AND TOXICITIES

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Introduction: A small subset of patients (pts) with Prostate Cancer (PCa) experiences a biochemical/clinical recurrence following radical prostatectomy (RPP). Even if Salvage Radiation Therapy (SRT) after RPP is recommended as soon as the PSA rises above 0.20 ng/ml, some pts show a loco-regional "clinically significant" relapse. Aim of the analysis was to evaluate the role of SRT with or without concomitant androgen deprivation therapy (ADT) in pts with clinical/radiological/metabolic loco-regional relapse. *Materials and Methods:* From 2007 to September 2015, fifty-five pts with regional macroscopic PCa relapse underwent radical SRT +/- concomitant/adjuvant ADT in two different Italian centers. Median age at time of SRT was 72 years. At time of diagnosis 32 pts had pT2 PCa, 6 pT3a and 19 pT3b according to TNM AJCC Stratification. Only 4 pts had abdominal node involvement (pN+). Gleason Pattern Score was <7 in 8 pts, 7 in 35 and >7 in 11 pts. At time of relapse all pts had an increase in PSA level: in 19 pts it was less than 1.0 ng/ml, in 22 between 1.1-5 ng/ml and in 15 pts more than 5 ng/ml. Before being submitted to SRT, most pts (44/56) were staged at least with 18F-Choline CTPET while 18 pts had also pelvic MRI to help with for a better RT planning. At the end of restaging 48/56 had just local relapse (prostatic bed), 3 nodal Involvement and 4 pts experienced both. Before SRT 23 pts were previously submitted to first line ADT, while 6 pts had already received two or more ADT lines due to clinical stage and PSA value. Finally SRT was delivered in association to concomitant ADT in 25/56 pts (19 pts with LHRH analogue, 6 pts with Bicalutamide) in 13 of whom it was continued with an adjuvant approach. *Results:* At a median follow up of 36 months all pts but 3 (5%) were still alive. All pts were treated with high dose RT with conventional (2 Gy/die, 35-37 total fractions) or moderately hypofractionated schedule (2,2-2,5 Gy, 27-30 fractions) with or without concomitant ADT. Median RT dose was 70 Gy (range 62-76Gy). Target volume encompassed prostatic bed and macroscopic lesion in 42 pts (75%), while in the other 14 pelvic abdominal RT was performed (in 10 pts with prophylactic intent, in 4 pts using a boost on 18F-Choline CT-PET positive nodes). Three- and 5-year actuarial OS were 97.6%(ES±2.4%) and 88.5%(ES±6.7%) respectively, while 3- and 5-year Biochemical Free Survival were 71.4%(ES±6.9) and 56.7% (ES±9.4), respectively. Nine pts (16%) experienced distant recurrences (6 pts bone lesions, 5 pts extra-pelvic nodes, 2 pts both). Regarding acute toxicities 19 pts had gastrointestinal (GI) side effects (12 pts G1, 7 pts G2) while 23/56 pts had the genitourinary (GU) ones (16 pts G1, 4 pts G2 and 3 pts G3); finally 4/56 pts (7%) experienced a worsening of urinary incontinency (UI). Regarding late toxicities 7 pts had G2 GI side effects, 6 pts G2 and 1 pt G3 (1.8%) GU side effects; finally 2 pts had G2 UI (3.5%). No grade 4 acute/late toxicities were found. *Conclusion:* Our results of SRT +/- ADT in pts with loco-regional macroscopic PCa relapse demonstrate an excellent profile in terms of both oncological and toxicity outcomes being well-tolerated and confirming again the important role of SRT even in this unfavourable pts subset.

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ROLE OF ^{18}F-FACBC PET/CT IN NODAL STAGING FOR HIGH-RISK PROSTATE CANCER: PRELIMINARY ANALYSIS

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Table I. *Clinical and pathologic characteristics of patients.*

	Overall (39 patients)
Age (years)	
Median (IQR)	65 (47-75)
PSA (ng/ml)	
Median (IQR)	8 (3-30)
Biopsy Gleason score (%)	
3+3	1 (2.3)
3+4	2 (5.1)
4+3	1 (2.6)
4+4	22 (56.4)
4+5	10 (25.6)
5+4	3 (7.7)
Surgical approach	
Robotic Radical Prostatectomy	35 (90)
Open Radical Prostatectomy	4 (10)
Pathologic Gleason score (%)	
3+3	0 (0)
3+4	1 (2.6)
4+3	10 (25.6)
4+4	11 (28.2)
3+5	1 (2.6)
4+5	14 (35.9)
5+4	2 (5.1)
Lymph nodes retrieved	
Median (IQR)	19 (6-49)

Table II. *Sensivity, specificity and accurancy of 11C-Choline and 18F-FACBC.*

39 pts	Sensitivity (%)	Specifity (%)	PPV (%)	NPV (%)	Accuracy (%)
11C-Choline	25	63	7	88	59
18F-FACBC	25	77	13	90	72

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Introduction: To assess the role of 18F-FACBC-positron emission tomography/computer tomography (PET/CT) in nodal staging due to aid lymph-node-dissection (LND) during radical prostatectomy (RP) in high-risk primary prostate cancer (PCa). *Materials and Methods:* 39 patients were consecutively and prospectively enrolled and underwent 18FFACBC-PET/CT. Inclusion criteria were: high-risk biopsy-proven PCa according to D'Amico risk group classification; standard staging workup (including 11CCholine-PET/CT); no hormonal-therapy; eligible and motivated for RP with LND. Number of leisons, size and site SUVmax and target-to-background-ratio were recorded and PET/CT results were compared, on a per-patient basis analysis, with histopathology examination of lymph node. *Results:* In Table I we showed clinical and pathologic characteristics of 39 patients. Overall, 913 lymphnodes were removed and 14 LN metastasis (LNM) were counted, all showing millimetric deposits (range=1-5 mm). Compared with final pathologic results, we found 13 with FACBC and 8 FP Choline; while 3 FN were found with both tracers. Choline PET/CT and FACBC PET/CT diagnostic performance is presented in Table II: sensitivity, specificity and accuracy were 25%, 63% and 59% *vs.* 25%, 77% and 72% for, respectively. *Conclusion:* FACBC showed low sensitivity, comparable to Choline, but slightly better overall diagnostic performance in nodal staging. Due to small size of LNM, PET remains a suboptimal tool to investigate the presence of LNM. Enrollment and further analyses (region-based/semi-quantitative/uni-multivariate-logistic-regression to evaluate predictive factors) are ongoing but these early results seem to suggest a role of FACBC PET/CT in identification of LN involvement.

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ONCOLOGICAL *VERSUS* OTHER-CAUSE MORTALITY IN ELDERLY PATIENTS UNDERGOING RADICAL PROSTATECTOMY: A COMPETING RISK ANALYSIS

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Introduction: The choice of which treatment is better-suited for older individuals affected by prostate cancer (PCa) is still under debate. Elderly patients usually share a higher amount of co-morbidities and a worse performance status, often leading clinicians to a non-surgical management of their disease. Nonetheless, the continous prolonging of life expectancy in overall population, especially in healthy individuals, could lead to consider a surgical management of PCa even in ≥75-year-old men. The target of the study was to assess and compare cancer-specific mortality (CSM) and othercause mortality (OCM) rates in PCa patients aged ≥75 years treated with radical prostatectomy (RP) to a younger patients' population, to investigate whether a

Table I. *Overall patient characteristics (n:1,518) according to age at surgery (namely, age <75 yrs vs. age ≥75 yrs).*

Variable		Overall	Age <75	Age ≥75 yrs	*p*-Value
No. of patients (%)		1518 (100)	1401 (92.3)	117 (7.7)	-
Age	Median	67	66	75	<0.001
	IQR	62-71	61-70	75-76	
ASA Score (%)	1-2	1255 (82.7)	1172 (83.7)	83 (70.9)	0.001
	3-4	263 (17.3)	229 (16.3)	34 (29.1)	
Cardiovascular co-morbidity (%)	No	773 (50.9)	734 (52.4)	39 (33.3)	<0.001
	Yes	745 (49.1)	667 (47.6)	78 (66.7)	
Pulmonary co-morbidity (%)	No	1234 (81.3)	1152 (82.2)	82 (70.1)	0.002
	Yes	284 (18.7)	249 (17.8)	29.9	
Preoperative PSA (ng/ml)	Median	7.2	7.2	7.1	0.6
	IQR	5.3-10.7	5.3-10.8	5.3-10.0	
Biopsy Gleason Score (%)	<7	859 (56.6)	818 (58.4)	41 (35.0)	<0.001
	7	468 (30.8)	416 (29.7)	52 (44.4)	
	8-10	181 (11.9)	157 (11.2)	24 (20.5)	
Clinical stage (%)	T1a-T1b-T1c	596 (39.3)	556 (39.7)	40 (34.5)	0.2
	T2	877 (57.8)	802 (57.2)	75 (64.7)	
	T3	44 (2.9)	43 (3.1)	1 (0.9)	
Pathologic Gleason Score (%)	<7	551 (36.3)	527 (37.6)	24 (20.5)	<0.001
	7	717 (47.2)	656 (46.8)	61 (52.1)	
	8-10	250 (16.5)	218 (15.6)	32 (27.4)	
Pathologic stage (%)	pT2	885 (58.3)	826 (59.0)	59 (58.3)	0.09
	pT3a	416 (27.4)	374 (26.7)	416 (27.4)	
	pT3b-pT4	217 (14.3)	201 (14.3)	217 (14.3)	
Surgical margins status (%)	Negative	931 (61.3)	863 (61.6)	68 (58.1)	0.7
	Positive	586 (38.6)	537 (38.3)	49 (41.9)	
Number LNs removed	Mean±SD	8.3±9.2	8.4±9.2	6.7±8.6	0.006
Number positive LNs	Mean±SD	0.2±1.5	0.2±1.4	0.2±1.9	0.9
Adjuvant therapy (%)	No	1125 (74.1)	1040 (74.2)	85 (72.6)	<0.001
	aRT	195 (12.8)	182 (13.0)	13 (11.1)	
	aADT	73 (4.8)	58 (4.1)	15 (12.8)	
	aRT+aADT	125 (8.2)	121 (8.6)	4 (3.4)	
Salvage therapy (%)	No	1360 (89.6)	1252 (89.4)	108 (92.3)	0.5
	sRT	22 (1.4)	20 (1.4)	2 (1.7)	
	sRT+sADT/sADT/Others	136 (9.0)	129 (9.2)	7 (6.0)	

ASA: American Society of Anesthesiologists; PSA: prostate specific antigen; LN: lymph nodes; IQR: interquartile range; aRT: adiuvant radiotherapy; aADT: adjuvant androgen deprivation therapy; sRT: salvage radiotherapy; sADT: salvage androgen deprivation therapy.

radical surgical approach should be proposed also in older individuals. *Materials and Methods:* In total 1,518 consecutive PCa patients surgically treated at tertiary care centre between 1998 and 2015 were considered. Kaplan-Meier analyses were used to define CSM and OCM rates at 8 years follow-up after stratifying patients according to age at surgery (namely, age <75 yrs *vs*. age ≥75 yrs). Uni- and multivariable competing-risk Cox regression analyses were used to assess CSM and OCM. *Results:* Table I represents overall patients' characteristics. After stratifying patients according to age at surgery, significant differences were recorded with regards to ASA score, cardiovascular co-morbidity, pulmonary co-morbidity, biopsy and pathological Gleason score, number of lymph nodes retrieved and adjuvant therapies status (all $p \leq 0.006$). Patients aged <75 yrs at surgery showed lower OCM rates at 8 yrs follow up as compared to those aged ≥75 yrs at surgery (6.1% *vs*. 33.4%; $p<0.04$). Age at surgery ≥75, a higher preoperative ASA score and time to BCR were found to be independent predictors of OCM (all $p<0.03$; Table II). *Conclusion:* Despite similar CSM rates in patients aged <75 yrs and ≥75 yrs, older individuals present a significantly higher rate of OCM. RP should be proposed to a selected number of elderly patients, with an adequate pre-operative co-morbidities profile and a relatively good life expectancy.

Table II. *Univariable and multivariable competing-risks regression models predicting cancer-specific mortality (CSM) and other causes of mortality (OCM) in overall population (n=1,518).*

Variables	Cancer specific mortality				Other causes of mortality			
	Univariable analyses		Multivariable analyses		Univariable analyses		Multivariable analyses	
	HR (95% C.I.)	*p*-Value	HR (95% C.I.)	*p*-Value	HR (95% C.I.)	*p*-Value	HR (95% C.I.)	*p*-Value
Age at surgery (years)								
<75 yrs	Reference		Reference		Reference		Reference	
≥75 yrs	0.36 (0.05-2.75)	0.3	0.42 (0.04-4.46)	0.5	3.78 (2.18-1.42)	<0.001	4.35 (2.45-7.72)	<0.001
Preoperative ASA score								
1-2	Reference		Reference		Reference		Reference	
3-4	1.13 (0.41-3.15)	0.8	1.09 (0.45-2.65)	0.9	2.26 (1.28-3.98)	0.005	1.94 (1.07-3.52)	0.03
Pathological stage								
pT2	Reference		Reference		Reference		Reference	
pT3a	3.28 (1-10.8)	0.05	1.17 (0.33-4.11)	0.8	1.38 (0.84-2.26)	0.1	1.47 (0.87-2.48)	0.2
pT3b-pT4	13.11 (4.32-39.72)	<0.001	3.12 (1.04-9.38)	0.04	0.44 (0.17-1.13)	0.09	0.46 (0.17-1.25)	0.1
Pathological Gleason Score								
pGs 6	Reference		Reference		Reference		Reference	
pGs 7	2.97 (0.99-8.84)	0.05	2.75 (0.90-8.34)	0.08	0.83 (0.47-1.46)	0.5	0.54 (0.28-1.06)	0.08
pGs 8-10	15.52 (5.64-42.7)	<0.001	3.93 (1.40-11.02)	0.01	1.65 (0.84-3.24)	0.2	1.29 (0.58-2.89)	0.5
LNI								
No	Reference		Reference		Reference		Reference	
Yes	10.89 (4.94-24.01)	<0.001	2.99 (1.35-6.60)	0.007	0.57 (0.23-1.42)	0.2	0.42 (0.14-1.25)	0.1
Time to BCR	0.93 (0.90-0.95)	<0.001	0.93 (0.90-0.95)	<0.001	0.99 (0.98-0.99)	<0.001	0.98 (0.98-0.99)	<0.001

ASA: American Society of Anesthesiologists; LNI: lymph node invasion; BCR: biochemical recurrence; HR: hazard ratio; C.I.: Confidence Interval.

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1.5-T SCAN AND 32-CHANNEL ENDORECTAL COIL IN BORE MRI-GUIDED PROSTATE BIOPSY: OUR PRELIMINARY RESULTS

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Introduction: Repeated negative prostate biopsies in individuals with clinically suspected prostate Cancer (PCa) can be troublesome for both the patient and the clinician. Multiparametric Magnetic Resonance Imaging (mpMRI) can be a precious tool to detect and characterize PCa, with complementary information about the gland. In recent years the role of mpMRI has increasingly gained importance as a tool to guide prostate biopsy, improving risk stratification and reducing false-negative rates and number of biopsy cores. The study aimed to test the feasibility and the diagnostic performance of endorectal MRI-guided biopsy (MRI-GB) on a 1.5 T MR scanner using a 32-channel coil in patients with suspected PCa. *Materials and Methods:* Between July 2013 and March 2016, 70 patients with biochemical and/or clinical PCa suspect and at least one suspicious area at the preliminary mp-MRI were prospectively enrolled. With the assistance of a specific needle-tracking software, MRI-GB was performed with a non-magnetic MRI biopsy device, a needle guide, a titanium double-shoot biopsy gun. The detection of at least a Gleason ≥7 in one core of the biopsy core was considered as a clinically significant PCa. *Results:* Median age was 63 (58-67) years and median PSA was 6.6 (4.9-9.1) ng/ml (Table I). At pre-biopsy mp-MRI, a total of 70 index lesions were identified and scheduled to MRI-GB procedure. Forty-eight (68.5%) lesions were in the peripheral zone, 7 (10%) in the central zone and 15 (21.5%) in the transitional zone. Twenty-nine out of 70 (42.9%) patients did not undergo previous prostate biopsies

Table I. *Characteristics of the studied population.*

Characteristics	Entire population (n=70)	Positive biopsy pts (n=32)	Negative biospy pts (n=38)	p-Value
Age, years				
Median (IQR)	63 (58-67)	66 (60-70)	61 (57-64)	0.014
PSA, ng/ml				
Median (IQR)	6.9 (4.97-9.05)	8.4 (5.96-14.8)	5.6 (4.87-8.55)	0.008
PSA density, ng/ml/cc				
Median (IQR)	0.14 (0.09-0.24)	0.18 (0.11-0.29)	0.10 (0.08-0.17)	0.004
Prostate volume, cc				
Median (IQR)	50 (34-65)	42 (32-66)	53 (36-65)	0.166
Previous TRUS-GB, n				
None	15 (46.8)	29 (41.4)	14 (36.8)	0.335
≥1	17 (53.2)	41 (58.6)	24 (63.2)	
Diameter of index lesion, mm				
Median (IQR)	12 (9-17)	13 (10-17)	11(8-17)	0.16
Sites of index lesion, n (%)				
Peripheral zone	55 (78.5)	21 (65.6)	34 (89.4)	0.02
Central Zone	15 (21.4%)	11 (34.4)	4 (10.6)	
Sites of index lesion, n (%)				
Anterior	19 (27.1)	14 (43.7)	5 (13.1)	0.006
Posterior	51 (72.9)	18 (56.3)	33 (86.9)	
PI-RADS-v2, n (%)				
3/5	32 (45.7)	8 (25.0)	24 (63.1)	0.001
4/5	25 (35.7)	13 (40.6)	12 (31.6)	
5/5	13 (18.6)	11 (34.4)	2 (5.3)	
PI-RADS-v2, Median (IQR)	4 (3-4)	4 (3-5)	3 (3-4)	
Gleason score at MRI-GB, n			-	-
6	8	8		
7 (3+4-4+3)	11 (8-3)	11 (8-3)		
≥8	13	13		
Cores taken per pts, n				
Median (range, IQR)	2 (1-6, 1-3)	2 (1-6, 1-2)	2 (1-6, 2-3)	0.078

Table II. *Biopsy-naive patients (n=29).*

Sites of the index lesion (Pi-RADS-v2)	Total number	Negative MR-GB n (%)	Positive MR-GB n (%)	*p*-Value
Peripheral	21	11 (52.4%)	10 (47.6%)	0.6
Central	8	3 (37.5%)	5 (61.5%)	
Posterior	23	11 (47.8%)	13 (52.2%)	0.9
Anterior	6	3 (50.0%)	3 (50.0%)	

Table III. *Patients with at least 1 previous set of TRUS-GB (n=41).*

Sites of the index lesion (Pi-RADS-v2)	Total number	Negative MR-GB n (%)	Positive MR-GB (%)	*p*-Value
Peripheral	34	23 (67.6%)	11 (32.4%)	0,01
Central	7	1 (14.3%)	6 (85,7%)	
Posterior	28	22 (78.6%)	6 (21.4%)	<0.001
Anterior	13	2 (15.4%)	11 (84.6 %)	

(Table II), whereas 41 had at least a previous biopsy set (Table III). MRI-GB was positive in 32 patients with a detection rate of 45.7%. In these patients the total PSA and PSA density were significantly higher compared to those with negative biopsies (all $p \leq 0.045$). Overall, 153 cores were taken, with a PCa detection rate of 41.1% (63/153) at a specimen analysis, and a median maximum cancer length of 6.2 mm (IQR 4.5-9.2). Overall, 24/32 (75%) patients presented a csPCa at final patological examination (11 patients had Gs=7 and 13 patients had Gs≥8). A strong and statistically significant correlation between PIRADS score and Gs in MRI-GB cores was found (r=0.839, 95% CI 0.535-0.951; $p=0.003$) in men with positive biopsies. No significant post-procedure complications were recorded. *Conclusion:* In our preliminary experience, MRI-GB is an interesting and promising tool that could help improve detection rate of clinically significant PCa, offering a better risk stratification and aiming to overcome the limits of standard TRUS-guided random prostate biopsy.

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SURVIVAL AND FUNCTIONAL OUTCOMES AFTER RADICAL PROSTATECTOMY: BIFECTA ACHIEVEMENT IN PATIENTS AGED ≥75 YEARS

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Introduction: Besides the oncological success, the achievement of complete urinary continence stands as the most important functional outcome in elderly men undergoing radical prostatectomy (RP) for prostate cancer (PCa), since age represents a critical predictor in the urinary recovery. Individuals who fail to reach bifecta after RP are a heterogeneous population made of patients with oncological failure and functional success, functional failure and oncological success or both oncological and functional failure. The aim of our study was to evaluate the bifecta rate, comparing two groups of men aged <75 *vs*. ≥75 years in terms of oncological/functional success. *Materials and Methods:* We retrospectively analyzed 1,953 PCa patients that underwent open or laparoscopic RP at tertiary care center between 1995 and 2015, with minimum follow-up of 1 year. Primary end-point was the bifecta rate. Survival was stratified according to the biochemical recurrence (BCR) status (S0: BCR absent; S1: BCR present) and continence status was assessed basing on the number of pad used at the time of last follow-up (C0: no pad/1 mini-pad for safety; C1: >1 pad). Surgical success was considered for patients defined as S0-C0; surgical failure was defined for all the individuals defined as S1-C0 or S0-C1 or S1-C1. *Results:* Table I depicts overall patients features; clinical Gleason score, pathological Gleason score, number of lymph nodes retrieved and adjuvant therapies status were found to be significantly different between the two groups (all $p \leq 0.03$). On the contrary, no statistically significant disparities were identified between two groups in terms of BCR and continence status at 12 months post-surgery. Higher bifecta rates (S0C0) were achieved in younger patients as compared to older (Table II, $p=0.02$). Among those patients considered as surgical failures, urinary incontinence was found to be the main reason for bifecta failure among men aged ≥75 years as compared to younger men group (Figure 1). *Conclusion:* Patients aged <75 years showed higher bifecta rate after RP, while older men are more likely to be incontinent with a nonetheless good oncological result. Despite a similar oncological success, indication to RP in elderly patients should be carefully pondered, because of a considerably higher risk of post-operative incontinence.

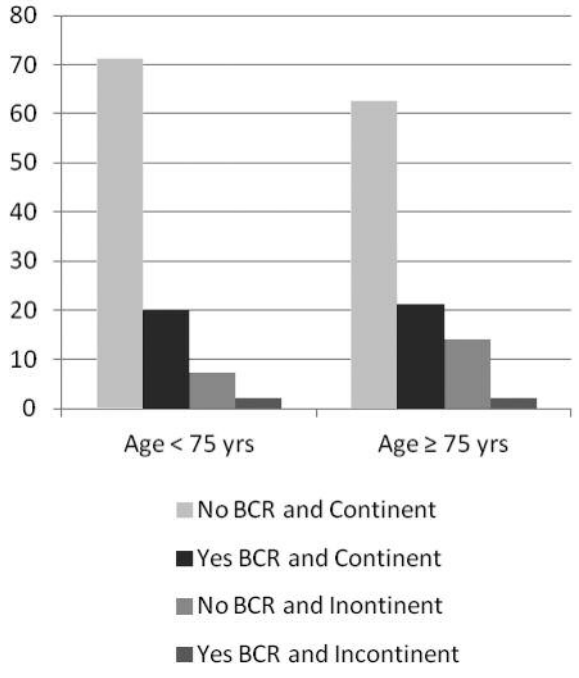

Figure 1. *Oncological and functional outcomes compared according to age at surgery.*

Table I. *Overall patient characteristics (n: 1,953) according to age at surgery (namely, age <75 yrs vs. age ≥75 yrs).*

Variable		Overall	Age <75	Age ≥75 yrs	*p*-Value
No. of patients (%)	1953	1811 (92.7)	142 (7.3)	-	
Preoperative PSA (ng/ml)	Median	7.5	7.6	6.8	0.1
	IQR	5.4-11.2	5.4-11.3	5.1-10.0	
BMI (Kg/m^2)	Median	26.4	26.4	26.3	0.6
	IQR	24.5-28.7	24.5-28.7	24.5-27.8	
Biopsy Gleason Score (%)	<7	1221 (62.5)	1161 (64.1)	60 (42.3)	<0.001
	7	523 (26.8)	468 (25.8)	55 (38.7)	
	8-10	193 (9.9)	166 (9.2)	27 (19.0)	
Clinical stage (%)	T1a-T1b-T1c	734 (37.6)	687 (37.9)	47 (33.1)	0.4
	T2	1143 (58.5)	1052 (58.1)	91 (64.1)	
	T3	76 (3.9)	72 (4.0)	4 (2.8)	
Pathologic Gleason Score (%)	<7	785 (40.2)	750 (41.4)	35 (24.6)	<0.001
	7	799 (40.9)	732 (40.4)	67 (47.2)	
	8-10	257 (13.2)	223 (12.3)	34 (23.9)	
Pathologic stage (%)	pT2	1084 (55.5)	1017 (56.2)	67 (47.2)	0.1
	pT3a	551 (28.2)	499 (27.6)	52 (36.6)	
	pT3b-pT4	316 (16.2)	293 (16.2)	23 (16.2)	
Surgical margins status (%)	Negative	1234 (63.2)	1149 (63.4)	85 (59.9)	0.6
	Positive	716 (36.7)	659 (36.4)	57 (40.1)	
Number LNs removed	Mean±SD	8.0±8.6	8.1±8.6	6.5±8.1	0.02
Number positive LNs	Mean±SD	0.19±1.0	0.19±0.9	0.23±1.7	0.6
BCR	No	1524 (78.0)	1415 (78.1)	109 (76.8)	0.4
	Yes	429 (22.0)	396 (21.9)	33 (23.2)	
Adjuvant therapy (%)	No	1473 (75.4)	1368 (75.5)	105 (73.9)	0.03
	aRT	219 (11.2)	205 (11.3)	14 (9.9)	
	aADT	137 (7.0)	119 (6.6)	18 (12.7)	
	aRT+aADT	124 (6.3)	119 (6.6)	5 (3.5)	
Salvage therapy (%)	No	1614 (84.5)	1505 (84.3)	109 (87.9)	0.05
	sRT	62 (3.2)	59 (3.3)	3 (2.4)	
	sRT+sADT/sADT/Others	232 (12.1)	221 (12.4)	11 (8.9)	
Continence status at 12 months after surgery (%)	Continent	1536 (84.9)	1427 (85.3)	109 (79.6)	0.08
	Incontinent	221 (12.2)	196 (11.7)	25 (18.2)	
Follow up time	Median	59	59	50	0.6
	IQR	33-90	33-89	29.8-99	

PSA: Prostate-specific antigen; BMI: body mass index; BCR: biochemical recurrence; IQR: interquartile range; aRT: adiuvant radiotherapy; aADT: adjuvant androgen deprivation therapy; sRT: salvage radiotherapy; sADT: salvage androgen-deprivation therapy.

Table II. *Surgical outcomes (namely, BCR and urinary continence) according to age at surgery (namely, age <75 yrs vs. age ≥75 yrs).*

Variable		Overall	Age <75	Age ≥75 yrs	*p*-Value
S0-C0 (%)	BCR Absent and Continent	1377 (70.5)	1288 (71.1)	89 (62.7)	0.02
S1-C0 (%)	BCR Present and Continent	388 (19.9)	358 (19.8)	30 (21.1)	0.4
S0-C1 (%)	BCR Absent and Incontinent	147 (7.5)	127 (7.0)	20 (14.1)	0.004
S1-C1(%)	BCR Present and Incontinent	41 (2.1)	38 (2.1)	3 (2.1)	0.6

S: survival; C: continence; BCR: biochemical recurrence.

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ROBOT-ASSISTED RADICAL PROSTATECTOMY: SURGICAL AND FUNCTIONAL OUTCOMES OF A SINGLE-SURGEON'S EXPERIENCE AFTER MODULAR TRAINING

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Introduction: To achieve better surgical and functional outcomes of robot-assisted radical prostatectomy (RARP), the learning curve in surgeons naive for robotic approach should be completed with structured and reproducible modular training. We describe outcomes of the first 100 RARPs performed by a single surgeon after intensive modular training. *Patients and Methods:* We prospectively analysed first 100 consecutive RARPs performed between January 2015 and March 2016 by single surgeon who previously completed an intensive modular training structured consecutive phases: observation of surgical procedures, table assistant and simulator for 1 month in a European training center, console training with 40 surgical steps in increasing

Table I. *Pre-operative patient characteristics of overall population and of every group.*

Variables	Overall population (n=100)	First twenty patients	Second twenty patients	Third twenty patients	Fourth twenty patients	Fifth twenty patients	*p*-Value
Age (years)							
Median	66	66	67.0	63.5	68.0	65	0.1
IQR	(60-69)	(58-73)	(64-69)	(57-67)	(64-72)	(58-70)	
PSA (ng/ml)							
Median	6.3	6.0	7.1	6.1	6.2	5.6	0.1
IQR	(5.0-8.4)	(5.0-6.6)	(5.1-14.1)	(5.0-7.9)	(4.8-7.0)	(5.0-5.6)	
BMI (Kg/m^2)							
Median	26.1	24.7	27.2	26.2	27.1	26.2	0.7
IQR	(23.7-29.4)	(22.2-29.4)	(24.1-28.7)	(23.8-29.1)	(24.4-30.9)	(23.3-29.3)	
CCI (%)							
0	89.3	89.5	90.0	90.0	75.0	98.0	0.07
≥1	10.7	10.5	10.0	10.0	25.0	2.0	
Clinical stage (%)							
pT1	34.9	36.8	20.0	50.0	25.0	41.7	0.1
pT2	63.2	57.9	80.0	50.0	75.0	54.2	
pT3/pT4	1.9	5.3	0	0	0	4.2	
Clinical Gleason Score (%)							
6	14.6	21.1	5.0	20.0	20.0	8.3	0.8
7	63.1	63.2	75.0	55.0	50.0	70.8	
8-10	22.3	15.7	20.0	25.0	30.0	20.9	
D'Amico risk group							
Low	19.6	15.8	20.0	25.0	26.3	7.1	0.7
Intermediate	51.1	57.9	50.0	55.0	31.6	64.3	
High	29.3	26.3	30.0	20.0	42.1	28.6	

Table II. *Intra- and post-operative functional characteristics of overall population and of every group.*

	Overall population (n=100)	First twenty patients	Second twenty patients	Third twenty patients	Fourth twenty patients	Fifth twenty patients	*p*-Value
Operative Time (minutes)							
Median	285	330	330	297	250	260	0.001
IQR	(330-250)	(350-310)	(263-360)	(310-238)	(270-240)	(308-228)	
Console Time (minutes)							
Median	220	270	260	232	200	180	≥0.001
IQR	(270-180)	(298-220)	(293-236)	(270-183)	(218-128)	(208-161)	
3 months continence	80	17	9	18	18	19	0.04
recovery (%)	(80)	(85)	(45)	(90)	(90)	(95)	
Intraoperative complications (%)	5	1	2	2	0	0	0.3
	(5)	(5)	(10)	(10)	(0)	(0)	

difficulty supervised by an expert mentor for a 3-month period. We divided patients in five groups (twenty consecutive patients per group), according to increasing prowess of the surgeon. Pre-operative patient characteristics, operative and console time, intra- and post-operative complications, intra-operative blood loss, positive surgical margins rate and early post-operative continence recovery (3 months after removal of catheter) were recorded, analysed and compared. *Results:* The five groups were comparable in terms of demographic, clinical and pathological characteristics as showed in Table I (all $p>0.05$). 67 patients underwent nerve-sparing surgery and lymphnodes (LN) dissection, median 15 LN retrieved, were performed in 61 cases (4 N1 patients). Median operative time and console time significantly decreased according to increasing surgeon's prowess ($p\leq0.001$), also median intra-operative blood loss and complication rates progressively deacresed (Table II). Early continence (no pad or 1 safety pad) and sexual potency (IIEF >20) rates were significantly higher in the latter groups when compared to the former ($p=0.04$), overall positive surgical margins were not statistically significant ($p=0.9$). *Discussion and Conclusion:* RARP is the most frequently perfomed procedure for prostate cancer (Pca) treatment in US and its diffusion is rapidly increasing in West European countries. A structured modular training for RARP in robotic naive surgeon allowed to obtain early optimal perioperative, functional and oncologic outcomes, and to shorten the learning curve of the surgeon.

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PHASE-II STUDY OF SBRT FOR LOCALIZED PROSTATE CANCER: OUTCOME AND LATE TOXICITY

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Introduction: To evaluate the clinical outcome and late toxicity of a phase II study dealing with stereotactic body radiotherapy (SBRT) with a total dose of 42 Gy in 7 fractions, in patients with localized prostate cancer at low/intermediate risk (according to NCCN score) and at risk of pelvic lymph node involvement inferior to 17% as evaluated by the Roach formula. *Materials and Methods:* This study was based on a prospective analysis of 42 patients enrolled between May 2013 and November 2014 (see Table I; Abstract 26). Patients underwent CT-based virtual simulation with 3-mm thick slices obtained at 3 mm intervals in the supine position. For planning, the GTV included the prostate with the 1/3 proximal seminal vesicles without margin; a margin of 5 mm in all directions around the GTV was applied to define the PTV. All patients were treated with IG-SBRT at a Clinac iX® linear accelerator (Varian Medical Systems, Palo Alto, CA, USA), utilizing VMAT technique with a 2 full arcs arrangement and photons with beam energy of 6 MV, according to pre-established treatment dose specifications and DHV constraints: in particular, for PTV plans were optimised aiming to obtain V95%>95% D98%>94%, V2%<108%; concerning the rectum, the requirements were: mean<18Gy, V20<35%, V32 <10%, V37<5%, D1%<40Gy, while for the bladder, the goal was to keep mean dose <14 Gy and V21 <40%, V33 <30%, V38 <13%, D1%<40Gy; for the penile bulb: mean <10 Gy. All dose distributions were computed with the Anisotropic Analytical Algorithm (AAA) implemented in the Eclipse® planning system with a calculation grid resolution of 2.0 mm. Routine institutional image-based patient position verification protocols foresaw daily on-line matching by CBCT. The acute and late toxicities were recorded using the RTOG/EORTC scale. Additional data were collected by means of I-PSS (International Prostate Symptom Score) e IIEF-5 (International Index of Erectile Function) questionnaires. Biochemical failure was determined using the Phoenix definition. *Results:* The median follow-up duration was 27 months (range: 24 to 36 months). The median age was 74 years (range: 57-80 years). Most dosimetric parameters for the OARs are well within the protocol constraints, with the notable exception of maximal doses to rectum and bladder for which the constraints are exceeded in about 20% of cases, but we did not observe any statistical correlation. Acute GU toxicity of grade 2 (increase in urinary frequency) was observed in 7% of the patients. The incidence rates of late GI and GU toxicity of any grade were 14.2% and 35.7%, respectively. The late GU toxicity of grade ≥2 was 4.7%. No GE late toxicity ≥2 was noted. Previous abdominal surgery appeared to be statistically significant ($p=0.004$; Fisher's test) for the increase of probability of late GE toxicity. The 3-year local recurrence-free survival rate was 98%, only one patient had clinical abdominal lymph node failure. Among the dosimetric data, only V21 revealed to be statistically significant for the late GU ($p=0.035$; Wilcoxon Mann Whitney Test). *Conclusion:*

Our experience with VMAT-based SBRT in low-and intermediate–risk prostate cancer demonstrates favorable efficacy in tumor control and toxicity profile with no decrease in QOL as determined by I-PSS, IIEF. The general good quality of the clinical outcome and the results concerning GI and GU toxicities seem to confirm the robustness of the dosimetric paradigm adopted. Longer follow-up is needed to investigate complete safety and efficacy of the stereotactic treatments.

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WHOLE-PELVIC NODAL IRRADIATION WITH HYPOFRACTIONATED SIMULTANEOUS INTEGRATED BOOST FOR HIGH-RISK PROSTATE CANCER: OUTCOME AND LATE TOXICITY

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Table I. *Patient characteristics (n=41).*

Characteristic	No. of patients
Age (yr),	
Mean±DS	72±6
Median	72
Range	(52-81)
Clinical T stage (n)	
T1-2c	37
T3a-T4	4
Gleason score	
7 (3+4)	3
7 (4+3)	14
8-10	25
Baseline PSA, ng/ml	
Median	11.5
≤10	15
≥10 but <20	15
≥20	11
Androgen suppression (mo)	
Median	15
Range	6-26
Follow-up (mo)	
Median	59
Range	(48-80)
With diabetes	5 (12%)
With hypertension	22 (54%)
With oral anticoagulant	10 (24%)

SD, Standard deviation; PSA, prostate-specific antigen; ECOG, Eastern Cooperative Oncology Group. Data are presented as number of patients, with percentages in parentheses.

Introduction: To report the clinical outcome and toxicities of patients with high-risk localized prostate cancer treated using a concomitant hypofractionated, intensity-modulated radiotherapy boost (IMRT-SIB) combined with androgen deprivation therapy. *Materials and Methods:* A prospective Phase II study of patients with any of the following: clinical stage T3 (2002 American Joint Committee on Cancer staging system), prostate-specific antigen level ≥ 20 but <100 ng/mL, and Primary Gleason score ≥4. Elective pelvic nodal treatment was administered according to a proposed >15% risk of occult nodal involvement as calculated by a standard nomogram. All patients received androgen suppression (luteinizing hormone-releasing hormone agonist only), which typically started 3-6 months before RT and continued for a total duration of ≥12 months. The median duration androgen suppression was 15 months (range, 6-26) The SIB-IMRT treatments were designed to deliver 67.5 Gy in 25 fractions (2.7 Gy/fraction) to the prostate, while simultaneously delivering at least 56.25 Gy (2.25 Gy/fraction) to the seminal vescicles and 50 Gy (2.0 Gy/fraction) to the pelvic lymph nodes. Image guidance was performed using three gold seed fiducials. The National Radiation Therapy Oncology Group scores were used to assess acute and late toxicities. The International Prostate Symptom Score, International Index of Erectile Function-5 (IIEF-5), were tabulated. Biochemical failure was determined using the Phoenix definition. *Results:* Between March 2009 and March 2012, 41 patients were enrolled in this prospective study, the median follow-up duration was 59 months (range=48-80 months). The patient characteristics are summarized in Table I. The median age was 72 years (range=51-81 years). Acute GI and GU toxicities of any grades were observed in 36% and 39% of patients. The only grade 2 symptom was diarrhea requiring medication. The only acute grade 2-GU toxicity was an increase in urinary frequency, with voiding intervals of less than 2 hour. Medication was needed until the completion of RT. The incidence rates of late GI and GU toxicity of any grade were 14% and 17%, respectively. Regarding late GU toxicity the rate of late grade 2 was 9.76%. Diabetes and Dmax-rectal appear to be statistically significant risk factors for the increase of probability of late rectal toxicity. At 6

years, the biochemical failure-free survival (BFS), local recurrence-free survival, and distant metastasisfree survival rates were 92.6%, 100%, and 100%, respectively. The disease-free survival and overall survival rates were 80.5% and 97.5%, respectively. *Conclusion:* Our results showed very interesting disease control rates when using high-dose irradiation on whole pelvic and SIB to the prostatic area, in association with ADT, confirming a good tolerance of the employed treatment modality. These encouraging findings have led us to introduce this therapeutic approach in our current clinical practice.

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SMALL COHORT OF NIVOLUMAB EXPANDED ACCESS PROGRAMME (EAP) PATIENTS: DATA FROM A REAL-WORLD POPULATION

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Introduction: Nivolumab is the first checkpoint inhibitor, approved for the treatment of renal cell cancer, to show a survival benefit in a randomised phase III trial 1. The experience of patients and physicians in routine clinical practice is often different than that in a controlled clinical trial setting. The aim of this study was to retrospectively evaluate its efficacy and safety in real life patients. *Patients and Methods:* Nivolumab was available upon physician request for patients (pts) aged ≥18 years who had relapsed after a minimum of one prior systemic treatment for stage IV renal cell cancer. Nivolumab 3 mg/kg was administered intravenously every 2 weeks. Pts included in the analysis had received ≥1 dose of nivolumab and were monitored for adverse events using Common Terminology Criteria for Adverse Events. *Results:* In total, 15 pts referring to our centre, participated in the EAP. Table I shows pts' baseline characteristics. With a median follow-up of 4.3 months (range=0.9-6.3), the disease control rate (DCR) among 14 pts evaluable for response was 21.42%: 2 pts (14.29%) with partial response and 1 pt (7.14%) with stable disease. To date, median time of treatment is 3.67 months (range=0.5-6.3), with 6 patients treated beyond progression, since we observed a clinical benefit. Among 15 pts, only 1 (6.67%) patient discontinued treatment due to severe toxicity, namely grade-4 asthenia. Treatment was well tolerated in most patients. Grade 3 or 4 treatment-related adverse events occurred just in 1 (6.67%) patient receiving nivolumab. The most common event with nivolumab was fatigue, observed in 6 (40%) patients, of which just one pt with grade-4 and the others with grade-1 fatigue. Other relevant adverse events were anemia in 2 pts (13.33%), both of which grade-2, mild stomatitis in 1 pt (6.67%), and grade-2 hypothyroidism in 1 pt (6.67%). *Discussion and Conclusion:* Even if this is a limited, retrospective experience, it can be explicative of the use of Nivolumab in everyday clinical practice. Nivolumab was demonstrated to be a safe therapy for pre-treated pts with metastatic renal cell carcinoma. Despite a DCR of 21.42%, we observed a clinical benefit in the majority of treated patients (9 patients, that is 3 patients with an objective radiological response and 6 patients with a clinical benefit, despite a radiological progression).

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Table I. *Patients' demographics and clinical caracteristics.*

Demographics	
Median age (range), yr	63 (34-81)
Gender	
M	10 (66.67%)
F	5 (33.33%)
MSKCC	
Favourable	8 (53.33%)
Intermediate	7 (46.67%)
Poor	0
Disease sites that could be evaluated	
1	2 (13.33%)
≥2	13 (86.67%)
Sites of metastasis	
Lymph nodes	13 (86.67%)
Lung	11 (73.33%)
Liver	6 (40%)
Bone	10 (66.67%)
Previous nephrectomy	
Yes	15 (100%)
No	0
Previous regimens	
1	4 (26.67%)
≥2	11 (73.33%)
Previous regimens	
Sunitinib	14 (93.33%)
Pazopanib	4 (26.67%)
Axitinib	6 (40%)
Everolimus	5 (33.33%)

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MODERATE HYPOFRACTIONATION IN POST-OPERATIVE RADIOTHERAPY: A SINGLE-CENTER EXPERIENCE ON 125 PATIENTS

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Introduction: The aim of this study was to evaluate the acute toxicity profiles of a moderate hypofractionated regimen with volumetric modulated arcs therapy (VMAT) in prostate cancer (PC) patients after radical prostatectomy (RP). *Materials and Methods:* From December 2012 to February 2016, 125 patients, previously submitted to RP, received adjuvant (64 patients) or salvage (61 patients) radiotherapy (RT) inside an institutional protocol of moderate hypofractionation schedule using VMAT technique (Varian RapidArc, Palo Alto, CA, USA). Eligible patients were <85 years old, with an ECOG performance status of 0-2, histologically proven adenocarcinoma of the prostate without distant metastases, and pathological stage pT2-4 N0-1, with at least one of the following risk factors: capsular perforation, positive surgical margins, seminal vesicle invasion and/or postoperative PSA >0.2 ng/ml. Patients were stratified into low (1%), intermediate (9%), and high-risk (90%) groups. The median age was 68 years. The median doses were 66 Gy (range 65.5-71.4) to the prostatic bed and 52.5 Gy (range 50.4-54) to the pelvic lymph nodes, in 28 or 30 fractions. The acute genitourinary (GU) and gastrointestinal (GI) toxicities were scored according to the Common Terminology Criteria for Adverse Events CTCAE v4. *Results:* All the 125 patients completed the planned treatment, with good tolerance. After RT, the median follow-up was 15 months. Acute toxicities were recorded for the GU [G0=45/125 (36%), G1=63/125 (50.4%); G2=16/125 (12.8%); G3=1/125 (0.8%)], the GI [G0=42/125 (33.6%); G1=72/125 (57.6%); G2=11/125 (8.8%); no G3]. Analyzing data according to RT intent, a higher rate of GU toxicity ≥2 was found in the adjuvant setting (17.1%) respect to salvage group (9.8%); p=0.01 at Fisher's exact text. Furthermore, at statistical analysis no difference was found between the type of surgery (Robotic, Laparoscopic or Open) and incidence of urinary incontinence (p=0.8). The actuarial Kaplan-Meier for biochemical disease free survival (BDFS) were 94% and 77% for adjuvant and salvage RT, at 36 months. *Conclusion:* Moderate hypofractionated postoperative RT with VMAT was feasible and safe with acceptable acute GU and GI toxicities. Longer follow-up is needed to assess late toxicity and clinical outcome.

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MAGNETIC RESONANCE IMAGING ULTRASOUND SMART FUSION-GUIDED BIOPSY IN THE PROSTATE CANCER DIAGNOSIS: SINGLE CENTER EXPERIENCE

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Introduction: Ultrasound (US)-guided prostate biopsy represents nowadays the standard care to detect prostate cancer (PCa) (1). The application of Multiparametric Magnetic Resonance Imaging (mpMRI) before biopsy seems to be helpful in the management of patients with clinically significant (CS) cancer (2). In the last decade the employment of US devices with mpMRI Fusion system is rising, in order to execute targeted samples. Nevertheless, is becoming more common the idea that the best practice is represented by a combined approach with MRI-targeted biopsies and standard biopsies (3). In this perspective study we report our experience and results obtained on 90 patients with suspect of CS PCa that undewent both an US-guided prostate biopsy with mpMRI Smart Fusion system and a standard one. *Materials and Methods:* Between January and October 2016, 90 patients were subjected, as said, both to a US-guided prostate biopsy with mpMRI Smart Fusion system and a standard one. All subjects had a sustained suspicion of PCa in accordance with the European Association of Urology (EAU) guidelines - based on PSA kinetics and/or suspicious digital rectal examination (DRE)(1) - and in accordance with European Society of Urogenital Radiology (SUR) guidelines - based on lesion described as PIRADS ≥3. Statistical analysis was performed by the use of the correlation test and the Spearman rank correlation test (p-value ≤0.001). *Results:* The median age of the subjects was 67.3 years (range=51-80 years). The median PSA level was 7.62 ng/mL (range=2.6-34 ng/mL) and DRE was suspicious in 15 cases (16.6%). The median volume of prostate gland was 56.5 mL (range=16-238 ml). 41 of the patients (45.5%) had undergone one or more previous prostate biopsies and 19 of them (21.1%) were in active surveillance regimen. mpRMI revealed 30 lesions PIRADS 3 (27.5%), 57 lesions PIRADS 4 (52.3%) and 22 lesions PIRADS 5 (20.2%).

Only the 23.3% (7/30) of PIRADS 3 lesions and the 26.3% (15/57) of PIRADS 4 lesions marked a CS PCa (Gleason Score 6 and Gleason Score ≥7), whereas the 72.7% (16/22) of PIRADS 5 lesions pointed a CS PCa. The statistical analysis did not find any significant correlation between detection rate of CS PCa and level of PIRADS lesion (p 0.22 and p 0.31). But we also observed PCa in random specimens as follows: 17.7% (16/90) and 16.6% (15/90) of patients was affected by PCa respectively with Gleason Score 6 and Gleason Score ≥7. *Discussion:* US-guided prostate biopsy with mpMRI Smart Fusion system is an effective procedure to detect CS PCa, with greater clinical benefit than the standard biopsy alone. In this context, our preliminary perspective single center study did not confirm a strength correlation between detection rate of CS PCa and level of PIRADS lesion. Furthermore, we observed a significant number of CS PCa in random samples. *Conclusion:* Our study seems to confirm the usefulness of a combined approach mpMRI-targeted biopsies and standard biopsies in order to increase the detection rate of higher Gleason score PCa.

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HEAD-TO-HEAD EXTERNAL VALIDATION OF R.E.N.A.L., PADUA, ABC SCORES AND C-INDEX IN NEPHRON SPARING SURGERY

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Introduction: Several nephrometry scores have been proposed to predict surgical complexity and outcomes of nephron sparing surgery (NSS). Three of them, R.E.N.A.L. score (radius, exophytic/endophytic properties, nearness of tumor to collecting system or sinus, anterior/posterior, location relative to polar lines), PADUA score (preoperative aspects and dimensions used for an anatomical) and Cindex (concordance index), have gained a significant popularity; recently, ABC score (arterial based complexity) has been suggested, but not validated. This study investigated the performances of these four nephrometry scores in an external setting. *Materials and Methods:* The CT scan of patients submitted to NSS between January 2014 and June 2016 at a referral tertiary academic institution were fully reviewed. After adequate radiological training, a urology resident measured R.E.N.A.L., PADUA, ABC scores and C-index for each case; data were then stratified into complexity levels. The MIC score (margins, ischemia, complication) was adopted as indicator of surgical outcomes, defined as the contemporary presence of negative surgical margins, ischemia time less than 20 min and no complications Clavien grade >2. Unadjusted and adjusted odds ratios (ORs) of the four scores were estimated using uni- and multivariariate logistic regression. Backward elimination was applied to multivariate models for selecting potential confounders. The agreement between observed frequencies and predicted probabilities was assessed by drawing calibration plots and calculating Brier score. The predictive ability of a logistic model was assessed estimating the area under the ROC curve (AUC) and its binomial exact confidence interval. *Results:* Overall, 234 patients were included (148 males, 86 females; age 63+/-10.9 years), submitted to open lumbotomic (176) or trans/retroperitoneal robot-assisted (58) NSS. The nephrometric-based tumor complexity was as follow: low, intermediate or high in 40.2%, 53.8% and 6.0% for R.E.N.A.L. score and 40.2%, 28.6% and 31.2% for PADUA score, low or high in 59.2% and 40.8% for C-Index and 56.3% and 43.7% for ABC score. A positive surgical outcome according to the MIC score was achieved in 185 procedures (79.1%). All the nephrometry score showed a significant relationship with MIC achievement at univariate analysis, confirmed by calibration plots (Brier score for R.E.N.A.L., PADUA, C-Index and ABC was 0.001, 0.002, 0.022 and 0.006, respectively). Once tumor diameter - the only factor found as possible confounder - was included into the model, a significant relationship in multivariate analysis was retained for PADUA (p=0.013, moderate *vs*. low OR 0.29, high *vs*. low OR 0.23), R.E.N.A.L. (p=0.029, moderate *vs*. low OR 0.29, high *vs*. low OR 0.19) and ABC (p=0.044, high *vs*. low OR 0.43), but not for C-index. Even if no differences in the comparison of the AUC were found (PADUA 0.72, R.E.N.A.L. 0.69, C-index 0.67, ABC 0.68, all paired comparison not significant), the PADUA score provided a borderline-significant improvement in the predictive ability of a standard model (model0 AUC 0.66 *vs*. model0+PADUA AUC 0.72, p=0.062). *Discussion and Conclusion:* PADUA, R.E.N.A.L. and ABC scores showed a good discriminative ability with respect to the MIC score achievement, whereas the C-index did not. The PADUA score achieved a fair, moderately good predictive ability and improved the performance of a standard model.

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IS A DELAY IN THE TIMING OF RADICAL CYSTECTOMY REALLY DETRIMENTAL? A RETROSPECTIVE STUDY

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Introduction: Radical cystectomy (RC) is indicated for muscle-invasive or high-risk non muscle-invasive bladder cancer (BC). EAU guidelines recommends surgery within a time span of 90 days from the diagnosis, otherwise the prognosis could be impaired. However, the literature on this issue reports controversial results. This study aims to evaluate if the latency between diagnosis and cystectomy (LDC) could affect oncological outcomes. *Materials and Methods:* We retrospectively analysed our perspectively-maintained institutional database that stores data of patients submitted to RC since 2009. LDC was defined as the number of days between RC and the last TURBT. The primary outcome was overall survival (OS), the secondary were: relationship between clinical and pathological features and a LDC >90 days and relationship between LDC and pathological upstaging (pUS) (shift from cT1-2 to pT3-4). Statistical correlations were evaluated by univariate and multivariate Cox regression and binary logistic models, considering as significant *p*-values <0.05. *Results:* Overall, 226 patients were included in the study from January 2009 to June 2016 (mean/median LDC 89/79 days). A LDC >90 days was observed for 84 patients (37.2%), while pUS in 48 patients (25.7%). After a median follow up time of 17 months, the overall mortality rate was 47.3% (98/226). Table I summarizes the results. Factors independently related to LDC >90 days were: age (RR=1.047), Charlson Comorbidity Index (CCI)=0 (RR=0.428), diagnosis of recurrent BC (RR=3.390) and lack of detrusor infiltration at TURBT (RR=0.490). Factors related to pUS were: age (RR=1.045) and detrusor infiltration at TURBT (RR=0.307), whereas no relationship was found with LDC (upstaging rate LDC<90 *vs*. >90 days 25.5% *vs*. 26%). OS was independently related to female gender (RR=0.597), CCI>0 (RR=1.377), advanced clinical and pathological staging, and lymph node invasion (RR=2.096), but not to LDC (estimated 2 years OS rate LDC<90 *vs*. >90 days 55% *vs*. 59%). *Discussion and Conclusion:* Elderly and healthier patients with recurrent or clinically NMIBC are more frequently submitted to RC after a long interval. In daily practice at referral institutions a comprehensive evaluation of the patient could balance known and unknown prognostic factors making negligible the impact of a delay in RC. A threshold of LDC of 90 days seems to affect neither the risk of pUS nor OS and should be discussed in further editions of Guidelines.

Table I. *Summary of results of factors related to latency between diagnosis and cystectomy (LDC), pathological upstaging and overall survival.*

	Univariate analysis		Multivariate analysis	
Factor	*p*-Value	RR (95% CI)	*p*-Value	RR (95% CI)
Factors related to LDC >90 Days				
Age (Years, continuous)	0.022	1.035 (1.005-1.066)	0.011	1.047 (1.010-1.084)
Charlson score (0 *vs*. >0)	0.028	0.540 (0.312-0.935)	0.011	0.428 (0.222-0.825)
First diagnosis *vs*. recurrence	<0.001	4.218 (2.296-7.751)	<0.001	3.390 (1.721-6.677)
Histology TURB (T1 *vs*. T2)	<0.001	0.227 (0.122-0.423)	<0.001	0.249 (0.127-0.488)
Endoscopic appearance (A-B *vs*. C-D)	<0.001	0.208 (0.101-0.430)	-	-
Clinical staging (T1-2 *vs*. T>2)	0.053	0.487 (0.235-1.009)	-	-
Factors eelated to pathological upstaging				
Age (Years, continuous)	0.050	1.044 (1.000-1.090)	0.056	1.045 (0.999-1.093)
Histology TURB (T1 *vs*. T2)	0.003	3.437 (1.527-7.737)	0.005	0.307 (0.135-0.698)
Factors related to overall survival				
Gender (female *vs*. male)	0.003	0.504 (0.321-0.791)	0.030	0.597 (0.375-0.951)
Charlson Score (0 *vs*. >0)	0.020	1.637 (1.082-2.476)	0.131	1.377 (2.150-5.514)
Histology TURB (T1 *vs*. T2)	0.015	0.777 (0.635-0.952)	-	-
Endoscopic appearance (A-B *vs*. C-D)	0.002	0.555 (0.384-0.802)	-	-
Clinical staging (T1-2 *vs*. T>2)	0.027	1.732 (1.063-2.821)	-	-
Pathological staging (T1-2 *vs*. T3-4)	<0.001	0.495 (0.396-0.620)	<0.001	3.443 (0.396-0.620)
Node staging (N0 *vs*. Nx *vs*. N1)				
N0	Referent		Referent	
Nx	<0.001	0.476 (0.360-0.630)	<0.001	2.565 (1.537-4.280)
N1	<0.001	2.054 (1.541-2.737)	0.003	2.096 (1.284-3.420)

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PERIOPERATIVE MORBIDITY OF CLAMP *VERSUS* OFF-CLAMP ROBOTIC PARTIAL NEPHRECTOMY: PRELIMINARY RESULTS FROM A MULTICENTRE RANDOMIZED CLINICAL TRIAL (THE CLOCK STUDY)

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Introduction: The impact of ischemia on kidney function residual to partial nephrectomy (PN) remains a controversial issue. The clamping of the artery is more frequent during the minimally-invasive PN compared with the open counterpart. The CLOCK study (CLamp *vs*. Off Clamp the Kidney during partial nephrectomy, clinicaltrial.gov registration n° NCT02287987) is a perspective, randomized, multicentre trial, started in September 2014, still ongoing, with a goal of 200 patients with primary outcome the comparison of renal function preservation; local ethical committee approval was obtained by every center. The present study is an ad interim analysis to compare perioperative morbidity of the two procedures. *Materials and Methods:* Up to September 2016, 137 patients were centrally randomized to be submitted to clamp *vs*. off-clamp robotic PN at 6 institutions. Inclusion criteria were normal coagulative function, healthy contralateral kidney, eGFR ≥60 ml/min, R.E.N.A.L score ≤10 and surgeon experience >50 robotic PN. Split renal function was evaluated pre- and post-operatively after 4-6 months by DTPA renal scan. Peri-operative data were collected in a dedicated ecrf. Any deviation from the assigned technique was recorded and explicitly motivated. *Results:* No significant differences between groups were observed in terms of baseline features, duration of surgery, oncological outcomes and complications, whereas there was a difference in the

Table I. Patients' characteristics and perioperative outcomes.

Preoperative features	Clamp=70	Off-Clamp=67
Gender F-M; n	28-42	25-42
Mean Age (yrs)	60.6	63.7
Mean BMI (kg/m^2)	26.2	26.3
Charlson Comorbidity Index; n (%)		
≤1	60 (85.7)	48 (71.6)
≥2	10 (14.3)	19 (28.4)
Mean Clinical Tumor diameter (cm)	3.0	2.8
Mean Preoperative Creatinine (mg/dL)	0.9	0.8
Mean Preoperative Hemoglobine (g/dL)	14.1	14.1
Median R.E.N.A.L. score (range)	6 (4-9)	7 (4-10)
Split renal function of the affected kidney	48%	48%
Mean eGFR (ml/min)	99.5	94.6
% Study arm shift		
% Shift to off-clamp; n (%)	10 (14.3)	-
% Shift to clamp; n	-	29 (43.3)
Intra-operative outcomes		
Surgical Approach; n (%)		
transperitoneal	56 (80)	53 (79)
retroperitoneal	14 (20)	14 (21)
Opinion on severity of bleeding (0-5); n (%)		
0	15 (21.4)	11 (16.4)
1	24 (34.3)	12 (17.9)
2	23 (32.9)	25 (37.3)
3	3 (4.3)	9 (13.4)
4	5 (7.1)	10 (14.9)
5	0 (0)	0 (0)
Mean Estimated Blood loss (mL)	102.1	160.5
Post-operative outcomes		
Median SIB score; n (range)	3 (0-5)	3 (0-5)
Histotype; n (%)		
ccRCC	28 (40)	29 (43.3)
pRCC	6 (8.6)	11 (16.4)
chRCC	6 (8.6)	6 (9)
cdcRCC	0 (0)	0 (0)
oncocytoma	16 (22.8)	5 (7.5)
AML	7 (10)	8 (11.9)
others	7 (10)	8 (11.9)
Clavien-Dindo Complications grade; n (%)		
0	52 (74.3)	53 (79.1)
1	11 (15.7)	8 (11.9)
2	4 (5.7)	4 (6)
3	3 (4.3)	0 (0)
≥4	0 (0)	2 (3)
Positive Margins rate; n (%)	3 (4.3)	1 (1.5)
Mean Pathological Tumor diameter (cm)	2.9	2.8
OR time (min)	122.4	132.1

severity of bleeding as perceived by the surgeon and in estimated blood loss (Table I). A shift from an off-clamp to clamp technique was observed in 29/67 patients (43.3%): the decision was taken preoperatively in 3 cases (10.3%), intraoperatively before the resection in 10 (34.5%) and during the resection because of prohibitive bleeding in 16 (55.2%). Among the patients randomized to a clamp procedure a shift to off-clamp was observed in 10/70 (14.3%), on the basis of a pre-operative decision. *Conclusion:* Off-clamp and clamped robotic PN are equally safe procedures in terms of oncological outcomes and complications. However, even for tumors with a low/intermediate complexity, in high-volume centers and for skilled surgeons, despite the firm indications given into the setting of a RCT, in a relevant rate of cases off-clamp PN is not feasible due to bleeding, and, on the opposite in a few cases clamping the artery can be redundant.

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GA-68 PSMA PET/CT AS A NEW TOOL IN THE DECISION-MAKING STRATEGY OF PROSTATE CANCER PATIENTS WITH LOW-LEVEL OF PSA

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Introduction: Currently, Choline PET/CT is under definitive assessment for staging of prostate cancer (PC) patients with PSA failure level up to 1.5-3 ng/ml. At lower level of PSA relapse, its accuracy is dramatically reduced. Thus, in this setting a reliable tool to detect PC recurrences is advocated. Aim of the study was to evaluate the impact of Ga-68 PSMA PET/CT in decision-making strategy of patients with PC who underwent radical prostatectomy (RP). *Materials and Methods:* Twenty consecutive patients, previously submitted to RP with a PSA value detectable in the range between 0.1 and 1.9 were recruited for Ga-68 PSMA-PET/CT restaging. Therapeutic strategy based on the Ga-68 PSMA PET/CT evaluation was compared with the strategy that would have been proposed in case of PET not available and/or not strictly indicated, according to international and national PC guidelines. *Results:* In twelve out of 20 patients (60%), Ga-68 PSMA PET/CT documented pathological uptake of the tracer. Considering the site of recurrence, lymph nodes metastases were found in 7 cases, prostatic bed relapse in 3 cases, bone in 3 cases. More specifically, multiple sites of recurrence were shown in 4 cases: in 2 cases prostatic bed and lymph nodes and in 2 cases bone and lymph nodes. According to Ga-68 PSMA PET/CT findings, the decision making strategy was changed as follows: radiation therapy was indicated in 9 out of 20 cases (45%) while systemic therapy was prescribed/or modified, when compared to the previous, in 6 out of 20 patients (30%). In detail, in 3 (15%) patients a complete androgenic blockade was administered, in 2 (10%) a manipulation of the androgen deprivation therapy, finally in a single case zoledronic acid was prescribed. *Conclusion:* Therapeutic strategy based on the Ga-68 PSMA PET/CT was changed in the 60% of patients analyzed compared to the strategy that would have been proposed in case of PET not available and/or not strictly indicated. Thus, Ga-68 PSMA PET/CT seems to be a promising diagnostic tool in patients with PC who underwent RP with PSA relapse values in the window between undetectability and 2 ng/mL. Looking at the present results, further studies investigating the role of Ga-68 PSMA PET/CT are needed in this scenario.

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EXPERIENCE WITH ROBOT-ASSISTED NEPHROURETERECTOMY IN A SINGLE DOCKING

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Introduction: The aim of the study was to demonstrate the feasibility of the execution of a three arm robot-assisted nephroureterectomy (RANU) in a single docking without prior endoscopic resection of the ureteral ostium through the use of the DaVinci robot. *Materials and Methods:* A total of 20 patients with a diagnosis of upper tract urothelial carcinoma underwent a robot-assisted laparoscopic nephroureterectomy using a Robot docking without change in the patient's position and without a prior resection of the ureteral ostium. *Results:* Robotic-assisted laparoscopic nephroureterectomy was successfully completed without open conversion in all 20 patients. The RANU technique was employed at our institution in 14 patients with a mean age of 64.3 years. Mean operative time was 222 min, with 216.7 mean bleeding and a mean hospital stay of 4.5 days. At examination 11/20 patients had a T2, and two patients had a tumor recurrence in the bladder. *Discussion:* The growing use of robotic surgery is leading to a significant increase in techniques and application to various diseases. The Robot-assisted nephroureterectomy appears to be extremely useful and effective during lymphadenectomy and in cistoraffia,

following excision of the distal ureter. The Single docking technique has proven to save time without adversely impacting feasibility and results. *Conclusion:* Robot-assisted nephouterectomy with distal ureterectomy in a single docking is feasible and safe, saving time and optimal oncological and functional results.

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RADIOFREQUENCY THERMAL ABLATION FOR RENAL CANCER IN VON HIPPEL-LINDAU SYNDROME PATIENTS: A PROSPECTIVE COHORT ANALYSIS

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Introduction: Management of RCC in VHL patients represents a clinical dilemma: the oncological outcomes must be weighted against the renal function preservation. Radiofrequency ablation (RFA) technique is used in selected cases for the treatment of small RCC. The aim of this study was to evaluate safety, complications, functional and oncological outcomes of RFA in the treatment of RCC in VHL patients. *Materials and Methods:* All patients underwent genetic evaluation to confirm VHL diagnosis. RCCs were treated with ultrasound guided RFA or with laparoscopic RFA. Clinical and radiological response, disease recurrence and survival outcomes were evaluated. Complications were recorded and graded. *Results:* 16 patients experienced RCC. A total of 20 RCC were treated with RFA. 19 RFA (95%) were US guided while 1 (5%) RCC was treated with laparoscopic-guided RFA. Median RCC size was 2.5 cm (IQR 2.0-3.0). RFA did not impair renal function (p=0.35). Two patients experienced disease persistence and one disease recurrence after 18 months. All these patients were re-treated with US guided RFA with complete response. De novo RCCs were recorded in 14 of 16 patients (87.5%). Median time to *de novo* RCCs presentation was 32 months (IQR 24-75). RFA treatment was overall well tolerated and safe. No complications were recorded. *Conclusion:* RCC occurred in about two third of VHL patients, with young age at presentation and it is frequently multifocal and recurrent. The use of RFA, with extended indications, could represent the tailored treatment for VHL patients, reducing the risk of renal failure and achieving satisfying oncological results.

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URINARY TYROSINE-PHOSPHORYLATED PROTEINS: A NON-INVASIVE MARKER FOR DIAGNOSIS, PROGNOSIS AND FOLLOW-UP FOR BLADDER CANCER

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Introduction: A non-invasive, high sensitive and specific urine test is needed for bladder cancer (BC) diagnosis, prognosis and surveillance to substitute the invasive cystoscopy and to overcome the limitations of urinary cytology. We previously described the diagnostic effectiveness of the urinary tyrosine-phosphorylated proteins (TPP) test. The aim of this study was to validate the diagnostic effectiveness of TPP and to evaluate the ability of the TPP test to predict BC recurrence and progression. We present the preliminary results of this ongoing study. *Materials and Methods:* Urine samples (100 ml) were obtained from BC patients at the time of first diagnosis, during their follow-up and from control volunteers. The TPP urinary value (standard unit – SU) was obtained through the TPP test. Wilcoxon and T-test were used to evaluate the correlation between the TPP SU and the BC grade. The BC recurrence rate and TPP SU correlation was evaluated using the Wilcoxon test. ROC curves were then created evaluating the ability of histology, TPP-test or both to predict BC progression and recurrence rates. *Results:* TPP cut off value was established in our previous trial in 261 SU. One hundred and twenty patients were enrolled. In 45 patients first diagnosis and first follow-up urine samples were collected; in 11 and 3 patients also second and third follow-up urine samples were collected, respectively. The TPP value was higher in patients who developed recurrence at 3 months, median 454 SU (IQR 370-545) *versus* 335 SU (IQR 284-447), p=0.03. The difference of TPP value between recurrent patients and controls or between negative follow-up cases and controls was higher in recurrent patients (p=0.04). TPP test was able to

predict recurrence and to increase the discrimination of a model based on pathology from 61% to 80%, even if these results were not statistically significant ($p>0.05$). *Conclusion:* The preliminary results of this prospective study are encouraging. The TPP tests correctly identify BC and BC recurrent patients from non-recurrent ones. TPP test, in this study, seems to be able to predict the recurrence rate. Confirmation of these results would show that the TPP test could become a useful non-invasive urinary test to predict BC prognosis.

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THE DIAGNOSTIC RELIABILITY OF DYNAMIC SENTINEL LYNPH NODE BIOPSY COMBINED WITH ULTRASOUND (US) IN PENILE CANCER

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Introduction: Dynamic sentinel node biopsy (DSNB) is considered "unsuitable" in patients with penile cancer and palpable inguinal lymph nodes. The aim of this study was to determine the diagnostic reliability of DSNB combined with ultrasound (US)-guided removal of additional suspicious lymph nodes as a minimally invasive diagnostic approach in these patients. *Materials and Methods:* A total of 34 consecutive patients with penile cancer and unilaterally or bilaterally palpable inguinal lymph nodes underwent DSNB. Before the combined staging procedure, the patients underwent preoperative US of both groins. During surgery, sentinel nodes and additional suspicious lymph nodes as determined by the US examination were removed under US guidance. A complete inguinal lymph node dissection was only performed in patients who had tumor-positive nodes. Follow-up consisted of control visits according to the European Association of Urology guidelines, including US investigation of the groins. *Results:* DSNB alone showed lymphatic spread in 12 inguinal regions. US-guided removal of suspicious nonsentinel nodes revealed 7 further inguinal basins with metastases, which would have been missed by DSNB owing to rerouting or complete blockage of the lymphotropic tracer. So far, no lymph node relapse has been observed in the 14 patients with nodenegative disease by this combined diagnostic approach with a median followup of 24 (16-46) months. The morbidity (post-operative bleeding and prolonged lymphorrhea) associated with this procedure was minor (4%). *Conclusion:* The results of this study imply that DSNB combined with US guided removal of suspicious lymph nodes is a reliable diagnostic approach in patients with penile cancer with palpable inguinal lymph nodes. DSNB alone in these patients leads to a significant false-negative rate.

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MALIGNANT MESOTHELIOMA OF TUNICA VAGINALIS TESTIS: CASE REPORT

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Introduction: Mesothelioma of the tunica vaginalis testis is a rare tumor and the most unusual type of mesothelioma with less than 300 cases published in the literature. The first case was described by Barbera in 1957. Due to its low incidence, it is unknown whether asbestos exposure plays a role in its etiology: less than half of reported mesotheliomas of tunica vaginalis testis are associated with asbestos exposure. Other suspected causes are scrotal trauma, log-term hydrocele, herniorraphy and exposition to radiation during radiotherapy. The diagnosis occurs often secondarily during surgery for other reasons (hydrocele, testicular tumor or inguinal hernia) *Materials and Methods:* We present a case of a 40-year-old patient, who was admitted to our department for routine left hydrocele surgery. The patient reported progressive scrotal enlargement without pain and the ultrasonography showed a simple left hydrocele with 350 ml in volume and normal testis. During the operation an anatomopathological analysis was requested because of the strange nodular thickening of tunica vaginalis: the examination revealed a malignant mesothelioma with epithelioid structure and tubule-papillary proliferation. *Results:* The patient agreed with a radical operation and a left hemiscrotectomy with left inguinal lymph node dissection was performed. The definitive histology confirmed the previous report of malignant mesothelioma with angioinvasion but normal testicle findings and negative lymph node. The patient underwent further examinations: computed tomography (CT) showed absence of lymph node enlargement or distant metastases. For the first 2 years a CT was repeated every 4 months, and then every 6 months for 3 years. Five years after surgery the patient has shown no signs of residual disease. *Conclusion:* Mesothelioma of the tunica vaginalis testis is a rare entity, often initially thought to be a hydrocele or an epididymal cyst. An aggressive approach with hemiscrotectomy with regional lymphadenectomy can reduce the risk of recurrence.

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SALVAGE LYMPH NODE DISSECTION FOR NODAL RECURRENCE AFTER RADICAL PROSTATECTOMY

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Introduction: The incidence of recurrence after radical treatment of local prostate cancer (PCa) is frequent, occurring in 30-50% after radical prostatectomy (RP) and in up to 80% after extracorporeal radiotherapy. These patients are normally managed with palliative androgen deprivation therapy (ADT), which is associated with significant toxicity and development of hormone-refractory disease. The aim of this study was to examine the outcome of salvage lymph node dissection (LND) in patients with nodal recurrence documented with C-choline-PET/CT *Patients and Methods:* Fifteen consecutive patients between 2007 and 2015 with biochemical failure and positive lymph nodes by C-choline-PET/CT were retrospectively included in the study. Because of PCa, 12 patients had initially undergone retropubic RP with LND and three perineal RP without LND. Biochemical response was defined as a prostate-specific antigen level of less than 0.2 ng/ml after salvage surgery. *Results:* Mean PSA at salvage LND was 2.1 ng/ml. Median follow-up after salvage LND was 52 months. A total of seven patients (46%) achieved a biochemical response. During follow-up, three patients (20%) remained free from recurrence (one of these patients died from another tumor 12 months after LND), while another two patients underwent adjuvant RT and ADT 6 and 72 months after LND and showed no progression of disease. Only one patient died of their disease 6 years after LND. The other eight patients are being managed with ADT. *Conclusion:* Salvage LND may represent a therapeutic option for selected patients with biochemical recurrence and nodal pathologic uptake by C-choline-PET/CT, improving cancer control and reducing the exposure time to ADT.

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PREDICTIVE FACTORS OF UPSTAGING, UPGRADING AND ADVERSE PATHOLOGICAL FEATURES IN FAVORABLE GS 3+4

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Introduction: Active surveillance (AS) is a valid option for the treatment of low-risk prostate cancer. Whether or not AS could also be offered to patients with intermediate-risk prostate cancer is a debated issue. Some AS protocols included selected patients (older) with Gleason score 3+4. In our study, we evaluated the risk of upgrading and upstaging, and predictive factors of adverse disease in patients with favorable Gleason score 3+4 and identified predictive factors. *Patients and Methods:* From database of our institution, we identified patients who underwent laparoscopic pelvic lymphadenectomy and radical prostatectomy; data on age, BMI, PSA, PSAD, percentage of positive cores, clinical stage, Gleason score, lymphadenectomy template, prostate volume, and number of removed nodes were available. We correlated these variables with upstaging (≥pT3), upgrading (≥GS4+3) and adverse pathological outcomes (non organ-confined disease or ≥GS4+3 or pN1) by logistic regression analysis (SPSS 24). *Results:* Baseline characteristics of the 82 patients with favorable Gleason score 3+4 PCa are reported in Table I. Surgical and pathological outcomes are reported in Table II. Upstaging to ≥pT3 occurred in 9.7% of patients; no variables were associated with upstaging (Table III). Upgrading occurred in 24.4% of patients; PSA was the only factor associated with upgrading (OR=2.12, p=0.04) (Tables IVA and IVB). Adverse pathological outcomes (non organ-confined disease or primary GS4 or pN1) occurred in 31.7% of patients; PSA correlated with adverse pathological outcomes (OR=2.87, p=0.01) (Tables VA and VB). Downgrading occurred in about 5% of patients. *Conclusion:* In patients with favorable Gleason score 3+4, adverse pathological outcomes, defined as non organ-confined disease or Gleason score 4+3 or pN1, occurred in 32% of the patients. PSA was a predictive factor of upgrading and adverse pathological features.

Table I. *Baseline characteristics*.

Patients	n	82
Age	Years	65.1±6.1
BMI	kg/m^2	27.5±3.0
PSA	ng/ml	6.7±1.9
Prostate volume	cc	55.6±20.3
PSAD	ng/ml/cc	0.13±0.06
cStage(%)	T1c	36.6
	T2a	63.4
Positive core percentage	%	39.3±24.0

Table II. *Surgical and pathological outcomes*.

Pathological stage,%	pT2a	17.2
	pT2b	7.3
	pT2c	65.8
	pT3a	7.3
	pT3b	2.4
Pathological Gleason,%	3+3	4.9
	3+4	70.7
	4+3	19.5
	>7	4.9
Positive SM	%	5
LAD template	Obturator (I)	48.8
	Iliac-obturator (II)	51.2
No. of removed nodes	n	20.0±10.4
pN1	%	2.4
Adverse pathology	%	31.7

Table III. *Predictive factors of upstaging (≥pT3): univariate analysis.*

Upstaging	Yes	No	*p*-Value
cT1c *vs.* cT2a (%)	11.5 *vs.* 6.7	88.5 *vs.* 93.3	0.61
LAD template: I *vs.* II (%)	0 *vs.* 19.1	100 *vs.* 80.9	0.22
Age (years)	65.0±2.3	65.1±6.4	0.99
BMI (kg/m^2)	29.9±5.5	28.1±2.8	0.24
PSA (ng/ml)	7.9±0.5	6.5±2.0	0.19
PSAD (ng/ml/cc)	0.13±0.02	0.13±0.06	0.99
Positive core percentage (%)	58.3±31.9	37.2±22.6	0.09
Prostate volume (cc)	59.5±12.4	55.2±21.1	0.61
No. of removed nodes (n)	25.5±14.6	19.4±9.9	0.29

Table IV. *A. Predictive factors of upgrading: univariate analysis.*

Upgrading	Yes	No	*p*-Value
cT1c *vs.* cT2a (%)	26.9 *vs.* 20.0	73.1 *vs.* 80.0	0.62
LAD template: I *vs.* II (%)	30.0 *vs.* 19.1	70.0 *vs.* 80.9	0.60
Age (years)	66.4±3.4	64.6±6.7	0.43
BMI (kg/m2)	28.3±3.5	27.1±2.7	0.32
PSA (ng/ml)	7.9±1.9	6.3±1.8	0.02
PSAD (ng/ml/cc)	0.15±0.06	0.13±0.06	0.28
Positive core percentage (%)	33.9±25.2	41.0±23.7	0.42
Prostate volume (cc)	56.9±13.5	55.2±22.3	0.77
No. of removed nodes (n)	19.0±11.9	20.4±10.0	0.72

B. Predictive factors of upgrading: multivariate analysis.

	OR	CI (95%)	*p*-Value
PSA	2.12	1.042-4.308	0.04

Table V. *A. Predictive factors of adverse pathology: univariate analysis.*

Adverse pathology	Yes	No	*p*-Value
cT1c *vs.* cT2a (%)	38.4 *vs.* 20.0	61.5 *vs.* 80.0	0.22
LAD template: I *vs.* II (%)	30.0 *vs.* 33.3	70 *vs.* 66.4	0.66
Age (years)	65.9±3.2	64.7±7.1	0.43
BMI (kg/m2)	28.1±3.4	27.1±2.8	0.45
PSA (ng/ml)	7.9±1.6	6.1±1.8	0.004
PSAD (ng/ml/cc)	0.15±0.06	0.13±0.06	0.36
Positive core percentage (%)	41.5±29.5	38.2±21.5	0.51
Prostate volume (cc)	58.1±13.1	54.4±23.0	0.64
No. of removed nodes (n)	21.1±12.9	19.5±9.1	0.63

B. Predictive factors of adverse pathology: multivariate analysis.

	OR	CI (95%)	*p*-Value
PSA	2.87	1.326-6.200	0.01

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LIPOSARCOMA OF SPERMATIC CORD: CASE REPORT

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Background: Paratesticular tumors are rare and account for 2% of scrotal neoplasm. They usually are benign; malignant tumors are commonly sarcomas and 7% of these are liposarcomas. The latter are tumors derived from mesodermal tissue. They present as large scrotal masses and can sometimes be mistaken for hydrocoeles and hernias. Their treatment consists of wide surgical excision. Lymphadenectomy is not recommended in cN0 patients. Adjuvant radiotherapy is indicated in cases with positive surgical margins. Recurrences have been reported even after 10 years, so a long follow-up is needed. We report a case of spermatic cord liposarcoma. *Patients and Methods:* A 67-year-old male presented at our Institution with a progressive swelling of the left scrotum which had been present for two years. The patient reported low discomfort without pain. Physical examination showed a large, mobile left scrotal mass. Blood tests including tumor markers were normal. Ultrasonography revealed an heterogeneous soft tissue mass measuring about 8 cm in the upper part of the scrotum; the left testis was normal. Magnetic resonance imaging showed a dismogeneous fat mass. *Results:* Patients underwent a left radical orchidectomy with inguinal access. Complete macroscopic excision was obtained. Histopathologic examination of the specimen revealed a large encapsulated soft yellow mass measuring 8×4 cm which surrounded the left spermatic cord. There was no necrosis or vascular invasion. This was consistent with a well-differentiated liposarcoma. Surgical margins were negative. No adjuvant therapy was performed. The patient is currently disease free. *Conclusion:* Although liposarcomas of the spermatic cord are rare, they should be considered in all cases of any inguinoscrotal mass. Radical inguinal orchiectomy is essential to prevent local or distant spread of disease. Long follow-up is also needed for low-grade tumors.

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COMPARISON OF TWO TEMPLATES OF LYMPHADENECTOMY IN PATIENTS AFFECTED BY HIGH-RISK PROSTATE CANCER

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Introduction: High-risk prostate cancer treatment considers an extended lymphadenectomy. We compared two templates of pelvic lymphadenectomy in high-risk patients undergone an extraperitoneal or transperitoneal laparoscopic radical prostatectomy. *Patients and Methods:* Two consecutive series of patients affected by high-risk prostate cancer underwent laparoscopic radical prostatectomy. In group 1 (116 patients), the procedure was realized by a preperitoneal access with an extended lymphadenectomy, including external iliac and obturator nodes; in group 2 (35 patients), access was transperitoneal with a broader lymphadenectomy consisting of common iliac, external iliac, hypogastric and obturator nodes. We compared perioperative outcomes in terms of number of nodes removed, positive nodes, and complications in the two groups of patients. Statistical analysis was realized using SPSS 24. *Results:* Data on 151 patients were analyzed. Baseline characteristics are reported in Table I. Preoperative data were balanced between the two groups of patients except for biopsy Gleason score. Postoperative outcomes are listed in Table II: Group 2 patients presented worse pathological stage, longer operative time, more nodes removed (mean 33.3 *vs*. 16.6, $p<0.001$) and more positive pathological nodes (22.9 *vs*. 1.7%, $p<0.001$). Moreover, a wider lymphadenectomy template was not associated with greater risk of complications or lymphocele. *Conclusion:* In our retrospective analysis, a transperitoneal laparoscopic radical prostatectomy with an extended lymphadenectomy template including obturator, external iliac, common iliac and hypogastric nodes allows removal of a greater number of nodes in order to obtain more positive nodes without increasing risk of complications.

Table I. *Baseline characteristics*.

	All patients	Group 1	Group 2	*p*-Value
Age				
Years	66.8±5.5	67.0±5.6	66.0±4.9	0.33
PSA				
ng/ml	11.8±8.1	10.9±6.2	15.0±12.0	0.06
PSAD				
ng/ml/cc	0.25±0.20	0.22±0.16	0.32±0.28	0.07
BMI				
kg/m^2	27.1±3.4	27.1±3.4	27.2 ±3.5	0.85
ASA				
I	2.9	2.5	5.1	NS
II	36.3	29.1	57.7	
III	57.8	65.8	31.2	
IV (%)	2.9	2.5	6.0	
C Stage				
T1c	43.7	48.3	28.6	0.84
T2	51.0	48.3	60.0	0.02
T3	5.3	3.4	11.4	
Bx Gleason				
3+3	6.6	8.6	0	0.004
3+4	4.6	3.4	8.6	
4+3	49.7	58.6	20.0	
>7	39.1	29.4	71.4	

Table II. *Postoperative outcomes*.

	Total	Group 1	Group 2	*p*-Value
Operative time				
min	248.3	241.7	271.1	0.01
	58.7	59.6	49.71.8	
Prostate volume				
g	52.4	52.7	51.3	0.72
	20.1	20.6	18.8	
Path. stage				
pT2	61.6	66.4	45.7	0.01
pT3a	23.9	23.3	25.7	
pT3b	13.2	9.4	25.7	
pT4	1.3	0.9	2.9	
Pathol. Gleason				
3+3	3.3	4.3	0	0.14
3+4	17.9	20.6	8.6	
4+3	44.4	43.1	48.5	
>7	34.4	32.0	42.9	
Positive SM				
%	21.8	18.1	34.3	0.06
Complications				
%	21.2	25.0	8.6	0.04
Lymphocele				
%	4.0	5.2	0	0.21
No. of nodes removed				
n	20.4	16.6	33.3	<0.001
	11.0	8.3	9.4	
Positive nodes				
%	6.6	1.7	22.9	<0.001

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PATHOLOGIC OUTCOMES IN PATIENTS AFFECTED BY VERY-LOW-RISK AND LOW-RISK PROSTATE CANCER AND ELIGIBLE FOR ACTIVE SURVEILLANCE

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Introduction: Active surveillance (AS) has emerged as a valid option for the conservative management of low-risk prostate cancer (PCa). The D'Amico classification is commonly used criterion for identification of low-risk (LR) patients. However, upgrading and upstaging at radical prostatectomy occurred in 20-54% and 6-26% of patients, respectively. Therefore more restrictive criteria have been adopted in several AS protocols. The Italian arm (SIURO) of the Prostate Cancer Research International Active Surveillance (PRIAS) inclusion criteria are stage cT1c/T2a, Gleason score (GS) <7, PSA ≤10 ng/ml, PSA density (PSAD) ≤0.20 ng/ml/cc, ≤2 positive cores. The aim of the study was to evaluate pathologic outcomes in patients affected by very low-risk (VLR) and LR PCa and eligible for AS. *Patients and Methods:* We conducted a retrospective analysis in patients with LR PCa who underwent laparoscopic radical prostatectomy at our Institution from 2005 to 2016. We identified patients with LR PCa defined as cT1c-T2a, GS <7, PSA ≤10 ng/ml and patients with VLR PCa as defined by Italian PRIAS. Complete information on PSA, PSAD, clinical stage, GS, percentage of positive cores, number of nodes removed, and pathological outcomes were available. We evaluated GS upgrading (to primary pattern 4), non-organ-confined disease and unfavorable disease (≥pT3, GS ≥4+3, pN1) in patients with LR and VLR PCa. Predictive factors of unfavorable disease were analyzed by logistic regression analysis (SPSS 24). *Results:* We identified 103 patients with LR PCa. of these, 58 patients had VLR PCa according to PRIAS criteria. Baseline characteristic of patients are described in Table I. There were no significant differences between LR and VLR patients. Pathological outcomes revealed upstaging in 9% and 1.7%, upgrading in 24.7% and 22.8% in LR and VLR patients, respectively. Unfavorable disease occurred in 28.2% and 22.4% of LR and VLR patients, respectively (Table II). At multivariate analysis, PSAD was the only predictive factor of unfavorable disease in LR patients (Table III). *Conclusion:* In our experience, upstaging and upgrading at laparoscopic radical prostatectomy occurred in 9% and 25% of low-risk patients and in 2% and 23% of very low-risk patients. About a quarter of the patients presented unfavorable disease (non-organ-confined, primary GS 4). PSAD was the only predictive factor of unfavorable disease.

Table I. *Baseline characteristics*.

		LR	VLR	*p*-Value
Age (average)	years	65.8±5.4	66.3±5.6	0.54
BMI (average)	kg/m^2	26.6±2.8	26.8±2.8	0.75
PSA (ng/ml)	ng/ml	6.4 ±1.9	6.2±2.1	0.48
PSAD	ng/ml/cc	0.12±0.05	0.12±0.06	0.52
Clinical stage	T1c T2a	88.4 11.6	93.1 6.9	0.54
Prostate volume	cc	57.4±21.0	58.8±24.0	0.70
Biopsy positive cores	%	27.4±18.5	15.5±6.5	<0.001

Table II. *Pathological outcomes in LR and VLR patients*.

	LR	VLR	*p*-Value
No. of removed nodes			
n	12.2±6.3	11.1±5.1	0.35
Positive surgical margin			
%	4.9	5.3	0.93
LAD			
Nx Obturator Iliacobturator	21.4	31.0	0.36
	62.1	56.9	
	16.5	12.1	
Pathological stage			
T0	3.0	5.3	0.64
T2a	19.8	28.0	
T2b	6.0	7.0	
T2c	62.2	57.9	
T3a	7.0	0	
T3b	2.0	1.7	
Gleason PT			
0	3.0	5.3	0.95
3+3	35.6	40.3	
3+4	36.6	31.6	
4+3	17.8	17.5	
4+4	5.9	5.3	
9	1.0	0	
Unfavorable disease			
%	28.2	22.4	0.43
Patients with complication			
%	10.7	8.6	0.67

Table III. *Multivariate analysis for predictive factors of unfavorable disease in LR and VLR patients*.

	LR			VLR		
	OR	*p*-Value	CI (95%)	OR	*p*-Value	CI (95%)
Age	1.093	0.26	0.94-1.28	1.13	0.31	0.89-1.45
BMI	0.935	0.57	0.74-1.18	0.86	0.39	0.61-1.21
PSA	0.905	0.60	0.62-1.31	0.98	0.95	0.55-1.73
PSAD	5.417	0.02	1.28-22.8	11.79	0.05	0.97-143.3
% positive cores	0.996	0.86	0.96-1.04	1.04	0.96	0.86-1.17
Clinical stage	0.339	0.20	0.67-1.76	0.29	0.45	0.01-7.32
N removed nodes	0.917	0.13	0.82-1.03	0.80	0.07	0.62-1.02

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PREDICTIVE FACTORS OF NODAL MICROMETASTASIS IN PATIENTS WITH ORGAN CONFINED PROSTATE CANCER

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Introduction: Aim of this study was to evaluate predictive factors of nodal metastasis in patients affected by organ-confined prostate cancer (PCa) who underwent laparoscopic radical prostatectomy (LPR). *Patients and Methods:* From the database of our Institution, we identified patients who had undergone a laparoscopic pelvic lymphadenectomy and radical prostatectomy; data on age, BMI, PSA, PSAD, positive core percentage, clinical stage, Gleason score, lymphadenectomy template, prostate volume, and number of removed nodes were available. We correlated these variables with pathological node metastasis by logistic regression analysis (SPSS 24). *Results:* Data on 183 patients were analyzed. Baseline characteristics are shown in Table I. On univariate analysis, PSA, PSAD, prostate volume, biopsy Gleason score were associated with pN1. Surgical and pathological outcomes are reported in Table II. At univariate analysis, pathological stage, positive surgical margins and LAD template (obturator and external *vs*. obturator, external hypogastric and common) correlated with pN1. At multivariate analysis, PSAD, prostate volume and superextended lymphadenectomy are associated with nodal metastasis. *Conclusion:* In our retrospective analysis, PSAD and prostate volume are predictive factors of nodal metastasis. Moreover, a superextended lymphadenectomy is also associated with nodal metastasis.

Table I. *Baseline patient characteristics*.

	All patients	N0	N1	*p*-Value
Patients	183	171	12	
Age				
Years	66.3±5.5	66.3±5.5	66.0 ±5.9	0.68
BMI				
kg/m^2	27.0±3.5	27.0±3.5	28.3±3.4	0.67
PSA				
ng/ml	11.0±7.2	10.5±6.3	17.1±13.8	<0.001
Prostate volume				
cc	53.0±20.7	52.5±19.9	59.8±29.9	0.006
PSAD				
ng/ml/cc	0.24±0.18	0.23±0.15	0.36±0.37	<0.001
cStage				
T1c	44.1	44.3	41.7	0.35
T2	53.6	53.9	50.0	
T3	2.3	1.8	8.3	
Biopsy Gleason score				
3+3	20.3	21.3	8.3	0.02
3+4	26.4	26.6	25.0	
4+3	27.5	28.4	8.3	
>7	25.8	23.7	58.4	
Positive core percentage				
(%)	45.7±24.2	44.5±23.9	61.1±24.1	0.83

Table II. Surgical and pathological outcomes.

	All patients	N0	N1	*p*-Value
	183	171	12	
Path. Stage				
pT2	65.0	68.4	16.7	<0.001
pT3a	20.2	20.5	16.7	
pT3b	13.1	9.4	66.6	
pT4	1.6	1.7	0	
Pathol. Gleason				
3+3	6.0	6.4	0	0.16
3+4	32.2	33.9	8.3	
4+3	39.4	39.2	41.7	
>7	22.4	20.5	50.0	
Positive SM				
%	43	37	6	0.02
LAD template				
Extended	77.6	80.7	33.3	<0.001
Superextended	22.4	19.3	66.7	
Number nodes removed				
n	23.3±9.5	22.9±9.3	28.6±11.4	0.39

Table III. *Multivariate analysis*.

	OR	*p*-Value	CI (95%)
PSAD	1.34	0.04	1.008-1.773
LAD template	0.13	0.003	0.032-0.498
Prostate volume	1.04	0.02	1.005-1.070

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PREDICTIVE FACTORS OF UPGRADING AND DOWNGRADING IN PATIENTS WITH PROSTATE CANCER

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Introduction: The aim of this study was to evaluate upgrading (UG) and downgrading (DG) rates and predictive factors in patients affected by prostate cancer (PCa). *Patients and Methods:* From the database of our Institution, we identified patients with organ-confined disease who underwent laparoscopic pelvic lymphadenectomy (LAD) and radical prostatectomy (RP); data on age, BMI, PSA, PSAD, positive core percentage, clinical stage, Gleason score (GS), lymphadenectomy template, prostate volume, and number of

removed nodes were available. We calculated UG and DG rates for all patients and for GS subgroups. We evaluated predictive factors of UG and DG in all patients and in GS subgroups. Statistical analysis was performed using chi-square test, Mann–Whitney, logistic regression test, as appropriate (SPSS 24). *Results:* Data on 374 patients were available. UG and DG occurred in 42.0% and in 13.1% of patients, respectively; Table I reports UG and DG in GS subgroups of patients. Univariate and multivariate analysis of UG are reported in Tables II and III; biopsy GS, PSA, PSAD and percentage of positive cores are predictive factors of UG. Univariate and multivariate analysis of DG are reported in Tables IV and V; biopsy GS, PSA, and PSAD are predictive factors of DG. *Conclusion:* In our experience, upgrading and downgrading occurred in 42% and 13% of patients, respectively. GS, PSA and PSAD are predictive factors of UG and DG.

Table I. *Upgrading (UG) and downgrading (DG) rates in all patients and in GS subgroups.*

	all	GS 3+3	GS 3+4	GS 4+3	GS 4+4
Upgrading	42.0	27.5	8.6	4.3	1.6
downgrading	13.1	-	0.8	5.1	7.2

Table II. *Upgrading: univariate analysis.*

Variable	All	3+3	3+4	4+3	4+4
Gleason bx	<0.001		-	-	-
Risk	<0.001	0.17	0.26	0.57	0.57
Nerve sparing/not	0.01	0.41	0.68	0.23	0.23
RP/TP	0.003	0.48	0.87	0.91	0.91
LAD	0.003	0.52	0.57	0.58	0.58
Clinical stage	0.54	0.02	0.21	0.83	0.83
Pathological stage	0.32	0.03	<0.001	0.29	0.29
Age	0.25	0.19	0.12	0.45	0.40
BMI	0.82	0.63	0.09	0.96	0.54
PSA	0.63	0.16	0.02	0.17	0.02
PSAD	0.27	0.006	0.06	0.09	0.03
Number of bx cores	0.18	0.27	0.52	0.34	0.36
% positive cores	0.17	0.07	0.82	0.46	0.01
Prostate volume	0.13	0.009	0.56	0.39	0.40
n° removed nodes	<0.001	0.45	0.38	0.03	0.17

Table III. *Upgrading: multivariate analysis.*

	Variable	OR	*p*-Value	95% CI
All pts	Gleason bx	1.20	0.03	1.098-3.896
3+3	PSAD	1.17	0.02	1.123-3.251
3+4	PSA	1.13	0.03	1.014-1.261
4+3	-	-	-	-
4+4	% positive cores	1.05	0.01	1.009-1.087

Table IV. *Downgrading: univariate analysis.*

Variable	All	3+3	3+4	4+3
Gleason bx	<0.001	-	-	-
Risk	<0.001	0.60	0.19	-
Nerve sparing/not	0.07	0.52	0.86	0.12
RP/TP	<0.001	0.52	0.31	0.19
LAD	0.001	0.13	0.73	0.48
Clinical stage	0.30	0.58	0.79	0.78
Pathological stage	0.28	0.31	0.29	0.17
Age	0.76	0.12	0.80	0.40
BMI	0.96	0.09	0.41	0.22
PSA	0.03	0.02	0.004	0.03
PSAD	0.36	0.05	0.01	0.08
Number of bx cores	0.30	0.52	0.79	0.36
% positive cores	0.054	0.82	0.12	0.67
Prostate volume	0.75	0.56	0.51	0.65
n° removed nodes	<0.001	0.38	0.52	0.34

Table V. *Downgrading: multivariate analysis.*

	Variable	OR	*p*-Value	95% CI
All pts	Gleason bx	1.20	0.01	1.067-1.981
All pts	PSA	0.88	0.04	0.806-0.959
3+4	PSA	1.20	0.05	1.001-1.445
4+3	PSAD	2.10	0.03	1.061-4.168
4+4	-	-	-	-

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BIOCHEMICAL AND RADIOGRAPHIC RESPONSE TO ABIRATERONE ACETATE IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER WITHOUT PREVIOUS CHEMOTHERAPY

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Introduction: Abiraterone acetate (AA) is a first in-class inhibitor of cytochrome P450c17, a critical enzyme in androgen synthesis. AA plus prednisone improves overall survival in patients with metastatic castration-resistant prostate cancer who have received or not docetaxel. *Patients and Methods:* In June 2011, a 71-year-old male patient was treated with leuprorelin and radical prostatectomy for prostate adenocarcinoma (Gleason score 4+4=8; t3b N0 Mx R1). From March to May 2012, he received external beam radiotherapy. In April 2013, the PSA value was 0.42 ng/dl. In November 2013, PSA increased to 1.9 ng/ml and the patient

started total androgen blockade with 50 mg/day bicalutamide and monthly 3.75 mg leuprorelin. A PET/CT scan performed on December 2014 showed diffuse abnormal uptake in bones and lymph nodes and PSA was 9 ng/dl. In January 2015, bone metastasis was confirmed by bone scan. In consideration of disease progression, in February 2015 the patient started AA at 1,000 mg/day plus 10 mg prednisone daily. After 3 months of therapy of As above, PSA decreased to 1.23 ng/ml. In June 2015, a CT scan showed the absence of lesions previously detected by PET/CT scan. PSA stabilized at 0.3 ng/ml. In October 2015, Co-PET scan confirmed complete response of disease. No severe side-effects, such as hypokalemia, hypertension, and water sodium retention, were detected. Currently, after 21 months of therapy, AA is ongoing. *Conclusion:* According to Prostate Cancer Working Group Criteria 2-3 (PCWG 2-3), we observed a complete and durable response to AA with a good tolerance.

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LONG SURVIVAL WITH ABIRATERONE ACETATE IN AN ELDERLY PATIENT WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

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Introduction: Abiraterone acetate (AA) is an oral selective inhibitor of cytochrome P450c17 (CYP17). It is approved for use with low-dose prednisone for treatment of patients affected by mCRPC in pre and post-docetaxel settings. AA prolongs overall survival in patients with mCRPC both in those whose disease progresses after chemotherapy and those who have not received prior first-line treatment. *Patients and Methods:* We report the case of an 82-year-old man with mCRPC. At the diagnosis in February 1997, prostate-specific antigen (PSA) was 29.5 ng/ml, Gleason score 7 (3+4) and the patient was treated with monthly 3.75 mg leuprorelin plus external-beam radiotherapy as primary radical therapeutic approach for localized prostate cancer. In March 2004, PSA increased to 2.76 ng/ml and total androgen blockade with 50 mg bicalutamide plus 3.75 mg triptorelin was started. In March 2010, PSA increased to 8.7 ng/ml and flutamide 250 mg was prescribed. The serum PSA level reached a nadir (6.45 ng/ml). In March 2011, PSA increased up to 36.8 ng/ml, a bone scan and choline-PET-CT scan showed multiple bone metastases. In May 2011, the patient started 75 mg/m^2 docetaxel. After 4 months of chemotherapy, no biochemical response was observed with a further increase of PSA to 132 ng/ml and a CT scan showed stable disease. In November 2011, he started 1000 mg AA plus 10 mg prednisone daily; a PSA response was observed (PSA nadir of 26.5 ng/ml). PSA, CT scan and bone scan were performed regularly to monitor progression of disease. After 46 months of AA, no progression was observed. Therapy is still ongoing with a good safety profile. *Conclusion:* We reported a case of long-term survival on AA treatment (46 months) in an elderly patient. AA plus prednisone resulted in prolonged overall survival, radiographic progression-free survival and delayed PSA progression in this patient with metastatic castration-resistant prostate cancer in the first- and second-line treatment settings.

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PRIMITIVE NEUROECTODERMAL TUMOR OF KIDNEY WITH THROMBOSIS OF THE INFERIOR VENA CAVA AND GOOD RESPONSIVE TO SURGICAL AND MEDICAL TREATMENT

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Introduction: Primitive neuroectodermal tumor (PNET) of kidney is a rare cancer typical of young adults, with few cases described in literature. We report a case of renal PNET in a 31-year-old man who presented to our Department with a CT scan revealing a large renal mass of 20 cm, with massive thrombosis of the inferior vena cava (IVC) (Figure 1A-B). The patient underwent radical nephrectomy with contextual retroperitoneal lymphadenectomy, and resection of IVC (Figure 2) needing Dacron prosthesis substitution (Figures 3 and 4). Definitive histopathological examination showed PNET of the kidney infiltrating the ipsilateral adrenal gland (Figure 5), massive cava thrombosis with infiltration of the vena cava wall (Figure 6) and one lymph nodal metastasis. Post-operative PET scan showed metastatic lesions in bilateral adrenal glands and pancreas. The patient received chemotherapy and currently is in follow-up after 26 months from initial diagnosis without any sign of recurrence of disease. Kidney PNETs are usually associated with poor prognosis hence they need early identification and differentiation from other similar small-cell tumors in order to obtain a good response to treatment.

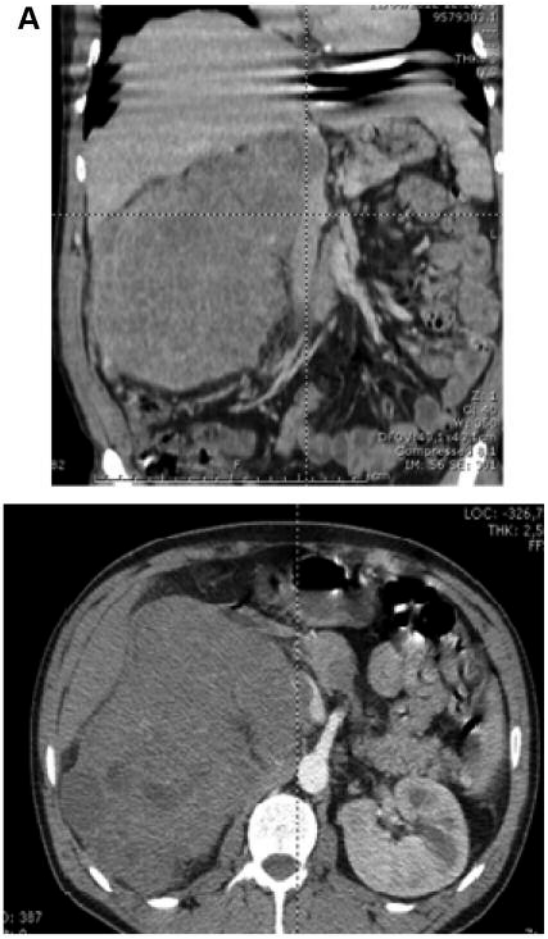

Figure 1. *Computed tomographic scan detected a large right renal mass with infiltration and thrombosis of inferior vena cava (A). Coronal scan shows infiltration of vena cava and diaphragm (B).*

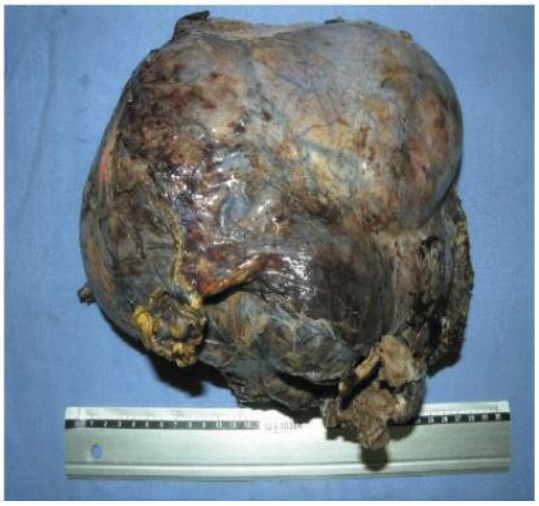

Figure 2. *Macroscopic aspect of operating specimen. The bulky renal mass of around 20 cm completely subverted the kidney anatomy.*

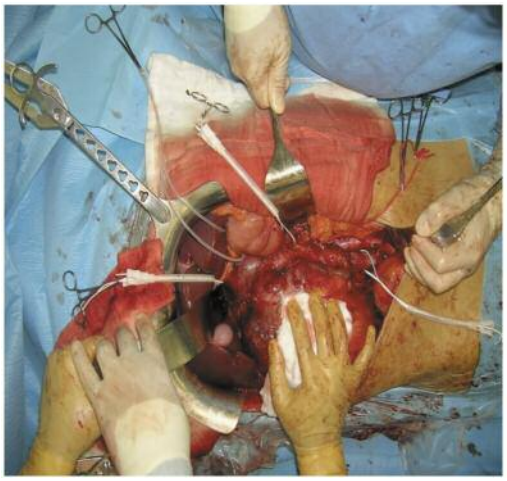

Figure 3. *Surgical access: before clamping, the vena cava was isolated and reperted by ribbons. To notice, the large right renal mass that dislocates liver and retroperitoneal vessels.*

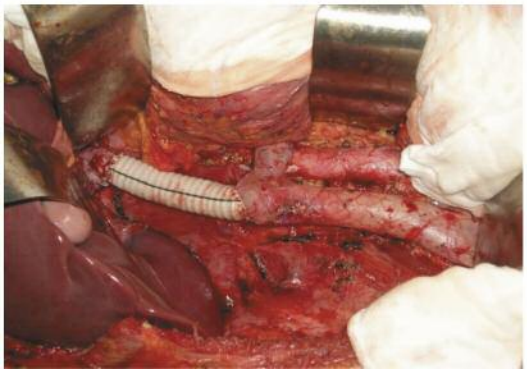

Figure 4. *Intraoperative image, showing Dacron prosthesis substitution of inferior vena cava.*

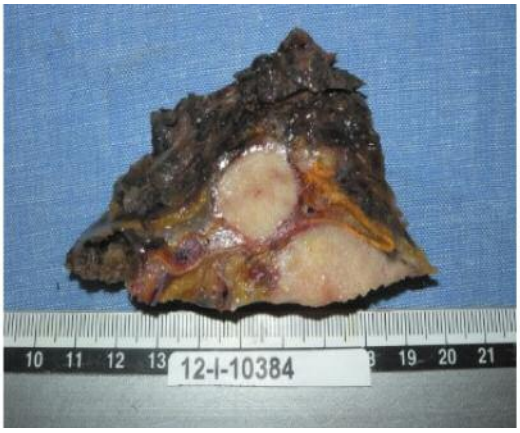

Figure 5. *Neoplastic mass clearly infiltrates right adrenal gland.*

Figure 6. *Vena cava specimen showing neoplastic thrombotic involvement with infiltration of the venal wall.*

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A LONG-TERM SURVIVAL IN METASTATIC PAPILLARY RENAL CELL CARCINOMA TREATED WITH TARGETED THERAPIES

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Introduction: Papillary renal cell carcinoma (PRCC) is the second most common histology of kidney cancer. Although targeted-therapy is particularly effective in advanced RCC data on non-clear RCC are still unclear. The optimal therapy for PRCC remains uncertain and the prognosis of metastatic disease is generally poor. We report the case of a patient with metastatic PRCC, with long survival. *Patients and Methods:* In February 2013, a 66-year-old male patient was submitted to a left radical nephrectomy with associated lymphadenectomy for a poorly differentiated (G3) type 2 PRCC, infiltrating the adipose perirenal tissue with exceeding Gerota capsule (pT4). Follow-up was negative until April 2014, when a CT scan highlighted locoregional recurrence and liver (at least 15 secondary lesions in both lobes), lung and lymph nodes metastases. One of the liver lesions was biopsied and found to be a metastatic site of PRCC. Considering the stage of disease, good MSKCC/Heng prognostic score and the histological subtype, the patient began first-line mTOR-targeted therapy with temsirolimus. In October 2014, the patient reported back pain and CT scan showed a lytic area in the D12 soma, with a further disease progression (PD) in the liver. Thus, we decided to treat the spinal D12 lesion with radiotherapy and start second-line therapy with sunitinib, a tyrosine-kinase inhibitor. After 4 months of treatment, the patient experienced additional PD in liver and lymph nodes and third-line therapy with sorafenib was started. After 4 months, a CT scan showed stable disease (SD). But after 4 months of treatment, the patient returned to the emergency room for angina with a diagnosis of acute coronary syndrome and sorafenib was permanently discontinued. In January 2016, a CT scan showed PD in liver and lung and SD in bone. Considering the good performance status, treatments previously received and the further PD, the patient was referred to fourth-line treatment with everolimus, another mTOR inhibitor. However, after 4 months, a CT scan showed SD despite a progressive clinical worsening of symptoms, as grade 3 fatigue and asthenia, severe pain and the therapy was continued at a reduced 50% dosage. After a further three courses of treatment, everolimus was definitively stopped because of clinical worsening of symptoms and the patient began a close follow-up program. Currently, the patient is still alive and is undergoing supportive care with good pain control, achieving an overall survival of 44 months. *Conclusion:* Targeted agents approved for the treatment of advanced clear cell RCC may also be useful for the treatment of advanced PRCC. Indeed, despite the poor prognosis of metastatic type 2 PRCC, targeted therapy improved long-term survival in our patient.

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CHANGES IN TUMOR BURDEN AND IMDC CLASS AFTER ACTIVE SURVEILLANCE FOR METASTATIC RENAL CELL CARCINOMA

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Introduction: Targeted therapies (TT) improve survival in patients with metastatic renal cell carcinoma (mRCC) but treatment-related toxicities may worsen quality of life and lead to treatment discontinuation. Active surveillance (AS) is a feasible strategy in patients with indolent disease but effects on tumor burden (TB) and prognosis have not been investigated. *Patients and Methods:* In this retrospective study, we investigated patients who received AS at our center. TB defined as the number of sites of disease was collected, with the IMDC class, immediately before and after AS. The time on surveillance (ToS) was defined as the time from the start of AS to the beginning of therapy or last follow-up. The OS was from the start of AS or TT. *Results:* A total of 48 patients started AS from January 2007 to April 2016. After a median follow-up of 37.3 months, 79.2% are still alive. At baseline, the main sites of metastases were: lung in 56%, nodes in 25%, pancreas in 14%, adrenal gland in 8%, SNC in 8%, and bone in 6%. TB was one site in 65%, two in 31% and >2 sites in 4%. The IMDC prognostic class was favorable in 68.8%, intermediate in 25% and poor in 6.3%. After a median ToS of 16.7 months (95% confidence interval=9.6-23.7) months, 34 patients (70.8%) started a TT, only 1/24 patient had progression as the best response. Significant difference in ToS were found when patients with good (19.9 months) or intermediate (17.7 months) class were compared to the poor group (5.2 months) ($p<0.04$). At the beginning of TT, the main sites of metastases were: lung in 71%, nodes in 44%, bone in 15%, adrenal gland in 15%, pancreas in 15%, and SNC in 9%. The TB was one site in 35%, two in 47% and >2 sites in 18%; and 14 patients had new sites of disease. The IMDC class changed in four patients from good to intermediate. The median OS was not reached from the start of surveillance and was 64.4 months from the start of TT. *Conclusion:* AS is an option for management of patients with mRCC with good and intermediate prognosis. AS allows the start of TT to be delayed, avoiding toxicity and worsening of quality of life. Although patients in AS have increased TB and, rarely, a worsening of prognostic class, the survival outcome is longer and the effectiveness of subsequent therapy seems not to be affected.

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DOES PREVIOUS ABDOMINAL SURGERY INFLUENCE THE PERIOPERATIVE OUTCOMES OF ROBOTIC PARTIAL NEPHRECTOMY FOR RENAL MASS?

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Introduction: Previous abdominal surgery (PAS) increases the risk of intra- abdominal adhesions, which may increase the risk for port trocar injury, perioperative complications and prolonged operative time. We evaluated the effect of PAS on perioperative outcomes in patients undergoing robotic partial nephrectomy (RPN) for renal masses. *Patients and Methods:* Medical records of patients who underwent RPN for renal mass from 2013 to 2016 were reviewed. Patients with and without PAS (no PAS) were compared. Within the PAS group, we considered two sub-groups: a) major PAS (M-PAS): ipsilateral upper quadrant scar; b) minor PAS (m-PAS): contralateral, or minimallyinvasive scar. Univariate and multivariate analyses were performed for factors predicting overall complications. *Results:* A total of 114 patients underwent transperitoneal RPN, of which 84 (73.7%) had a history of PAS. There were no statistically significant differences between patients with PAS and patients without PAS in terms of clinical characteristics, perioperative outcomes and complications (Table I). On univariate and multivariate analyses, history of PAS or of M-PAS were not predictors of complications. (Table II). *Conclusion:* Robotic partial nephrectomy is feasible in patients with PAS and it does not increase the risk of intraoperative and postoperative complications.

Table I. *Patient characteristics, perioperative outcomes and complications.*

Variable	PAS (n=84)	No PAS (n=30)	*p*-Value
Age, mean±SD (years)	63.64±13.3	62.37±15.8	0.880
BMI, mean±SD (kg/m^2)	27.14±4.16	26.21±4.28	0.245
Male, N (%)	10 (12%)	5 (17%)	0.536
ASA ≥3, N (%)	39 (46%)	8 (27%)	0.083
CCI>0, N (%)	49 (59%)	10 (33%)	0.019
Tumor size, mean±SD (mm)	3.16±1.81	3.36±1.55	0.466
Ischemia Yes, N (%)	50 (60%)	17 (59%)	1
WIT, median (IQR) (min)	20 (17-25)	18 (16-25)	0.437
Operative time, median (IQR) (min)	110 (95-148.8)	120 (90-143.8)	0.710
EBL, median (IQR) (cm^3)	170(80-300)	100 (72.5-300)	0.665
Hospital stay, median (IQR) (days)	5 (5-7)	6 (5-7)	0.507
Complications Yes, N (%)	12 (14%)	8 (27%)	0.162

Categorical variables are reported as absolute number and percentages. Quantitative variables are reported as mean and standard deviation (SD) or median and interquartile range (IQR).

Table II. *Logistic univariable and multivariable regression demonstrating factors predicting overall complications.*

	Univariate analysis		Multivariate analysis	
Variables	OR (95% CI)	*p*-Value	OR (95% CI)	*p*-Value
Age (years)	1.02 (0.99-1.07)	0.22		
BMI (kg/m^2)	0.95 (0.84-1.07)	0.44		
Male (N)	1.89 (0.48-6.33)	0.32		
ASA ≥3	0.94 (0.36-2.49)	0.90		
CCI	1.90 (0.71-5.45)	0.21	2.46 (0.87-7.67)	0.1
Tumor size (cm)	1.02 (0.75-1.31)	0.91		
Ischemia time (min)	0.81 (0.3-2.18)	0.67		
WIT (min)	0.96 (0.86-1.06)	0.51		
OR time (min)	1.00 (0.99-1.01)	0.33		
EBL (ml)	1.00 (0.99-1.01)	0.44		
Hospital stay (days)	2.42 (1.67-3.90)	<0.00001		
PAS *vs*. no PAS	0.46 (0.17-1.30)	0.13	0.36 (0.12-1.08)	0.06
M-PAS *vs*. no PAS	1.06 (0.35-2.96)	0.91		

BMI: Body mass index; CCI: Charlson comorbidity index; PAS: previous abdominal surgery; M-PAS: major previous abdominal surgery; EBL: estimated blood loss; WIT: warm ischemia time.

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ROBOTIC STEREOTACTIC BODY RADIOTHERAPY IN RECURRENT PROSTATE CANCER PREVIOUSLY TREATED BY RADICAL IRRADIATION

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Introduction: Biochemical recurrence can occur following definitive external beam radiation therapy (EBRT) for localized prostate cancer. Focal robotic stereotactic body radiotherapy (rSBRT) to the recurrent intraprostatic tumor is emerging as a valuable option in this setting. In this retrospective study, we evaluated efficacy and toxicity of robotic SBRT for exclusive local failure after primary EBRT. *Patients and Methods:* Data from 28 patients treated at our Institution from September 2012 to December 2015 with rSBRT for prostate cancer recurrence after definitive EBRT were retrospectively reviewed. Local intraprostatic recurrence was assessed by 18 F-choline positron-emission tomography–computed tomography (PET); a dose of 30 Gy was delivered in 5 fractions. PSA was assessed at 2 months, 6 months, and every 4 months following rSBRT. Toxicity was assessed by the Common Terminology Criteria for Adverse Events toxicity scale (CTCAE v.4.03). *Results:* Patients were stratified into low (n=5, 17.9%), intermediate (n=9, 32.1%) and high-risk group (n=14, 50.0%) at diagnosis. Median patient age at rSBRT was 78.5 (62-86) years. All patients received prior EBRT for a median total dose of 76 Gy (62-80 Gy) in 2 (1.8-3.1) Gy/fraction. Median time from primary treatment to relapse was 74.1 (19.3-149.2) months. Five patients were receiving androgen-deprivation therapy following prior biochemical failure; median pre-treatment PSA value was 2.7 (2.1-14.4) ng/ml. Twenty-five patients showed biochemical response to treatment at 2 and 6 months, median PSA decline was 54.0% (2.2-95.0%) and 76.0% (35.9-95.0%) respectively; three patients experienced early PSA progression at 2 and 6 months, median PSA elevation was 112.3% (20.0-204.5%) and 267.0% (41.9-309.1%), respectively. At the time of our analysis, after a median follow-up of 20.9 (6.3-49.2) months, 10 patients showed no evidence of disease, two continued androgen deprivation with stable PSA levels, while 10 patients experienced biochemical relapse; among them, metastatic recurrence occurred in four cases. Biochemical progression-free survival (bPFS) was 96.4% and 75.0% at 12 and 18 months, respectively. Rectal and bladder acute toxicity grade 1-2 was found in four and one case, respectively; grade 1-2 late rectal and bladder toxicity occurred in one and seven cases, respectively. One patient experienced both grade 3 acute and chronic bladder toxicity, consisting of acute urinary retention and hematuria respectively. At univariate and multivariate analysis of pre-treatment variables, impaired

bPFS was correlated only with high-risk category at diagnosis (hazard ratio=13.06, p=0.021). No predictive factor for improved bPFS was found at subset analysis in responding patients, although a trend was observed for PSA decline at 6 months >76.0% (p=0.06). *Conclusion:* Focal rSBRT can achieve long-lasting remission and delay initiation of hormone treatment, in particular in low-/intermediate-risk patients at diagnosis, with acceptable late toxicity.

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DIAGNOSTIC ACCURACY COMPARING PROSTATE CANCER DETECTION BY MULTIPARAMETRIC MAGNETIC RESONANCE IMAGING *VERSUS* PROSTATECTOMY FINDINGS

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Introduction: Advances in multiparametric magnetic resonance imaging (mpMRI) suggest that imaging and selective magnetic resonance-guided biopsy (MRGB) may be superior to transrectal ultrasound guided biopsy (TRUSGB). The use of mpMRI may be useful to select those suspicious areas of prostate cancer (PCa) where a focal treatment can be applied without compromising the quality of life of patients. Aim: To study the diagnostic accuracy comparing PCa detection by TRUSGB *versus* MRI with subsequent guided biopsy and the correlation with prostatectomy findings in biopsy-naïve patients. *Patients and Methods:* A total of 235 biopsy-naïve individuals with elevated PSA levels and/or an abnormal digital rectal examination were consecutively enrolled from July 2011 through October 2015. All patients underwent mpMRI of the prostate and TRUSGB. Those with normal MRI scans (PIRADS 1, 2) underwent TRUSGB only, following the Vienna nomogram; each equivocal (PIRADS 3) or suspicious lesion (PIRADS 4-5) was additionally biopsied using two cores. of 96 patients with PCa, 66 (68.8%) underwent LRP. Among these, we studied the correlation between mpMRI and histopathology of radical prostatectomy specimens, making a comparative analysis by areas. *Results:* of 235 men, 96 (40.9%) had PCa. TRUSGB detected 87 cases of PCa (37.0%) and 9 additionally cases of PCa were detected only by MRGB. The mpMRI was equivocal for PCa (PIRADS 3) in 70 patients and suspicious (PIRADS 4-5) in 103 cases. Among these, TRUSGB detected PCa with Gleason score ≥7 in 21.4% (PIRADS 3) and 71.2% (PIRADS 4-5) of the cases respectively. MRGB detected PCa with Gleason score ≥7 in 10% (PIRADS 3) and 74.2% (PIRADS 4-5) of the cases respectively. The estimated sensitivity of MRGB for PIRADS 3, and PIRADS 4-5 lesions was 75.0% and 96.9% respectively, with the same NPV in both groups (96.8%). A total of 66 patients underwent LRP. mpMRI was suspicious (PIRADS 4-5) in 52 patients (78.8%), equivocal (PIRADS 3) in nine cases (13.6%) and non-suspicious (PIRADS 12) in five (7.6%). Histological examination of radical prostatectomy specimens with suspicious and equivocal areas on mpMRI, showed Gleason score ≥7 in 59 cases (89.4%). Among these, 88.1% were men with suspicious mpMRI (PIRADS 4-5), 6.8% with equivocal mpMRI (PIRADS 3), and 5.1% with nonsuspicious mpMRI (PIRADS 12). The rate of detection of PCa Gleason Score ≥3 + 4 was higher in patients with suspicious mpMRI (PIRADS 4-5) compared to equivocal mpMRI (PIRADS 3) (sensitivity 94.5% and 57.1% respectively). The estimated PPV for PIRADS 4-5 and PIRADS 3 lesions was 98.1% and 50%, with a concordance of 92.9% and 36.4%, respectively. *Conclusion:* mpMRI followed by selective biopsy seems to improve the diagnosis of intermediate and high-risk PCa compared to standard TRUSGB. mpMRI seems to improve the identification of clinically significant PCa areas. However, it is still necessary to optimize imaging tests to provide a focal treatment in these patients.

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IMPACT OF PROSTATE WEIGHT ON ROBOTIC-ASSISTED LAPAROSCOPIC PROSTATECTOMY COMPLICATIONS AND OUTCOMES: SINGLE-SURGEON SERIES

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Introduction: Little is known about the relationship between prostate weight (PW) and robotic-assisted laparoscopic prostatectomy (RALP). The aim of the present study was to analyze the possible effect of PW on RALP oncological and functional outcomes and postoperative complications. *Patients and Methods:* We prospectively collected data about patients

Table I. *Demographics, outcomes and complications of the two groups.*

Perioperative and postoperative characteristics		Group 1 (n=39)	Group 2 (n=77)	Group 3 (n=56)	Total (n=172)	p-Value
Demographics						
Age	Mean (SD)	65.7 (4.3)	65.6 (3.5)	65.5 (3.7)	65.6 (3.7)	0.9
BMI	Mean (SD)	27.0 (2.3)	27.6 (1.2)	27.9 (4.4)	27.6 (2.8)	0.3
PSA pre	Mean (SD)	7.6 (3.5)	8.2 (3.8)	7.6 (4.2)	7.9 (3.9)	0.6
Console time	Mean (SD)	130.9 (39.2)	120.3 (44.2)	126.8 (40.8)	124.8 (42.0)	0.4
Antiplatelet therapy	Number (%)	7 (17.9)	7 (9.1)	6 (10.7)	20 (11.6)	0.5
Peri/postoperative						
Hb delta	Mean (SD)	3.1 (2.6)	2.7 (1.9)	2.6 (2.6)	2.8 (2.3)	0.6
Blood loss	Mean (SD)	144.9 (135.0)	171.4 (140.1)	158.4 (115.3)	161.2 (131.0)	0.6
Hospital stay	Mean (SD)	5.1 (2.9)	4.0 (2.6)	3.8 (2.2)	4.2 (2.6)	0.03
Drainage days	Mean (SD)	3.8 (2.9)	2.9 (2.5)	3.0 (2.3)	3.1 (2.6)	0.03
Catheter days	Mean (SD)	10.1 (3.8)	9.1 (3.2)	9.0 (3.3)	9.3 (3.4)	0.2
Complications	Number (%)	8 (20.5)	4 (5.2)	4 (7.1)	16 (9.3)	0.04
FU						
Last FU continence	Number (%)	26 (66.7)	35 (45.5)	24 (42.9)	85 (49.4)	0.08
Continence recovery time	Mean (SD)	30.4 (36.8)	32.8 (36.3)	32.3 (25.5)	31.9 (33.4)	0.9
Last FU erectile function	Number (%)	12 (38.7)	12 (24.5)	12 (35.3)	36 (31.6)	0.3
Spontaneous erection	Number (%)	15 (48.4)	25 (50.0)	12 (33.3)	52(44.4)	0.3
Oncological outcomes						
Biochemical relapse	Number (%)	2 (5.1)	4 (5.2)	4 (7.1)	10 (5.8)	0.2
Positive margins	Number (%)	12 (30.8)	18 (23.4)	13 (23.2)	43 (25.0)	0.3
Extracapsular extension	Number (%)	11 (28.2)	23 (29.9)	15 (26.8)	49 (28.5)	0.7

FU: Follow-up.

undergoing RALP at our center between March 2013 and March 2016. A single expert surgeon performed all the surgeries following Patel's technique, with da Vinci Si System. The approach was intraperitoneal, the Santorini plexus was systematically ligated with the anterior suspension of the urethra. No posterior rhabdomyosphincter reconstruction was preformed. Patients were divided into three groups based on their PW obtained from the final histological examination: group 1, <40 g (n=36); group 2, 40-60 g (n=95); group 3, >60 g (n=49). Preoperative, perioperative and postoperative data, such as long term oncological and functional outcomes, were compared between the three groups using multiple linear regressions and multiple logistic regression, based on the results of bivariate analysis. *Results:* One hundred and eighty RALPs were performed (Table I). Mean patient age was 65.6±3.7 years. Mean PSA and PW were 7.9±3.9 ng/ml and 55±20.7 g, respectively. Delta hemoglobin was 2.8±2.3 g/dl. Overall complication rate was 9.3%. Medium follow-up was 21.1±10.2 months. High PW had a significant effect on the length of drainage and hospital stay (p=0.03), resulting in a reduction of 0.44 and 0.43 days between group1 and group 3, respectively. PW also had a significant effect on the overall complications rate which was higher in group 1 (p=0.04), even if with low Clavien grade. A statistical trend toward significance was demonstrated in group 1 for the presence of continence at last follow-up (p=0.08). The positive margin rate was slightly higher in group 1 but not statistically significant. No other significant differences were found between the three groups. *Conclusion:* Our results showed that RALP is oncologically and functionally safe regardless of prostate size. PW affected only the length of hospital stay and complications, although the majority of these were of low grade.

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RETROGRADE INTRA-RENAL THULIUM LASER TREATMENT OF UPPER URINARY TRACT UROTHELIAL CELL CARCINOMA

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Introduction: Kidney-sparing surgery for low-risk (and for imperative high-risk) urinary tract urothelial carcinoma (UTUC) allows sparing the morbidity associated with radical surgery, without compromising oncological outcomes and kidney function. We evaluate the efficacy and safety of ureteroscopic thulium laser treatment of UTUC. *Patients and Methods:* Overall, 32 patients with a low-grade (or high-grade in imperative cases) UTUC undergoing conservative thulium laser treatment at two referral institutions between 2012 and 2015 were evaluated. Among imperative cases, three were solitary kidney patients and two had major comorbidities. All patients underwent a prior biopsy and then were subjected to thulium laser vaporization (using either RevoLix 200 W Continuous Wave Laser or Quanta System Cyber TM 150 W) of the lesion. A 265 micron and a 380 micron laser fiber was used with a flexible scope and a semirigid scope, respectively. Ablation was carried out at 10-20 W power. Postoperative complications (categorized according to the Clavien-Dindo classification) were assessed. Follow-up consisted of CT scan and ureterorenoscopy 4 months after surgery. Clinical recurrence was defined as relapse or occurrence of a new lesion. *Results:* Mean age at surgery was 68 years (SD 10.7 years). Mean tumor size was 15.2 mm (range=2-30 mm). Overall, six (15.6%) and 23 (71.8%) patients had a history of previous contralateral UTUC and bladder transitional cell carcinoma, respectively. Moreover, 10 (31.2%) patients had a lesion located in the renal pelvis, 11 (34.4%), four (12.5%) and three (9.4%) patients had a lesion located in the lower, middle and upper ureter tract, respectively and four (12.5%) patients had multifocal lesions. Overall, three (9.4%), 21 (65.6%) and eight (25%) patients had a positive, negative or suspicious preoperative urine cytology, respectively. Preliminary biopsy revealed the presence of low-grade disease in 22 (68.7%) patients, high-grade carcinoma in three (9.4%) and carcinoma in situ (CIS) is one (3.1%) patient, while it was not conclusive in six (18.8%) patients. Final stage was pTa and pTis in 31 (97%) and one (3%) patient, respectively. Overall, 42.9%, 53.6% and 3.6% of the patients experienced Clavien-Dindo grade I, II and III complications, respectively. Five (15.6%) patients underwent a second-look procedure due to presence of residual disease after first ablation. Eight (25%) patients experienced clinical recurrence and underwent one or more subsequent thulium laser vaporizations. Two patients (6.2%) underwent nephroureterectomy (one due to presence of CIS, the other refused second conservative treatment). Pathological outcomes were pTis and pT0, respectively. Median follow-up was 18.2 (range=0-51) months, and no progression of upstaging of disease occurred. *Conclusion:* Thulium laser management of UTUC is a safe and efficacious conservative treatment, even in solitary kidney patients or individuals with major comorbidities. This initial experience shows optimal vaporization and hemostatic control in the absence of major complications.

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ROBOT ASSISTED RETROPERITONEAL LYMPH NODE DISSECTION IS A SAFE AND FEASIBLE PROCEDURE FOR STAGE I AND II NON SEMINOMATOUS GERM CELL TESTICULAR CANCER

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Introduction: Robot-assisted retroperitoneal lymph node dissection (RA-RPLND) is an accepted staging and treatment option for non seminomatousgerm cell tumor (NSGCT). Robotic surgery offers technical advantages and is being increasingly used in urologic procedures. Aim of this study is to evaluate surgical, perioperative and pathological outcomes of the patients treated with RA-RPLND at our Institution. *Patients and Methods:* A retrospective review of RA-RPLND performed by the four more expert surgeons at our Institution from January 2012 to September 2016 was performed. Data were collected regarding patient demographics, primary tumor characteristics, pathological findings, and clinical outcomes. *Results:* In total, 16 patients were treated with RA-RPLND. Twelve were right RPLND and four left. Fourteen patients had clinical stage I, two had stage IIA NSGCT. The median (interquartile range [IQR]) body mass index was 24.75 (23.22-26.84) kg/m^2. Median (IQR) operative time was 240 (200–283) min, estimated blood loss was 100 (25-175) ml, node count was 15.50 (12-18), and length of stay was 6 (5-10) days. No blood transfusion was required. One intraoperative complication occurred: a duodenal lesion, robotically repaired, which required prolonged fasting. Five (31.25%) patients developed postoperative complications Clavien-Dindo grade II, all of them were chylos ascites which required total parenteral nutrition, fasting and prolonged drain maintenance. No late complications were recorded. At final pathological examination, four (25%) patients had positive nodes (pN1). Three patients received adjuvant chemotherapy. One patient had teratoma and thus there was no indication for adjuvant therapy. The median follow-up was 18.6 (1-53) months and no recurrence was recorded. Limitations include retrospective design, small population and limited follow-up. *Conclusion:* This series confirms the initial literature reported evidence that RA-RPLND is a safe, reproducible and feasible procedure for stage I-II NSGCT, in the hands of experienced surgeons. Oncological outcomes and postoperative morbidity

were similar to those reported for the traditional open surgery technique. Larger and comparative studies are needed in order to better support this evidence.

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TOMOTHERAPY OF OLIGOMETASTASES FROM PROSTATE CANCER: FIVE-YEAR EXPERIENCE

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Introduction: Oligometastases from prostate cancer are a new entity that needs very accurate diagnosis and modern therapy. In the past, the patients with oligometastatic disease were treated only with hormones or chemotherapy. The new guidelines also consider local therapy such as radiotherapy (RT). We present our experience with tomotherapy. *Patients and Methods:* From January 2010 to December 2015, 37 patients, mean age: 65 (range=47-81) years, mean Karnosky index 90 (range=100-70), were treated with RT for oligometastases. Pretreatment therapies were surgery (RP in 27 cases) with postoperative RT in six cases, radical RT in 10 cases. Seven patients also received androgen deprivation therapy. The number of oligometastatic sites was a mean of 2.5 (range=1-7), the great majority in lymph nodes and only six in the bones. The patients were staged with CT scan in six cases, bone scintigraphy in five, MRI in four and 37 with total body choline-PET; two patients were also biopsied. RT technique was a IMRT-SIB-IGRT by tomotherapy. RT doses were: from 46 to 50 Gy to the pelvis; from 66 Gy to 70.5 on N+ and 64 Gy in one case with recurrence in seminal vesicles. A total of 34/37 (90%) of patients received hormones, four received abiraterone, and two chemotherapy; one patient was treated with HIFU, two with surgery of nodes and lastly one with surgery of the prostate bed. The mean follow-up was 38 (range=10-69) months. *Results:* All patients but one had a good compliance to radiation treatment. At the last follow-up,22 patients had NED (5 treated with hormones), three were dead, eight were alive with progressive disease (two in bone, two in nodes, two in bone and nodes, two in nodes and visceral lesions; one was treated by a second course of RT) and one with biochemical disease. One patient had distant metastasis (lung) and two were lost at the last follow-up. The actual locoregional control was 61%; the mean time to progression was 17 months (range=6-43 months). *Conclusion:* We can conclude that RT by tomotherapy is feasible, effective and useful for this group of patients; more patients and long or follow-up is needed for a definitive conclusion.

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CLINICAL OUTCOME AFTER ADJUVANT POST-PROSTATECTOMY RADIATION THERAPY

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Introduction: To evaluate the outcome of patients treated for prostate cancer with postoperative radiotherapy (RT) after radical surgery in a 15-year experience (2000-2015). *Patients and Methods:* A total of 279 patients [median age=66 (range=42-77) years] operated on for prostate cancer were treated at our Institution with conformal 3D RT or with IMRT. Median preoperative PSA was 9 (range=0.5-104) ng/ml, median pathologic Gleason score 7 (range=4-10) and number of patients with ct1, cT2, cT3 and cT4 was 1, 60, 207 and 11, respectively. Lymph node invasion was present in 34 patients; the number of nodes removed was 7 (range=0-38); the number of patients with positive margins was 195 (69%); post-surgery PSA was 0.073 (range=0-6.22) ng/ml. RT was performed with Linac from 1999 to 2009 by 3DCRT and with Tomotherapy from 2010 by IMRT-IGRT. Radiation dose was 70.2 (range=61.6-75.6) Gy to the prostate bed and 46.8 (range=45-50.4) Gy to the pelvis, at 1.8 Gy per fraction. The pelvis was irradiated in 65 patients (24%). 64 patients (23%) were treated during RT with hormone therapy and 49 (18%) continued treatment after RT. *Results:* With a median follow-up of 73.4 (range=4-212) months from the end of radiotherapy, the 10-year prostate cancer-specific survival was 88%; the clinical relapse-free survival was 72% and biochemical relapse-free survival 60%. Cox univariate and multivariate analysis were performed. In multivariate analysis, the pathologic Gleason score (HR=1.49; $p<0.0001$) and last follow-up PSA (HR>1.0006; $p<0.001$) were significantly predictors for prostate cancer-specific survival, clinical relapse-free survival and biochemical relapse-free survival. *Conclusion:* In this study, based on a large database, it was found that the Gleason score and the PSA measured at last low-up were significantly independent prognostic factors

of survival for patients treated with post-prostatectomy adjuvant RT.

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CLINICAL OUTCOME AFTER SALVAGE POST-PROSTATECTOMY RADIATION THERAPY: FIFTEEN-YEAR EXPERIENCE

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Introduction: To evaluate the outcome of patients treated for prostate cancer with salvage radiotherapy (RT) after radical surgery in a 15-year (2000-2015) experience. *Patients and Methods:* At our Institution, we treated, for salvage, 234 patients (median age=64, range=44-75 years) affected by prostate cancer operated on for biochemical/clinical recurrences. The presurgical (initial) PSA was 9 (range=0.36-90) ng/ml, the pathologic Gleason score was 7 (range=4-9) and the clinical stage cT1, 2, 3 and 4 was 1, 61, 137 and 1, respectively. Lymph node invasion was presented in 11 patients; the number of nodes removed was 6 (range=0-40) and positive margins were 64 (27%); post-surgery PSA was 0.10 (range=0-2) ng/ml. RT was performed with Linac from 1999 to 2009 by 3DCRT and with tomotherapy from 2010 by IMRT-IGRT. Radiation dose was 70.2 (range=61.6-79.2) Gy to the prostate bed and 54 (range=45-57.6) Gy to the pelvis, at 1.8 Gy per fraction; the pelvis was irradiated in 46 patients (20%). Sixty-six patients (28%) were treated during RT with androgen deprivation therapy. The median time from surgery to RT was 40.7 (range=6-212) months. *Results:* With a median follow-up of 117 (17.6-303) months, the 10-year prostate cancer-specific survival was 88%; clinical relapse-free survival was 67% and biochemical relapse-free survival only 36%. In Cox multivariate analysis, predictive factors for cancer specific survival were preRT PSA (HR=1.18; p=0.0018), PSA measured at last follow-up (HR=1.04; p=0.0018) and nodal invasion (HR=5.9; p=0.024); for biochemical-free survival were D'Amico classification (HR=1.6; p=0.002) and cT (HR=1.7; p=0.007); for clinical relapse-free survival GS (HR=1.7; p=0.0008) and last follow-up PSA (HR=1.02; p=0.0001). *Conclusion:* In this study, based on a large database, it was found that the PSA measured at last follow-up was predictive of prostate cancer-specific and clinical relapse-free survival, while GS and D'Amico classification were significantly independent prognostic factors of clinical relapse and biochemical-free survival for patients treated with post-prostatectomy salvage RT.

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VINFLUNINE IN PATIENTS WITH ADVANCED OR METASTATIC UROTHELIAL CANCER AFTER A FIRST-LINE PLATINUM-CONTAINING REGIMEN

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Introduction: Vinflunine is recommended in the European guideline for the treatment of advanced or metastatic urothelial cell carcinoma (UCC) after failure of platinum-based therapy. The purpose of this study was to examine the efficacy and toxicity of vinflunine in patients with locally advanced or metastatic UCC failed after a platinum-based regimen. *Patients and Methods:* We retrospectively collected data on nine patients with advanced or metastatic UCC undergoing vinflunine treatment at the Radiation Oncology Department, AOU Careggi in Florence from October 2013 to September 2016. Data were retrospectively collected from patient charts and covered the following: Patient and disease characteristics, prior treatment, including type of platinum-containing chemotherapy, vinflunine treatment, toxicity, response, and survival parameters. Responses were evaluated by the local radiologist at each center according to RECIST 1.1 criteria. *Results:* The primary tumor was predominantly located in the urinary bladder (66.7%) and had a high grading in the majority of cases. All the patients received platinum based (67% cisplatin, 23% carboplatin) chemotherapy prior to vinflunine, with a median of four cycles (range=3-6) prior to vinflunine treatment. Vinflunine was always administered as second-line therapy. The starting dose of vinflunine was 320 mg/m^2 in 44.4% of patients and 280 mg/m^2 for the rest. Dose reduction was performed only in one patient. The median number of vinflunine cycles was eight (mean=6.5; range=2-9). Stable disease was reported in one patient (11.1%) and partial response to vinflunine treatment was observed in two (22.2%) out of the nine patients, resulting in

an objective response rate of 33.3%. No complete response was observed in this cohort. Investigating survival data, two out of nine patients (22.2%) died within the follow-up period. Median observation time was 1.8 years (SD=1.0; range=0.7-3.46). The median progression-free survival under vinflunine amounted to 4.6 (95% confidence interval =2.8-6.8) months. The median OS time was 7.9 (95% confidence interval=4.3-10.7) months. No grade 3 or 4 toxicities, according to NCI-CTCAE version 4.0, were recorded in our cohort. The most frequent treatment-related adverse events considering all grades of intensity were hematological toxicities: anemia in 44.4%, leucopenia in 44.4%, and thrombocytopenia in 11.1%. The most commonly reported nonhematological toxicities considering all grades of intensity were asthenia in 44.4%, constipation in 33.3% and vomiting in 22.2%. *Conclusion:* Vinflunine is currently the only registered option in Europe for patients with progressive disease after treatment with platinum-containing chemotherapy. This retrospective study confirms that the clinical outcomes obtained from our Institution are in line with the data observed in clinical trials. Furthermore, our study confirms the role of performance status (PS) at the beginning of vinflunine treatment was statistically significant (p=0.044). The group of patients with ECOG PS0 should be treated at an early stage after platin relapse to avoid decline in PS and probably benefited the most from vinflunine treatment.

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DRUG–DRUG INTERACTIONS BETWEEN ABIRATERONE (ABI) OR ENZALUTAMIDE (ENZ) AND CONCOMITANT MEDICATIONS IN PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC)

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Introduction: Patients with mCRPC are generally elderly with several comorbidities requiring concomitant medications. ABI and ENZ are two oral drugs approved for treatment of mCRPC that target androgen signaling. Since these drugs have comparable results, the therapeutic choice might be driven by patient's comorbidities and concomitant therapies. ABI is metabolized by the enzyme sulfotransferase 2A1 and by CYP3A4. ENZ is metabolized by enzyme CYP2C8, with minor CYP3A4/5 involvement. Our aim was to evaluate the most frequent concomitant medications in patients with mCRPC and their possible interaction with ABI and ENZ. *Patients and Methods:* Patients with mCRPC treated at our Institution were assessed, concomitant medications were registered and those with hepatic metabolism were examined for possible interaction with ABI and ENZ. Descriptive statistics were used. *Results:* Forty-five patients with mCRPC were included: the median age was 67.8 years. The most frequent comorbidities were hypertension in 55%, hypercholesterolemia in 13%, ischemic heart disease in 11%, and diabetes mellitus in 9%. The most frequently medications taken by patients were: lansoprazole in 47%, oxycodone in 27%, paracetamol in 22%, statins in 13%, codeine in 13%, and warfarin in 4%. Lansoprazole is metabolized by CYP2C19 and CYP3A4, which are both moderately inhibited by ABI, whereas ENZ is a strong CYP3A4 inducer and moderate CYP2C19 inducer. Statins are metabolized by CYP3A4. Oxycodone, codeine and paracetamol are metabolized by CYP2D, which is strongly inhibited by ABI, while ENZ is a weakly inducer. Warfarin is metabolized by CYP2C9, which is induced by ENZ. *Conclusion:* ABI and ENZ differently affect the metabolism of some common concomitant medications in patients with mCRPC with possible reduced efficacy or increased toxicity. The different pharmacokinetic profile should be accounted in the choice of treatment for mCRPC.

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ROBOTIC-ASSISTED RADICAL PROSTATECTOMY IN YOUNGER MEN (AGE ≤50 YEARS) AT A TERTIARY REFERRAL CENTER: CLINICAL CHARACTERISTICS, ONCOLOGICAL AND FUNCTIONAL OUTCOMES

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Introduction: Prostate cancer (PCa) in younger men (age ≤50 years) appears to present differently compared with older men. We report the risk factors and the oncological and functional outcomes of younger patients (age ≤50 years) treated with robotic-assisted radical prostatectomy (RARP) for localized PCa. *Patients and Methods:* A total of 103 (3.5%) younger patients (age ≤50 years) with clinically localized PCa who underwent RARP at a single referral tertiary center between 2006 and 2015 were identified. Comorbidities were assessed

according to Charlson Comorbidity Index (CCI) while perioperative complications where categorized according to the Clavien-Dindo classification. Urinary continence was defined as the use of no pads, while biochemical recurrence (BCR) was defined as two consecutive PSA values ≥0.2 ng/ml. Kaplan–Meier analysis assessed time to BCR. *Results:* Table I summarizes clinical characteristics and risk factors. Median (IQR) operative time was 210 min (174-240). Median (IQR) blood loss was 200 (100-200) ml, and only 1 (0.97%) patient needed blood transfusion. Overall, two (1.9%), one (0.97%) and two (1.9%) patients had Clavien I, II and III complications, respectively. At final pathology, 65.1%, 23.3%, 5.8% and 1% of patients presented a pT2, pT3a, pT3b and pT4 stage respectively. Pathological Gleason score was 6, 7 and 8 or higher in 70%, 25% and 5% of patients, respectively. Moreover, 58.3% of patients had perineural involvement and 2.9% had vascular invasion. Positive surgical margin rate was 15.5% and 4.9% of patients had positive lymph nodes. Finally, 6.3% and 6.3% of patients underwent adjuvant RT and HT respectively, 5.2% and 1% of patients required salvage RT and HT, respectively. Median (IQR) follow-up was 27 (23-29) months. At last follow-up, the BCR-free survival rate was 94.6%, urinary continence rate was 93.6% and potency rate was 92.6%. *Conclusion:* RARP in younger men (age ≤50 years) is a safe procedure with excellent oncological and functional outcomes in a high-volume center.

Table I. *Clinical characteristics and risk factors.*

Characteristic	Value
Median age at surgery (IQR), years	48 (46-49)
Median BMI (IQR), kg/m^2	25.88 (24.38-28.08)
CCI index (%)	
0	91.3
1	7.8
≥2	1.0
Median PSA at diagnosis (IQR), ng/ml	5.47 (4.14-8.55)
Biopsy Gleason score, %	
6	70
7	25
8-10	5
Median no. of biopsy cores taken (IQR)	12 (11-14)
Median no. of biopsy cores positive (IQR)	4 (2-6)
Median positive cores (IQR), %	33.33 (19.69-57.44)
Positive family history of cancer , %	70.4
No. of relatives diagnosed with cancer, %	
1	69.4
2	24.5
3-4	6.1
Coffee consumption, %	93.8
Median no. of cups per day (IQR)	2 (1-3)
Alcohol consumption, %	63.4
Median no. of glasses per day (IQR)	1 (1-2)
Smoking, %	34.4
Median no. of cigarettes per day (IQR)	15 (6.5-20)

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STEREOTACTIC RADIOTHERAPY WITH BEACON TRANSPONDERS IN INTERMEDIATE-RISK PROSTATE CANCER: PRELIMINARY RESULTS OF TOXICITY AND EFFICACY

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Introduction: Improved diagnostic accuracy has led to an increased incidence of early-stage prostate cancer. For patients affected by this disease, a traditional radiotherapy course, lasting 7-8 weeks, remains a critical issue. Furthermore, acceleration of radiation treatment could improve therapeutic ratio, especially in intermediate-risk patients. For this reason, we designed a study of hypofractionated stereotactic body radiation therapy (SBRT) delivered by volumetric modulated arc therapy (VMAT) with flattening filter-free (FFF) beams and gated using beacon transponders. We report our preliminary results on feasibility and early side-effects. *Patients and Methods:* Patients affected by histologically proven prostate adenocarcinoma, PSA ≤20 ng/ml and Gleason score (GS) 7 (NCCN intermediate class of risk), no distant metastases, no previous surgery other than transurethral resection of the prostate, no malignant tumors in the previous 5 years, IPSS <7, were enrolled in this phase II study. Patients were submitted to pelvic MRI. Beacons transponders were positioned transrectally within the prostate parenchyma (three beacons: apex, left lobe, right lobe) by an urologist; this procedure was ultrasound-guided and performed 7-10 days before simulation CT scan. Magnetic resonance images were then registered with those of simulation CT in order to better define prostate parenchyma and organs at risk. The radiotherapy schedule was 38 Gy in four fractions delivered every other day. The VMAT radiotherapy technology, with 10-MV FFF photons was used in all cases. Toxicity assessment was performed according to Common Terminology Criteria for Adverse Events v4.0 scale. *Results:* Between July, 2014 and October, 2016, 25 patients were enrolled in this study. Median age was 74 (range=59-79) years, Median initial PSA was 7.0 ng/ml (range=3.1-14 ng/ml). Acute toxicities were as follows: three patients (12%) presented G1 proctitis. Genitourinary toxicity was observed in 52% of patients (n=13): in particular, seven patients had G1 cystitis (28%) with four of these presenting even G1 increased urinary frequency (16%), G2 cystitis was observed

in six patients (24%) with a G2 urinary frequency observed in two of these patients (8%); a G2 urinary retention was observed in only one patient and it was treated with transient catheterization and oral and rectal medications. No acute gastrointestinal ≥G2 or genito-urinary ≥G3 toxicity was found. No other toxicities were observed. A rapid PSA decrease was observed in all patients. Median nadir-PSA after treatment was 0.1(range=0.1-4.8) ng/ml. At a median follow-up of 16 months (range=5-28 months, calculated from the time of diagnosis), only one patient presented an outfield relapse of disease, which was treated with androgen deprivation therapy. No other biochemical recurrences or disease progressions were observed. *Conclusion:* Preliminary findings show that stereotactic radiotherapy, delivered with FFF-VMAT and gated using beacon transponders, is a valid option for intermediate risk prostate cancer. Early results in terms of feasibility, toxicity profile and disease control are encouraging and warrant the prosecution of the study.

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THE ROLE OF PROSTATE MRI 3D-RECONSTRUCTION ROBOT-ASSISTED RADICAL PROSTATECTOMY IN REDUCING POSITIVE SURGICAL MARGIN RATE

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Introduction: The use of prostate multiparametric MRI in pre-surgical setting is widespread. However, the surgeon does not have the right perception of the true localization of lesions because MRI offers 2D images without volumetric assessment. 3D reconstruction of MRI could be carried out prior to radical prostatectomy in order to guide the surgeon in a cognitive radical prostatectomy. The aim of this study was to evaluate the role of 3D MRI reconstruction in the eventual reduction of the positive surgical margin (PSM) rate during robot-assisted radical prostatectomy (RARP). *Patients and Methods:* Patients with localized prostate cancer undergoing prostate multiparametric MRI prior to RARP were evaluated (3D group). MRI consisted of T2-WI, DWI, and DCE. MRI was performed at three reference centers with the same characteristics of equipment and experience of radiologists. Usable data of patients were obtained from T2-W sequence of MRI scans in DICOM format. 3D Slicer, open-source software for the analysis and visualization of medical images, was used for segmentation and 3D reconstruction. The surgeon was able to rotate and orientate the 3D model so that it was presented exactly like the real prostate in the operative field, in order to perform a cognitive procedure. A control group of patients underwent MRI without 3D reconstruction prior to RARP was chosen. Demographics (age, BMI, ASA score, PSA, DRE, biopsy GS), radiological [number, localization, PIRADS v.2 score, presence of extracapsular extension (ECE) or seminal vesicle invasion (SVI) of each lesion diagnosed], intraoperative (operative time, type of nerve-sparing technique according to Pasadena), and pathological (pT, PSM rate) variables were recorded. *Results:* A total of 27 patients were analyzed in each group. The groups were comparable in terms of demographic variables. *Results:* Data are reported in Table I. The PSM rate was 14.8% in the 3D group and 25.9% in the control group (p=0.49). In pT2 lesions, the PSM rate was 0% and 7.7% in the 3D and control groups, respectively (p=0.44), whilst in pT3 lesions it was was 26.7% and 42.8%, respectively (p=0.33). *Conclusion:* In our experience, 3D reconstruction by MRI prior to RARP demonstrated a trend towards a reduction of the PSM rate and a significant reduction of operative time. A larger sample size is needed in order to confirm these preliminary outcomes and increase the level of evidence.

Table I. *Demographic, radiological and hostopathological characteristics of the studied population.*

Variable	3D group	Control group	*p*-Value
No. of patients	27	27	
No.of lesions, total	35	33	
No. of lesions, mean (SD)	1.29 (±0.46)	1.37 (±0.62)	0.59
Location, no. of lesions		0.14	
Apical	10	10	
Equatorial-apical	5	4	
Equatorial	7	13	
Equatorial-basal	2	2	
Basal	12	4	
PIRADS, no. of lesions			
3	9	6	0.26
≥4	26	27	
ECE, no. of lesions	9	12	0.57
SVI, no. of lesions	0	3	0.23
Mean operative time, min (SD)	107 (±22.02)	123 (±29.84)	0.03
Nerve sparing, no. of cases		0.23	
Full	3	2	
Partial	4	9	
Minimal	10	16	
pT, no. of cases		0.12	
pT2	13	12	
pT3a	9	13	
pT3b	5	2	

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PROSPECTIVE RANDOMIZED CONTROLLED TRIAL COMPARING LAPAROSCOPIC *VERSUS* ROBOT-ASSISTED RADICAL PROSTATECTOMY: OUTCOMES AFTER FIVE-YEAR FOLLOW-UP

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Introduction: The aim of this study was to report the 5-year functional and oncologic outcomes of our previously published prospective randomized study comparing RARP *vs.* LRP. *Patients and Methods:* From 1/2010 to 1/2011, 120 patients with organ-confined prostate cancer were enrolled and randomly assigned to RARP or LRP. All patients were treated by a single surgeon with a transperitoneal anterograde approach. Continence, potency and serum PSA were reported at 1.3.6.12 months and then every 6 months until the 60th month postoperatively. For the survival analysis biochemical recurrence (BCR) was defined as any postoperative cancer treatment (radiation, hormonal/chemotherapy) or PSA above 0.2 ng/ml. A Generalized Estimating Equations model was used to compare the time series of functional results, Kaplan–Meier and Cox model were used to analyze the oncologic outcomes. *Results:* The probability of being continent and potent over time was more than doubled in the RARP group (OR=2.47, $p<0.021$ and OR=2.35, $p<0.028$, respectively). Five years BCRFS was 81.6% for both the RARP and LRP groups. In Cox proportional hazards models, pathological GS, positive surgical margins and pT (pT3a *vs.* pT2; pT3b *vs.* pT2) stage were associated with a significant increase of BCR risk (HR=3.74, 4.61, 2.80 and 12.69, respectively) None of the patients died due to oncological causes; conversely, three patients in the RARP group and two patients in the LRP group died due to cardiovascular events. *Conclusion:* From the 5-year follow-up, the robotic approach allows for better functional results if compared to pure laparoscopic approach, without compromising oncological outcomes.

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FUSION TARGETED BIOPSY MAY IMPROVE THE AGREEMENT BETWEEN BIOPTICAL AND PATHOLOGICAL GLEASON SCORE

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Introduction: A matter after radical prostatectomy (RP) is the frequent upgrading in Gleason score (GS) when analyzing the whole prostate with respect to the GS observed at biopsy samples. Targeted prostate biopsy (TBx) is increasingly used in urological practice and could have a role in this field, potentially targeting the socalled index lesion, therefore better representing the worst GS. The aim of this study was to investigate if TBx has superior performance compared with standard untargeted biopsy (SBx) in determining the optimal agreement between biopsy and whole prostate GS. *Patients and Methods:* From January 2014 to December 2015, we retrospectively reviewed our institutional database dedicated to robot-assisted RP and we identified patients who underwent SBx (18 standardized transrectal ultrasound peripheral/transitional zone cores) or TBx alone (two cores for each lesion suspicious for prostate cancer PCa at multiparametric magnetic resonance imaging, PIRADS >3) after a negative first SBx. In the selected cohort, the concordance of GS at biopsy with GS at whole prostate analysis, as well the association between categorical variables (age, DRE, TNM and PIRADS), were analyzed by the Fisher's exact test. *p*-Values of less than 0.05 were considered as statistically significant. *Results:* Two hundred and forty-six patients diagnosed with PCa (117 SBx *vs.* 129 TBx diagnosis) underwent robotassisted RP in the considered period. The detection rate for PCa was 32.0% in SBx group and 49.3% in TBx one. The rate of correctly classified, upgraded and downgraded GS was 53.8 *vs.* 91.5%, 39.3 *vs.* 7.8% and 6.8 *vs.* 0.8% for SBx and TBx, respectively ($p<0.001$). The GS concordance rates for SBx and TBx cohort, respectively were: 14.3 *vs.* 41.7% for GS 6, 61.0 *vs.* 83.8% for GS 3+4, 56.3 *vs.* 75.0% for GS 4+3, 27.3 *vs.* 100% for GS 8 and 80 *vs.* 100% for GS 9. *Conclusion:* In our experience, TBx allowed for a

higher PCa detection accuracy and a better performance in discriminating significant PCa from insignificant when compared to SBx. TBx significantly reduced the risk of GS upgrading/downgrading at RP for all histopathological categories. The results of our study suggest that targeted biopsies could be a viable tool for a better counseling of patients with very unaggressive tumors for active surveillance.

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IS MRI HELPFUL IN LYMPH NODE INVASION DETECTION IN ADDITION TO BRIGANTI UPDATED NOMOGRAM?

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Introduction: Pelvic lymph node dissection (PLND) is considered the surgical standard for staging of prostate cancer (PCa). Guidelines recommend performing PLND if the calculated probability of lymph node invasion (LNI) based on the Briganti updated nomogram (BN) is >5%. Indeed, BN demonstrated high predictive accuracy but it lacks of information obtained by imaging. The multiparametric prostate MRI (mp-MRI) is able to diagnose extracapsular extension (ECE) or seminal vesicle invasion (SVI); moreover, it can predict tumor aggressiveness as calculated by the correlation between DWI and predominant Gleason pattern 4 (pG4). The primary aim of the study was to evaluate the role of mp-MRI in the indication to perfom PLND or not in patients with risk of LNI according to BN <5%. The secondary aim was to identify independent predictors of LNI. *Patients and Methods:* From 04/2013 to 09/2016, 297 patients who underwent preoperative mp-MRI for staging purpose and then robot-assisted extended PLND were retrospectively evaluated. mp-MRIs consisted of T2WI, DWI and DCE. Two surgeons, three radiologists and one uro-pathologist, all experts in the field, were involved in the study. Whether the decision to undergo a RAEPLND changed on the basis of findings at mp-MRI was assigned as a binary variable. Univariate analysis and multivariate logistic regression analysis were used in order to identify predictors of LNI. *Results:* The median patients' age was 64 (IQR=59-68) years. The median preoperative PSA level was 9.5 (IQR 6-13.5) ng/ml. A total of 6,612 lymph nodes were harvested, with a median number of 23 (IQR 18-29) lymph nodes removed per patient. 42 (14.1%) patients had histologically proven pN1 disease. The total number of metastatic nodes was 95 with a median number of 1 (IQR=1-3) positive lymph nodes per patient. Overall, 220 patients (74.1%) with a risk of LNI >5% as calculated by the BN underwent RAEPLND. Thirty-two patients (14.5%) were staged pN1 at final histopathological analysis. A total of 77 patients (25.9%) with a risk of LNI <5% as calculated by BN underwent RAEPLND anyway according to the finding at mp-MRI of ECE and/or SVI and/or pG4. In this group of patients, the rate of pN1 stage was 14.3% (11/77). At multivariate logistic regression analysis, the three MRI parameters (presence of ECE, SVI, pG4) were significant independent predictors of LNI after RAEPLND. ECE was the most significant parameter, showing a risk of LNI 7x higher when detected at imaging. *Conclusion:* In our experience, the role of mp-MRI seemed to be important in patients with a risk of LNI <5% as calculated by the BN. Moreover, the presence of ECE, SVI or pG4 at mp-MRI was found to be an independent predictor of LNI by itself. Larger sample size would hopefully confirm our data and define the exact role of mp-MRI in this scenario.

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PAIN CONTROL DURING PROSTATE MRI-TRUS FUSION SOFTWARE-BASED TARGETED BIOPSY

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Introduction: MRI-TRUS fusion software-based targeted biopsy (fusion biopsy, FB) is a recently introduced technique

that is acquiring an increasingly role in the diagnosis of prostate cancer (PCa). MRI-TRUS software-based registration is probably the most reproducible targeted biopsy strategy, combining the diagnostic accuracy of multiparametric prostate MRI (mp-MRI) with the accessibility of TRUS and the guidance of a fusion software. Some systems allow FB using a transperineal approach usually with the need to perform the procedure in the operating room under sedation or spinal anesthesia. This is clearly in contrast with the idea of mini-invasive procedure, prolonging the biopsy time and increasing costs. The aim of our study was to present the experience in our tertiary center where we perform FB in an outpatient setting under local anesthesia. *Patients and Methods:* Patients with suspicion of PCa and the presence of one or more lesion of interest (LOI) on MRI were enrolled in this prospective study (09/2015-09/2016). The MRI study consisted of T2-weighted, DWI and DCE imaging. All lesions were classified according to PIRADS v.1 system. All patients were subjected to FB using the Biojet® system (D&K Technologies), sampling at least three cores for LOI. Transrectal (TR) approach was used for LOIs in the peripheral zone while transperineal (TP) approach for LOIs in the transition, central or anterior zone. In FB under TR approach, local anesthesia was performed by injection of 2% lidocaine (6-8 ml) at the angle between the seminal vesicle and prostate base, identified in the longitudinal TRUS scan. In FB under TP approach, was administered 1 ml of 2% lidocaine into the perineal subcutis at the point suggested by Biojet® software to perform the sampling, and then 3-4 ml of 2% lidocaine through a 18-G spinal needle along the route up to periapical site. The pain was assessed using an 11-point visual analog scale (VAS) from 0 (no discomfort) to 10 (the most severe pain). *Results:* Overall, 226 patients were enrolled. 43% patients were biopsied under TP approach, whilst 57% under TR approach. In 52.7% of cases, a standard biopsy was added to targeted one, due to first biopsy or active surveillance protocol. Mean operative time for TR and TP approach was 22.6 (±5.7) and 18.1 (±5.1) minutes, respectively. No intraoperative complications occurred, and no intravenous sedation was required. VAS score was 1.93 (±0.97) and 1.67 (±0.88) for TP and TR approach, respectively (p=NS). 8.8% patients referred a mild post-operative pain controlled with 1 g paracetamol. *Conclusion:* In our experience, local anesthesia during FB procedures had a good efficacy in intra- and postoperative pain control. Larger sample size and the use of QoL assessments would definitely confirm our data.

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OUR EXPERIENCE WITH T1 RENAL MASSES: RESULTS AFTER 600 LAPAROSCOPIC PARTIAL NEPHRECTOMIES

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Introduction: In the last 20 years, partial nephrectomy has become the gold standard treatment in the management of T1 renal tumors. The aim of this study was to evaluate perioperative, pathological and early functional outcomes of patients treated with laparoscopic partial nephrectomy (LPN) for T1 renal tumors. *Patients and Methods:* All patients who underwent LPN between 06/2000 and 06/2016 were enrolled in this study and analyzed retrospectively. All the surgical procedures were performed by the same surgeon. Demographics variables, such as gender, age, BMI and comorbidity (classified by Charlson Comorbidity Index) were evaluated; preoperative variables, such as side, size and surgical complexity of the lesion (classified by PADUA score), perioperative variables, like blood losses, intra- and post-operative complications (as classified by the Clavien system) and hospital stay were considered. Concerning pathological variables histology and positive surgical margins rate were analyzed. Functional outcomes such as serum creatinine (SCr) and estimated glomerular filtration rate (eGFR) were evaluated preoperatively and at discharge. *Results:* A total of 600 patients were included in the present study: 410 of them (68.4%) were males, median age was 60 (range=58-63) years, mean BMI was 26.2±6.1 and mean CCI 0.88±0.9. Lesions were right-sided in 52.6% (316/600), with a mean size of 35.4±21.2 mm and a mean PADUA score of 7.9±1.1. Twenty-nine patients (4.8%) had solitary kidney. Concerning perioperative variables mean operative time was 111.4±55.3 min, with mean blood losses of 187.9±230.7 ml. Mean ischemia time was 21.5±15.4 min, 29% (174/600) of the procedures were performed without clamping of the renal artery. Intraoperative complications rate was 1.83% (11/600). The rate of postoperative complications was 8.9% (53/600), with Clavien >3 in 10 patients only. Mean hospital stay was 6±3 days. Concerning pathological findings 125 lesions (20.8%) were benign, while 475 malignant (79.2%, with 119 papillary and with 287 clear cell carcinoma). Positive surgical margins rate was 2.8% (17/600). No differences were found in terms of SCr and eGFR between preoperative and postoperative (at discharge) evaluation (SCr: 0.98±0.2 mg/dl *vs*. 1.06±0.3 mg/dl; GFR: 86.1±10.4 *vs*. 75.1±21.4 respectively, p>0.05). *Conclusion:* The present study highlighted that LPN, if performed by experienced hands, could be a viable approach in the organ sparing surgery for renal cancer. Indeed tin our experience the laparoscopic approach offered good postoperative and functional outcomes with short ischemia times (<25 min), minimal impairment of renal function, low complications rate and successful oncological outcomes.

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MANAGEMENT OF FUSION PROSTATE BIOPSY LOOKING FOR A BETTER INDEX TUMOR DETECTION AND CHARACTERIZATION

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Introduction: Fusion prostate biopsy is an emerging technique with the potential advantage of reducing the number of cores. The correct number and spatial distribution of cores at the time of target prostate biopsy is still a matter of debate. The aim of the study was to evaluate the minimum cores number for a better index tumor detection, to investigate the best core site and biopsy Gleason score (GS) heterogeneity within the same index lesion, to optimize the highest GS detection. *Patients and Methods:* A total of 327 patients with negative DRE underwent MRI/TRUS fusion software-based targeted biopsy (TBx) for elevated/rising PSA, and/or ≥1 detectable lesions at multiparametric MRI after previous negative standard biopsy. Depending on the diameter of each index lesion, ≤8 or >8 mm, four or six cores were taken respectively, according to a well-determined sequence. *Results:* 166 (50.7%) patients were diagnosed as having prostate cancer; among them 79 (47.6%) and 87 (52.4%) had an index lesion ≤8 mm or >8 mm, respectively. Patients with 1, 2, 3 or 4 positive cores with an index tumor ≤8 mm were 7 (8.9%), 31 (39.2%), 27 (34.2%) and 14 (17.7%). Similarly, there were 8 (9.2%), 30 (34.5%), 13 (14.9%), 14 (16.1%), 12 (13.8%) or 10 (11.5%) patients with 1, 2, 3, 4, 5 or 6 positive cores (lesion >8 mm). The major positive core prevalence was observed in the central zone of the target. GS heterogeneity was observed in 12.6% *vs*. 26.4%, for ≤8 or >8 mm target, respectively, with a slight prevalence of Gleason pattern ≥4 in the central zone. *Conclusion:* Approaching fusion TBx with a single core might be inadequate. Taking two cores in the central zone of the index lesion may provide more accurate cancer detection and optimize the chances of finding the highest GS.

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ROBOTIC PARTIAL NEPHRECTOMY FOR RENAL MASSES IN ELDERLY PATIENTS: IS IT FEASIBLE AND SAFE?

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Table I. *Patient characteristics, perioperative outcomes and complications.*

Variable	Group 1 (<65 years) (n=53)	Group 2 (≥65 years) (n=61)	*p*-Value
Age, mean±SD (years)	51.34±10.4	73.70±5.05	0.000
BMI, mean±SD (kg/m^2)	26.46±4.16	27.27±4.22	0.306
Male, N (%)	2 (4%)	13 (21%)	0.005
ASA ≥3, N (%)	14 (26%)	33 (54%)	0.004
CCI≥1, N (%)	21 (40%)	38 (62%)	0.024
Tumor size, mean±SD (mm)	3.26±1.89	3.17±1.62	0.715
Ischemia Yes, N (%)	38 (72%)	29 (48%)	0.013
WIT, median (IQR) (min)	19 (16-25)	24.50 (17.5-25)	0.246
Operative time, median (IQR) (min)	110 (90-146.2)	110 (90-145)	0.496
EBL, median (IQR) (cm^3)	150(50-300)	150 (100-300)	0.588
Hospital stay, median (IQR) (days)	5 (4-7)	6 (5-7)	0.264
Complications Yes, N (%)	7 (13%)	13 (21%)	0.326

Categorical variables are reported as absolute number and percentages. Quantitative variables were reported as mean and standard deviation (SD) or median and interquartile range (IQR).

Introduction: The incidence of renal masses in elderly patients is expected to increase as the general population ages. The aim of the study was to analyze prospective data of elderly patients in comparison to younger patients who underwent to robotic-assisted partial nephrectomy (RAPN) for renal masses. *Patients and Methods:* Medical records of patients who underwent RAPN for renal mass from 2013 to 2016 were analyzed. Patients were divided into two groups according to the age at the time of RAPN: group 1: <65 years; group 2: ≥65 years. We evaluated Charlson Comorbidity Index (CCI), preoperative data, perioperative outcomes and complications using Calvien-Dindo system for each group. Variables were compared with the Wilcoxon rank-sum test. Univariate and multivariate analyses were performed for factors predicting overall complications. *Results:* A total of 108 patients underwent 116 transperitoneal RAPN, of whom 61 (56.5%) were aged ≥65 years. Group 2 had an overall higher ASA score and CCI; the tumor characteristics were comparable (Table I). Perioperative outcomes and overall intraoperative and postoperative complications rate were similar between group 1 and group 2. On univariate and multivariate analyses, age ≥65 years was not a predictor of complications (Table II). Limitations are this was a nonrandomized study, with a limited number of patients and at a single center. *Conclusion:* Our study found no differences between young and elderly people after RAPN in terms of outcomes and complications. RAPN is a safe procedure even in aged population, where there is an increase of comorbidities and risks of medical complications.

Table II. *Logistic univariable and multivariable regression demonstrating factors predicting overall complications.*

	Univariate analysis		Multivariate analysis	
Variable	OR (95% CI)	*p*-Value	OR (95% CI)	*p*-Value
Age ≥65 years	1.06 (0.35-2.96)	0.91		
BMI (kg/m^2)	0.95 (0.84-1.07)	0.44		
Male (N)	1.89 (0.48-6.33)	0.32		
ASA ≥3	0.94 (0.36-2.49)	0.90		
CCI	1.90 (0.71-5.45)	0.21	2.46 (0.87, 7.67)	0.1
Tumor size (cm)	1.02 (0.75-1.31)	0.91		
Ischemia time (min)	0.81 (0.3-2.18)	0.67		
WIT (min)	0.96 (0.86-1.06)	0.51		
OR time (min)	1.00 (0.99-1.01)	0.33		
EBL (ml)	1.00 (0.99-1.01)	0.44		

BMI: Body mass index; CCI: Charlson comorbidity index; PAS: Previous abdominal surgery; NPAS: No previous abdominal surgery; M-PAS: major previous abdominal surgery; EBL: estimate blood loss; WIT: warm ischemia time.

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PROSTATE RE-BIOPSY AFTER LONG-COURSE ANDROGEN DEPRIVATION THERAPY: CASE REPORT

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Introduction: Prostate carcinoma, even at advanced stages, is responsive in most patients to androgen deprivation therapies (ADT). However, more than half of such tumors, in the range of 1 to 3 years, elude the effectiveness of these therapies, proceeding towards hormone-refractory condition. This seems to be related to a neuroendocrine differentiation. The trend in neuroendocrine phenotype is attributable to different microenvironmental conditions, including the depletion of androgens induced by LH-RH agonists or antagonists, anti-androgens and 5-α- reductase inhibitors. *Patients and Methods:* We report a case of 79-year-old man with prostate cancer diagnosed in November 2012. Histological examination was adenocarcinoma, Gleason score 9 (4+5) (Figure 1). Staging examination diagnosed organ-confined disease. Due to comorbidities, he was treated with ADT alone, with a long and excellent PSA control (oscillating between 0.07 and 0.3 ng/ml), interrupted only once for 9 months (from June 2014 to February 2015), with a growth of serum PSA level (5.8 ng/ml). Restarting ADT, the PSA level return indosables and the patient continued in follow-up. In February 2016, a staging CT diagnosed a inhomogeneous solid lesion of prostate (51×48 mm), infiltrating seminal vesicles, the lower wall and the back of bladder, being in proximity to the terminal part the left ureter. Simultaneously, pelvic pain and left hydronephrosis appeared. The PSA value was 0.78 ng/ml. *Results:* A re-biopsy diagnosed a poorly differentiated neuroendocrine carcinoma (Figure 2), a small-cell carcinoma with the following immunohistochemical characteristics: CKPAN$^+$, CROM$^+$, Ki-67: 70%, SYN$^+$. The patient started chemotherapy with carboplatin and etopiside (three cycles, from April to June 2016). Subsequently the patient underwent palliative radiation treatment to the pelvic lesion (36 Gy/12 fr), completed in August 2016. Both chemotherapy and radiotherapy were discreetly tolerated. The patient is undergoing follow-up checks. *Discussion and Conclusion:* Neurendocrine prostate carcinoma, either co-present with adenocarcinoma or as a result of transdifferentiation, is described as one of major process of emerging resistance to ADT. Clinically, there are some differences with

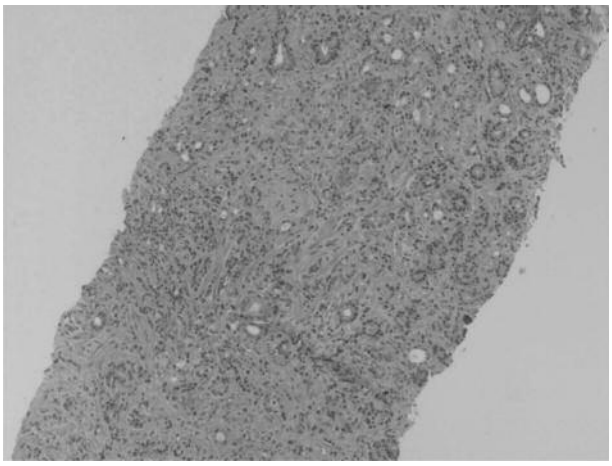

Figure 1. *First diagnosis (biopsy). Fragments of prostate tissue with evidence of differentiated atypical glandular proliferation coherent with adenocarcinoma Gleason Score 4+5=9 (grade group 5). Nuclear morphological detail appears characterized by evident nucleolar expression.*

Figure 2. *Re-biopsy after long-course ADT. Glandular population consisting of small cells, for the most part monomorphic, with a central nucleus and nucleus-cytoplasm ratio shifted in favor of nucleus. Poor nucleolar evidence. Immunohistochemistry: positivity to test for chromogranin confirmed a neuroendocrine origin of lesion.*

adenocarcinoma: rapidly progressive visceral disease, relative low serum PSA concentration and high response rate to platinum-based chemotherapy (1). In the case reported, a re-biopsy was performed for the suspicion of trans-differentiation: local progression and no distant metastases. The new diagnosis has allowed a more correct antiblastic therapy. Many patients undergo for years to hormonal therapies and often are used second-line drugs. It thus increase the time of androgen suppression and therefore the possibility of inducing differentiation. However, the re-biopsy is not a routine. But due to the low complication rate, it can be widely indicated after long course ADT. Nouri *et al*. studied pathways of epithelial-to-mesenchymal transition arguing that androgen-targeted therapy induces epithelial– mesenchymal plasticity and neuroendocrine transdifferentiation in prostate cancer (2). Understanding tumor cell plasticity will be important in further defining the rational use of hormonal therapies. With increasing recognition of cancer as a multifaceted process, the identification and characterization of specific cell phenotypes or the diagnosis of a trans-differentiation occurred, can help clinicians to make more targeted therapies, an opportunity for intervention to prolong survival in metastatic prostate cancer patients (3).

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LOWER RESPONSE TO INTRAVESICAL ADJUVANT THERAPY IN HIGH-RISK BLADDER CANCER COULD BE RELATED TO THE UROTHELIAL EXPRESSION OF EGFR

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Introduction: Studies on the role of EGFR in non-muscle-invasive bladder cancer (non-MIBC) are lacking. EGFR expression has been determined mainly in tissue specimens of MIBC and its overexpression has been associated with worse prognosis and shorter survival. Urothelial EGFR status after transurethral resection (TUR) of non-MIBC could indicate the risk of recurrence and progression. We investigated the feasibility of EGFR measurement in bladder washings of patients undergoing intravesical adjuvant therapy for non-MIBC and its usefulness in identifying risk subgroups. *Patients and Methods:* Our prospective study included patients after TUR of non-MIBC and healthy controls. Samples of bladder washings were centrifuged at 4˚C for 10 minutes at 1500 rpm, washed in cold phosphate buffer saline solution and centrifuged again obtaining a cellular pellet stored at −80˚C until RNA extraction was performed by miRNeasy Mini Kit (Qiagen®). A Nanodrop ND-2000 spectrophotometer was used

to check for good quality of RNA. RNA criteria to proceed with reverse transcription to cDNA: minimum 500 ng/ml, protein (260/280) solvents and organic compounds (260/230), contamination ratio 1.7-2.5. The cDNA obtained from RNA by High Capacity cDNA Reverse Transcription Kit (Life Technologies®) was used to perform a gene expression analysis by a real-time PCR, according to the method of the comparative quantification (ΔΔCt) with an endogenous control (cyclophilin). Every reaction was set in triplicate as a further guarantee of quality. The patients were grouped for EAU risk class and maintained in follow-up. *EGFR* expressions were statistically analyzed according to EAU risk groups and to patients' outcomes. *EGFR* gene expression values were expressed in folds of change compared to healthy controls (*EGFR*=1). *Results:* Fifty-eight patients and 21 healthy age-matched controls were entered. An adequate cellular pellet was obtained in 50 patients (86.2%) showing a median *EGFR* expression of 2.0-fold (IQR=0.6-4.3-fold, p=0.0004). The median level of *EGFR* varied considerably among the EAU risk classes. After TUR and adjuvant intravesical therapy, in 22 (55%) out of 40 high-risk patients, EGFR decreased to 1.3-fold (IQR=0.9-1.5-fold), while 18 (45%) showed elevated EGFR, median=4.7-fold (IQR=4.1-11.6-fold). At 25 months median follow-up (IQR=19.0-34.8 months), 20 (40%) patients experienced recurrence and six (12%) progression. Among patients with and those without *EGFR* gene increase, disease in nine (22.5%) and five (12.5%) recurred and in five (12.5%) and one (2.5%) progressed, respectively. *Conclusion:* In our experience *EGFR* expression measurement was feasible in more than 85% of patients and was related to EAU risk classes for recurrence and progression, showing different behavior during intravesical therapy. It was possible to identify a subgroup of high-risk patients overexpressing *EGFR* in spite of intravesical adjuvant therapy. *EGFR* evaluation in bladder washing could represent a repeatable and useful tool to identify a subgroup of patients at risk for progression predicted as not being responsive to intravesical adjuvant therapy and candidates for early radical cystectomy.

We wish to thank GSTU Foundation for data and statistical management.

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STEREOTACTIC BODY RADIATION THERAPY AS A VIABLE OPTION FOR ELDERLY PATIENTS WITH LOCALIZED PROSTATE CANCER

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Introduction: Radiotherapy (RT) for the treatment of elderly patients with prostate cancer is associated with a cancer specific mortality risk reduction of 2.6% at 10 years, even after adjusting for several confounders, including 12 comorbid conditions. The aim of the present study is to evaluate the efficacy and toxicity of high-dose, non-invasive stereotactic body radiation therapy (SBRT) in a group of elderly patients affected by low and intermediate risk prostate cancer. *Patients and Methods:* Patients aged ≥75 years, with biopsy-confirmed prostate cancer were enrolled. Inclusion criteria were: initial prostate-specific antigen (PSA) ≤20 ng/ml, Gleason Score ≤7, International Prostate Symptom Score ≤7. SBRT was performed with gantry-based volumetric modulated arc therapy (VMAT) in its RapidArc form and the use of flattening filter-free beams. The treatment schedule was 35 Gy in five fractions delivered on alternate days. Planning target volume included the prostate for low-risk and prostate plus seminal vesicles for intermediate risk, with a 5 mm margin of expansion in all directions. Toxicity was recorded according to CTCAE criteria v4.0. Biochemical failure was calculated according to the Phoenix definition. The Expanded Prostate Cancer Index Composite questionnaire was used to record health-related quality of life. *Results:* From May 2012 to April 2016, 50 patients were enrolled in the trial. Twenty-five patients were classified in low-risk group and 25 in intermediate-risk group. The mean age was 78 (range=75-84) years; Gleason score was 6 in 26 and 7 in 24 patients. Median initial PSA was 6.43 (range=2.6-17) ng/ml. Median follow-up was 26 months. Acute toxicity was mild. Rectal toxicity was reported as grade 1 in five (10%) cases and grade 2 in one (2%) cases; grade 1 and grade 2 genitourinary toxicity was described in 13 (26%) and 14 (28%) patients, respectively. In the late setting, three (6%) patients reported rectal grade 1 toxicity. Genitourinary late effects were reported as grade 1 in 13 (26%) patients and grade 2 in two (4%) patient. When evaluating outcome, median nadir PSA was 0.51 ng/ml (range=0.01-3.12) ng/ml. No biochemical relapses were observed during follow-up and all patients were alive at the time of the analysis. *Conclusion:* Gantry-based SBRT with VMAT and flattening filter-free can be considered an effective, non-invasive and safe approach for elderly patients affected by prostate cancer at low and intermediate risk. Randomized trials comparing SBRT with other approaches in this setting are necessary.

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DIFFERENT MOBILITY OF SEMINAL VESICLE AND PROSTATE

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Introduction: Different IGRT protocols need to be applied when prostate only or prostate plus seminal vesicles (SV) are treated; in fact, prostate organ motion is characterized mainly by shifts, while SV motion results in deformation and tilt. We have been using online correction protocol with gold markers to treat prostate only, and adaptive off-line re planning protocol (REPLANNING) to compensate for prostate plus SV motion. The aim of this study was to evaluate the organ motion and to investigate the possibility of using a standard CTV-PTV margin avoiding REPLANNING extra time. *Patients and Methods:* We analyzed prostate and SV movement in 50 patients treated with REPLANNING IGRT protocol where the first five CBCTs were used to create an adapted ITV named PTV replanning (re-PTV) to compensate for organ motion. Patients with siphon-like rectum were excluded. The distance between CTV and re-PTV, was measured as maximum shift on the planning CT, in all the directions (anterior, posterior, left, right, inferior, superior), for prostate and SV, separately. We compared prostate and SV motion for each direction using a paired *t*-test procedure with Bonferroni correction. Then we tested anisotropy of prostate and SV motion using one-way ANOVA and *post hoc* analysis with Bonferroni correction. *Results:* Descriptive statistics of prostate and SV motion is reported in term of median, range, interquartile range and 95th percentile (Table I). SVs exhibited statistically significant greater mobility than the prostate in anterior, posterior and caudal directions (corrected *p*-value<0.001) with a difference in mean value of 0.36±0.09 cm, 0.23±0.06 cm and 0.38±0.08 cm, respectively. Anisotropic motion effect was found with one-way ANOVA for both prostate and SV (*p*-value<0.001). With *post hoc* analysis, for SV, a greater motion in the anterior direction respect to lateral and cranio-caudal direction was famed (corrected *p*-value<0.05), with an average difference in mean value of 0.40±0.03 cm. Prostate motion in the posterior direction was greater than in lateral and cranio-caudal directions but the difference in mean was statistically significant only in cranial (0.32±0.10 cm) and right (0.34±0.10 cm) directions (corrected *p*-vaule<0.05). For both prostate and SV, differences between anterior and posterior motion were not significant. Finally we observed a lower displacement for prostate in the caudal direction (corrected *p*-value<0.001) with respect to anterior posterior and cranial directions, with an average difference in mean of 0.33±0.01 cm. *Conclusion:* SV exhibits different and statistically significant greater mobility than the prostate in anterior (up to 2.8 cm), posterior (up to 1.8 cm) and caudal (up to 2.7 cm) directions; an anisotropic motion was observed for both prostate and SV. As the margin needed to cover 95% of cases was larger than 1 cm in almost all directions and up to 2.5 anteriorly for SV, it was considered too extensive to be applied to the whole population of patients and not adequate for replacing REPLANNING.

Table I. *Descriptive statistics of data.*

	Direction	Median (cm)	Range (cm)	Interquartile range (cm)	95th Percentile (cm)
Seminal vesicles	Anterior	0.7	0-2.8	0.65	2.49
	Posterior	0.8	0-1.8	0.64	1.49
	Cranial	0.49	0-0.81	0.34	0.80
	Caudal	0.5	0-2.7	0.83	1.88
	Right	0.35	0-1.6	0.4	1.10
	Left	0.5	0-2	0.3	1.23
Prostate	Anterior	0.47	0-1.2	0.42	1.09
	Posterior	0.55	0-1.7	0.5	1.10
	Cranial	0.4	0-1.7	0.6	1.49
	Caudal	0.1	0.1	0.35	0.70
	Right	0.3	0-1	0.28	0.70
	Left	0.4	0-1	0.24	0.99

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PREOPERATIVE CLINICAL CHARACTERISTICS ARE PREDICTIVE OF CLINICAL SIGNIFICANT DISEASE AT FINAL PATHOLOGY IN PATIENTS WITH PROSTATE CANCER LESION WITH PIRADS SCORE ≤3: IMPLICATIONS FOR SELECTION OF CANDIDATES FOR ACTIVE SURVEILLANCE

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Introduction: Lately multi parametric magnetic resonance imaging (mpMRI) of the prostate has increased its role in diagnosing and staging prostate cancer (PCa). While lesions with PIRADS score ≥4 are predictive of clinically significant disease, lesions with PIRADS score ≤3 are equivocal. We present the pathological outcomes of PCa patients who underwent robot-assisted radical prostatectomy (RARP) and had a lesion with PIRADS ≤3 at mpMRI. *Patients and Methods:* A total of 265 (13%) patients with clinically localized PCa and a lesion with PIRADS score ≤3 at mpMRI who underwent RARP at a single referral tertiary center between

June 2011 and December 2015 were identified. All patients underwent 1.5 Tesla mpMRI with an eight-channel phased-array coil and images were reviewed by a highly experienced dedicated radiologist, using PIRADS version 1. Uni- and multivariate logistic regression analyses assessed the impact of preoperative patient and disease characteristics on the risk of clinically significant disease (defined as extracapsular disease or Gleason score ≥7) at final pathology. In particular, covariates consisted of type of mpMRI lesion (focal *vs*. diffuse), size of the mpMRI lesion (≥15 *vs*. <15 mm), preoperative clinical characteristics stratified into risk groups (low-risk: biopsy Gleason score sum ≤6, total PSA <10 ng/ml and cT1-cT2 stage; high-risk: biopsy Gleason score sum ≥7 or total PSA ≥10 ng/ml or cT3 stage). *Results:* Median age at surgery was 63 years. Overall, 41 (15.5%) and 224 (84.5%) patients had a lesion with PIRADS score 2 or 3, respectively. The median (interquartile range) size of the mpMRI lesion was 14 (10-21) mm. Moreover, 90 (34%) and 175 (66%) patients had a diffuse or focal lesion at mpMRI, respectively. Finally, 154 (63.4%), 84 (34.6%), and 5 (2%) patients had pathologic Gleason score ≤6, 7, and ≥8, respectively. Overall, 32 (14.3%) patients had positive surgical margins and 212 (87.2%), 31 (12.8%), 56 (21.1%) and 209 (78.9%) patients had pT2, pT3a/3b, pN0 and pNx, respectively. Moreover, 100 (41.3%) patients experienced clinically significant disease at final pathology. In univariate analyses, the high-risk group was significantly associated with the risk of clinically significant disease (p=0.02). In multivariate analyses, high-risk group (odds ratio=2.05; 95% confidence interval=1.00-4.21; p=0.05), but not the type of mpMRI lesion or the size of the mpMRI lesion, represented an independent predictor of clinically significant disease at final pathology. *Conclusion:* In patients with PCa with a lesion with PIRADS score ≤3, preoperative clinical characteristics, and not mpMRI characteristics of the lesion, are predictive of clinical significant disease at final pathology. These results have implications in the risk stratification assessing which patients with a lesion with PIRADS score ≤3 are suitable for active surveillance *versus* curative treatment.

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RE-IRRADIATION OF LOCALLY RECURRENT PROSTATE CANCER: RESULTS OF EFFICACY AND SAFETY

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Introduction: Despite considerable advances in technologies for delivering radiotherapy, re-treatment of locally recurrent prostate cancer with external beams radiation therapy remains controversial because of fear of major complications or unbearable side-effects. In this study, we report our experience on re-irradiation in a sample of 17 patients previously irradiated for prostate cancer. *Patients and Methods:* Patients affected by prostate cancer and previously submitted to radiotherapy were included in this study, provided that they had an increased PSA that could be diagnostic for biochemical relapse and a choline-PET revealing the presence of a local recurrence of disease. Re-irradiation consisted of a stereotactic treatment delivered by image-guided radiation therapy–volumetric modulated arc therapy technology in five daily fractions. Toxicity was recorded according to CTCAE criteria (v 4.0). *Results:* Between November, 2012 and May, 2016, 17 patients (median age=78 years, range=59-82 years) were submitted to re-irradiation to the prostate (n=10, 58.8%), prostatic bed (n=5, 29.4%) or prostate and local recurrence (n=2 seminal vesicle, ischium 11.8%). Previous treatment consisted on a median total dose of 74 Gy to the prostate or prostatic bed (range=66-76 Gy). Ten patients had also received radiotherapy to seminal vesicles, four patients to pelvic lymph nodes. Median time from previous radiotherapy was 80 (range=26-116) months. Median PSA at the time of recurrence was 3.1 (average=4, range=1.2-13.5) ng/ml. As re-irradiation, a median total dose of 25 (range=25-30) Gy was delivered in a median of five fractions (range=5-6). An immediate biochemical response was observed in all cases. Median PSA nadir after treatment was 0.77 (average=1.33, range=0.19-6.0) ng/ml (p=0.0004). The sole acute toxicity reported was genitourinary, mainly represented by pollakiuria and dysuria grade 1 (n=9, 52.9%) or grade 2 (n=2, 11.8%). One patient (5.9%) had a grade 3 hematuria, was hospitalized and submitted to continuous bladder irrigation. A late grade 1 genitourinary toxicity was observed in three patients (17.7%). No other toxicities were observed. At a median follow-up of 16 months (range=6-36 months, calculated from the time of recurrence diagnosis), eight patients (47.1%), experienced a biochemical recurrence, confirmed by a positive choline-PET in five cases (29.4%). Median BFS was 19 months, 1- and 2-year BFS was 84.6% and 32.2%, respectively. Median LC was 24 months, 1- and 2-year LC was 90.9% and 40.4%, respectively. All patients are still alive, five of them with measurable disease. Median OS was 96 months from the initial diagnosis (range=59-151 months). *Conclusion:* With the technological novelties offered by modern radiotherapy, re-irradiation of patients affected by prostate cancer and previously treated with radiation therapy, confirm its safety and efficacy. Therefore, it can be considered a valuable option for local recurrence of this disease.

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PREOPERATIVE CLINICAL CHARACTERISTICS, SURGICAL AND PATHOLOGICAL OUTCOMES OF ANTERIORLY LOCATED PROSTATE CANCER TREATED WITH ROBOT-ASSISTED RADICAL PROSTATECTOMY AT A SINGLE REFERRAL TERTIARY CENTER

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Introduction: Anteriorly located prostate cancer (PCa) frequently require several sets of prostate biopsy to diagnose it. The introduction of multiparametric magnetic resonance imaging (mpMRI) of the prostate has improved the diagnosis of anterior tumors. We present the preoperative characteristics, surgical and pathological outcomes of PCa anteriorly located at mpMRI in patients who underwent robot-assisted radical prostatectomy (RARP). *Patients and Methods:* A total of 116 (6.1%) patients with clinically localized PCa and an anterior lesion at mpMRI who underwent RARP at a single referral tertiary center between 2012 and 2015 were identified. All patients underwent 1.5 Tesla mpMRI with an eight-channel phased-array coil and images were reviewed by a highly experienced dedicated radiologist. Preoperative characteristics, surgical, perioperative and pathological outcomes were assessed. Univariate logistic regression analyses assessed the impact of PIRADS score on the risk of clinically significant disease (defined as pT3a/3b or pT4 or Gleason score ≥8 disease) at final pathology. *Results:* Median age at surgery was 66 years. Overall, 46 (39.7%) and 70 (60.3%) patients had only anterior or anterior and posterior lesions, respectively. Moreover, three (3%), 20 (20.4%) and 75 (76.5%) patients had a PIRADS ≤3, 4, and 5, respectively. Median [inter quartile range (IQR)] PSA and size of the mpMRI lesion were 8.65 (6.20-16.12) ng/ml and 32 (23- 44) mm, respectively. Finally, 36 (31.3%) patients had one or more previous prostate biopsies and 61 (64.2%), 31 (32.6%), three (3.2%), patients had cT1, cT2, and cT3 disease, respectively. Overall, at biopsy, 63 (54.8%), 43 (37.4%), and nine (7.8%) patients had a Gleason score ≤6, 7, and ≥8, respectively. Median (IQR) operative time and blood loss was 194 (170-234) min and 150 (100-200) ml, respectively. Moreover, 67 (58.8%), 24 (21.1%), and 23 (20.1%) patients underwent a bilateral, unilateral and non-nerve-sparing procedure, respectively. Median (IQR) urinary catheter stay was 5 (5-6) days. Finally, 24 (20.9%), 66 (57.4%), and 25 (21.7%) patients had pathologic Gleason score ≤6, 7, and ≥8, respectively. Overall, 60 (52.2%), 46 (40%), eight (7%), 12 (10.3%) patients had pT2, pT3a and pT3b, pN1 disease, respectively. Moreover, 41 (36%) patients had a positive surgical margin, of which 11 (26.8%), 20 (48.8%), 21 (51.2%) were focally positive, anteriorly located or postero-laterally located, respectively. In univariate analyses, PIRADS 5 lesions were significantly associated with the risk of clinically significant disease (odds ratio=6.00; 95% confidence interval=1.82-19.7; p=0.03). *Conclusion:* Anteriorly located PCa often harbors unfavorable characteristics at final pathology. PIRADS 5 lesions are associated with an adverse pathological outcome. In this scenario, mpMRI plays a fundamental role in the management of this tumors.

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THULIUM LASER TREATMENT OF EARLY-STAGE PENILE CANCER: INITIAL RESULTS AND FUNCTIONAL OUTCOMES

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Introduction: Traditional surgical treatment of penile carcinoma was amputation of the glans, resulting in organ dysfunction and disfigurement, with a strong impact on the patient's quality of life. Several conservative treatment modalities have been introduced with the goal of achieving conservative treatment. We present our initial experience with thulium laser excision of early-stage penile lesions. *Patients and Methods:* A total of 20 patients with early-stage penile lesions undergoing thulium laser treatment in a tertiary referral center between 2013 and 2016 were identified. Patients underwent ablation with a RevoLix 200 W continuous wave laser. Under local anesthesia, the procedure was carried out with a pen-like laser-handpiece, using a 360 micron laser fiber and 15-20 W of power. Perioperative characteristics, pathological and functional outcomes were assessed. *Results:* Median age at surgery was 64 years. Only one (4.5%) patient had previous sexually transmitted diseases and six (31.6%) had had more than 20 different previous partners. First observation of the lesion occurred <6 months, 6-12 months and >12 months before seeking medical advice in 57.9%, 15.8% and 26.3% of patients, respectively. Overall, at diagnosis, nine (45%), six (30%) and five (25%) patients presented with an erythematous area, a nodular lesion or a

warty lesion, respectively. Median (inter quartile range) size of the lesions was 15 (6-21) mm. Sixteen (80%) patients presented with glans involvement and four (20%) patients with coronal sulcus disease. Overall, one (5%), seven (35%), two (10%), two (10%) and eight (40%) at final pathology presented balanitis, spinocellular carcinoma (4 pT1, 1 pT2 and 3 pT3), dysplasia, lichen and penile intraepithelial neoplasia respectively. Moreover, six (27.3%) patients had a recurrence, of which four (85.7%) and two (14.3%) patients developed an invasive or in situ recurrence. The site of recurrence was the treated area in 85.7% of patients and elsewhere in 14.3% of patients. Finally, five (83.3%) and one (16.7%) of the recurring patients underwent repetition of laser treatment and amputation (pT3), respectively. After treatment, eight (44.4%) patients reported a conserved penile sensitivity, while seven (38.9%) and three (16.7%) patients experienced a better or worse sensitivity after ablation, respectively. Overall, seven (43.8%), three (18.8%), three (18.8%) and three (18.8%) patients had erections after less than a week, more than a week, within 1 month and after 1 month, respectively. Post-treatment sexual activity was achieved in 80% of patients, of which 53.3% experienced sexual intercourse within the first month after laser ablation. *Conclusion:* Early-stage penile carcinomas can be effectively treated with an organ-preservation strategy. Thulium laser treatment with a pen-like laser-handpiece is more ergonomic than the traditional peniscopically controlled CO_2 laser treatment. Conservative treatment with thulium laser is easy, safe and offers good functional outcome, with a minor impact on patient's quality of life.

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ROBOT-ASSISTED PARTIAL NEPHRECTOMY FOR CLINICAL STAGE ≥T1B TUMORS: PERIOPERATIVE, ONCOLOGIC AND FUNCTIONAL OUTCOMES

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Introduction: Nephron-sparing surgery (NSS) represents the gold standard treatment for small renal masses and recently, indications have been extended to larger lesions. It has been demonstrated that NNS has equivalent oncological outcomes, improved renal function outcomes and reduced cardiovascular morbidity compared with radical nephrectomy. We present the outcomes of patients who underwent robot-assisted partial nephrectomy (RAPN) for ≥cT1b renal mass. *Patients and Methods:* A total of 51 (25.1%) patients with ≥cT1b renal mass who underwent RAPN at a single referral tertiary center between 2010 and 2016 were identified. Comorbidities were registered according to Charlson Comorbidity Index (CCI) and lesions were categorized according to Preoperative Aspects and Dimensions Used for an Anatomical (PADUA) score. Surgical strategies were stratified using the surface-intermediate-base (SIB) margin score and perioperative complications were categorized according to the Clavien-Dindo classification. Paired *t*-test assessed the differences in pre- and postoperative estimated glomerular filtration rate (eGFR). *Results:* Median age at surgery was 58 years. Overall, 38 (74.5%) and 13 (25.5%) patients were male and female, respectively. Moreover, 35 (68.6%) and 16 (31.4%) patients had a CCI ≤2 and >2, respectively. Median [interquartile range (IQR)] size of the lesion at preoperative imaging was 49 (44-55) mm. Finally, four (54.8%), 43 (37.4%), and nine (7.8%) patients had, at biopsy, a Gleason score ≤6, 7, and ≥8, respectively. Overall, four (11.2%), 19 (52.7%) and 13 (36.1%) patients had a low (6-7), an intermediate (8-9) and high (≥10) PADUA score, respectively. Moreover, 27 (52.9%) and 24 (47.1%) patients underwent a pure enucleation and a enucleo-resection. Median (IQR) operative time, warm ischemia time and blood loss were 170 (132-230) min, 20 (17-25) min and 200 (100-600) ml, respectively. Median (IQR) size of the lesion at final pathology was 49 (4-60) mm. Overall, 56.3%, 25% and 18.7% of patients achieved a SIB margin score of 0-1, 2-3, 4-5, respectively. Moreover, 32 (64%), 11 (22%) and seven (14%) patients at final pathology had a clear cell renal carcinoma, a chromophobe renal cell carcinoma and a papillary renal cell carcinoma, respectively. Finally, 43 (84.3%), three (5.9%), five (9.8%), two (3.9%) and 49 (96.1) patients had pT1b, pT2, pT3, pN0 and pNx disease, respectively. Overall, five (10.4%), 36 (75%) and three (14.6%) lesions were Fuhrman grade 1, 2 and 3, respectively. Positive surgical margin rate was 2%. Moreover, four (7.8%), two (3.9%) and one (2%) patient had Clavien I, II, III complications, respectively. Median (IQR) follow-up was 21 (10-38) months without any recurrences. Median (IQR) pre- and postoperative eGFR was 99 (85-121) ml/min/1.73 m^2 and ml/ml (79-114) ml/min/1.73 m^2, respectively (p=0.9). *Conclusion:* RAPN is a safe and efficacious procedure for the treatment of ≥cT1b renal masses, with excellent intermediate oncological and functional outcomes.

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ULTRA CONSERVED LONG NONCODING RNAS IN BLADDER CANCER ANALYSIS REVEALS A NETWORK BETWEEN NON-CODING RNA AND MICRO-RNA

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Transcribed ultraconserved regions (T-UCRs) are pieces of human genome located both intra- and inter-genically. They are conserved between orthologous regions of the human, rat and mouse genomes. They are frequently located at fragile sites and genomic regions involved in cancer (1). By using genome-wide profiling, we identified 289 ucRNAs de-regulated in patients with bladder cancer (BC) compared to control cases (24 different tumors, four healthy controls). The greatest difference was noted for ultraconserved element 8 (uc.8+), which was increased in expression by 5.45± 0.9-fold (p=0.001), and for ultraconserved element 388 (uc.388+), which was decreased in expression by 0.23-fold. Expression level of the most deregulated T-UCRs was validated in 60 patients and 16 normal donors. We showed that uc.8+ functions as a natural decoy RNA for miR-596 in BC. We also observed that the up-regulated, as well as the most down-regulated T-UCRs in BC, showed putative binding sites for mir-596, with a minimum free energy <−30 kcal/mol for each duplex formed. Our studies demonstrated and experimentally validated the interaction of miRNAs and T-UCRs as network to modulate the availability of these non-coding RNAs in BC cells. We experimentally validated this interaction and showed that the perturbation of one element of this network changes the expression levels of other interactors. These new findings for the first time describe a network between T-UCRs and miRNA, pointing out the existence of an additional layer of gene expression regulation in bladder carcinogenesis.

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STEREOTACTIC RADIOTHERAPY IN PATIENTS WITH OLIGOMETASTATIC RENAL CELL CARCINOMA

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Introduction: The aim of this study was to evaluate the performance of stereotactic radiotherapy (SRT) with either CyberKnife (Accuray; Sunnyvale, CA, USA) or Vero™ (BrainLab; Mitsubishi Feldkirchen, Germany) in term of toxicity and local control (LC) of cranial of extracranial metastasis in patients with oligometastatic renal cell carcinoma (RCC). *Patients and Methods:* Between January 2012 and September 2015, 26 patients (overall 33 metastatic lesions) with metastases of RCC were treated. SRT was performed on a singular lesion at a new site or on residual disease during systemic therapy. Disease control was evaluated with serial imaging. Toxicity was recorded according to the Common Toxicity Criteria version 4.0 and reported as early and late. The total radiotherapy doses ranged from 10 to 54 Gy, given in one to three fractions. The biological equivalent doses (BED) and 2 Gy-per-fraction equivalent dose (EQD2) were calculated using α/β=10 for tumors. We stratified the patients into three groups according to the EQD2 delivered: group 1: range=12-36 Gy; group 2: range=42-50 Gy; group 3: range=66-126 Gy. *Results:* After a median follow-up of 14 (range=1-36) months, we achieved the best result in group 3 with CR and SD in 77.7% and 22.3% of patients *versus* 60% and 40% in group 2 and 50 and 50% in group 1. Only out-of field progression of disease was observed in eight cases after a median 5.1 months from SRT. No toxicity was registered. Eleven patients had more than 12 months' follow-up: 11/11 had CR at the site of treatment and two of these had PD at another site (two patients were of group 1). Clinical and radiological response was thus evaluated in all patients. *Conclusion:* SRT is a feasible approach in patients with oligometastatic RCC with an

excellent LC and a favorable toxicity profile. SRT could play a role in the therapeutic strategy for these patients, allowing them a delay in the start of a systemic therapy and its toxicity or a drug holiday after a long treatment period. Further studies are warranted to increase the quality of evidence of such a composite approach.

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THE ADHERENCE TO THE EAU GUIDELINES ON PENILE CANCER TREATMENT COULD INFLUENCE SURVIVAL: MULTICENTER, RETROSPECTIVE, EUROPEAN STUDY

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Introduction: Penile cancer (PC) is uncommon in Western countries, with an incidence of ≤1.0/100,000 males, aged 50-70 years. Circumcision in childhood is protective. Due to its low incidence and low volume of surgical series, it is difficult to achieve good quality guidelines with robust recommendations. Aims of this study were i) to evaluate the adherence to the EAU guidelines on PC in terms of primary treatment and lymphadenectomy; ii) to determine the impact of adherence on survival outcomes. Patients and Methods. We retrospectively reviewed the clinical charts of 176 patients who underwent penile surgery for neoplasms in eight European centers (2010-2016). Demographics, patient comorbidity, circumcision, site of primary lesion, perioperative and histopathological data were collected and analyzed. The follow-up was updated by recall of all patients. For each case, the theoretical adherence to 2016 EAU Guidelines for the primary surgery and the lymphoadenectomy were evaluated. A comparison between theoretical and practical surgical approach was made in order to evaluate the adherence rate. The TNM 2009 was used to classify stage and grade. Descriptive, univariate and multivariate analyses were performed to evaluate the impact of the adherence on survival. Kaplan–Meier curves were estimated. *Results:* 176 patients were enrolled (median age=66.5±11.3 years). A total of 956.5% were uncircumcised. The lesions were located at the glans, the prepuce and at both sites in 55%, 11% and 34%, respectively. The surgical approaches adopted were radical circumcision, tumor excision, glansectomy, penile partial amputation, total emasculation in 7%, 24%, 15%, 39%, 15%, respectively. All PCs were squamous carcinoma. The staging was 16% <pT1 (incl. PeIN, Tis, Ta), 38% pT1, 34% pT2.12% pT3-4. The grading was G1, G2 and G3 in 37%, 47% and 16%, respectively. The surgical margin was negative in 83%; 30% had palpable lymph nodes and 45% of patients underwent lymphadenectomy (LY). The pathological nodal status was 42% N0, 26% N1, 32% N2. The adherence to the EAU guidelines for primary treatment was respected in 66% of patients. In non-adherent cases, the reasons for discrepancy was the choice of the patient in 17%, of the surgeon in 36% and other causes in 47%. The adherence to the EAU guidelines in terms of LY was respected in 70% of patients. Survival estimates showed that the adherence to the EAU Guidelines on Primary Surgery, after adjustments for age, TNM stage and LY significantly influences the overall survival (hazard ratio=0.42, 95% confidence interval=0.23-0.79, p=0.007)). Moreover the adherence to the EAU Guidelines for LY, after adjustments for age, TNM stage, palpable nodes and grade, significantly influences the overall survival (hazard ratio=0.30, 95% confidence interval=0.16-0.58, p<0.001). The adherence to EAU Guidelines showed a trend of statistical significance for effect on progression-free survival. *Conclusion:* Our data showed that adherence to the EAU Guidelines on PC is quite optimal across eight European centers and strongly influences the survival outcomes; adherence should be reinforced, endorsed and encouraged at all the centers treating PC.

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ABIRATERONE ACETATE FOR TREATMENT OF METASTATIC CASTRATION-RESISTANT PROSTATE CANCER IN CHEMOTHERAPY-NAIVE PATIENTS: AN ITALIAN MULTICENTER 'REAL-LIFE' 1-YEAR STUDY

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Introduction: To better understand the real-life experience with abiraterone acetate (AA) in men with chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC), we present an Italian multicenter real-life analysis with a mid-term follow-up. *Patients and Methods:* A consecutive series of patients with mCRPC treated with AA from eight Italian tertiary centers was collected. Demographics, clinical parameters, treatment outcomes and toxicity were recorded. The Brief Pain Inventory scale Q2 was recorded and patient treatment satisfaction was evaluated. Univariate and multivariate analyses were performed to identify factors for treatment satisfaction. Kaplan–Meier curves were estimated. *Results:* We included 145 patients (mean age=76.5 years). All patients were on androgen deprivation therapy. Patients had prior radiotherapy, radical prostatectomy, both treatments or exclusive androgen deprivation therapy in 17%, 33%, 9% and 40%, respectively. The rate with Gleason score >7 at diagnosis was 57%. Asymptomatic patients were 62%. The median serum total PSA at AA start was 17 (range=0.4-2100) ng/ml. Overall, the median exposure to AA was 10 (range=1-35) months. Among the patients that had ≥3 months of AA the proportion of patients achieving a ≥50% PSA decline was 49%. Patient satisfaction was 31% greatly improved, 37% improved, 24% not changed, 7% worsened; and significantly correlated at multivariable analysis with baseline PSA [odds ratio (OR)=1.43, 95% confidence interval (CI)=1.03-1.98; p=0.033], pain (OR=9.3, 95% CI=3.33-26.09; p<0.0001), duration of ADT>12 months (OR=5.5, 95% CI=1.43-21.57; p=0.014). With a median follow-up of 13 months, median progression-free and overall survival were 17 and 26.5 months, respectively, and correlated with patient satisfaction, pain, PSA decline (all p<0.001). *Conclusion:* AA is effective and well tolerated in asymptomatic or slightly symptomatic patients with mCRPC in a real-life setting. These preliminary data should be confirmed after longer follow-up, nevertheless the baseline PSA, the presence of pain and the duration of ADT are predictors of patient satisfaction. The survival outcomes depend on patient satisfaction, pain, and PSA decline.

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COMPARING THULIUM LASER *EN-BLOC* ENUCLEATION AND TRANS-URETHRAL RESECTION IN THE TREATMENT OF NON-MUSCLE-INVASIVE BLADDER CANCER

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Introduction: The gold standard procedure for non-muscle invasive bladder cancer (non-MIBC) is still trans-urethral resection of the bladder tumor (TURBT). Laser enucleation is a new technique that has been recently used as treatment for bladder tumors (1). TURBT is still associated with several complications as tumor recurrence, bleeding, bladder perforation. Laser *en bloc* enucleation could offer some advantages compared with standard resection (2). In this study, we compared TURBT with laser *en bloc* enucleation in two groups of patients. *Patients and Methods:* From November 2015 to April 2016, 54 patients (mean age=56.5

years) were enrolled with a new diagnosis of non-MIBC. The tumor diameter ranged form 0.4 to 3.8 cm, with a mean value of 2.2 cm. They were randomly divided in two groups: Group A (30 patients) underwent *en bloc* enucleation using a front-firing thulium laser, group B (24 patients) underwent conventional monopolar TURBT. We analyzed the differences in the two techniques in terms of operative time, hospital stay, blood loss, catheterization time. Patient were checked at 3-months' follow-up with cystoscopy and biopsy at the tumor base in order to assess any recurrence. *Results:* Group A was associated with shorter operative time (21 *vs*. 25 minutes), shorter hospital stay (2.0 *vs*. 2.6), less blood loss (Hb 0.8 *vs*. 1.4 mg/dl), shorter catheterization time (2.2 *vs*. 3.2 days), and less bladder perforations (3 *vs*. 6 patients) compared with group B. No patient in group A experienced obturator nerve reflection intraoperatively. At 3-months' follow-up, the biopsy at the tumor base was positive in one patient (3.3%) in group A *vs*. two (8.5%) in group B. *Discussion:* Laser *en bloc* enucleation leads to lower complication rates compared to normal TURBT (3). These results are possibly due its hemostatic effect and perhaps to avoiding the obturator nerve reflex, leading to a shorter hospitalization and catheterization. *Conclusion:* Our preliminary data showed that laser enucleation proved to be a safe and efficient method and presented several advantages compared with conventional TURBT. As a promising technique, it could be used as a first-line treatment for superficial bladder tumor. Another advantage seems to be accurate pathological staging of *en bloc* tumors. Further randomized controlled trials are still needed to support the assumed advantages of *en bloc* resection over standard TURBT in terms of long-term recurrence rate and accurate staging.

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AN EVALUATION OF MORPHOLOGICAL AND FUNCTIONAL MULTI-PARAMETRIC MRI SEQUENCES IN CLASSIFYING NON-MUSCLE AND MUSCLE-INVASIVE BLADDER CANCER

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Introduction: Our goal was to determine the ability of multiparametric magnetic resonance imaging (mpMRI) to differentiate muscle invasive bladder cancer (MIBC) from non-muscle invasive bladder cancer (non-MIBC). *Patients and Methods:* Patients underwent mpMRI before tumor resection. Four MRI sets: T2-weighted plus perfusion-weighted imaging (PWI), T2-weighted plus diffusion weighted imaging (DWI), T2-weighted plus DWI plus PWI, and T2W plus DWI plus PWI with diffusion-tensor imaging (DTI) were interpreted qualitatively by two radiologists, blinded to histology. *Results:* PWI, DWI and DTI were also analyzed quantitatively. Accuracy was determined using histopathology as reference standard. *Results:* A total of 61 tumors were analyzed. All non-MIBC (n=41) lesions were correctly characterized by the T2-weighted–DWI–PWI image set. Overall accuracy of the complete mpMRI protocol was 95% in differentiating NMIBC from MIBC. Quantitative PWI, DWI and DTI parameters were shown to be significantly different in cancerous *versus* noncancerous areas within the bladder wall in T2-labelled lesions. *Conclusion:* mpMRI with DWI and DTI appears a reliable staging tool for bladder cancer. If our data are validated, then mpMRI could precede cystoscopic resection to allow a faster recognition of MIBC and accelerated treatment pathways.

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DETECTION OF MRI INDEX LESION WITH TRANSRECTAL ULTRASOUND-MAGNETIC RESONANCE IMAGING FUSION-GUIDED PROSTATE BIOPSIES: DOES IT CORRESPOND WITH HISTOPATHOLOGY?

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Introduction: To assess the histopathological correspondence on MRI index lesion between magnetic resonance imaging (MRI)/transrectal ultrasonography (TRUS) fusion and radical prostatectomy. *Patients and Methods:* We selected 101 consecutive patients treated with radical prostatectomy for a clinically localized prostate cancer diagnosed on MRI/TRUS fusion. Three to five biopsy specimens for each MRI index

lesion were taken for each patient. A correlation analysis between MRI/TRUS fusion and pathological findings of radical prostatectomy was performed. Factors associated with determining the accuracy of dimension and Gleason score (GS) on targeted biopsy were statistically assessed. *Results:* For the MRI index lesion, we found a detection rate of 100% of dimensions from 7 mm to 3 cm, and 83% for the GS. In particular, we found that in multifocal cases, 40% of patients the MRI index lesion corresponded to the most aggressive lesion. *Conclusion:* MRI/TRUS fusion biopsy has a high dimensional and histological detection rate of MRI index lesions that drives the progression of prostate cancer.

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EVALUATION OF NEGATIVE PREDICTIVE VALUE OF MULTIPARAMETRIC MRI FOR PROSTATE CANCER - A RETROSPECTIVE ANALYSIS AFTER FIVE YEARS OF CLINICAL EXPERIENCE

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Introduction: To retrospectively evaluate the negative predictive value (NPV) of multiparametric MRI (mpMRI) for prostate cancer after 5 years of clinical activity. *Patients and Methods:* Seven hundred and forty-five men suspected of harboring prostate cancer with negative MRI findings were included. Imaging studies were evaluated according to PI-RADS score. Patients with negative mp-MRI findings and high and stable PSA values were followed up with mp-MRI for at least 1 year. Patients with positive transrectal ultrasound-guided biopsy or prostatectomy findings were defined as false-negative. Patients with negative findings by digital rectal examination, MRI and biopsy and no increase in PSA at 5-year follow-up were defined as clinically negative. The clinical NPV of mp-MRI was calculated. Moreover, imaging findings of patients with positive mp-MRI who underwent prostatectomy were retrospectively analyzed. In cases where pathology results showed cancer in only one half of the prostate, mp-MRI examinations were reviewed. NPV of mp-MRI was assessed taking into account only the unaffected part of the gland. *Results:* The clinical NPV of mp-MRI was 96.1% for significant prostate cancer. Small cancers, prostatitis, and benign prostatic hypertrophy masking prostate cancer returned false-negative results. In patients whose prostate harbored cancer in only one half of the gland, NPV of mp-MRI was 98.7% if the cancer-free part of prostate was considered. *Conclusion:* mp-MRI revealed a high clinical NPV and is a useful tool to rule out clinically significant prostate cancer when used to follow-up patients with high and stable PSA levels and to avoid a substantial number of unnecessary biopsies.

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EVALUATION OF COMPLIANCE OF PATIENTS WITH PROSTATE CANCER WITH ACTIVE SURVEILLANCE PROTOCOL IN A LARGE MULTI-CENTRIC ITALIAN POPULATION

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Introduction: To report compliance rates in active surveillance (AS) for prostate cancer in Italian patients enrolled in the Prostate cancer Research International: Active Surveillance (PRIAS) international study. *Patients and Methods:* From December 2009 to October 2016 SIUrO-PRIAS-ITA working group enrolled in PRIAS and followed-up 954 patients. PRIAS protocol suggests PSA examination in the first 2 years every 3 months and DRE every 6 months, and afterwards PSA examination every 6 months and DRE every 12 months. Biopsy is repeated in years 1, 4 and 7 of follow-up. Patients are advised to switch to active treatment if disease reclassification is detected. We analyzed PSA, biopsy and PSA and biopsy compliance in two follow-up time windows (≤2 years and 2-4 years) to evaluate compliance in the Italian centers participating in SIUrO PRIAS ITA. Minimum compliance with PSA monitoring was defined as having at least siX PSA tests in the first time-window or at least eight in the second time-window. Compliance with biopsy monitoring was defined as having at least one biopsy per time-window. Centers with at least 10 patients per time-window were considered for center-specific analysis. *Results:* A total of 954 patients were enrolled in 11 centers. Median time in AS was 26.47 (range=1.94–114.74) months, with 627 patients still being on AS. Overall, 493 patients had at least 2 years' follow-up (limit for the first time-window) and were thus included in the present analysis. Considering the needs for having at least 10 patients for the center-specific analysis, 448 patients from seven centers for the first time-window and 187 patients from three centers for the second time window were considered. Overall compliance was quite good in both periods, with a compliance higher than 84% for PSA, 78% for biopsy and 77% for PSA plus biopsy. Significative differences ($p<0.001$) were found in center-specific compliance; in the first 2 years, two groups of centers similar in compliance level were observed. Variations of compliance among centers was between 35.7% and 100% for PSA, 30.8% and 94.9% for biopsy and 23.1% and 91.6% for PSA plus biopsy. In the second time-window, a good compliance was found for two out of three centers (<90% for PSA, 82-95% for biopsy and PSA plus biopsy), while for the third center, we observed decreasing compliance with increasing follow-up time (from 31% to 29% for PSA, 49% to 17% for biopsy and 26% to 12% for PSA plus biopsy). Detailed results are reported in the Figure. *Conclusion:* Compliance with AS protocols for PCa in a large multicentric AS cohort was evaluated. We observed good overall compliance, with a decreasing compliance comparing the first and the second time-window, especially for biopsies. Adherence to biopsy monitoring protocol decreases after a long time in AS, probably due to reluctance to proposed further biopsies in men with a long history of non-rising PSA or introduction of magnetic resonance that could negatively influence biopsy compliance and procrastinate re-biopsy. Difference were also

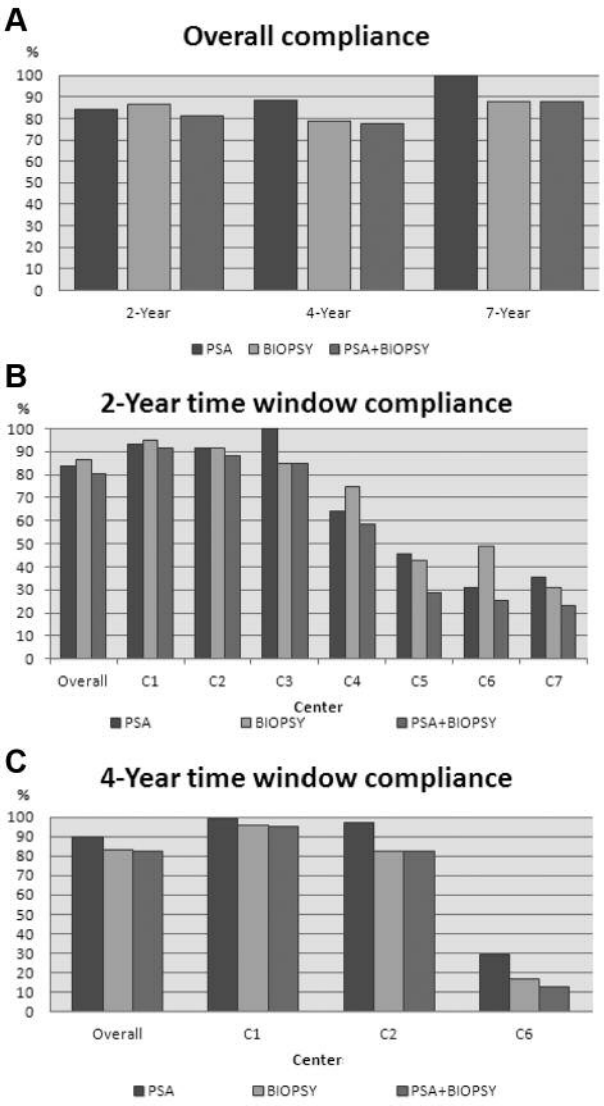

Figure 1. *PSA and Biopsy compliance (%) to PRIAS protocol, A) overall compliance in three time-windows, B) Center specific compliance in 2-year time window, C) Center specific compliance in 4-year time window.*

observed among centers. Specifically, a group of centers: different approaches such as multidisciplinary clinics or the presence of resources specifically dedicated to patients in AS could be explain these differences.

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ELEVEN YEARS' EXPERIENCE OF ACTIVE SURVEILLANCE OF LOW-RISK PROSTATE CANCER

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Introduction: The aim of the present study was to evaluate the outcomes of selected patients with low-risk prostate cancer (PCa) in two active surveillance (AS) protocols and identify possible predictors of disease reclassification. *Patients and Methods:* We implemented a single-center AS protocol (SAINT) in 2005 and joined the PRIAS study (1) in 2007. Eligibility criteria included clinical stage ≤T2a, iPSA <10 ng/ml, and Gleason score (GS) ≤3+3 in both protocols, ≤20% positive cores (≤25% since 2011) with a maximum

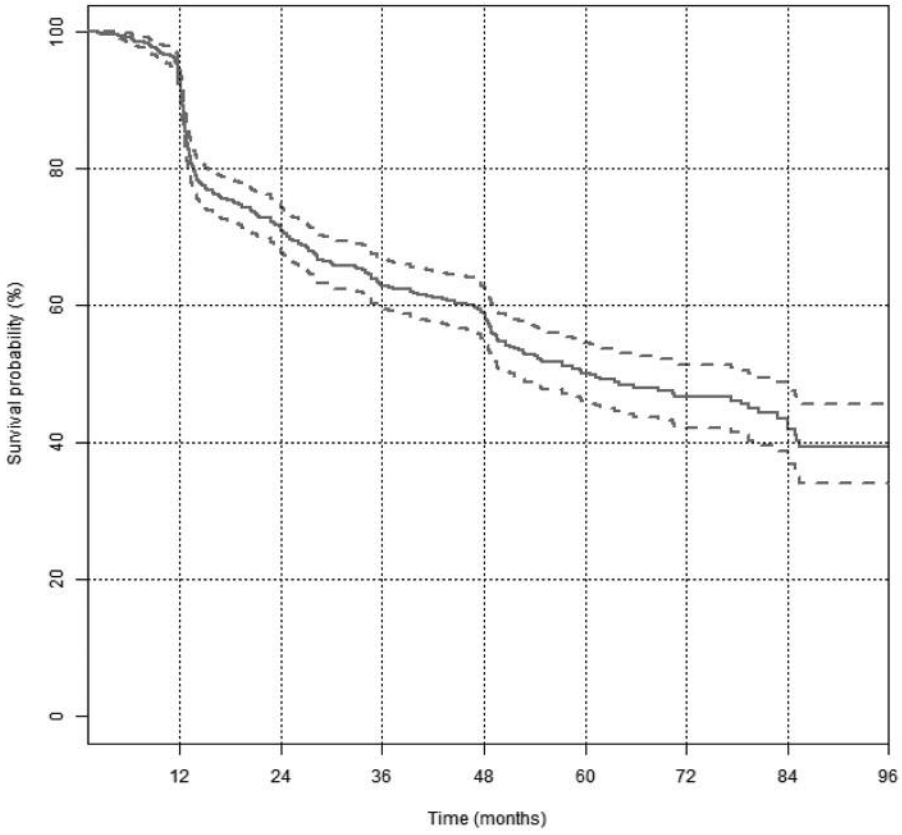

Figure 1. *Active treatment-free survival for all causes.*

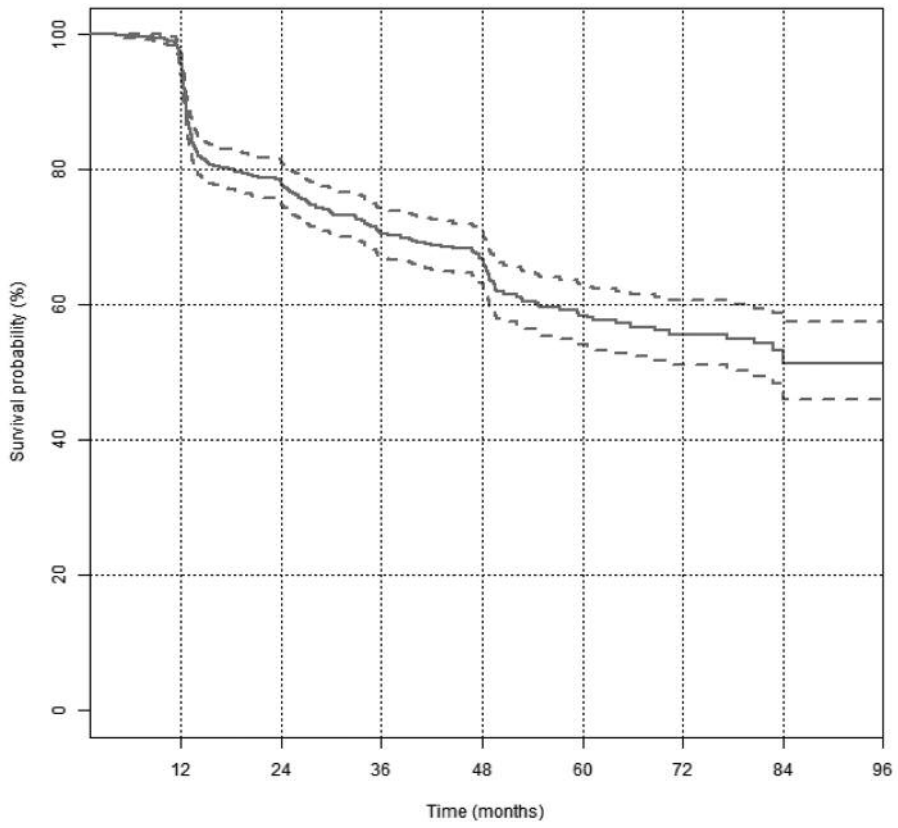

Figure 2. *Active treatment-free survival (biopsy related).*

core length containing cancer of ≤50% in SAINT, or ≤2 cores of a volume-dependent total core number and PSA density <0.2 ng/ml/cm^3 in PRIAS. Worsening of GS, an increase in the number of positive cores, or PSA doubling time <3 years advised switching to active treatment. Active treatment-free survival (ATFS) was assessed using the Kaplan–Meier method. *Results:* As of October 2016, 818 patients had been included in AS protocols (SAINT n=288; PRIAS n=530). The median age at enrolment was 66 (range=60-71) years, and median iPSA was 5.7 (range=0.83-10) ng/ml. After a median follow-up of 60 (range=4.1-145.2) months, ATFS was 49.8% (Figure 1). Overall, 404/818 patients (49.4%) discontinued AS. of these, 335/404 (82.9%) patients underwent active treatment and 69/404 (17.1%) remained treatment free (watchful waiting, patient choice etc.). A total of 274 patients dropped out for protocol-specified disease reclassification/ progression, which included PSA DT in 19/404 patients (4.7%) and upgrading/upsizing at rebiopsy in 255/404 (63.1%) patients. More than half (139/255) discontinued AS after the first rebiopsy. Note, the rebiopsy at 1 year was negative in 39.8% of patients. Overall, 9/404 patients (2.2%) discontinued AS because of anxiety, while 121/404 patients (30%) discontinued for off-protocol reasons, including worsening of performance status, age >80 years, refusal to undergo rebiopsy or to continue follow-up and non PCa-related death (five patients). Patients enrolled in the SAINT protocol were significantly more likely to discontinue AS than patients in the PRIAS protocol (hazard ratio (HR)=1.65, p<0.0001]. Biopsy reclassification during AS (Figure 2) was positively associated with PSA density >0.12 ng/ml/cm^3 (HR=2.17, p<0.0001), age >66 years (HR=1.4, p=0.006), maximum percentage of core length containing cancer ≥ 10% (HR=1.6, p=0.001), more than one positive core at diagnostic biopsy (HR=1.5, p=0.001) and negatively associated with prostate volume >50 cm^3 (protective factor, HR=0.45, p<0.0001), and >12 cores at diagnostic biopsy (protective factor, HR=0.7, p=0.002). Clinical stage and PSA at diagnosis were not associated with biopsy-related ATFS. Of note, a higher proportion of patients (about 60%) remained treatment-free after 4 years. *Conclusion:* PSA density, age, prostate volume, maximum percentage of core length containing cancer, number of positive cores at diagnosis and number of biopsy cores were associated with disease reclassification. SAINT has a wider enrollment window leading to enhanced probability of PCa reclassification and consequent drop-out from AS. Nevertheless, SAINT still

provides the opportunity of avoiding overtreatment for a significant fraction (ATFS for SAINT at 60 months was 38.6%) of patients with PCa. Repeated biopsies help a progressive, better selection of patients with low-risk PCa during AS. Biopsy remains the main key point in AS follow-up, with a possible significant burden in terms of tolerability, suggesting the need for new strategies to improve patient selection and to reduce biopsy burden during follow-up.
We express our thanks to Fondazione I. Monzino which supports the research of the Prostate Cancer Program.

1 Bokhorst L, Valdagni R, Rannikko A, Kakehi Y, Pickles T, Bangma CH, Roobol MJ6; PRIAS study group: A Decade of Active Surveillance in the PRIAS Study: An update and evaluation of the criteria used to recommend a switch to active treatment. Eur Urol *70(6)*: 954-960, 2016.

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SMALL RENAL MASSES IN 100 PATIENTS: HOW MANY TUMORS ARE DETECTED WITH IMAGING-GUIDED RENAL BIOPSY?

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Introduction: As the use of radiological investigations has increased in the last years, the detection of small renal masses (SRMs) <4 cm has become more frequent. In most cases, the radiological distinction between benign and malignant SRMs cannot be made. According to the results of recent studies, the use of ultrasound (US)-guided percutaneous renal biopsy (RTB) or computerized tomography (CT)-guided RTB is diagnostic and accurate, with low complication rates. *Patients and Methods:* We performed a retrospective analysis of our experience with US/CT-guided RTBs of SRMs suspicious for renal cancer from 2010 to 2015. We collected and analyzed our data on size, site, histopathology, type of radiological imaging used to perform a biopsy, perioperative complications, surgical treatment of tumors and number of RTBs required to obtain a correct diagnosis. Patients whose first RTB was non-diagnostic of renal cell carcinoma were followed-up and they underwent a second biopsy if required. *Results:* A total of 100 patients were enrolled with an average age of 71 years: 46 SRMs were detected in the right kidney, 52 in the left and two in both. SRMs were detected by means of US-guided biopsies and CT-guided biopsies in 19% and 81% of cases respectively. Local anesthesia was performed in 97% of cases. The lesions were located in the right, left or in both kidneys in 46%, 52% and 2% of cases, respectively. Postoperative complications occurred in 3% of cases. 66% of the lesions proved to be malignant. In 54% of cases, physicians had performed a US-guided RTB, and in 12% a CT-guided RTB. A total of 6% of RTBs were non-diagnostic because they contained insufficient material for the analyses (3% necrotic tissue and/or blood 2%, 1% inflammation/ fibrosis), 9% revealed benign lesions and 6% were overdiagnoses. Overall, 77% (n=51) of patients whose RTBs detected the presence of cancer were treated at our clinical center: 29% were treated with partial nephrectomy, 48% with tumorectomy. A strong link (86% rate) was highlighted between the histological findings in the biopsy and the postoperative ones. We followed-up patients with a first non-diagnostic RTB: 21% were diagnostic after a second RTB, 2% were non-diagnostic and 11% were diagnostic after a third biopsy. *Discussion:* The use of CT and US-guided biopsy is a safe and accurate method to discriminate between benign and malignant lesions. Its limits reside in the amount of tissue removed. Our study was aimed to assess its efficacy and to determine how many biopsies are required in order to make a correct diagnosis. Thus US or CT-guided renal biopsies are a valid method of investigating suspicious renal lesions (<4 cm) thanks to their high reliability and a low complication rate. *Conclusion:* US and TC-guided biopsy is a safe method, with 3% rate of complications, and has an accuracy of 86% for SRMs diagnosis at the first biopsy and 14% at the second biopsy.

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OUTCOME OF PATIENTS WITH PROGRESSING OLIGOMETASTATIC RENAL CELL CARCINOMA TREATED WITH LOCOREGIONAL THERAPY: A MULTICENTER RETROSPECTIVE ANALYSIS

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Introduction: Locoregional treatment with radical intent should be considered during targeted therapy (TT) in patients with metastatic renal cell carcinoma (mRCC), not only to achieve a complete response but also when a slow or oligo-progression occurs in one or more metastatic site. No survival outcomes on continuing the same TT beyond progression or switching to second-line options are available in this scenario. *Patients and Methods:* We retrospectively enrolled 55 patients who experienced disease progression after at least 6 months from first-line therapy in one or more metastatic sites radically treated with locoregional treatments. Post-first-progression-free survival (PFPFS) and post-first progression overall survival (PFPOS) in patients who continued the same TT *versus* those who switched to another TT after locoregional treatment were analyzed *via* the Kaplan–Meier method and Mantel–Haenszel log-rank test. Homogeneity of the two groups relating to variables distributions was tested by means of chi-squared test for difference in proportions. After radical treatment, 83.6% of patients (N=46) did not switch to another tyrosine kinase inhibitor and continued the same TT agent used before the locoregional therapy, while 12.8% of patients (N=7) switched to another therapeutic agent. A Cox regression model was applied to the data with a univariate and multivariate approach in order to analyzed possible predictive and prognostic factors of PFPFS and PFPOS. *Results:* The global median PFPOS and PFPFS were 37 (95% confidence interval=25.2-48.7) months and 14 (95% confidence interval=6.9-21) months, respectively. Patients who continued the same therapy after a locoregional treatment to a site of progression had a significantly longer median PFPOS compared to patients who switched to another therapy (39 *vs*. 11 months, p=0.014). An advantage in median PFPOS was also observed in patients with a good risk score compared to patients of the intermediate-risk group (39 *vs*. 29 months, p=0.036) and in patients with bone metastases *versus* visceral metastases (not reached *vs*. 31 months, p=0.045). None of the other variables considered were significantly associated with an increased survival after first progression. At multivariate analysis, change of treatment after first progression (hazard ratio=4.140, p=0.008) and bone metastases as site of first progression (hazard ratio=0.456, p=0.041) were independent predictive factors of poorer and better prognosis in terms of median PFPOS, respectively. Considering median PFPFS, patients with Fuhrman grade 2 and ECOG PS of 0 or 1 had a longer median PFOPFS compared to patients with a PS or more than 1 (14 *vs*. 7, p=0.065) or Fuhrman grade of 1, 3 and 4 (22 *vs*. 4 *vs*. 10 *vs*. 6 months, p=0.009) respectively. No statistically significant differences in terms of PFPFS were observed between patients who continued the same treatment after oligo disease progression and those who changed therapy (15 *vs*. 7 months, p=0.207). Furthermore, none of the other variables analyzed (age, gender, histology, prior nephrectomy, MSKCC risk group) were significantly associated with a prolongation of PFPFS after a locoregional approach. *Conclusion:* Locoregional treatments represent an option for oligometastatic mRCC treated with TT. Continuing the same systemic treatment after radical locoregional treatment in one or more metastatic sites appear to be an independent predictive factor of better outcome in this subset of patients. Bone oligoprogressive mRCC showed similar better outcome. Furthermore, no difference in terms of PFS was found between patients who continued the same TT and those who switched to another TT. Prospective analyses are warranted.

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IMPERATIVE PARTIAL NEPHRECTOMY *VERSUS* RADICAL NEPHRECTOMY IN PATIENTS WITH RENAL CELL CARCINOMA AND VENOUS THROMBUS

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Introduction: Standard treatment for renal cell carcinoma (RCC) with renal (T3a) or caval (T3b-c) vein thrombosis is Radical nephrectomy (RN) plus thrombectomy. Partial nephrectomy (PN) plus thrombectomy may be used in these cases, however little evidence exists about this procedure. *Materials and Methods:* From 2,552 patients with RCC T3a-c of a multicentre series, 22 had an imperative PN plus thrombectomy and were compared, through an individual matched analysis, with 22 controls who underwent RN plus thrombus excision. Primary outcomes were long term renal function, evaluated through serum creatinine levels (sCr), and cancer specific survival (CSS). Kaplan-Meier curves were plotted and log-rank test were used for group comparisons. *Results:* The 2 groups had no differences in median age (PN 59, IQ range (IQR) 48-66 years; RN 61, IQR 59-67 years; p=0.3), mean pre-operative sCr (PN 1.24±0.57 mg/dL; RN 1.17±0.35 mg/dL; p=0.76), mean maximum tumour diameter (PN 4.86±2.1 cm; RN 5.03±1.9 cm; p=0.79), mean BMI (PN 27.9±7.68 and RN 28.59±4.7 Kg/m^2; p=0.37), mean blood loss (PN 1670±2535 mL; RN 2162±3257 mL; p=0.74), median Fuhrman grade (3 in both groups) and metastasis (4 PN and 3 RN patients; p=1). Para-aortic lymphadenectomy was performed in 6 cases per group (p=1) and postoperative complications were experienced by 10 PN and 14 RN patients (p=0.36). Mean follow up was 45±47 months (p=0.78), in this time 9 PN and 13 RN patients died because of disease progression with a CSS of 59.09% and 40.91% respectively (Figure 1, p=0.428). At last follow up sCr levels were 1.53±0.63 in PN group and 1.99±2.27 mg/dl in RN group (p=0.62). At univariate analysis deceased patients, compared to alive patients at last follow up, had an increased surgical blood loss (2794.12±3633 *vs*. 750±630 mL; p=0.018), an increased operation time (343.86±148 *vs*. 218.47±97 min; p<0.01) and longer hospital stay (14.43±7.5 *vs*. 8.19±5.18; p=0.0049). *Discussion and Conclusion:* In patients with high-risk RCC plus renal or caval thrombi PN, compared to RN, may have a non-inferior CSS; maintaining comparable long-term sCr levels and postoperative complication rates. Further studies are needed to evaluate the potential role of PN in T3a-c RCC.

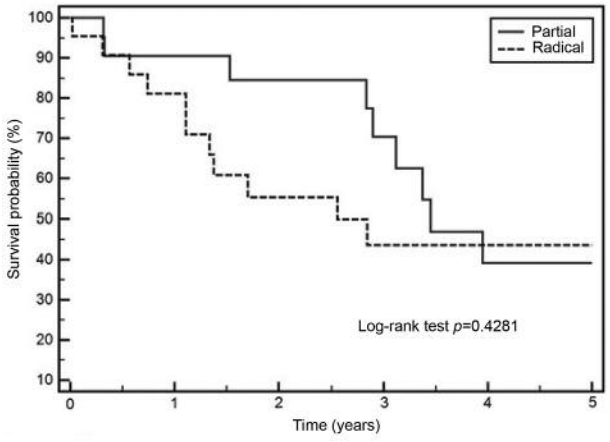

Figure 1. *Kaplan-Meier curves for CSS in partial and radical groups.*

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WHATSAPP MESSENGER AS A REAL-TIME TOOL FOR A LONG-DISTANCE ACTIVITY OF A MULTIDISCIPLINARY

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Introduction: Communication between doctors is traditionally conducted by written clinical charts. Mobile health is becoming an integral part of modern medical systems, improving accessibility and quality of medical care. Recent papers suggest that an increasing number of doctors are using in their clinical practice mobile tools to communicate clinical informations (1, 2). The aim of our study was to verify the adoption of WhatsApp Messenger in everyday clinical practice to obtain a real-time multidisciplinary collaboration among medical centers located in different areas of the city. *Materials and Methods:* In January 2016 a WhatsApp Messenger group was created among 25 specialists: 9 urologists, 9 oncologists, 3 urology residents, 3 radiotherapists and 1 general practitioner. A general coordinator and a group coordinator for each specialty was monthly appointed. The participants were invited to interact within the group clinical cases of genitourinary tumors of particular complexity requiring a multidisciplinary approach. All the chats were registered. A preliminary analysis of the activity of the group was planned after the first 10 entered patients. An evaluation questionnaire was sent after 6 months to evaluate the level of appreciation. The questionnaire was composed of a first section investigating the appreciation among the members of the group and a second section analyzing the impact in their everyday clinical practice of whatsapp multidisciplinary consultation. *Results:* In 10 (91%) out of 11 patients the WhatsApp consultation was completed, one case was not of oncological interest. An average of 8 (range=2-13) specialists joined the chat for each patient. An average of 17.6 (range: 4-43) interventions for each clinical case was recorded. On the average, 27%, 54% and 19% of the interventions for each clinical case were provided by oncologists, urologists and radiotherapists respectively. In 9 (81.8%) cases a final agreement on the patient's management was reached. At the evaluation questionnaire in a scale 1-10, the average rating score of appreciation was 7.8 (range=4-10). Relevant suggestions to improve the Whatsapp Messenger consultation were obtained and will be considered for future application the ameliorate the tool. *Discussion:* WhatsApp is a useful alternative and powerful complementary communication tool because of its capability to rapidly transfer large amount of clinical and radiological data. In our experience this new approach for multidisciplinary consultations improved collaboration among different specialist in different areas of the city through an easier and more informal change of opinions. In difficult and complex cases a rapid multidisciplinary approach allowed to offer the patient a personalized and tailored therapy management. GSTU Foundation.

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DOSE-EFFECT FOR LATE URINARY TOXICITIES AFTER PROSTATE CANCER RADIOTHERAPY: RESULTS FROM A PROSPECTIVE COHORT STUDY

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Introduction: The aim of the present study was to assess dose factors affecting the incidence of patient-reported urinary toxicity at three years after radical radiotherapy (RT) for prostate cancer in a large group of patients enrolled in a prospective, multi-centric trial in the period 2010-2014. *Patients and Methods:* Enrolled patients were treated in seven

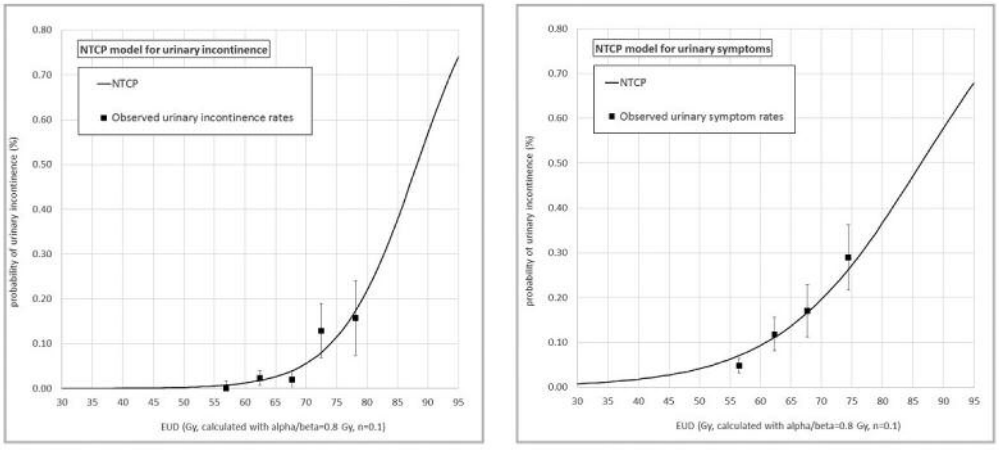

Figure 1. *Dose-response curves for urinary incontinence and for urinary symptoms as a function of bladder equivalent uniform dose (EUD). Continuous lines represent the normal tissue complication probability model (NTCP), while symbols represent the observed toxicity rates.*

Institutions in Italy at different prescribed doses with conventional (74-80 Gy at 1.8-2 Gy/fr) or moderately hypo-fractionated RT (65-75.2 Gy at 2.2-2.7 Gy/fr) in 5fractions/week. All doses were corrected to 2 Gy/fraction, using the linear-quadratic model by applying alpha/beta ratios of 0.8, 3 and 5 Gy, according to values recently reported in the literature. Bladder dose-volume histograms were reduced to equivalent uniform dose (EUD), with volume parameter n derived from maximum likelihood fit. Two kinds of late toxicities were here considered: (a) Urinary incontinence as evaluated through the International Consultation on Incontinence Modular Questionnaire short form (ICIQ) filled in by the patients at start/end of RT and every 6 months until 5 years of follow up. In the current analysis, patients with ICIQ available at 36 months (and at least 3 ICIQ evaluation between 6 and 36 months) were considered and the incidence of incontinence at 3 years was defined as the occurrence of an ICIQ value >12 (as calculated in the first 3 questions: frequency of urinary incontinence, amount of leakage, overall impact of urinary incontinence) at least once between 6 and 36 months. Patients with baseline ICIQ>5 in the first 2 questions were excluded from the analysis. (b) Urinary obstructive symptoms as evaluated with the International Prostate Symptom Score (IPSS) questionnaire filled in by the patients at start/end of RT and every 6 months until 5 years of follow up. The incidence of late toxicity at 3 years was defined as the occurrence of an IPSS ≥15 at least once between 6 and 36 months. The analysis focused on patients with IPSS available at 36 months, with at least 3 IPSS evaluations during the follow up and without toxicity before RT (baseline IPSS <12). Logistic analysis was performed to determine the quantitative association between bladder EUD and urinary toxicity probability. *Results:* 247 patients were available for urinary incontinence analysis: 10/247 (4%) showed moderate/severe late urinary incontinence. 217 patients were available for obstructive symptoms analysis: 30/217 (14%) with moderate/severe late urinary symptoms. For both toxicity endpoints maximum likelihood estimation pointed toward EUD values with low n=0.1 and low alpha/beta=0.8 Gy. Thus indicating a serial behaviour of bladder for this toxicity (*i.e.* high doses to small bladder volumes are more effective that lower doses to large volumes) and a high sensitivity of urinary toxicity to fractionation. Dose-response curves for the two end-points are presented in Figure 1.

The logistic dose-response curve indicates a steep dependence of urinary incontinence probability on dose, with an OR of 2.17 every 5 Gy in EUD, and a quasi-threshold effects around EUD=70 Gy (which approximately corresponds to a prescribed dose of 82 Gy, 2 Gy-equivalent). The dose-response curve for obstructive symptoms is more shallow, with an OR of 1.5 every 5 Gy in EUD and presence of a not-negligible toxicity probability also below EUD=65Gy. *Conclusion:* NTCP dose-response models for prediction of late urinary toxicities were determined. Bladder was found to act as a serial organ, with toxicity risk highly depending on small bladder volumes irradiated to high doses. The dose-response relationships point-out that hypofractionation (resulting in higher EUDs) should to be coupled to optimisation in the bladder-PTV overlap in order to reduce the risk of late urinary toxicity. A previously suggested low alpha-beta value (0.8 Gy) for late urinary incontinence resulted in higher likelihoods, consistently with a high sensitivity of late urinary toxicity to fractionation.

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PROSTATE VOLUME INDEX STRATIFIED PROSTATE CANCER RISK IN PATIENTS ELECTED TO A FIRST RANDOM BIOPSY SET

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Introduction: The aim of the study was to investigate on prostate volume index (PVI), defined as the ratio of volume of the transitional zone (TZV) on that of the peripheral zone (PZV), as a factor stratifying prostate cancer (PCA) risk in patients elected to a first random biopsy set. Patiens and Methods: The study evaluated 596 patients who were elected to a first random biopsy set because of suspected PCA in a period between September 2010 and September 2015. PVI was dichotomized to PVI ≤1 *vs*. PVI >1. The multivariate logistic regression model investigated clinical factors with dichotomized PVI associating with PCA. *Results:* The detection rate of PCA was 49%. The dichotomized PVI >1 stratified PCA risk (odds ratio (OR)=0.455; $p<0.0001$) beyond age (OR=1.062; $p<0.0001$), PSA (OR=1.167; $p<0.0001$), PV (OR=0.957; $p<0.0001$) and abnormal DRE (OR=2.094; $p<0.0001$). The goodness of fit statistics assessed model efficacy. *Conclusion:* A large cohort of patients elected to a first random biopsy set had PCA risk stratified by dichotomized PVI beyond other clinical independent factors. PVI related to zone anatomy volumes of the aging prostate. PVI associates with PCA biology since expressing different growth rates between the TZV and PZV along the endocrine axis. Confirmatory studies are required.

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HEALTH-RELATED QUALITY OF LIFE OF MEN ON ACTIVE SURVEILLANCE: ASSOCIATION WITH PSYCHOLOGICAL FACTORS

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Introduction: Men on Active Surveillance (AS) present unique care needs. Identifying factors related to their Health Related Quality of life (HRQoL) may help clinicians promptly address patients care management (2). Several studies have focused on the role of clinical variables on HRQoL (1), however, little attention has been given to the psychological factors (3). In particular, patient strategies to adjust to cancer diagnosis (*e.g.* their coping styles) can be relevant to the improvement of HRQoL. The present study aims to investigate differences in coping strategies and PCa related anxiety among patients with high and low HRQoL levels. *Patients and Methods:* Patients with prostate cancer were enrolled in active surveillance according to the Prostate Cancer Research International: Active Surveillance (PRIAS) protocol. An ancillary study on HRQoL is proposed to all patients on AS. HRQoL was evaluated with the Medical Outcome Study Short Form Health Survey (SF-36) questionnaire: Mental Health (MH) scale and Physical Health (PH) scale, both ranging between 0 and 100. Possible psychological factors associated with MH and PH were evaluated with two different questionnaires. The Mini-Mental Adjustment to Cancer scale (Mini-MAC Scale) was used to measure cancer-related coping styles: fighting spirit, hopelessness/helplessness, avoidance, fatalism and anxious preoccupation (score between 0 and 4 for each style, higher values indicating higher presence of the specific style). The Memorial Anxiety Scale for Prostate Cancer (MAX-PC) was used to assess anxiety related to prostate cancer, to PSA testing and to fear of tumour progression (score between 0 and 3 for each factor, higher values indicating higher presence of anxiety). Patients with low MH and PH were identified as those with SF-36 MH and PH scoring below the 10th percentiles of our sample distributions. Patients with scores >2 and >1.5 in a specific MINI-MAC or MAXPC item were considered to have the related psychological factor. Chi-square test was employed for evaluating associations between the presence of psychological dimensions and patient MH and PH. *Results:* 286 patients completed the SF-36 questionnaires. In general, enrolled patients showed high MH and PH with average scores equal to 77±17 and 82±14, respectively, both above the normative values (see Figure 1). From patients, 29/286 (10%) and 20/286 (7%) showed low MH and PH, below the 10th percentile cut-off values fixed at 55 and 60 respectively. Except for fighting spirit, the proportion of patients adopting a specific coping style (as described by MiniMAC) and showing anxiety for cancer (as described by MAX-PC) is higher in the group of patients with low HRQoL (see Table). In particular, the proportion of patients with hopelessness/helplessness is significantly higher in

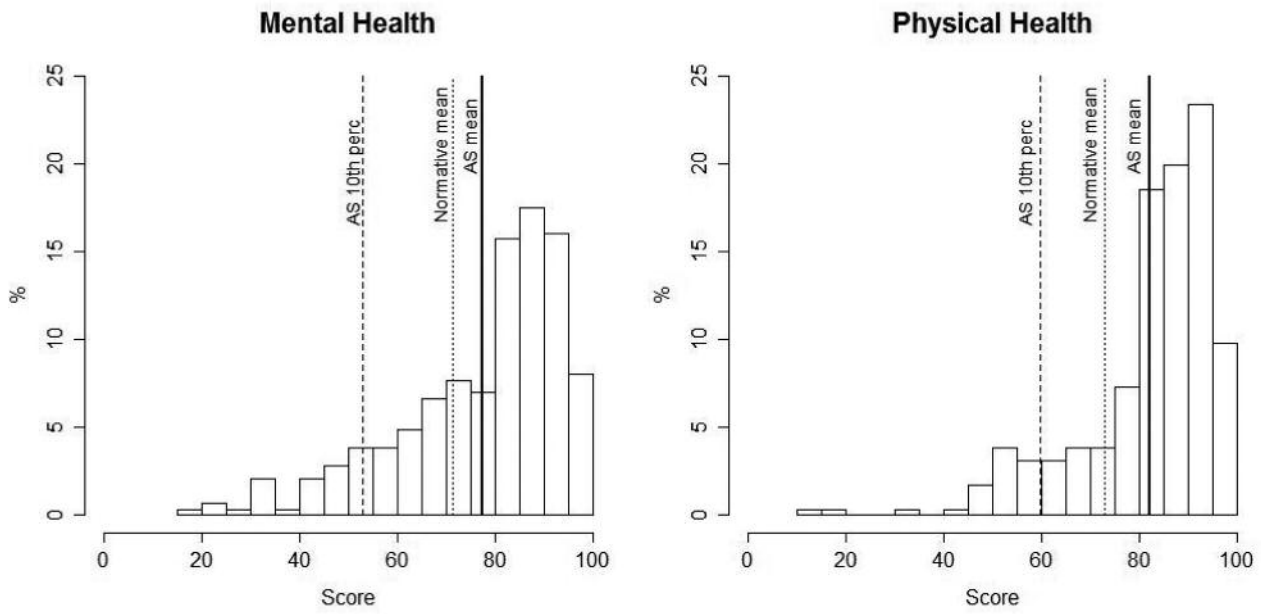

Figure 1. *The distribution of Mental Health and Physical Health scores obtained with the SF36 questionnaires are shown. The 10th percentile and the mean of this active surveillance (AS) sample are also shown along with the normative mean. Normative means refer to men with age between 55-64 and are equal to 71 an 73 respectively, lower values (not shown) are reported for older men (Apoloni et al.).*

Table I. *Chi-square test results for MINI-MAC and MAX-PC.*

	SF36 Mental Health			SF36 Physical Health		
	High MH (n=266)	Low MH (n=20)	*p*-Value	High PH (n=257)	Low PH (n=29)	*p*-Value
Mini-MAC (cutoff >2)						
Fighting spirit	93%	89%	0.61	93%	89%	0.5
Hopelessness	6%	45%	<0.0001*	6%	34%	<0.0001*
Avoidance	63%	84%	0.07	62%	82%	0.04*
Fatalism	50%	67%	0.16	49%	67%	0.08
Anxious preoccupation	39%	68%	0.013*	39%	57%	0.07
MAX-PC (cutoff >1.5)						
Anxiety for cancer	14%	50%	<0.0001*	14%	34%	0.004*
Fear of tumour progression	20%	55%	<0.001*	20%	41%	0.01*
Anxiety for PSA level	1%	10%	0.003*	1%	7%	0.03*

patients with low MH and low PH ($p<0.0001$ for both). In addition, the proportion of patients with anxious preoccupation is also significantly higher in patients with low MH ($p=0.013$), while the proportion of patients adopting avoidance in significantly higher in patients with low PH ($p=0.04$). Anxiety related to prostate cancer, to PSA level and fear of tumor progression are significantly more present in patients with low HRQoL ($p<0.05$). *Discussion and Conclusion:* The present study demonstrated that there are main differences in PCa related anxiety when patients' perception of QoL decrease. Moreover, when men react avoiding cancer thoughts and feelings they are likely to perceive low physical health. This, in turn, may exacerbate and enhance their anxiety and fears. Psychological factors can be relevant factors in perceptions of QoL, and patients' abilities to adjust to cancer diagnosis highly affect their QoL during AS (4). In men with critical QoL particularly attention should be given to anxiety and fear of recurrence. Interventions focused on patients' abilities to cope with cancer diagnosis may increase and strengthen their QoL outcomes, while avoiding their fears.

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CLINICAL FACTORS PREDICTING AND STRATIFYING THE RISK OF LYMPH NODE INVASION IN LOCALIZED PROSTATE CANCER

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Introduction: The aim of the study was to investigate clinical factors associating with occult lymph node micrometastases (pN1 disease) in a contemporary cohort of organ confined prostate cancer (PCA) patients staged as cN0. *Materials and Methods:* The study evaluated 184 consecutive patients who underwent radical prostatectomy with lymph node dissection between January 2013 and December 2015. Associations of clinical factors with pN1 disease were assessed by multivariate logistic regression analysis. *Results:* Lymph node invasion was detected in 33 out of 184 cases (17.9%). Independent factors associating with pN1 status were prostate specific antigen (PSA; odds ratio(OR)=1.054; p=0.004), percentage of positive biopsy cores (PPC; OR=1.030; p=0.013) and biopsy Gleason pattern (BGP)>4+3 (OR=3.666; p=0.004). A clinical model predicting the risk of pN1 disease was computed. In the PCA population at diagnosis, the model identified 4 prognostic groups of pN1 disease. *Conclusion:* In a contemporary cohort of PCA patients who were clinically staged as localized disease with cN0 status and underwent RP, lymph node invasion was negligible and was detected in 17.9% of cases. The study assessed an independent clinical risk model of pN1 disease predicted by clinical factors including PSA, PPC and BGP. The model showed that the risk of lymph node invasion was directly proportional to PPC and more stratification of the risk of pN1 disease was operated by PSA and BGP. The model allowed stratification of the patient population in four groups and showed that the risk of lymph node invasion progressively increased as the risk group ranked from 1 to 4. Confirmatory studies are required.

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VISUALIZATION OF PERIPROSTATIC NEUROVASCULAR BUNDLES BEFORE AND AFTER RADICAL PROSTATECTOMY BY MEANS OF DIFFUSION TENSOR IMAGING (DTI), WITH CLINICAL CORRELATIONS

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Introduction: The aim of this study is to evaluate if DTI is able to detect changes of periprostatic neurovascular bundles (pNVB) before and after radical prostatectomy (RP) and if this changes are related to post-surgical complications, such as urinary incontinence and erectile dysfunction. Material and methods Twenty-five Patients (mean age=64.8 years) with biopsy-proven prostate cancer underwent MRI including DTI sequence before and after RP, between February 2014 and August 2016. Images were independently analyzed by two radiologists placing six ROIs respectively at base, mid gland and apex, one for each side, to obtain tractographic reconstruction of the fiber. To investigate urinary continence and erectile function at each MRI, patients were asked to fill ICIQ-SF and IIEF-5 questionnaires. Fractional anisotropy (FA), number and length of fibers for each ROI before and after RP were compared by means using T-Test. Spearman test was used to evaluate correlation between DTI parameters and questionnaires scores before-after RP. *Results:* Mean number of fibers decreased in all six ROIs after RP (p<0.01). Mean FA of fibers decreased at the two ROIs at mid gland after RP (p<0.05); the FA of the other 4 ROI and fiber length did not demonstrate statistical difference. There was correlation between number of fibers and the erectile function score (p<0.05). No correlation was found between DTI parameters and urinary incontinence score. Interobserver agreement was goodexcellent. *Conclusion:* DTI is able to detect the decrease number of fibers in pNVB after RP; this decrease correlates with erectile function, making it a potential good and reproducible technique to evaluate RP functional outcome.

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FIDUCIAL MARKERS IMPLANTATION FOR PROSTATE IMAGE-GUIDED RADIOTHERAPY: TRANSPERINEAL APPROACH

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Introduction: In the external-beam prostate cancer radiation therapy, daily gland displacement can lead to a target missing. Prostate pelvic motion up to 2 cm are reported, so that the use of intra-prostatic gold fiducial markers for daily prostate position verification and correction before treatment delivery (image-guided radiotherapy, IGRT) is widely used in the radiation therapy centers. The most commonly used implantation procedure involves transrectal ultrasound-guided insertion of fiducial markers, with not negligible complications. We report our experience in prostate fiducial markers implantation through a transperineal approach. *Patients and Methods:* Between September 2011 and November 2016 at our Center 85 patients underwent gold seed fiducial marker implantation for prostate IGRT. The procedure was done using transrectal ultrasound guidance; local anesthesia was performed by subcutaneous and transperineal periprostatic Mepivacaine injection. Three gold markers of 1, 2×3 mm or 1×5 mm were inserted into the prostate gland through the perineum in a sterile field. No antibiotic prophylaxis was used. Patients were instructed to contact the treating radiation oncologist if there were complications. *Results:* All procedures were uncomplicated. In one patient a single episode of self-limiting urinary bleeding occurred just after. No other complication was recorded. No rectal bleeding, no urinary obstruction or infection, no episode of hematospermia occurred. *Discussion and Conclusion:* The insertion of intra-prostatic markers for IGRT is commonly done through the rectum, with not negligible complications. Despite antibiotic prophylaxis, a rate of urinary infection of 7.7% with a total of 2.8% of patients requiring hospital admission for infective complication is reported (1). Rates of 3.8-15% of haematuria, 18.5% of haematospermia, 49.1% of rectal bleeding are reported (2). In our series only one patient (1.2%) showed a single episode of self-limiting haematuria. No worsening of baseline urinary obstruction symptoms was reported by the patients. According to our experience, prostate fiducial markers implantation through a transperineal approach is safe and should be recommended.

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ROLE OF DIFFUSION TENSOR IMAGING (DTI) AND TRACTOGRAPHY IN DETERMINATION OF PERINEURAL INFILTRATION IN PATIENTS WITH PROSTATIC CANCER

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Introduction: The aim of this study is to evaluate if DTI is able to detect periprostatic neurovascular bundles invasion by prostatic cancer. *Materials and Methods:* Fifteen Patients (mean age=64.8 years) with biopsy-proven prostate cancer underwent MRI including DTI between March 2012 and August 2016. 4/15 (27%) had anatomic pathology diagnosis of perineural invasion on examination of surgical specimen (pT3 patient). Retrospectively two radiologists analyzed images independently: at the level of the lesion, using DWI and T2 images as reference, the periprostatic fat tissue was divided in four quadrants. For all quadrants tractographic reconstruction was performed. In pT3 patient the ratio for each DTI parameter (fractional anisotropy (FA), number and length of fiber) was calculated between the quadrant with the lesion and the controlateral one. If ratio of pT3 Patients shows univocal tendency (all >1 or <1) they were compared by means of *t*-test with ratio of control Patients. ROC analysis was performed to evaluate if there was a cut-off value of RATIO between pT3 and control Patients. *Results:* Only RATIO of FA showed a univocal tendency (<1) for all pT3 Patient (range=0.90-0.71) and was statistically different compared to controls ($p<0.001$). ROC analysis of RATIO of FA showed that the best cut-off value to discriminate pT3a Patients from control was 0.82 ($p<0.0001$, AUC=0.95, sensibility: 100%, specificity: 85%). *Conclusion:* DTI is able to detect perineural infiltration by prostatic cancer as a decrease of FA value, which represent the destruction of

fibers induced by tumor infiltration. FA cut-off value of 0.82 can be useful to differentiate early T3a from T2 prostate cancer.

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CLINICAL FACTORS PREDICTING TUMOUR UPGRADING IN PATIENTS UNDER ACTIVE SURVEILLANCE AND ELECTED TO ACTIVE TREATMENT AFTER DISEASE RECLASSIFICATION OR PROGRESSION

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Introduction: To evaluate clinical factors associating with tumour upgrading (UPG) in active surveillance (AS) patients who had disease reclassification or progression (DR/P) and underwent radical prostatectomy (RP) *Materials and Methods:* The evaluated factors were considered at time of DR/P and included prostate specific antigen (PSA), tumour volume (TV), PSA density (PSAD), number of positive biopsy cores (BPC), digital rectal exam (DRE) and the PI-RADS score by multiparametric magnetic resonance imaging (mpMRI). The multivariate logistic regression analysis was performed. *Results:* The study evaluated 24 patients who had tumour upgrading in 13 cases (54.2%). Independent factors associating with tumour UPG included PSA, PV and BPC. Two models were selected the first including PV (odds ratio (OR)=0.80) and BPC (2.2) the second including PSA (OR=2.1) and BPC (OR=3.1). Final analysis considered model A including PV (OR=0.80) and BPC (n=1 *vs*. n>1; OR=24) as well as model B including BPC (OR=2.8) and PSA (≤4.0 *vs*. >4 ng/ml; OR=0.1). Both models were effective in predicting UPG. Conclusions PSA, PV and BPC were independent clinical factors that predicted tumour upgrading in AS patients who had active treatment after DR/P. Risk models were able to stratify the risk of tumour UPG. Confirmatory studies are required.

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CRYOABLATION OF SMALL RENAL MASSES: OUR INITIAL EXPERIENCE

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Introduction: Several treatment options are available today for the treatment of small renal masses, defined as tumors not larger than 4 cm in diameter, including the active surveillance (AS), the thermal ablation (TA), and the radical (RN) or partial nephrectomy (PN). We report our series of small renal masses treated with CT-guided percutaneous cryoablation in terms of safety and initial oncological results. *Materials and Methods:* From June 2013 to October 2016 we selected, at our U.O. Urology, 16 patients with renal neoplasm diagnosis satisfying the following inclusion criteria: tumor diameter <4 cm; clinical anesthesia contraindications to nephron-sparing surgery; patient's will. All patients underwent surgery CT-guided percutaneous cryoablation preceded by needle biopsy of the lesion. The operations were performed using a argon/helium gas-based system (Endocare, HealthTonics Inc., Austin TX, USA). The procedure was performed under local anesthesia. The number of cryoprobes used is varied as a function of the size of the lesion: 5 patients treated with the probe 1, 8 pcs with 2 probes, 3 pcs with 3 probes. At the end of the control CT procedure is performed with contrast medium to evaluate intervention completeness and possible bleeding in place. The follow-up included CT abdomen-pelvis at 3, 6 and 12 months. The definition of incomplete treatment is the persistence of the EC at the end of the same; the definition of relapse is the appearance of the EC to the 6-month control TC. *Results:* From June 2013 to October 2016, at our U.O., were selected 16 patients with a mean age of 72.5 years (range 61-84). The average size of the tumor was 3.5 cm (1.6-5.5 cm). All patients were subjected to biopsy of the lesion with the following histological outcome: RCC 15/16 (94%), Chromophobe 1/16 (6%). Of the 16 patients operated on 14/16 (88%) had a incidentaloma, 2/16 (12%) were post-RFA relapses. Have been used, depending on the size of the tumor, on average 2 cryoprobes (range=1-3) and were performed 2 cycles of freeze-thaw of the duration of 10 minutes each in 9 patients, and 3 cycles of 5 minutes each in 7 patients. It has worked cryoprobes 2.4 mm. Complications were: 1 effusion not clinically significant transitional perirenal, 1 regressed back pain with analgesic therapy. The hospital stay was 3 days (range 2-4). The average was 21 months follow-up (range=1-41); Under no circumstances they are documented incomplete treatment and local relapse or secondarismi CT abdomen-pelvis with contrast medium at 3.6 and 12 months. The levels of postoperative creatinine were identical with preoperative levels. *Conclusion:* The results of our experience, although still characterized by a short follow-up, allow us to state that percutaneous cryoablation of small renal masses is a safe technique, simple to perform, burdened with few complications peri and post-operative, well accepted by the patient and is therefore a viable therapeutic alternative, as documented by the recent published meta-analysis, the nephron-sparing surgery, which remains, as guidelines, the "gold standard" for the treatment of small renal masses.

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DECISION CONFLICT OF PROSTATE CANCER PATIENTS ON ACTIVE SURVEILLANCE: WHAT'S THE ROLE OF PERSONAL CHARACTERISTICS AND COPING STRATEGIES?

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Introduction: Treatment decision-making process (TDM) could be particularly relevant and complex for patients diagnosed with prostate cancer (1). In particular, men with low-risk prostate cancer often have multiple options to consider, such as radical treatments or Active Surveillance (AS) (2). Understanding the factors that can impact on TDM can help medical staff in supporting patient's decision-making. Different studies explored the potential impact of PCa patients' personal characteristics on the TDM, such as personality, socio-demographical characteristics, personal attitudes toward life and previous stressful events (3-5). However, to the best of our knowledge, there are no studies in the literature exploring the factors affecting decisional conflict among patients in AS. In the present study we aim to explore the potential role of personality traits, socio-demographic characteristics and coping style on decisional conflict among patients on AS. *Patients and Methods:* Patients with prostate cancer were enrolled in active surveillance according to the Prostate Cancer Research International: Active Surveillance (PRIAS) protocol. An ancillary study on quality of life is proposed to all patients on AS. Decisional conflict was evaluated with Decisional Conflict Scale (DCS) questionnaire (0 for low conflict, 5 for high conflict). Possible factors associated with DCS were evaluated with two different questionnaires. The Eysenck Personality Questionnaire (EPQR-A) was used to measure four patient personality traits: extraversion, neuroticism, psychoticism, lie (at least 4/6 positive answers in the considered trait indicated its presence). The Mini-Mental Adjustment to Cancer scale (Mini-MAC Scale) measured cancer-related coping styles: fighting spirit, hopelessness/helplessness, avoidance, fatalism and anxious preoccupation (score between 0 and 4 for each style, higher values indicating higher presence of the specific style). The Memorial Anxiety Scale for Prostate Cancer (MAX-PC) was used to assess anxiety related to prostate cancer, to PSA testing and to fear of tumour progression (score between 0 and 3 for each factor, higher values indicating higher presence of anxiety). Socio-demographic features (*e.g.*, having a job, education) were also considered. Patients with scores >2 and >1.5 in a specific MINI-MAC or MAX-PC item were considered to have the related psychological factor. Patients with low DCS were identified as those with scoring above the 90th percentiles of our sample distributions. Chi-square test was employed for evaluating associations between the presence of psychological dimensions and patient DCS. *Results:* 161 patients completed the DCS questionnaires. In general, enrolled patients showed low DCS, median value was 1.0 (interquartile range=0.7-1.2). 17/161 (10.6%) patients had DCS above the 10th percentile cut-off value at 1.5. This group of patients, with higher decisional conflict, showed significantly higher proportions of patients with high neuroticism trait (p=0.0024), see Table 1, of patients who do not adopt a specific coping style – hopelessness/helplessness and fatalism - (as described by Mini-MAC) and showing anxiety for cancer (as described by MAX-PC) (p<0.05 for both) (Figures 1 and 2, Tables I and II). *Discussion and Conclusion:* The present study confirmed that – also for what cancer AS - a central role in TDM is played by some specific personality traits, level of anxiety and the way in which this emotion is managed. Results showed indeed that men who present higher level of TDM conflict also present neuroticism personality trait, characterized by general high levels of anxiety. At the same time, results highlighted that these men showed high level of anxiety related to their PCa diagnosis and that their cancer-related coping strategies are mostly dysfunctional (*e.g.* fatalism, hopelessness/helplessness). Data confirmed that even though decisional conflict is not excessively high a critical aspect is represented by emotional overload and inadequacy of handle it for the activation of a real therapeutic engagement. On the other hand, in contrast to previous researches (3), the present study showed that occupation of patients on AS may not impact on their TDM. Interestingly, our results also showed no association between educational level and decisional conflict, despite literature showed how highly educated men have a harder time selecting the treatment whereas less educated men are usually more inclined to assume a passive TDM style (5). These data need further investigation to understand how the factors that can impact on TDM can help medical staff in supporting decision-making for patients diagnosed with prostate cancer and to delineate specific tools that could help this process.

The Authors would like to acknowledge Foundation I Monzino Onlus.

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Table I. *Chi-square test results for neuroticism samples*.

	Low decisional conflict	High decisional conflict
Sample size	144	17
Lowest value	0.0000	0.0000
Highest value	1.0000	1.0000
Median	0.1667	0.5000
95% CI for the median	0.1667 to 0.3333	0.3333 to 0.6667
Interquartile range	0.0000 to 0.3333	0.3333 to 0.6667
Mann-Whitney *U*	683.00	
Test statistic Z (corrected for ties)	3.038	
Two-tailed probability	*p*=0.0024	

Table II. *Chi-square test results for MAX-PC samples*.

	Low decisional conflict	High decisional conflict
Sample size	144	17
Lowest value	0.0000	0.06061
Highest value	2.0303	2.0278
Median	0.6969	1.0152
95% CI for the median	0.5867 to 0.7328	0.8426 to 1.1709
Interquartile range	0.4091 to 0.9646	0.7367 to 1.1812
Mann-Whitney *U*	772.50	
Test statistic Z (corrected for ties)	2.484	
Two-tailed probability	*p*=0.0130	

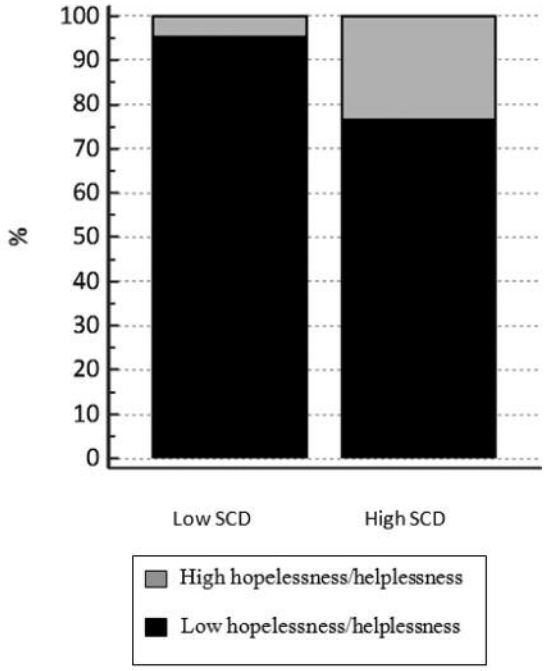

Figure 1. *Chi square test results for hopelessness/helplessness*.

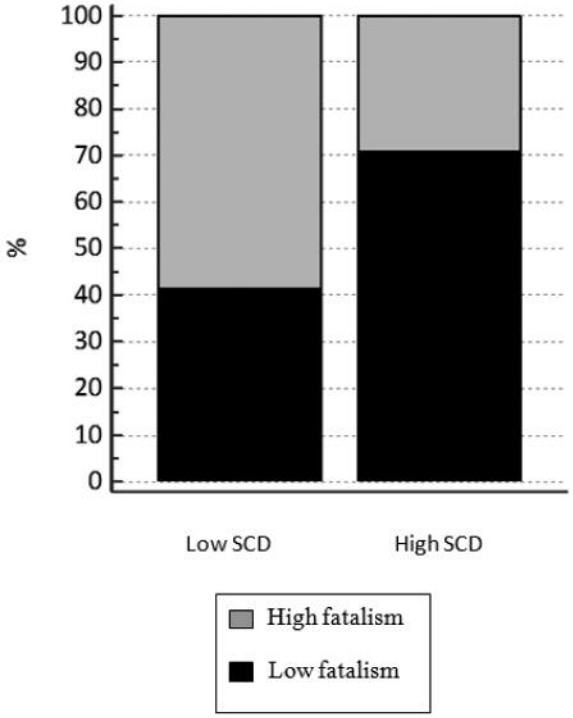

Figure 2. *Chi-square test results for fatalism*.

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WHAT ARE THE FACTORS ASSOCIATED WITH PHYSICAL ACTIVITY IN PROSTATE CANCER PATIENTS ON ACTIVE SURVEILLANCE?

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Introduction: Patients diagnosed with low-risk potentially non-aggressive prostate cancer (PCa) may choose the option of Active Surveillance (AS) in alternative to radical therapies (surgery, radiotherapy, brachytherapy) (1). There is large evidence that lifestyle modification, and, in particular, Physical Activity (PA), can be beneficial for the physical and psychological health of PCa patients on AS (2, 3). Since making recommendations for PA is not enough, it is crucial to understand the factors associated with PA in patients in AS to optimize participation and health outcomes. The present study aimed to examine PA levels of men on AS and to investigate the role of socio-demographic factors, anxiety levels and coping strategies on their engagement in PA. *Patients and Methods:* Patients with PCa were enrolled in the Prostate Cancer Research International: Active Surveillance (PRIAS) study conducted by the Prostate Cancer Program of Fondazione IRCCS Istituto Nazionale dei Tumori (Milan, Italy). Participants accepted to participate in an ancillary study on quality of life. Styles of coping with cancer were assessed through the Mini-Mental Adjustment to Cancer (Mini-MAC). Anxiety was assessed through the Memorial Anxiety Scale for PCa (MAX-PC); furthermore, socio-demographic features (*e.g.*, having a partner, education, occupation) were recorded. PA was measured using the International Physical Activity Questionnaire (IPAQ) short form, which asks respondents to report frequency and duration of sitting, walking, moderate-intensity and vigorous-intensity activity performed weekly. After weighting reported minutes per week in each category by a metabolic equivalent (MET), IPAQ scores were categorized into three levels of PA: "low" (physically inactive), "moderate" (meeting PA guidelines of 30 minutes of moderate intensity activity 5 days a week, 20 minutes of vigorous activity 3 days a week, or a combination) and "high" levels of PA (approximately twice the MET-minutes of the "moderate" level). These categories were based on standard scoring criteria http://www.ipaq.ki.se. All the scales were completed 10 months after the diagnosis. Descriptive analyses were performed and a Kruskal Wallis ANOVA was conducted to evaluate if anxiety levels and styles of coping with cancer differed across PA ranks (low, moderate or high). Chi-square test was employed for evaluating associations between the presence of specific socio-demographic features across patients engaging in low and high PA. *Results:* A total of 84 patients completed the questionnaires. Most of them had a high educational level (71%), were retired (63%) and lived with a partner (90%). In total, 20% (n=17) of

Table I. *Kruskal Wallis ANOVA test results and median scores for MAX-PC and MINI-MAC across PA levels.*

	IPAQ Physical Activity			
	Low PA (n=17)	Medium PA (n=44)	High PA (n=23)	*p*-Value
Mini-MAC				
Fighting spirit	2.8 (2.0-3.2)	2.8 (1.6-3.8)	2.9 (1.5-4.0)	0.69
Hopelessness	1.5 (1.0-3.9)	1.2 (0.9-2.3)	1.1 (1.0-3.0)	0.19
Avoidance	2.5 (1.0-3.5)	2.2 (1.0-3.8)	2.0 (1.0-3.5)	0.22
Fatalism	2.6 (1.3-3.3)	2.3 (1.0-3.3)	1.8 (1.0-3.3)	0.16
Anxious preoccupation	1.2 (0.0-2.3)	1.0 (0.0-2.5)	0.5 (0.3-2.0)	0.13
MAX-PC				
Total scores	1.0 (0.0-1.8)	0.6 (0.0-2.2)	0.5 (0.1-2.0)	0.60
Anxiety for cancer	1.3 (0.0-1.8)	0.8 (0.0-2.6)	0.6 (0.1-2.0)	0.80
Fear of tumour progression	2.3 (1.1-3.0)	2.0 (1.0-3.6)	1.7 (1.0-3.3)	0.17
Anxiety for PSA level	0.0 (0.0-2.0)	0.0 (0.0-0.7)	0.0 (0.0-2.0)	0.09

participants referred to be physically inactive and did not meet PA recommendations based on IPAQ scores. Kruskal Wallis ANOVA revealed no significant differences in both anxiety and coping styles rankings among PA groups (Table I). However, median scores of anxiety showed a positive trend across PA level groups: lower anxiety scores were reported in the high PA group. This trend was particularly evident for PSA-related anxiety (p=0.09) and fear of tumor progression (p=0.17). Trends of median scores for coping styles across PA groups were similar: higher maladaptive coping styles (*e.g.*, hopelessness, fatalism, anxious preoccupation) and lower fighting spirit occurred among patients engaging in low PA levels. In particular, anxious preoccupation (p=0.13), fatalism (p=0.16), and hopelessness (p=0.19) coping styles were the ones accounting greater differences across PA levels. Some non-significant relationships between education level, occupation and marital status and PA levels were revealed by Chi-squared tests, with patients more educated (p=0.09), occupied (p=0.17) and living with a partner (p=0.15) also reporting higher PA (Table II). *Discussion and Conclusion:* The present study revealed that almost 1/5 of the PCa patients in AS did not meet minimum PA recommendations. Individuals with PCa in AS may be susceptible to low PA levels. Nor socio-demographic nor psychological factors were found to significantly differ among patients engaging in low, moderate or high PA. However, trends in averages' scores suggested that patients with less anxiety and adopting more adaptive coping styles (*i.e.*, cognitive avoidance, fighting spirit) were also those ones engaging in higher PA. These factors have been proved in other studies with wider samples to significantly impact on the PA levels of cancer patients (2, 3). A larger sample may thus provide greater insight into this area. Further studies are needed to increase our understanding of factors associated with PA in wider sample of patients on AS. Indeed, as PA is vital for improving health and well-being for all individuals, personalized PA recommendations taking into account socio-demographic circumstances and individual psychological features can facilitate adherence to PA guidelines in patients on AS.

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Table II. *Chi-square test results for socio-demographic characteristics and IPAQ.*

	IPAQ Physical Activity			
	Low PA (n=17)	Medium PA (n=44)	High PA (n=23)	p-Value
Education	14%	18%	39%	0.09
Occupation	10%	19%	35%	0.17
Marital status	19%	26%	45%	0.15

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MULTIPARAMETRIC MRI AND TARGETED PROSTATE BIOPSY WITH MOLECULAR BIOLOGICAL BIOMARKERS ANALYSIS

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Introduction: Patient Specific Antigen (PSA) for risk categorization of prostate cancer (PCa) is not enough, as it is an organ- but not cancer-specific biomarker. In the context of the ongoing clinical trial "Short-term radiotherapy for early prostate cancer with concomitant boost on the dominant lesion (DIL)", the patient affected by prostate cancer may undergo a magnetic resonance imaging (MRI)-guided biopsy of the DIL to investigate the presence of aggressive phenotype markers. An

immunohistochemical (IHC) assay is performed to determine a panel of biomarkers (Ki67, Phosphatase and tensin homolog-PTEN) known to be related to PCa progression. The aim of this study was to evaluate the correlation between tumour aggressiveness and clinical outcomes in PCa patients treated with ultra-hypofractionated RT. *Patients and Methods:* The patient enrolment of the clinical trial started in July 2015, and we plan to complete the recruitment of 65 consecutive patients by the end of 2016. The tumour samples were collected *via* a MRI-guided biopsy of the DIL from the 14th recruited patient onward. Ki67 and PTEN status are assessed by an IHC assay and a re-evaluation of the Gleason Score (GS) is performed. *Results:* At present, 12 patients performed a MRI-guided biopsy of the DIL without complications. At a preliminary analysis, as far as the re-evaluation of GS is concerned, for 5 patients the MRI-guided analysis was confirmed as compared to the results of the first random-biopsy. On the contrary, for 5 patients an upgrade of GS was found, with 4 patients classified as intermediate-risk instead of low-risk, 1 patient as high-risk instead of intermediate-risk; for 2 patients a downgrading of GS was found, with one patient classified as low-risk instead of intermediate-risk. The IHC analysis performed in 9 patients showed a Ki-67 ≤10% in 2 patients and a Ki-67 ≥10% in the remaining 7 patients. The obtained IHC analysis of Ki67 and PTEN will be correlated with the clinical outcomes at the end of RT course, after a suitable follow-up period. *Conclusion:* Preliminary data could suggest the higher accuracy of the MRI-guided biopsy in GS definition. Moreover, it is well known that the random biopsy strategy is often subject to sampling error, which might result in downgrading of the class risk. MRI-guided prostate biopsy of the DIL may improve also the risk stratification, but without changing the actual RT course. Further investigations will be performed towards the identification of a pattern in the tumour aggressiveness-response in PCa treated with extremely hypofractionated RT. Moreover, a possible relationship between biomarker analysis and imaging textural features will be also explored.

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BLADDER PRESERVATION IN NON-METASTATIC MUSCLE-INVASIVE BLADDER CANCER (MIBC): A SINGLE-INSTITUTION EXPERIENCE

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Introduction: The aim of this study was to access the feasibility, toxicity profile, and tumour outcome of an organ preservation curative approach in non-metastatic muscle-invasive bladder cancer. *Materials and Methods:* A retrospective analysis was conducted on patients affected by M0 bladder cancer, who refused cystectomy and were treated with a curative approach. The standard bladder preservation scheme included maximal transurethral resection of bladder tumour (TURBT) and combination of radiotherapy and platin-based chemotherapy, followed by endoscopic evaluation, urine cytology, and instrumental evaluation. Thirteen patients fulfilled the inclusion criteria. TNM stage was cT2cN0M0 and cT2cNxM0, in 12 and one patients, respectively. All patients had transitional cell cancer. Twelve patients completed the whole therapeutic programme (a bimodal treatment without chemotherapy for one patient). Median follow-up was 36 months. None of the patients developed severe urinary or intestinal acute toxicity. In 10 patients with a follow-up >6 months, no cases of severe late toxicity were observed. Response evaluated in 12 patients included complete response and stable disease in 11 patients (92%), and one patient (8%), respectively. At the time of data analysis (March 2016), 10 patients (77%) are alive with no evidence of disease, two patients (15%) died for other reasons, and one patient has suspicious persistent local disease. The tri-modality approach, including maximal TURBT, radiotherapy, and chemotherapy for muscle-invasive bladder cancer, is well-tolerated and might be considered a valid and feasible option in fit patients who refuse radical cystectomy

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QUALITY OF SAMPLING IN REPEATED PROSTATE BIOPSY: EXPERIENCE IN A LARGE SERIES OF FOLLOW-UP AFTER DETECTION OF ISOLATED ASAP

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Introduction: Trans-rectal needle prostate biopsy strategies are based on random or targeted sampling of different

zones of prostate with a variable number of cores, from 12 to 18, of peripherical zone. Our objective was to evaluate if there are differences in biopsies set of two groups of patients with ASAP and follow-up respectively positive and negative for prostate cancer. *Materials and Methods:* From our database of prostate biopsy (from 1998 to 2016) we evaluated 182 patients with an initial detection of Atypical Small Acinar Proliferation (ASAP) and at least one re-biopsy. For each biopsy with ASAP and for last biopsy of each patients we collected PSA, prostate volume, PSA Density, number of cores, mean length of cores, total length of cores and Byoptic Density (ratio between total length of cores and prostate volume, expressed in cm of tissue/ml of prostate). Then, we divided each set of biopsy, first (F) and last (L) in 3 groups: all the patients(a), the patients with negative follow-up (n) and patients with positive follow-up (p). SPSS software have been used for statistical analysis (univariate, bi-variate and multivariate analysis; statistical significance is set to 0.05). *Results:* At first biopsy, prostate volume is higher in group Fn (58) than group Fp (51), with statistically significant difference (p=0.016). No statistically significant differences were observed in age, PSA, number of cores, mean length of cores, total length of cores and bioptic density. At last biopsy, the total lenght is higher in group Lp (21.4 cm) than Ln (20.78 cm); comparing the first and last biopsy in all group, we observed a big difference in total length of cores (respectively 15, 85 *vs*. 21). Also, the bioptic density seems to have the same correlation, with a greater quantity of prostatic tissue analyzed for each ml of prostate volume. *Discussion and Conclusion:* These findings can be explained by the need of greater precision when a rebiopsy is performed: to do this a greater number of cores is sampled. Moreover, volume of prostate is to consider for the decision of performing a prostate biopsy: prostate cancer have a minor risk to be detected in bigger prostates. Also for biopsy strategy, volume is important to plan how many cores to take. The risk of underrate prostate cancer can be high if in a big prostate we perform the same number of a small prostate. Modern software memorizing tracking of cores, usually used for imaging fusion biopsies, can be useful also to have a global view of tissue sampled inside the gland, already to the initial biopsies set.

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FOLLOW-UP OF ISOLATED ASAP: PATHOLOGICAL FINDINGS AFTER CANCER DETECTION AND RADICAL PROSTATECTOMY

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Introduction: Atypical Small Acinar Proliferation (ASAP) is not a diagnosis, but a pathological finding indicating the presence of small acini suspicious but not diagnostic for cancer, despite immunochemistry; it is associated to a high detection rate of PCa in follow-up biopsy and the right time of follow-up is still unclear. Our objective is to evaluate pathological findings in patients with diagnosis of prostate cancer after ASAP, underwent radical prostatectomy. *Materials and Methods:* We retrospectively reviewed our database of prostate biopsies performed from 1998 to 2016, selecting 239 patients, mean age=64.58 (43-88) years, with initial isolated ASAP and considering 182 patients underwent at least one rebiopsy. *Results:* Overall, Prostate Cancer was found after a mean follow-up of 17.96 (1-120) months in 98 (53.55%) patients; global cancer detection rate at first biopsy was 76.53% (98 patients), at second biopsy was 8,24% (15 patients), at third biopsy was 6.12% (6 patients), at fourth biopsy was 4,08% (4 patients) and 1,02% (1 patients) at fifth biopsy; no cancer was detected at sixth biopsy. First re-biopsy was performed in 182 patients, after 11.55 (1-120) months from ASAP biopsy, with specific cancer detection rate of 41,21% (75 patients); second re-biopsy was performed in 49 patients, after 26.4 (4-111) months from ASAP biopsy, with specific cancer detection rate of 30.61% (15 patients); third re-biopsy was performed in 19 patients, after 44 (16-111) months from ASAP biopsy, with specific cancer detection rate of 31.71% (6 patients); fourth rebiopsy was performed in 7 patients, after 62 (33-123) months from ASAP biopsy, with specific cancer detection rate of 57.4% (4 patients); fifth re-biopsy was performed in 3 patients, after 82.33 (69-98) months from ASAP biopsy, with specific cancer detection rate of 33.33% (1 patients); sixth re-biopsy was performed in 1 patients, after 79 months from ASAP biopsy, with none specific cancer detection rate. After prostate cancer diagnosis, we lost follow-up of 39 patients (39.7%); 7 patients (7.14%) underwent radiotherapy, 3 (3.06%) androgen deprivation therapy, 2 (2.04%) cryoablation, 5 (10%) are still under Active Surveillance protocols. 42 patients (42.86%) underwent radical prostatectomy; pathological analysis is available for 34 patients. Pathological stage is pT2a in 6 patients (17,65%), pT2c in 18 patients (52.95%), pT3a in 9 patients (26.47%) and pT3b in 1 patient (2.94). Positive margins were found in 5 (14.7%) patients. In patients underwent lymphadenectomy, negative lymph nodes were found in all cases. GS, foci number and index volume were available in 32 patients. GS was 3+3 in 16 patients (50%), 3+4 in 8 patients (25%), 4+3

in 4 patients (12.56%), 4+4 in 0 patients, presence of Gleason 5 in 2 patients (6.25%). Only one focus was detected in 8 patients (25%), 2 foci in 9 patients (28,13%), 3 foci in 7 patients (21.87%), 4 foci in 6 patients (18.75%) and more than 4 foci in 2 patients (6.25%). Mean index volume was 0.56 (0,11-3,229) cc; volume was ≤0.5 cc in 20 patients (62.5%), between 0,5 and 1 cc in 7 patients (21.8%) and ≥1 cc in 5 patients (15.6%). *Discussion and Conclusion:* ASAP can be considered a false positive for PCa (when follow-up is negative) and a false negative for PCa (when follow-up is positive). Cancer detected can be is still curable but sometimes can present adverse findings, such as extraprostatic extension (26.47%), seminal vesicles invasion (2.94%), positive margins of resection (14.7%). More foci and a small volume of cancer were found in many patients (75% and 62.5%, respectively), suggesting that at initial biopsy the sampling of cancer can be missed, mostly if cancer is located in unusual zones (anterior, sub-urethral).

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IMPORTANCE OF LENGTH OF RADIAL EXTRAPROSTATIC EXTENSION IN 101 PATIENTS PT3A R0 LVI0 N0

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Introduction: Extraprostatic extension (EPE) after radical prostatectomy is associated to a high risk of biochemical recurrence. Our objective is to evaluate predictive factors of biochemical recurrence of prostate cancer of patients underwent radical prostatectomy with extracapsular disease, negative margins and negative lymph nodes. *Materials and Methods:* From our database of radical prostatectomies, from 2009 to 2014, we evaluated all patients with EPE without seminal vesicles invasion and without positive surgical margins. EPE is calculated according to radial distance. Furthermore, we excluded patients underwent radiation therapy or androgen deprivation therapy and patients lost during follow-up. We collected data about age, basal PSA, follow-up time, grading group (from 1 to 5), radial length of EPE, linfo-vascular invasion, biochemical recurrence incidence, time of biochemical recurrence. We determined as EPE cut-off 0,5 mm, 1 mm and 2 mm, evaluating numbers of biochemical recurrence compared to grading groups during time of follow-up. SPSS software has been used for statistical analysis (bivariate, multivariate correlation, survival COX and Kaplan-Meier curve); statistical significance is considered $p<0.05$. *Results:* We selected 101 patients with mean age 66.5 (51-77, DS±5.65) years and mean follow-up of 63 (32-96, DS±21) months. Grading group of all patients was 1 in 13 patients (12.87%), 2 in 47 patients (46.53%), 3 in 25 patients (24.7%), 4 in 8 patients (7.9%) and 5 in 8 patients (7.9%). Mean length of extra prostatic extension in all patients was 2.25 mm (0-7.6 mm; DS±1.06). Biochemical recurrence occurred in 10 patients (9,9%). Grading group was 1 in 1 patient (10%), 2 in 3 patients (30%), 3 in 2 patients (20%), 4 in 2 patients (20%) and 5 in 2 patients (20%). Mean length of EPE in patients with biochemical recurrence was 1.25 (0-5.32). Age, basal PSA, length of EPE, linfo-vascular invasion did not result independent predictive factors of biochemical recurrence. Grading Group is resulted the only independent predictive factor of biochemical recurrence (RR 20%, $p=0.04$) Among grading groups 1, 2 and 3, biochemical recurrence resulted less frequent in patients with EPE length <0.5 mm compared to EPE length >0.5 mm. Among grading groups 4 and 5 none difference was observed in patients with EPE <0.5 mm and >0.5 mm. This result is resulted statistically significant ($p<0.05$). *Discussion and Conclusion:* Patients with EPE have a high risk to develop biochemical recurrence. Many methods are utilized to evaluate EPE: Epstein's criteria (focal *vs*. non-focal), Wheeler's method and radial distance. In our institution, radial distance is indicated in definitive pathologic report. Patients with grading groups 1,2 and 3 and a short length of EPE (<0.5 mm) have a minor risk of biochemical recurrence compared to all other patients. This result can be considered for the decision about adjuvant radiation therapy in patients with extra prostatic extension.

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IDENTIFICATION OF PARAOXONASE-2 AS POTENTIAL BIOMARKER FOR BLADDER CANCER

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Introduction: Paraoxonase-2 (PON2) is a member of the multigene family of paraoxonases. Unlike Paraoxonase-1 (PON1) and Paraoxonase-3 (PON3), PON2 is an enzyme ubiquitously expressed, exerting its functions in the intracellular environment. In vascular cells, PON2 localizes in endoplasmic reticulum, in nuclear lamina and in mitochondria, counteracting in the latter the reactive oxygen species (ROS) production associated with the mitochondrial respiratory chain. While the antiapoptotic and antioxidative roles of PON2 in cardiovascular and neurodegenerative diseases were extensively investigated, only few studies have been focused on clarifying its function in cancer cells. The aim of this study was to speculate the role of PON2 in bladder cancer. *Materials and Methods:* Real-Time PCR analysis was used to evaluate PON2 expression levels in paired normal and tumour tissue samples obtained from 17 patients affected with BC. PON2 expression was also investigated in urinary exfoliated cells obtained from 41 patients with urothelial bladder cancer and 55 healthy donors, to explore the potential suitability of PON2 expression levels determination for early and non-invasive diagnosis of this neoplasm. Moreover, the effect of PON2 overexpression on cell proliferation was evaluated on T24 human urinary bladder cancer cell line. *Results:* Data obtained from analyses performed on tissue samples showed that PON2 expression levels were significantly ($p<0.05$) higher (2.01-fold) in BC compared with non-tumour tissue. Interestingly, although urinary enzyme expression did not differ significantly between pathological samples and healthy controls, PON2 mRNA levels inversely correlated ($p<0.05$) with pT parameter: PON2 urinary expression was higher in non-invasive papillary carcinomas (pTa) than in invasive lesions (pT1-3). After transfection, enzyme up-regulation led to a significant ($p<0.05$) increase in proliferative capacity of T24 cells. *Discussion and Conclusion:* Results reported in this study demonstrated a marked increase of PON2 level in tumour tissue, thus indicating that the enzyme could represent a potential biomarker for bladder cancer. Furthermore, the identification of an inverse correlation between urinary PON2 expression levels and pT seems to suggest a potential role of this enzyme as a prognostic factor for BC. PON2 up-regulation observed in BC tissues as well as the great impact of enzyme overexpression on T24 cell proliferation, strongly suggest that enzyme levels could influence the resistance of cancer cell to oxidative stress. In this light, further analyses performed on tumour cell lines will clarify whether PON2 expression modulation is able to affect the efficacy of antineoplastic drugs whose mechanism is based on ROS production.

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EXTENDED PELVIC LYMPH NODE DISSECTION FOR INTERMEDIATE –HIGH RISK PROSTATE CANCER: FREQUENCY AND DISTRIBUTION OF NODAL METASTASES

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Introduction: Standard extended pelvic lymph node dissection (ePLND) included the removal of external iliac, obturator and internal iliac chains. However, Mattei *et al*. demonstrated, in their mapping study, that extending template up to the ureteric crossing would remove approximately 75% of all primary landing sites, while only 63% were located in the intrapelvic area. Moreover, Joniau *et al*. suggested to add presacral node dissection to ePLND, in order to correctly remove nodal metastases in 97% of patients. To describe the frequency and distribution of metastases to pelvic nodes, in patients (Pts) with clinically localised, intermediate-high risk prostate cancer (PCa) according to the EAU guidelines, treated with radical prostatectomy and ePLND. *Patients and Methods:* We retrospectively evaluated 554 consecutive Pts with clinically localized, intermediate-high risk PCa, treated with open radical prostatectomy and ePLND between 2009 and 2015 at a single institution by multiple experienced surgeons. The ePLND always consisted of the external iliac, obturator, internal iliac, presacral and common iliac nodal site up to the ureteric crossing. Specimens from each anatomic site were sent in separate packets. *Results:* The median number of removed nodes was 22 (range=9-61). Positive nodes (LN+) were found in 119 patients (21.4%). The mean and median number of positive nodes were 2.9 and 1 (range=1-18), respectively. The median number of removed nodes was 6, 8, 5, 2, and 1 for external iliac, obturator, internal iliac, common iliac, and presacral site, respectively. Out of the 119 Pts, nodal metastases were found in 54 (45.4%), 50 (42%), 56 (47.1%), 12 (10.1%) and 15 (12.6%) in the external iliac, obturator, internal iliac, common iliac, and presacral sites, respectively. However, when analyzing the presence of

positive nodes only in a single anatomic area, nodal metastases were present in 19 (16%), 18 (15.1%), 25 (21%), 0, and 3 (2%) in the external iliac, obturator, internal iliac, common iliac, and presacral site, respectively (Figure 1). A limited LND would have correctly staged 92 (77%) Pts and would have removed all LN+ in 37 (31%) Pts. An extended LND would have correctly staged 116 (97%) Pts but removed all LN+ in only 93 (78%) Pts. *Conclusion:* Internal iliac and presacral nodes harbored metastases in more than 60% of cases, and positive nodes were present only in these areas in 23% of cases. On the contrary, metastases at common iliac nodes were always associated with concomitant involvement of external iliac, obturator and/or internal iliac nodes. An extended LND would have correctly staged 116 (97%) Pts but removed all LN+ in only 93 (78%) Pts.

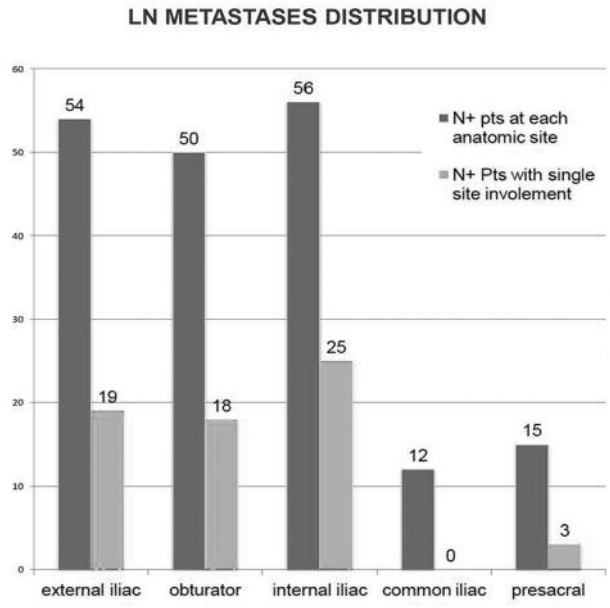

Figure 1. *LN metastases distribution.*

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SMALL TESTICULAR MASSES: A MULTICENTRIC EXPERIENCE

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Introduction: Scrotal ultrasound increased identification of small and non-palpable testicular lesions. The incidence of benign tumors is clinically relevant in lesions smaller than 18 mm (1). This suggest organ-sparig surgery rather than radical. Aim of this study was to verify the efficacy of the diagnostic-therapeutic pathway recently adopted in the surgical management of small testicular masses. *Materials and Methods:* In this multicenter study, patients with single testis lesion ≤15 mm at ultrasound as main diameter. We applied the diagnostic-therapeutic pathway described by Sbrollini *et al*. (2) which comprises of: i) testicular tumor markers, ii) repeated scrotal ultrasound at the tertiary center, iii) surgical exploration with inguinal approach, intraoperative ultrasound, and intraoperative pathological examination. Definitive histology was reviewed by a dedicated uro-pathologist. *Results:* We recruited 28 patients, mean age was 38 (18-68) years with mean lesion size was 9.3 (range=2.5-15) mm. Oncological testicular markers were normal except in a case who had small increase beta-HCG. Intraoperative ultrasound was necessary in 8/28 cases. We perfomed 11 (39.3%) immediate radical orchidectomy and 17 (60.7%) excisional biopsies with consequent testis-sparing procedures. Definitive pathological results were: malignant tumor in 6 cases (seminoma), benign tumor in 10 cases (5 Leydig tumors, 2 Sertoli tumors, 1 epidermoid cyst, 1 adenomatoid tumor, 1 angiofibroma), benign disease in 11 (8 inflammation with hemorragic infiltration, 2 tubular atrophy, 1 fibrosis), and normal parenchyma in 1 case. We observed a good concordance between frozen section examination and definitive hystology. *Discussion:* Our study has shown the reliability of the diagnostic-therapeutic pathway suggested by Sbrollini et al in the management of single testicular masses below 15 mm. The higher incidence of benign lesions in this group of tumors makes often orchidectomy an overtreatment. *Conclusion:* Testicular sparing surgery of small, single testicular nodules is a safe option, but requires a standardized pathway in diagnosis. The pathway described by Sbrollini et al has shown good reliability and security profile to be applied in a multicenter management for small scrotal masses.

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ONCOLOGICAL OUTCOMES OF PATHOLOGIC NODE POSITIVE PATIENTS, FOLLOWING RADICAL PROSTATECTOMY AND EXTENDED PELVIC LYMPH NODE DISSECTION

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Introduction: To evaluate oncological outcomes of patients affected by pathologic node positive (LN+) prostate cancer (PCa) following radical prostatectomy and extended pelvic lymph node dissection (ePLND) *Patients and Methods:* We retrospectively evaluated 93 pts treated with open radical prostatectomy and ePLND between 2009 and 2014, with pathologic node positive disease (Table I). The ePLND consisted of the external iliac, obturator, internal iliac, presacral and common iliac nodal site up to the ureteric crossing. Specimens from each anatomic site were sent in separate packets. The estimated cancer-specific survival (CSS) and biochemical disease-free survival (bDFS) were calculate by Kaplan-Meier method. Multivariable Cox regression models assessed for prognostic factors of bDFS *Results:*

Table I. *Uni- and multi- variable Cox regression models predicting bDFS.*

Variables	Univariable analyses		Multivariable analyses	
	HR	*p*-Value	HR	*p*-Value
Age				
Continuous variable	0.954	0.102	0.981	0.574
pT				
pT3b-4 *vs*. pT2c-3a	1.781	0.130	1.487	0.364
Adjuvant HT				
Yes *vs*. No	0.366	0.003	2.233	0.038
Adjuvant RT				
Yes *vs*. No	1.455	0.247	0.642	0.183
LN positive				
>2 *vs*. ≤2	0.292	0.001	2.253	0.026
Gleason score				
8-9 *vs*. 7	0.492	0.045	1.220	0.634

Median follow-up was 43 months (range=12-84); six pts (6%) died of disease at follow-up, while 39 (42%) experienced biochemical failure (PSA >0.2 ng/ml). Out of 93 patients, 53 pts did not receive adjuvant hormone therapy (AdjHT), 46 pts harboring ≤2 LN+. The median number of nodes removed was 22 (range 9-61). The mean and median number of positive nodes was 2, 7 and 1 (range=1-18), respectively. The estimated 5-year CSS was 90%; 5-year bDFS was 45%. Pts with ≤2 LN+ had significant better 5-year bDFS than those with >2 LN+ (59% *vs*. 15%; $p<0.001$; Figure 1). Pts with

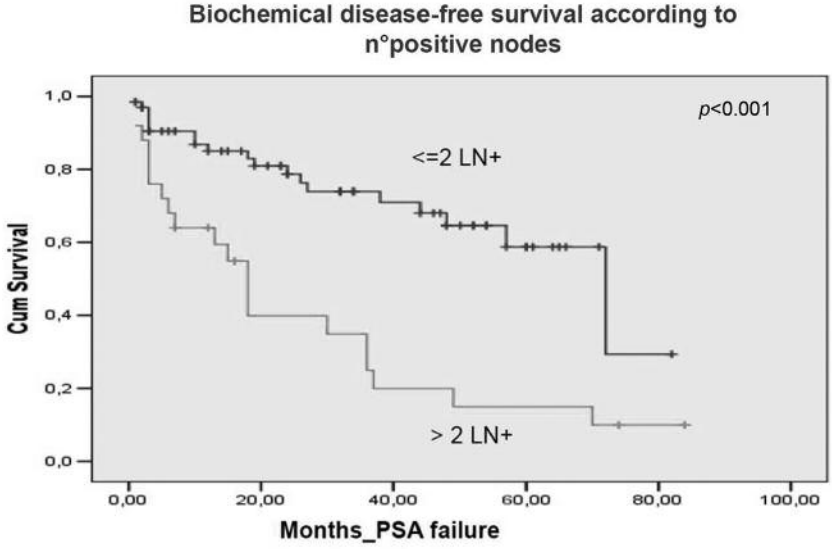

Figure 1. *Biochemical disease-free survival according to number of positive nodes.*

Gleason score 7 had better 5-year bDFS than those with Gleason score 8-10 (58% *vs*. 36%; p=0.039). At multivariable Cox regression analysis, presence of more than 2 LN+ was an independent predictor of worse bDFS (p=0.026; HR 2.2). Among pts who did not receive AdjHT, the estimated 5-year bDFS was 60%, and was significantly higher in pts with ≤2 LN+ than those with >2 LN+ (64% *vs*. 34%; p=0.032). *Conclusion:* Among pts with pathologic node positive disease following radical prostatectomy and ePLND, those with <2 LN+ showed more than 50% bDFS at 5-year follow-up. Good cancer control seems to be achieved also without AdjHT, in pts with limited nodal burden.

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NEPHRON-SPARING SURGERY IN PATIENTS WITH SYNCHRONOUS MULTIFOCAL IPSILATERAL RENAL MASSES USING ENUCLEO-RESECTION TECHNIQUE

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Introduction: The aim of the study was to evaluate functional and oncological outcomes in nephron sparing surgery in multiple renal masses in the same kidney. *Materials and Methods:* Ninenty patients underwent nephron-sparing surgery using enucleo-resection technique (1). Among these cases, 13 patients underwent conservative surgery for multiple tumours in the same kidney: 3 with solid tumors, 10 with solid tumors plus cystic mass. We evaluated overall 28 esophitic masses. Median tumor diameter was 2.89 (0.5-5.3) cm. Median RENAL score was 6.25 (4-11). Baseline tumour stage was: 10/13 (77%) cT1a and 3/13 (23%) cT1b. Chronic Renal Failure (CRF) was staged according to pre-operative eGFR measurement: normal or minimally reduced RF stage I in 7/13 (54%) patients, stage II in 3/13 (23%), stage III in 3/13 (23%), stage IV and stage V in 1 (0%). The patients underwent a 12 months follow-up. *Results:* We performed open-flank incision and retroperitoneal approach. Warm Ischemia (WI) was used in the enucleo-resection of 5/28 (18%) masses (all of them were solid), with a mean Warm Ischemia Time (WIT) of 11.6 (5-18) minutes. Any intra- or postoperative nephrectomy was done. To verify intraoperative urine leakage, we used saline flushing from the ureteral catheter in 5/13 (38%) cases. 1/13 (8%) patient required intra- or post-operative blood transfusion. According to Trifecta, any patient had post-operative complications (2, 3); 1/13 (8%) case had focal positive margin; renal function (according to 5-day post-op eGFR) worsened in 3/13 (23%) patients, with 1 stage decline. All the patients had pathological diagnosis of renal neoplasm: 6/13 (46%) cases with clear cell renal cell tumor, 3/13 (23%) with cromophobe tumor, 2/13 (15%) with angiomyolipoma, 1/13 (8%) with papillary tumor and 1/13 (8%) oncocitoma (4). All cystic masses resulted simple renal cysts All patients underwent abdominal CT in the follow-up: any urinary fistula, delayed bleeding or artery-venous fistula has been observed after a mean 12 (8-48) months. *Conclusion:* Conservative surgery enucleo-resection for multiple solid renal masses, if technically feasible, can represent a valid approach, to prevent significative CRF worsening. Warm ischemia can be avoided in our experience without significant bleeding. Considering indicators of quality of the oncologic surgery (positive margins and oncologic outcome), our data are interesting and remarkable, but limited the number of cases.

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PSA-IGM BASED ALGORITHM (IXIP SCORE) DURING FOLLOW-UP OF ACTIVE SURVEILLANCE

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Introduction: The aim of the study is to evaluate prospectively the accuracy of PSA-IgM based algorithm in predicting Gleason score upgrading in active surveillance patients for prostate cancer. *Patients and Methods:* Thirty-five patients diagnosed with prostate cancer and undergoing active surveillance (T1/T2, biopsy Gleason score ≤6, PSA ≤10 ng/ml, and ≤2 positive biopsy cores) were evaluated by multiparametric Magnetic Resonance Imaging (mpMRI), measuring prostate volume, EPE, SVI and PI-RADS v.2 score and by determining TPSA, PSAD and iXip, a novel algorithm for PCa detection based on PSA-IgM determination (Prostate-IC, Xeptagen) at time 0, 12 and 24 months. A saturation biopsy was performed in all patients at 12 and 24 months *Results:* At diagnosis, the medium age was 62,3 years, medium PSA was 5.3 ng/ml, median iXip score 0,565 and mpMRI data were: PI-RADS 2 in 2, PI-RADS 3 in 26 and PI-RADS 4 in 7. No EPE or SVI were found. During the study period 7 patients (20%) discontinued active surveillance before the first year for personal preference and no upgrading occurred at definitive pathology. In the 28 patients, remaining tumor upgrading occurred in 3 after 12 months biopsy and in 5 after 24 months biopsy (28,6%). A statistically significant increase in iXip score between patients with Gleason upgrading and patient without Gleason upgrading was found (p=0.03); TPSA e PSAD failed to reach significance. Tumor upgrading was also highly associated with PI-RADS upgrading (p=0.000). The estimated optimal cutoff value of iXip score was 0.2 (ROC analysis: AUC=0.68; p=0.021). By associating iXip score to mpMRI PI-RADS upgrading all Gleason upgrading events were detected before biopsy. *Conclusion:* iXip is a useful tool in predicting Gleason score upgrading in low-risk prostate cancer. In the era of mpMRI the evaluation of iXip should be considered during follow-up of patients enrolled in active surveillance programs.

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COGNITIVE ZONAL FUSION BIOPSY OF THE PROSTATE: AN ORIGINAL TECHNIQUE BETWEEN TARGET AND SATURATION

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Introduction: Multiparametric magnetic resonance (mpMRI) help us see significant index lesions, improve detection of significant tumors, improve amount of tumor and reduce number of cores (1, 2). The question is if we should omit systematic conventional biopsies in patients with negative mpMRI (3). The aimof the present study was to describe the technique and evaluate benefits of the cognitive zonal biopsy based on mpMRI in addition to standard biopsy. *Materials and Methods:* This was a single-center prospective study on 58 pts: 25 biopsy-naïve men, 25 men with previous negative biopsy and in 8 men in active surveillance. DRE: positive in 9 men (15%); mean PSA: 6.8 (0.7-22.6) ng/ml. PI-RADS and zonal anatomical identification of the Region of Interest (ROI) were evaluated with mpMRI. If mpMRI was negative, subjects received a standard 12-core biopsy. If mpMRI was suggestive or positive of cancer (PI-RADS ≥3) underwent 12-core biopsy plus targeted 2 to 6 cores using cognitive zonal fusion technique, based on cognitive target biopsy (CTB) on ROI and Zonal Saturation Biopsy (ZSB) on MRI anatomical zones containing the region of interest. Cognitive Target Biopsy (CTB) on ROI was done on a target if a correspondence was found between MRI and ultrasound. If no ultrasound lesion or anatomic marker was detected comparing ultrasound with MR imaging, a Zonal Saturation Biopsy (ZSB) was done. *Results:* 31/58 (53.4%) patients had cancer, 18/31 high grade tumors. 25/31 (80.6%) had a clinically significant prostate cancer and 6/31 (19.3%) not significant cancer. MRI cancer detection rate was 18/31 (58.1%), and 9/18 (50%) in high-grade tumors: sensitivity was 18/22 (81.8%); 11/19 (58.9%) for high-grade tumors, specificity was low. Cancer detection rate inside ZSB/CTB was 14/25 (56%) for clinically significant cancer and 4/6 (66.7%) for not significant cancers. Outside ZSB/CTB 5/13 (38.5%) had clinically significant cancer and 4/7 (57.1%) not significant cancers. Cancer detection rate was 8/17 (47%) in PI-RADS 4/5, 16/36 (44%) in PI-RADS 3 and 0/5 in PIRADS 0-2. Mean core number taken with cognitive zonal fusion biopsy was 6.1 (2-17). Overall 15.4 cores (12-22) were taken. Mean core length was 1.5 (0.8-1.9) cm. Cancer amount was 7.3 (1-54.5) mm in ZSB or CTB and 5.2 (1-23.5) mm outside. Prognostic grading Group 2-5 was detected in 11/23 in ZSB/CTB and in 13/23 outside. Largest percentage of cancer involvement inside ZSB or CTB was 19.4% (0-67.5%) and 15.9% (0-50.7%) outside. *Conclusion:* MRI should be used to guide anatomical zone of saturation biopsies and not to decide whether to submit the patient to biopsy. Cognitive zonal biopsy based on mpMRI findings in addition to standard biopsy identifies clinically relevant cancer in 80%, has larger cancer extension in fusion biopsies than in random biopsies, and reduce the number of cores if compared to saturation biopsy.

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FOCAL THERAPY OF LOCALIZED PROSTATE CANCER WITH "FUSION" INTEGRATED PATH AND HIGH INTENSITY FOCUSED ULTRASOUND (HIFU): INITIAL EXPERIENCE

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Introduction: Focal therapy is an emerging mini-invasive treatment modality for localized prostate cancer (PCa) aimed to reduce the morbidity associated with radical therapy while maintaining optimal cancer control. The technological improvement of multiparametric magnetic resonance imaging (mpMRI), 3Dultrasound and software for image fusion in order to locate more accurately PCa foci provides an optimal technology combination for the ideal focal efficacy. We report the 6-months oncological and functional results of primary focal ablation high-intensity focused ultrasound (HIFU) after fusion biopsy diagnosis of PCa in a prospective cohort of patients. *Materials and Methods:* Single-center prospective evaluation of focal therapy for organ-confined PCa was performed from November 2015 through April 2016 using Focal-One® device (EDAP TMS). PCa diagnosis and localization was done based on mpMRI and -3D ultrasound-targeted fusion biopsy (Trinity, Koelis) plus standard biopsy. HIFU focal ablation using Focal-One® device was carried out under general anesthesia to immobilize the target lesion. The MRI/US imaging fusion of the target area was transported directely from Trinity to Focal One through specific software for the treatment. Treatment oncologic outcomes were evaluated with PSA and mpMRI 6 months after treatment. Targeted fusion biopsy after HIFU treatment was performed only in mpMRI positive patients. Functional outcomes were assessed with validated questionnaires for genitourinary symptoms. *Results:* Forty-one patients underwent focal therapy and were included in the study. Mean age was 70 (55-79) years. Mean PSA was 6.8 (0.5-18) ng/ml. National Comprehensive Cancer Network low-, intermediate-, and high-risk disease was 29 (70.8%), 10 (24.4%), and 2 (5.8%), respectively. Mean pre-treatment prostate volume was 39.7 (14-66) ml; Mean volume of tissue treated was 13.5 (4-30) ml. In three patients a ThuLEP procedure was performed 2 months before HIFU. In thirty-three patients (80,3%) the catheter was removed in day 7 after HIFU; in eight patients (19.5%) the catheter was maintained until day 15. Nine men (21.9%) had self-resolving, mild to moderate, dysuria (median duration 7 days). Urinary tract infection was noted in 5 men (12.2%). Mean 6-months PSA was 2.4 ng/ml (0.2-9). Forthy patients (97.6%) had normal mpMRI findings 6-months after HIFU. One patient showed focal abnormal signal at mpMRI around the treated area: fusion biopsies confirmed the persistence of microfocal PCa with Gleason score 3+3 (treatment failure); in this patients a retreatment was performed. No major complication was observed. IPSS score showed no significant difference before and 6-months after HIFU. At 6 months, all patients were completely continent, and potency was maintained in 30 of 31 preoperatively potent patients. *Conclusion:* The integration between fusion biopsy and Focal One device allows to date the most accurate detection and treatment of index focus of PCa. This preliminary experience with 6-months follow-up time indicates that HIFU focal ablation of prostate cancer leads to "Trifecta" outcomes (cancer control, continence, sexual potency) in 91,5% of 41 men. The integration of new technologies enables the accurate and early diagnosis of recurrence after focal ablative treatment, leaving the possibility of a precise HIFU retreatment.

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THE ACCURACY OF ^{64}CU-PSMA PET/TC IN IDENTIFYING THE SITE OF BIOCHEMICAL RECURRENCE AFTER RADICAL PROSTATECTOMY IN PATIENTS WITH LOW PSA VALUES (<2 ng/ml)

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Introduction: The PSMA (Prostate Specific Membrane Antigen) is a cell surface protein with high levels of expression in prostate cancer. The physical characteristics of

the isotope 64 of Copper (^{64}Cu) allow to achieve a stable binding with PSMA and to obtain highresolution images with PET scan. The ^{64}Cu biophysical characteristics (high concentration in prostate cancer cell nucleus and beta particles/Auger electrons emission) lead to hypothesize a possible theranostic application of this nonoparticle in prostate cancer (fusion of diagnosis and therapy). We prospectively examined the performance of PET/Tc with ^{64}Cu-PSMA for its ability to delineate prostate cancer distribution and extent after radical prostatectomy (RP) in patients with low PSA values (<2 ng/ml). Method: Between April and October 2015 36 men with PSA elevation (≤2 ng/ml) after RP were evaluated with PET/Tc performed at 1 h, 3 h and 24 h after injection of 200-450 MBq of ^{64}Cu-PSMA (average activity 4 MBq/kg). The dosimetric evaluation was performed using manual VOI on various organs. Co-registered TC images were analyzed in order to determine the corresponding volume of interest (VOIs) to measure specific activity (Bq/ml) and to calculate the maximum standardized uptake value (SUV_{max}). Data analysis from the activity/time curves was performed with the Olinda method/EXM software for adsorbed dose calculation. ^{64}Cu-PSMA PET/Tc images were analyzed blind by three observers and compared with TC investigations and/or NMR. Two reviewers analyzed the final data and compiled a final evaluation table. The ^{64}Cu-PSMA labelling was performed on 30 micrograms of liquid +200 mMNaOAc incubated with 10 mCi $^{64}CuCl_2$ to pH 5.5 for 10 min at room temperature. The ITLC for quality control revealed a radiochemical purity of 99%. All patients were evaluated with PSA 10 days after ^{64}Cu-PSMA PET/Tc. PET/Tc-positive patients were treated with hormone therapy plus targeted radiotherapy. A new PSA and PET/Tc with ^{64}Cu-PSMA was performed 3 months after treatment. *Results:* Mean initial PSA was 1.1 ng/ml (0.4-1.9 ng/ml). The ^{64}Cu-PSMA PET/Tc image analysis from the evaluation board have documented the presence of areas of abnormal uptake in all patients (100%) with lesion/background ratio greater than 10. The PET/Tc-positive lesions (n=63) had a mean size of 5.2 mm (3-9 mm) and were localized in the lymph-nodes (n=48), anastomotic site (13) and bone (n=2). The PSA 10 days after ^{64}Cu-PSMA PET/Tc decrased with a mean of 0.3 (0.1-0.5) ng/ml. PSA 3 months after RT was 0.0 ng/ml in all patients. The ^{64}Cu-PSMA PET/Tc 3 months after RT was negative in all patients. *Conclusion:* The ^{64}Cu-PSMA PET/Tc is proposed as a high-sensitivity diagnostic test in patients with biochemical recurrence after RP and low PSA levels. The physical characteristics of the ^{64}Cu gives potential benefits in terms of resolution power and halflife. The possibility to identify the sites of PCa biochemical recurrence in early stage improves treatment times and enable to modulate the therapeutic strategy. The observed PSA reduction after ^{64}Cu-PSMA PET/Tc confirm the potential theranostic use of ^{64}CuPSMA.

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DIFFERENCES IN CLINICAL AND PATHOLOGICAL RESPONSE TO NEOADIUVANT CHEMOTHERAPY IN PATIENTS WITH INVASIVE BLADDER CANCER

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Introduction: Neoadjuvant cisplatin-based chemotherapy prior to radical cystectomy (RC) for muscle-invasive urothelial carcinoma of the bladder is underutilized, besides having been supported by guidelines. This study was undertaken to determine the rate of neoadjuvant gemcitabine and cisplatin (GC) use before radical cystectomy (RC) and lymphadenectomy and to assess its effect on the pathologic response rates and surgical outcome and complication rate. *Patients and Methods:* This retrospective study examined all patients having a RC between January 1, 2012 and September 2016. We collected patient demographics, pre-treatment clinical stage, type of chemotherapy, post-RC pathologic data and survival data. Response Evaluation Criteria in Solid Tumors (RECIST, ver.1.0) was used to asses clinical response to GC (CR for complete response, PR for partial response, PD for progression of disease and SD for Stable disease on CT). Pathological Tumor Regression Grade (TRG) was evaluated according AJSP vol 38, pag 325, 2014. *Results:* A total of 84 RC were performed of which 74 (88%) were for stage cT2-T4 urothelial carcinoma of the bladder. Salvage cystectomies were excluded (n=10). Of the 74 patients, 30 (40.5%) received neoadjuvant GC. Based on CT scan, clinical response to chemotherapy was evaluated using RECIST criteria: CR was observed in 2 pts (6%), PR in 18 (60%); PD in 1 (3%) and SD in 9 (30%) regarding primary bladder tumor. In 12 pts with enlarged lymph nodes, the response to chemotherapy was CR in 1, PR in 10 and SD in 1. Patients receiving neoadjuvant GC had a greater chance of achieving a pathologically lower stage compared to the untreated population: organ-confined cancer in 53.3% (16/30) *vs.* 33% ($p<0.001$). Lymph node metastasis resulted in 25% patients after GC (n=10) *vs.* 45.5% of untreated patients (n=20) ($p<0.001$). Considering patients resulted CR and PR after GC (n=20), 70% had down-staging on pathologic report after RC. Complication rates were higher

in neoadjuvant GC group with adverse events (4 thromboembolisms; 2 sepsis; 12 hematologic complications), all complications were not related to surgery. Survival correlated with pathological stage was: pT3a patients had a median OS and CSS of 48.8 and 51.2 months compared to an OS and a CSS in pT3b patients of 21.8 and 28.1 months, respectively ($p<0.0001$). Pathological TRG after chemo was not correlated to clinical regression grade. *Conclusion:* Neoadjuvant chemotherapy for urothelial carcinoma of the bladder is more frequently administered at our institution compared to the published literature. We have found that neoadjuvant chemotherapy increases the rate of down-staging and is associated to increased risk to complications that may be prevented using tailored strategies. Pathological regression grades after chemo are not correlated to RECIST criteria based on CT.

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IMPACT OF DYNAMIC CONTRAST-ENHANCED (DCE) IMAGING IN MPMRI PROSTATE CANCER DIAGNOSIS EVALUATED BY 5 RADIOLOGY RESIDENTS

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Introduction: The relative importance of dynamic contrast-enhanced imaging (DCE) to the combination of T2-weighted imaging (T2W) and diffusion-weighted imaging (DWI), in prostate cancer (PCa) diagnosis, is not well-defined. We compared the performance of bi-parametric (T2W+DWI) and tri-parametric (T2W+DWI+DCE) MRI, in the diagnosis of the index lesion. *Materials and Methods:* We performed a retrospective analysis of 57 patients (who underwent preoperative mpMRI and radical prostatectomy) and 23 controls (examined by mpMRI, with at least a 2-year follow-up excluding PCa). Five independent radiology residents with an 8-month dedicated MRI experience, blinded to clinical and pathological and clinical data, reviewed bi-parametric MRI and, 4 weeks later, tri-parametric MRI (the latter according to PI-RADSv2). Whole-mount histological sections were reviewed by a senior consultant uro-pathologist according to 2014 ISUP protocol and used as the reference standard for comparing diagnostic accuracy. The index lesion was defined as the largest PCa focus identified at the final pathology. *Results:* In a pooled analysis of the 5 readers, no statistically significant difference in the diagnosis of index lesion was observed among bi- and triparametric MRI. Sensitivity was 72% and 81% respectively ($p=0.08$); specificity was 78% and 79% ($p=0.92$); accuracy was 74% and 81% ($p=0.12$; Figure 1). The index lesion had the higher Gleason score compared to other lesions in 53/57 patients (92,9%). No significant difference between bi- and tri-parametric MRI ($p=0.54$) emerged in measuring lesion diameters, although dimensions

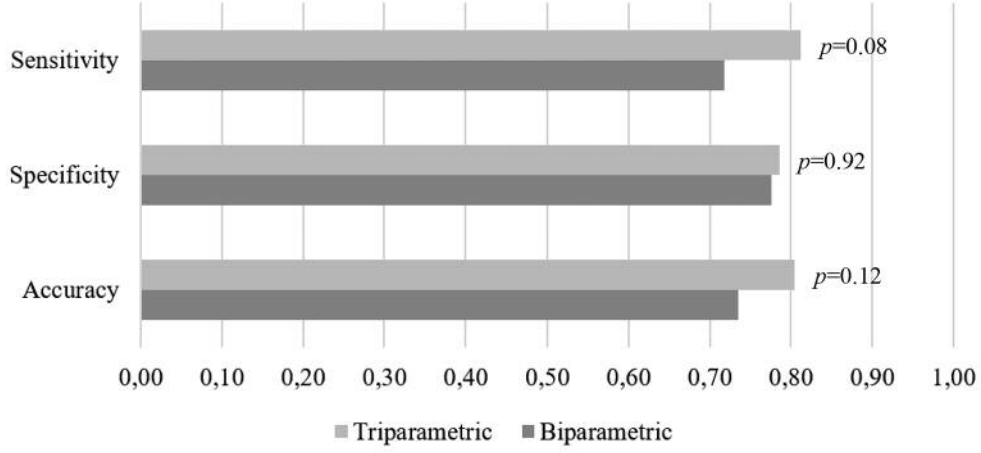

Figure 1. *Diagnostic parameters for detection of index lesion; pooled analysis of all readers.*

were underestimated in both cases if compared to histologic value (-35% on average, p=0.01). *Conclusion:* No statistically significant difference in detecting and measuring the index lesion emerged between biparametric and triparametric MRI protocols, among intermediate-experienced readers. A good diagnostic accuracy, on index lesions, may be reached by the sole use of bi-parametric prostate MRI.

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LUMEN SPACE/EPITHELIUM AREA RATIO AND MRI APPARENT DIFFUSION COEFFICIENT CORRELATION IN PROSTATE CANCER: INITIAL DATA

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Introduction: MRI Apparent Diffusion Coefficient (ADC) reflects Brownian motion of water molecules in a tissue. Several studies have demonstrated a significant correlation between ADC and prostate tumour grading, but the precise histological characteristics underlying ADC changes have not been fully clarified yet. In this pilot study, we describe a simple method to determine quantitative histological parameters and we correlate ADC values and the composition of normal and malignant tissue, in a small sample. *Materials and Methods:* Three cases were randomly chosen for digital analysis of slides from a retrospective series of patients who underwent radical prostatectomy after pre-operative MRI of the prostate. For each selected patient, one normal area and the index lesion were manually identified both on ADC map and on whole-mount section. ADC values were measured and histological slides were processed using Image J 1.50b (Wayne Rasband, NIH, USA), by in-house developed macros based on single-patient colour thresholding, colour deconvolutions for H&E stain and image noise reduction. Nuclear count was performed and image segmentation provided areas of epithelium, stroma and lumen space. Univariate linear regression models were used to assess the correlation of ADC with tissue component areas and cell density. *Results:* Image segmentation of digitally acquired whole-mount sections provided satisfactory visual results (Figure 1). Nuclear density, as a surrogate of cell density, did not show a significant correlation with ADC. Lumen space/Epithelium area ratio, instead, was a significant predictor of ADC (beta=1.8; p=0.02; r2=0.78). *Conclusion:* Basic digital analysis of sections can cast new light on the correspondence between ADC and pathological grading. In particular, some of the gland features on which pathological grading is evaluated, such as presence and size of lumen space, could directly play a major role in determining ADC. Further studies are required to confirm these data and develop accurate predictive models for clinical practice.

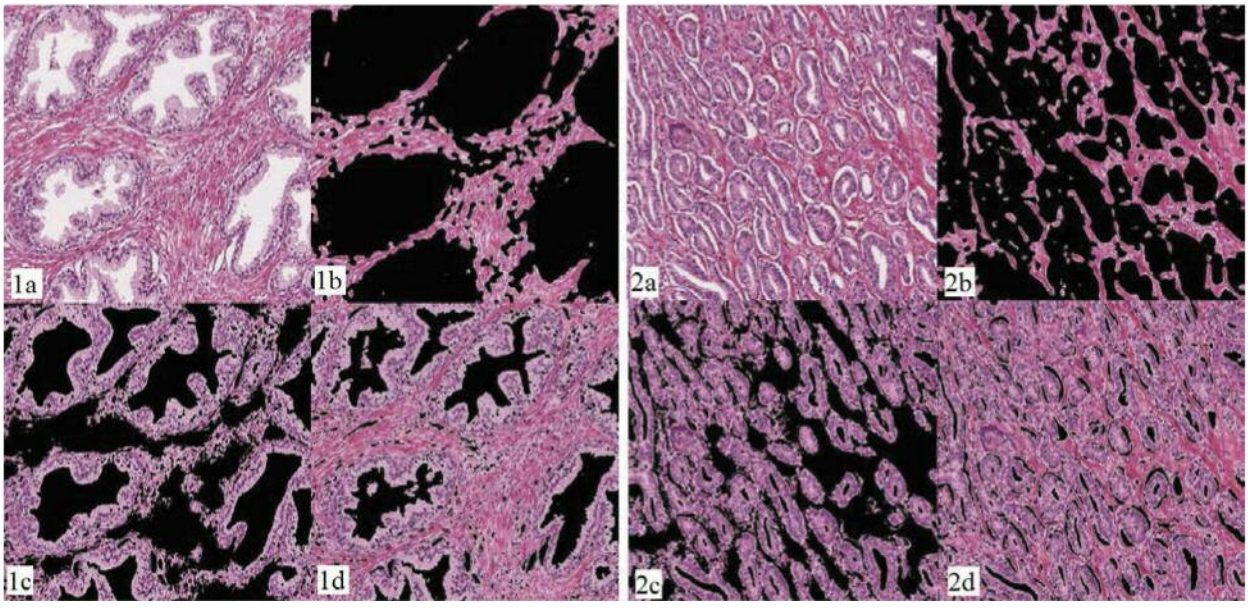

Figure 1. *Result of segmentation (example): 1, normal; 2, malignant; a, original slide; b, stroma; c, epithelium, d, lumen space (in black).*

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INTER-READER AGREEMENT OF THE PI-RADS VERSION 2 AMONG 4 RADIOLOGY RESIDENTS

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Introduction: By refining previous criteria, Prostate Index – Reporting and Data System (PI-RADS) version 2 score aims to reach a higher standardisation and precision in prostate MRI. We evaluated inter-observer agreement among 4 intermediate-experienced readers, considering detection rate and measurement of prostate cancer (PCa) index lesions. *Materials and Methods:* Forty mpMRI studies of the prostate (12 controls, 28 cases) were retrospectively reviewed by 4 independent radiology residents. Readers used the PI-RADS version 2 score, blinded to clinical and histological data; before the study start, each one had interpreted 250-350 prostate MRIs. The discriminating ability was estimated by the ROC curve and associated diagnostic parameters by using pathological whole-mount sections review (for the cases) or negative follow-up (for the controls) as reference standard. Inter-observer agreement on PIRADSv2 score was globally evaluated by Fleiss' Kappa, whereas Cohen's Kappa was used to quantify agreement of readers 2, 3 and 4 with respect to reader 1. Eta 2 coefficient and the percentage of pairs of measures with a difference <5 mm were used to evaluate agreement in assessing the lesion diameter. *Results:* Table I summarizes sensitivity, specificity and area under the ROC curve (AUC) and reports also the outcomes of the comparisons between the three pairs of readers. Fleiss' kappa was 0.54±0.07, with Cohen's kappa coefficients for pairs of readers ranging from 0.51-0.60 (Figure 1). Considering the lesion diameter, the percentage of measures differing less than 5 mm between reader 1 and each other varied from 78% to 91%. Eta 2 coefficients ranged from 0.76 to 0.97. However, all readers significantly underestimated lesion diameter compared to pathologic examination (p=0.01). *Conclusion:* High sensitivity and specificity results in PCa diagnosis were reached by radiologists in training, with no significant differences among their performances and a moderate agreement on PI-RADSv2 score. Also the inter-reader agreement on lesion diameter was good. PCa diameters were generally underestimated.

Table I. *Diagnostic parameters and Area Under the ROC Curve. p-Values for differences among readers are reported in italics.*

Reader	Sensitivity	Specificity	AUC
R1	0.83	0.82	0.86
R2	0.90	0.78	0.90
p (R1vsR2)	*0.74*	*0.74*	*0.90*
R3	0.71	0.82	0.79
p (R1vsR3)	*0.40*	*>0.99*	*0.45*
R4	0.74	0.77	0.80
p (R1vsR4)	*0.55*	*0.83*	*0.51*

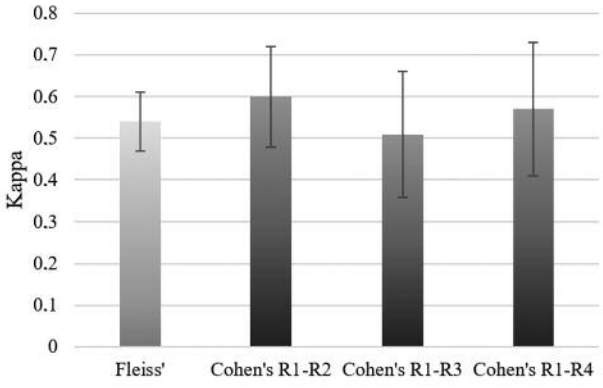

Figure 1. *Fleiss' and Cohen's Kappa values for inter-reader agreement; whiskers represent Standard Error.*

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IMPACT OF DYNAMIC CONTRAST-ENHANCED (DCE) IMAGING IN MPMRI PROSTATE CANCER LOCAL STAGING EVALUATED BY 5 RADIOLOGY RESIDENTS

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Introduction: The relative importance of dynamic contrast-enhanced imaging (DCE) to the combination of T2-weighted

imaging (T2W) and diffusion-weighted imaging (DWI), in prostate cancer (PCa) staging by MRI, is not well-established. Our aim was to compare the performance of biparametric (T2WI+DWI) and multiparametric MRI (T2WI+DWI+DCE) in local staging. *Materials and Methods:* We retrospectively evaluated 57 patients with pre-operative MR (1.5 T, surface coil). Five radiology residents with an 8-month experience, blinded to clinical and pathological results, independently reviewed biparametric and multiparametric MRI studies, allowing a 4-week interval between the two sessions. Prostatectomy whole-mount section review, according to 2014 ISUP protocol and to the pT3 sub-classification by Ball MW *et al*., 2015, was used as the reference standard, distinguishing focal extraprostatic extension (F-EPE, pT3a), nonfocal extraprostatic extension (NF-EPE, pT3a) and seminal vesicles invasion (SVI, pT3b). *Results:* In PCa local staging, there was no statistically significant difference between bi- and multiparametric MRI, in a pooled analysis of all readers. Sensitivity of bi- and multiparametric MRI for EPE (both focal and non-focal) was respectively 65.4% and 55.8% (p=0.32); specificity was 87.8% and 91.1% (p=0.47); accuracy was 79.6% and 78.2% (p=0.77). Table I summarizes the results for EPE (all types), NF-EPE and SVI invasion. *Conclusion:* MRI local staging performance was not significantly changed by the evaluation of DCE sequences in addition to T2W and DWI, among radiology residents having intermediate experience. Moreover, if NF-EPE can reliably be diagnosed by MRI, detection of F-EPE and SVI still represents a critical issue.

Table I. *Sensitivity and specificity with and without DCE (dynamic-contrast enhanced) imaging for EPE, NF-EPE, SVI.*

	EPE	NF-EPE	SVI
Sensitivity with DCE	0.56	0.81	0.30
Sensitivity without DCE	0.65	0.88	0.40
p	0.32	0.99	0.99
Specificity with DCE	0.91	0.81	0.98
Specificity without DCE	0.88	0.75	0.97
p	0.47	0.28	0.99

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OPEN *VERSUS* ROBOT-ASSISTED SALVAGE RADICAL PROSTATECTOMY: FUNCTIONAL OUTCOMES AND COMPLICATIONS OF A MULTICENTRE SERIES

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Introduction: Salvage radical prostatectomy (sRP) has been associated with an elevated frequency of complications and unsatisfying functional outcomes. We evaluated and compared a large contemporary series of robotic (RsRP) *vs*. open (OsRP) sRP. *Materials and Methods:* Data from 376 men undergoing sRP between 2000 and 2015 were retrospectively collected from 13 Tertiary referral centres. Complications were graded according to the Clavien-Dindo score. Erectile function (EF) and urinary continence (Con) were assessed before sRP, at 6 and 12 months with IIEF before and according to the type of therapy needed to obtain erections after sRP and with number of pads/day used respectively. We excluded men with insufficient data or a

follow-up<12 months. For continuous variables group comparisons were made with Wilcoxon-Mann-Whitney; for categorical variables with Chi-square or Fisher's exact tests; analysis of variance for repeated measures was used to evaluate Con trends. *Results:* Two hundred forty-three men (138 OsRP and 105 RsRP) who underwent sRP after primary active treatments were included. No significant differences were present baseline amongst the two groups except for the the CCI, higher in the RsRP group (2.7±2.4 *vs*. OsRP=0.9±1.38; $p<0.01$) and the lymph-node template used, more extended in the OsRP group ($p<0.01$). A higher number of patients underwent monolateral (1.9% *vs*. 0.72%) or bilateral (15.2% *vs*. 4.35%) nerve sparing in the RsRP group ($p<0.01$). Mean operating time was lower for OsRP (175.3±83 *vs*. 195.3±84 min; $p<0.01$). Mean blood loss (BL) was higher for OsRP (529.3±445 *vs*. 228.4±170 ml; $p<0.01$). However, no differences in post-operative transfusions were present (6.17% of men received ≥1 unit; $p=0.28$). Mean hospital stay (HS) was shorter for RsRP (2.98±2.7 *vs*. 4.32±4.1 days, $p<0.01$). All (47.8% *vs*. 32.3%; $p=0.018$) and of major type complications (Clavien Dindo ≥3, 30.4% *vs*. 11.4%; $p<0.01$) were more frequent for OsRP, including anastomotic stricture (18.8% *vs*. 8.5%; $p=0.03$). Rectal injury was rare (3.62% of OsRP *vs*. 0.9% of RsRP; $p=0.23$). At 1 year spontaneous erections rate was 7.6% whereas 55.4% of men had complete impotence (no group differences $p=0.06$); Con rate was 31.1%; 35.1% of patients had severe incontinence using ≥3 pads/day (no group differences $p=0.35$). *Conclusion:* Acceptable functional outcomes and complication rates are observed after sRP, when performed in tertiary referral centers. RsRP favours shorter HS, lower BL and lower complication rates compared to OsRP. However, no significant differences emerged in terms of Con and EF.

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ONCOLOGICAL OUTCOMES IN A MULTICENTRE SERIES OF 243 SALVAGE RADICAL PROSTATECTOMIES

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Introduction: A valid treatment option with curative intent, in men with biochemical recurrence (BCR), is represented by salvage radical prostatectomy (sRP). We evaluated the oncological outcomes of a contemporary series of sRP. *Materials and Methods:* We retrospectively analyzed 376 men with biochemical recurrence (BCR), who underwent sRP between 2000 and 2015 at 13 Tertiary referral centres. Age, PSA, clinical and pathological TNM, primary and pre-sRP biopsy and sRP gleason score (GS), surgical margins, imaging type and positive sites, lymphadenectomy template used, number of lymph-nodes removed and positive, ASA score and ECOG performance status and use of hormonal treatment (HT) were collected for each patient. Exclusion criteria were a follow up<12 months or unavailability of the data. Continuous variables were tested for normal distribution and then compared using the Wilcoxon-MannWhitney test; differences in categorical variables were assessed by Chi-square or Fisher's exact tests. *Results:* We included 243 men. Primary treatments were external-beam radiation therapy in 69.5%, cryotherapy in 3.7%, HIFU in 4.1%, brachytherapy in 21.4% and other primary treatments in 1.2% of the patients. Mean PSA and age pre-sRP were 6.32±8.23 ng/mL and 64.7±8.35 years, respectively. Pre-operatively, 1 men had radiological evidence of retroperitoneal nodal involvement,

no extra-nodal metastasis were present, 88 men (37.13%) were on HT whereas 15 (6.22%) had castration resistant prostate cancer (CRPC). ASA score was 3 in 63 (26%) patients. A super-extended lymphadenectomy, including retroperitoneal nodes was performed in 6 cases (2.49%). At final pathology, 85 patients (38.6%) had a GS ≥8, whereas local extra-prostatic extension (T stage ≥3) was diagnosed in 118 patients (48.96%). Surgical margins were positive in 89 patients (37.09%). Mean number of nodes removed and positive were 11.6±9.27 and 0.68±2.55, respectively. After a median follow-up of 36.8 months (IQ range 22.7-61.4), BCR had occurred in 104 patients (44.07%) and 16 patients (6.5%) developed CRPC. Overall survival (OS) was 92.95% and cancer specific survival (CSS) 95.85%. *Conclusion:* Salvage radical prostatectomy can yield promising oncological outcomes. Despite significant rates of BCR and positive surgical margins, OS and CSS prove relatively high on a short-medium term follow-up. To validate the present findings, longer follow-up and higher number of patients are needed.

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OPEN *VERSUS* ROBOT-ASSISTED SALVAGE RADICAL PROSTATECTOMY: A COMPARISON OF ONCOLOGICAL OUTCOMES IN A RETROSPECTIVE MULTICENTRE SERIES

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Introduction: Salvage radical prostatectomy (sRP) is a valid treatment option in men with biochemical recurrence (BCR) after primary treatment. Oncological outcomes of Robotic (R) and open (O) approaches have not been compared. We report and compare oncological outcomes of R and OsRP in a large contemporary series. *Materials and Methods:* We retrospectively analysed 376 men with BCR, who underwent sRP between 2000 and 2015 at 13 Tertiary referral centres. Age, PSA, clinical and pathological TNM, primary and pre-sRP biopsy and sRP gleason score (GS), surgical margins, imaging type and positive sites, lymphadenectomy template used, number of lymph-nodes removed and positive, ASA score and ECOG performance status and use of hormonal treatment (HT) were collected for each patient. Exclusion criteria were a follow-up<12 months or unavailability of the aforementioned data. Continuous variables were tested for normal distribution and then compared using Wilcoxon-Mann-Whitney test; differences in categorical variables were assessed by Chi-square or Fisher's exact tests. *Results:* We included 243 men. Primary treatments were: external beam radiation therapy in 69.5% of patients, cryotherapy in 3.7%, HIFU in 4.1%, brachytherapy in 21.4% and other primary treatments in 1.2% of the patients. No differences were observed regarding: pre-operative PSA (p=0.46), age (p=0.053), ASA score (p=0.06), patients receiving HT (p=0.22) and final pTNM (p=0.91) and mean number of pathologically positive nodes (0.9±3.0 in the OsRP *vs.* 0.3±1.2 in the RsRP group (p=0.1)). However, before sRP castration resistant prostate cancer (CRPC) was higher in the OsRP group (9.5% *vs.* 1.92%; p=0.01), sRP GS was ≥8 in 42% of OsRP *vs.* 32% of RsRP (p=0.04) and median follow-up was longer for OsRP (46.7 months, IQ range 30.2-81.1 *vs.* 27.9 months, IQ range 13.5-44.4, in the RsRP group; p<0.01). Surgical margins were focally or extensively positive in 12.59% and 24.4% of the OsRP group *vs.* 24.7% and 12.38% of the RsRP group (p<0.01). No significant differences were detected in BCR (46.62% of OsRP *vs.* 40.8% of RsRP p=0.4) or progression to CRPC (17.7% of

OsRP *vs*. 11.5% of RsRP; p=0.31). OS was higher for RsRP (98% *vs*. 88,9% for OsRP (p<0.01)) and CSS was 98% for RsRP and 94.1% for OsRP (p=0.057). Conclusions Salvage radical prostatectomy can yield promising oncological outcomes. The robotassisted procedure has similar BCR rates but can allow lower incidence of extensively positive surgical margins and may favour higher OS and CSS trends, compared to the open approach. To validate the present findings, a longer follow-up and a higher number of patients are needed.

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PRE-SURGICAL ASSESSMENT OF EXTRA-PROSTATIC INVASION USING PROSTATE MRI: UPDATE AFTER 400 CASES

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Introduction: Multi-parametric Magnetic Resonance Imaging (mp-MRI) allows for a precise local staging of prostate cancer (Pca). Specifically, seminal vesicles involvement and extra-prostatic extension are well predicted by this kind of imaging. Conversely, literature data are lacking concerning the relationship between tumor and prostate capsule. The aim of the study was to evaluate the ability of mp-MRI in identifying prostatic capsular invasion by matching the imaging with the histopathological analysis data. *Materials and Methods:* Since January 2015, 401 consecutive patients who were diagnosed with PCa suitable for robotassisted radical prostatectomy (RARP) and underwent preoperative mp-MRI were included. Mp-MRI consisted of T1 and T2 weighted sequences. Acquisition of images was performed with and without contrast enhancement. Radiological images were analyzed by dedicated uroradiologists. RARPs were performed by a single surgeon. Specimens were examined by a dedicated uro-pathologist. Classification of capsular involvement was assigned according to Wheeler (1). Both in cases of mp-MRI and histopathological analysis, location and extension of every lesion suspected for PCa were evaluated. Degree of invasion of prostate capsule was defined as reported in Table I. *Results:* Overall, 658 PCa lesions were identified at histopathological analysis. pT2a-b tumors were 16.9% (68); pT2c 52.2% (209); pT3a 20% (80); pT3b 10.9% (44). Mp-MRI correctly identified 90.6% (174/192) as rL0-1, 92.9% (79/85) as rL2, 95.7% (67/70) as rL3F and 100% (50/50) as rL3E 50/50 (100%) lesions. They were classified at histopathological analysis as L0-1, L2, L3F and L3E, respectively. Kappa Cohen coefficient was 0.857. We underline that the radiologists and the pathologist involved in the present study had consistent experience. *Discussion and Conclusion:* Our data seemed to confirm the accuracy of mp-MRI in predicting the degree of prostate capsular invasion, with excellent agreement with histopathological analysis.

1 Wheeler TM, Dilliogluglil O, Kattan MW, Arakawa A, Soh S, Suyama K, Ohori M and Scardino PT: Clinical and pathological significance of the level and extent of capsular invasion in clinical stage T1-2 prostate cancer. Hum Pathol *29(8)*: 856-862, 1998.

Table I. *Classification of capsular involvement according to Wheeler et al.*

Level of PCI	Histology	mpMRI
L0	Tumor confined to prostatic stroma within the boundary of normal prostatic acini	Tumor no more than 10 mm from the capsule without signs of alteration of that
L1	Tumor confined to prostatic stroma, but outside the boundary of normal prostatic acini	
L2	Tumor confined to the prostate but within a layer more fibrous than muscular, *e.g*. capsule	Tumor with little margin of contact with the capsule (less than 15 mm) or when prostate margini s redundant or retracted
L3f	Tumor outside the prostate to a depth of less than one high-power field on no more than two separate sections	Any mild irregularities of the fibrous capsule to outward extension
L3e	Any amount of extraprostatic tumor more than L3	Asymmetry of the neurovascular bundles and obliteration of recto-prostatic angle, direct evidence of abnormal tissue in the periprostatic adipose tissue, generally associated with disruption of the fibrous capsule

Table I. *Comparison of histopathological characteristics and complication rates between arm A (positive MRI) and arm B (negative MRI).*

	Biopsy approach	Patients #	Samples mean (SD)	PC # (%)	CS/total PC n/N (%) mm (IQR)	Total Cancer Core Lenght,	Complication # (%)
ARM A pos MRI	FB	98	5.1 (2.6)	59 (60.2)	55/59 (93.2)	17 (11-32)	3 (3.1)
neg MRI	SB	43	12 (0)	10 (23.2)	1/10 (10.0)	3 (2-3)	3 (7.0)
ARM B	SB	139	12 (0)	42 (30.2)	25/42 (59.5)	6 (2-21)	16 (11.5)
p-Value FB *vs*. SB			<0.0001	0.002	0.0003	0.0002	0.08

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STANDARD PROSTATE BIOPSY *VERSUS* MRI-FUSION BIOPSY: RESULTS AFTER TWO YEARS OF A PROSPECTIVE RANDOMIZED STUDY

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Introduction: With the introduction of multiparametric MRI it is nowadays possible to evaluate lesions suspicious for prostate cancer (PCa) and, thanks to dedicated softwares, to perform targeted biopsies MRI/TRUS fusion (FB). In patients who have already undergone a biopsy, this path is already coded and recommended by the guidelines. Scarce literature is available in the setting of biopsy-naïve patients. The aim of this randomized, prospective, two-arm, study was to evaluate the efficacy of a new diagnostic path based on MRI and on FB, comparing to diagnostic standard in biopsy-naïve patients. *Materials and Methods:* After the approval of the local Ethics Committee, all naïve patients suspected for prostate cancer (PSA <15 ng/ml, negative DRE, <75 years) were randomized into 2 groups using a computer-generated random allocation in a 1:1 ratio: Arm A (undergoing MRI) and arm B (not undergo MRI). The MRI study consisted of T2-weighted, diffusion-weighted and dynamic contrast-enhanced imaging, all lesions were classified according to PIRADS system. The patients were then biopsied as follows: - Arm A with positive mp-MRI (PIRADS score >3): MRI/TRUS fusion software-based targeted biopsy using the Biojet® system (D&K Technologies), carrying out at least 3 samples for suspected lesion; - Arm A with negative mp-MRI or lesion of low suspicion (PIRADS score <3) - Arm B: transrectal TRUS-guided systematic biopsy (SB) with 12 samples. PCa were considered clinically significant (CS) according to START consortium definition (for FB) and Epstein criteria (for SB). *Results:* During the period 09/2014 – 09/2016 280 patients were enrolled. Median age was 63 (49-74) years, mean PSA was 6.4 (+3.5) ng/ml. The patients' demographics were comparable in both arms and in the subgroups in arm A. Table I reports the preliminary results of the study. *Discussion and Conclusion:* In the reported study, the detection rate in Arm A was significantly higher than Arm B. These results were even more significant considering if CS PCa. In patients in arm A submitted to FB, results further improved. In patients in arm A submitted to SB, the probability of finding a CS PC was minimal. Although larger sample size is needed, this new diagnostic path based on MRI and FB technique seemed to be safer and more effective than the standard.

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CT2 KIDNEY CANCER: COULD BE MANAGED WITH AN ORGAN-SPARING APPROACH?

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Introduction: A nephron-sparing approach is recommended by the guidelines when embarking in the surgical management of T1 renal masses. But a paucity of data is available in Literature about partial nephrectomy (PN) for clinically-staged T2 (cT2) renal masses. The aim of the study was to evaluate perioperative, pathological and early functional outcomes of laparoscopic PN for cT2 renal tumors. *Materials and Methods:* All patients who underwent Laparoscopic PN between 06/2000 and 06/2016 were included in the analysis and retrospectively evaluated. All the surgical procedures were performed by the same surgeon. Demographics variables (gender, age, BMI and comorbidities, as classified by Charlson's Comorbidity Index) were evaluated; preoperative variables (side, size and surgical complexity of the lesion as classified by PADUA score), perioperative variables (blood losses, intra- and post-operative complications as classified by Clavien system) and hospital stay were considered. Concerning pathological variables, histology and positive surgical margins rate at final pathology were analyzed. Functional outcomes like serum creatinine (SCr) and estimated glomerular filtration rate (eGFR) were evaluated preoperatively and at discharge. *Results:* 21 patients were included in the present study: 14 of them (66.6%) were males, median age was 56 years (IQR 54-60), mean BMI was 24.4+3.34 and median CCI 2 (IQR 1-3). Lesions were right-sided in 42.8% (9/21), with a mean size of 76.5+11.1 mm and a median PADUA score of 10 (IQR 9-11). Two patients (9.5%) had solitary kidney. Concerning perioperative variables mean operative time was 131.4+40.9 min, with mean blood losses of 259.5+212.1 ml. Mean ischemia time was 22.4+13.1 min, 19% (4/21) of the procedures were performed without clamping of renal artery. Intraoperative complications rate was 9.5% (2/21). The rate of postoperative complications was 23.8% (5/21), with Clavien >3 complications recorded in 1 patients only. Median hospital stay was 7 (IQR 5-8) days. Concerning pathological findings, 13 lesions were malignant (61.9%). Positive surgical margins rate was 0% (0/21). No significant differences were found in terms of SCr and eGFR between the preoperative assessment and the discharge (crs: 1.03+0.17 *vs*. 1.19+0.26; GFR: 82.2+18.4 *vs*. 72.2+24.2, respectively, $p>0.05$). *Discussion and Conclusion:* The present study suggested that, if performed by experienced hands, an organ-sparing approach can be offered even in case of very large renal masses. In a cohort of cT2 renal masses, in our experience LPN offered satisfactory postoperative and functional outcomes, allowing for the preservation of kidney units if compared to the competitor radical nephrectomy. Further studies with larger sample size should confirm these findings and determine the real benefits over radical nephrectomy of an organ sparing approach.

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STRATEGICAL IMPLICATIONS OF THE INTRODUCTION OF AN ALTERNATIVE TREATMENT MODALITY (HIGH I NTENSITY FOCUS ULTRASOUND) IN A MULTIDISCIPLINARY TEAM

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Introduction: The critical evaluation of a new modality of treatment which employs a new technology has to be considered in the context of "Health Technology Assessment" (HTA). This analysis leads to documents whose utility is essential for both National Health System and the stakeholders, *i.e*. subjects who are interested in the technology itself and who can judge it from different point of view, varying from costs to clinical references. We considered the introduction of an alternative treatment modality, *i.e*. High Intensity Focused Ultrasound (HIFU) in the context of the Prostate Cancer Unit (PCU) in our Centre. PCU is a multi-disciplinary team (MDT), constituted by an Urologist, a Medical Oncologist and a Radiation Oncologist, who manages almost 100 case of prostate cancer (PCa) per year, according to the position paper of European School of Oncology. The capacity of offering to the patients the ordinary therapies and also alternatives, due to clinical experience of the Centre, plays a fundamental role for the correct management of PCa. The aim of the present study was to contextualize the results of the analysis among the strategies of MTD, also evaluating the social impact. *Materials and Methods:* We analyzed the patients affected by PCa, who were all evaluated by MTD in 2015. For the purpose of the study, we considered only low risk patients, according to Epstein's criteria. The available therapeutic alternatives in Our Centre were: radical prostatectomy (open or robotic) (RRP), radiation therapy (RT), active surveillance (AS) and HIFU. We compared our experience with those reported in literature, searching for the key words: "multidisciplinary team", "prostate cancer" and "High Intensity Focused Ultrasound". *Results and Discussion:* In our Centre 360 patients with PCa were evaluated by PCU in 2015. During the same year we executed 500 prostate biopsy, among these 146 pts were affected by low risk PCa. The partition of patients according to chosen treatment modality is described in Table I. *Conclusion:* Different treatment

Table I. *Division of patients followed by Prostate Cancer Unit according to treatment modality.*

N° PTS followed by PCU in 2015				360					
N° PTS with low risk PCA				146					
	Active surveillance 144			Prostatectomy 32		Radiation therapy 72			Alternative
	Inserted in 2015	1 year in 2015	4 years in 2015	RRP	RARP	3D-CRT	IMRT	VMAT	HIFU
N° PTS	31	27	86	17	15	3	59	10	11
% related to chosen treatment	-	-	-	53	47	4	82	14	100
% related to low risk PCA N PTS	21	-	-	12	10	2	41	6	8

PTS, Patients; RRP, retropubic radical prostatectomy; RARP, robotic-assisted radical prostatectomy; 3-D, 3-dimensional conformational radiation therapy; IMRT, image modulated radiation therapy; V-MAT, volumetric modulated arc therapy; HIFU, high intensity focus ultrasound; PCA, prostate cancer.

modalities may be offered to the patients after the diagnosis of PCa; obviously, every alternative may have both physical and psychological side-effects, all significantly impact on the quality of life. The management of the patient in the context of MDT may change, especially regarding therapy itself; this is due to the fact the decisions of the MTD are applicable and reproducible, according to the internal guidelines followed by all the members. Our MTD follows data literature, especially regarding the orientation towards AS and RT. Additionally, patients tend to chose RT during the PCU visits. There are no available data about the impact of MTD on survival, or about a correlation between the MTD and improvement of the outcome of the patients. Nevertheless, a clear idea about the overall survival of the single-treatment modality may lead to a more simple choose by the patients. In this context, we could not have certainties, because of the too recent follow-up, as well as the recent introduction of PCU in Our Center.

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SALVAGE HIGH INTENSITY FOCUS ULTRASOUND (HIFU) FOLLOWING PRIMARY BRACHYTHERAPY FOR PROSTATE CANCER: CASE REPORT AND LITERATURE REVIEW

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Introduction: The treatment of recurrent disease following primary brachytherapy (BT) for localized prostate cancer (PCa) is feasible, but nothing about this field is described in the literature. Theoretical therapeutic options may include salvage prostatectomy, salvage radio-therapy, hormonal therapy, observation and salvage HIFU. *Materials and Methods:* We report our experience with one patient with PCa treated with BT and retreated with HIFU because of local recurrence. We searched Medline using the key words "prostate cancer", "prostate barchytherapy", "salvage High Intensity Focus Ultrasound". *Results and Discussion:* A 69 year-old man, treated with BT because of prostatic adenocarcinoma Gleason 3+3 in another center, PSA 3.5 ng/ml. The patient did not describe any short- or long term complications, except erectile dysfunction. PSA progressively increased during years after the procedure, until it reaches 5.35 ng/ml. Thus, the patient executed HIFU. There were no short- or long-term complications. The man described mild urgency but no urinary incontinence. The PSA nadir was 0.48 ng/mL, 6 months after the salvage HIFU. The last PSA, 24 months after the treatment, was 0.48 ng/mL. No androgenic blockade was administered. He is still on follow-up. We did not find any paper about the sequential employment of BT and HIFU for the treatment of PCa. *Conclusion:* Salvage HIFU after BT is feasible, without significant short- and long-term complications. It allows a good control of PCa, granting a good quality of life for the patient. More trials are necessary to obtain some definitive conclusions. HIFU represents a chance of curing patients who refused surgery or are preferable not to be administered with androgenic blockade.

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SALVAGE HIGH-INTENSITY FOCUS ULTRASOUND (HIFU) FOLLOWING PRIMARY HIFU FOR PROSTATE CANCER MAY BE CONSIDERED AS AN ALTERNATIVE TREATMENT FOR LOCAL RECURRENCE

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Introduction: Recurrent disease following primary high-intensity focus ultrasound (HIFU) for localized prostate cancer (PCa) is feasible, but nothing about this field is described in the literature. Theoretical therapeutic options may include salvage prostatectomy, salvage radio-therapy, hormonal therapy, observation and salvage HIFU. *Materials and Methods:* We report our experience with three patients affected by PCa, treated with HIFU, and retreated with HIFU because of local recurrence. We also reviewed the literature, searching for the key words: "Prostate Cancer Recurrence", "Focal Therapy", "High Intensity Focus Ultrasound" and "Salvage Therapy". *Results and Discussion:* Case 1: A 69 year-old man, treated with trans-urethral resection of prostate (TURP) and HIFU because of prostate adenocarcinoma (ADK) Gleason 3+3, PSA 3.07 ng/ml. There were no short- or long term complications. PSA progressively increased during years after the procedure, until it reaches 5.94 ng/ml. He executed a Coline PET-CT with evidence of captation by the right lobe. A multiparametric Magnetic Resonance Imaging documented a lesion with diameters of 15×9×13 mm, in right median paramedian zone, with PI-RADS 5. Thus, the patient executed HIFU only in the right lobe. There were no short- or long term complications. The man described only mild urgency. The last PSA was 0.47 ng/ml, 20 months after the salvage HIFU. Case 2: 64 year-old man, treated with trans-urethral resection of prostate (TURP) and HIFU because prostate ADK Gleason 3+3, PSA 2.98 ng/ml. Additionally, the pathological report after TURP evidenced a prostate ADK Gleason 3+3 in the transitional zone, in <5% of the specimens. There were no short- or long term complications. Six years after the first HIFU the patient executed a prostate biopsy, with a PSA of 0.57 ng/ml. The pathological report documented a single core with prostate ADK Gleason 3+3, located in a different zone of the prostate comparing with the first biopsy. There were no short- or long-term complications. The last PSA was 0.93 ng/ml, 26 months after the salvage HIFU. Case 3: A 60 year-old man, treated with HIFU because prostate ADK Gleason 3+3, PSA of 6,4 ng/ml. The man reported significant pain during micturition and recurrent prostatitis; thus he used the sovra-pubic catheter during 2 months after the procedure. 48 months after HIFU, PSA was 1.28 ng/ml. Thus, the patient executed a second biopsy, with diagnosis of prostate ADK Gleason 4+4 in the left lobe. He executed salvage HIFU, describing urgency during the following months. 12 months after the second HIFU PSA was 4.05 ng/ml. Thus he underwent Imaging Modulated RadioTherapy with a total dose of 70 Gy. The last PSA was 2.38, with a coline CT-PET without recurrence. He is still in follow-up, still reporting urgency. No androgenic blockade was administered in all the cases. *Conclusion:* Salvage HIFU is a feasible therapeutic option for PCa recurrence after primary HIFU, with no or mild complications. It should be considered for patients who refuse surgery or radiotherapy, or for whom with contraindications for androgenic blockade. More trials are necessary to confirm these preliminary data.

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EN BLOC RESECTION OF NON-MUSCLE INVASIVE BLADDER CANCER: EXPERIENCE IN SANT'ANNA HOSPITAL –COMO-

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Introduction: The goal of traditional trans-urethral resection of bladder tumors (TURBT) is to remove all visible cancers and obtain tissue for pathological diagnosis, with minimal morbidity to the patient, even if the tumor is removed in piecemeal. Additionally, detrusor muscle (DM) is absent in up to 50% of cases. Moreover, residual disease is diagnosed in the final pathology in up to 76% of cases of the restaging TURBT. Recently, the urologists' approach to the management of superficial bladder cancer has been evolving and the basic principle of oncologic surgery of removing the entire tumor "*en bloc*" by dissecting through normal tissue to prevent the scatter of malignant cells and positive surgical margins is becoming more and more important. The aim of the present study is the description of both "*en bloc*" technique in Our Centre and the medium-term results of our single-center experience with "*en bloc* resection of bladder tumors" (ERBT) in a selected group of patients. *Materials and Methods:* We retrospectively analyzed the story of 24 patients consecutively underwent to ERBT. A single expert urologist executed the procedure using a mono-polar or bipolar Storz 24 Ch resector. The surgeon executed a "U-shaped" incision anteriorly to the lesion, with a mucosal margin of 3 mm, including macroscopically sane tissue. Thus, the incision was conducted in retrograde way going under the lesion, until obtaining a complete detachment from the bladder wall. Laterally, the incision included the margin of sane mucosa. The depth of the incision included the muscle layer. A trans-urethral catheter was positioned after the operation; the same was removed after 48 hours. We also compared our experience with data literature, searching for the key words: "*En bloc* resection", "Trans-urethral resection" and "Non Muscle Invasive Bladder Cancer". *Results:* We

enrolled 24 patients (21 males and 3 females); all showed a Non Muscle Invasive Bladder Cancer (NMIBC) urothelial carcinoma; among these, 3 had High grade NMIBC, 1 Carcinoma *in situ*, 1 PULMP, and 20 showed low grade NMIBC at the definitive pathology. All the ERBT samples showed the presence of DM. The mean age at diagnosis was 69 years (range 53-87), presenting with a mean tumor diameter of 8±3 mm and a median number of resected tumors per patients of 1 (range=1-3). In 7 cases the procedure (first in all patients) was associated with early instillation of epirubicin within 30 minutes after TUR. In 6 cases the ERBT was not the first TUR in the history of the patients. The mean follow-up was 25 months (range=7-60 months) and there was a recurrence rate in 7/24 patients, with low-grade final pathology. The main limitation of the study consists in the absence of a control group. *Conclusion:* Our findings confirmed the feasibility and safety of *en bloc* resection of bladder tumor, with a recurrence-free survival of 71%.

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THE ROLE OF MULTIPARAMETRIC RESONANCE IN THE MULTIDISCIPLINARY TEAM FOR PROSTATE CANCER

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Introduction: Multi-Parametric Magnetic Resonance Imaging (MP-MRI) may improve the detection of clinically significant prostate cancer (PCa). Thus, the examamination may be extremely useful in the context of multidisciplinary team (MDT) of prostate cancer unit (PCU). We analyzed the clinical significance of MP-MRI in the context of the PCU of our Centre during 2015. Additionally, we compared our experience with those reported in literature. *Materials and Methods:* We analyzed the story of patients (pts) followed by PCU, constituted by an Urologist, a Medical Oncologist and a Radiation Oncologist during 2015. All the patients executed MP-MRI. Moreover, we reviewed literature using Medline, Embase and Cochrane Library with the key words: "Prostate Cancer", "Multi-Disciplinary Team", "Multi-parametric Magnetic Resonance". *Results and Discussion:* One hundred and twenty pts with PCa were followed by PCU in 2015 in Our Centre. They all executed mp-MRI. The pts' main features were reported in Table I. The main indication for mp-MRI was surveillance because both of pre-neoplastic lesions, and elevated PSA level and active surveillance protocol itself (Figure 1). The clinical utility of MP-MRI, defined as the ability to change the management of the pts was about 57%. The details are reported in Table II. Since its beginning in 2014, the total cost of MP-MRI in the context of PCU was about €30.256,8. The mean annual cost was about €15.128.We considered these costs as adequate relating to the clinical advantages. According to the most recent literature, mp-MRI plays a fundamental role in the management of the pts by the MTD of PCU. *Conclusion:* Mp-MRI is an important exam for the diagnosis, therapy and follow-up of pts in the context of PCU. The costs are not so high and well balanced by the clinical advantages. Additional perspectives trials are necessary to confirm these data as well as Specialists dedicated PCa, including members of PCU, an Uro-Radiologist and a Pathologist.

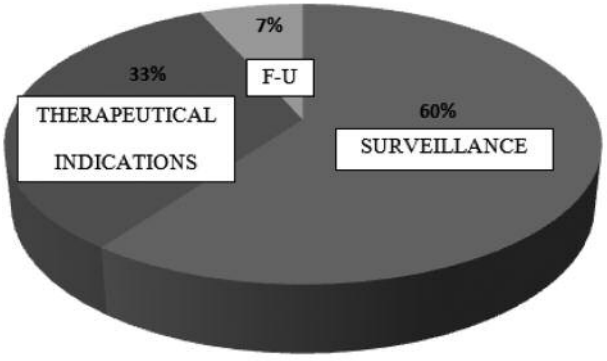

Figure 1. *Main indications for mp-MRI in Sant'Anna Hospital, Como, Italy.*

Table I. *Division patients with prostate cancer who executed magnetic resonance in the context of multidisciplinary team.*

Surveillance	N pts	Therapeutical indications	N pts	Follow-up	N pts
	72		40		8
Pre-neoplastic lesions	8	Radiation therapy	21	Radiation therapy	1
High PSA levels	32	Radical prostatectomy	12	Radical prostatectomy	2
Active surveillance	32	Bladder invasion from prostate cancer	1	HIFU 4	4
		HIFU	5	Brachytherapy	1
		Brachytherapy	1		

Table II. *Utility and usefulness of magnetic resonance in the context of multidisciplinary team for prostate cancer.*

Indications to exam	% Utility	% Usefulness
Surveillance	80% (58/72)	20% (14/72)
Therapy	8% (3/40)	92% (37/40)
Follow-up	100% (8/8)	0% (0/8)

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SPINDLE CELL SARCOMATOID CARCINOMA OF THE PROSTATE: AN EXCEEDINGLY RARE AND CHALLENGING OCCURENCE

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Introduction: Spindle cell lesions of the prostate are uncommon entities with a broad differential diagnosis, including mesenchymal neoplasms, metastasis and carcinomas (1). Morphological assessment of the benign or malignant nature of these lesions is also challenging. We describe here a case of "pure" spindle cell carcinoma of the prostate diagnosed on needle biopsy. *Patients and Methods:* A case of "pure" spindle cell sarcomatoid carcinoma of the prostate diagnosed on transrectal needle biopsy is here described. Clinical history and follow-up was reported. Immunohistochemical stains were performed by an automated immunostainer (ULTRAView, Ventana/Roche) using the following primary antibodies: cytokeratins (AE1/AE3), desmin, smoothmuscle-actin, S100, DOG1, CD31, CD34, NKX3.1, Ki67, PSA. *Results:* The patient is a 81 year-old male presenting with urinary obstructive symptoms and progressive increase of serum PSA (from 4.3 in 2014 to 15 ng/ml in march 2016). Prostatic examination revealed a firm and hard consistency of the right lobe. Trans-rectal biopsies (seven) in each lobe were performed demonstrating a "pure" spindle cell proliferation with irregular and hyperchromatic nuclei was observed in all samples from th right lobe, while the left lobe was negative. Spindled-shaped cells expressed pan-cytokeratins (AE1/AE3) but did not stain with desmin, smooth-muscle-actin, CD34, CD31, DOG1, S100 and PSA. Some nuclei stained with NKX3.1 and Ki67 proliferative index was 45%. A diagnosis of spindle cell sarcomatoid carcinoma (Gleason score: 5+5) of the right prostatic lobe was made. Since the patient was not eligible for surgery, he was treated with hormonal therapy leading to decrease of PSA (3.2 ng/ml) and he started the first cycle of radiotherapy. The patient is still alive with disease at 2 months' follow up. *Discussion and Conclusion:* Sarcomatoid carcinoma is a rare type of prostate cancer representing <1% of all prostate neoplasms (1, 2). It is usually diagnosed on surgical specimen and shows a conventional acinar component akin to a sarcomatoid part with blending of the two in various areas, but "pure" spindle cell carcinoma is still rarer (1, 2). Patients with sarcomatoid carcinoma have a dismal prognosis and the tumor can develop in the absence of PSA elevation (3). Differential diagnosis includes benign and malignant sarcomas (solitary fibrous tumor, angiosarcoma, leiomyoma/ leiomyosarcoma, stromal sarcoma), inflammatory myofibroblastic tumor, metastatic gastrointestinal stromal tumor (GIST) and desmoplastic melanoma. Immunostains are mandatory to reach the correct diagnosis and NKX3.1 expression is superior to PSA to indicate the prostatic origin. The management of sarcomatoid carcinoma of the prostate has no standard treatment recommendations and operable tumors should be treated with surgery. Hormonal treatment and radiotherapy seems to be effective in unresectable tumors. To the best of our knowledge, this is the first example of "pure" spindle cell sarcomatoid carcinoma lacking an acinar component and diagnosed on needle biopsy.

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ECONOMICAL IMPLICATIONS OF THE INTRODUCTION OF AN A LTERNATIVE TREATMENT MODALITY FOR PROSTATE CANCER (HIGH-INTENSITY FOCUS ULTRASOUND) IN A MULTIDISCIPLINARY TEAM

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Table I. *Division of patients followed by Prostate Cancer Unit according to treatment modality.*

N° PTS followed by PCU in 2015				360					
N° PTS with low risk PCA				146					
	Active surveillance 144			Prostatectomy 32		Radiation therapy 72			Alternative
	Inserted in 2015	1 year in 2015	4 years in 2015	RRP	RARP	3D-CRT	IMRT	VMAT	HIFU
N° PTS	31	27	86	17	15	3	59	10	11
% related to chosen treatment	-	-	-	53	47	4	82	14	100
% related to low risk PCA N PTS	21	-	-	12	10	2	41	6	8

PTS, patients; RRP, Retropubic Radical Prostatectomy; RARP, Robotic-Assisted Radical Prostatectomy; 3-D, 3-Dimensional Conformational Radiation Therapy; IMRT, Image Modulated Radiation Therapy; V-MAT, Volumetric Modulated Arc Therapy; HIFU, High-intensity Focus Ultrasound; PCA, prostate cancer.

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Introduction: The critical evaluation of a new modality of treatment which employs a new technology has to be considered in the context of "Health Technology Assessment" (HTA). This analysis lead to documents whose utility is essential both for National Health System and the stakeholders, *i.e.* subjects who are interested in the technology and who can judge it according different point of view, varying from costs to clinical references. We analyzed the economic impact of the introduction of an alternative treatment modality, *i.e.* High Intensity Focused Ultrasound (HIFU) in the context of the Prostate Cancer Unit (PCU) in our Centre. The PCU is a multidisciplinary team (MDT), constituted by an Urologist, a Medical Oncologist and a Radiation Oncologist, who manage almost 100 case of prostate cancer (PCa) per year, according to the position paper of European School of Oncology. The capacity of offering to the patients both the common and the alternative treatment modalities, related to clinical experience of the Centre, plays a fundamental role for the correct management of patients with PCa. *Materials and Methods:* We retrospectively analyzed all the patients affected by Pca and evaluated by PCU during 2015. We selected low risk patients, according to Epstein's criteria. Thus, we calculated and compared the costs of the four treatment modalities available in Our Centre for these pts: active surveillance according to PRIAS (AS), radical prostatectomy (open –RRP- or robotic – RARP-), radiation therapy [3D-conformational (3D-CRT), Imaging Modulated Radiation Therapy (IMRT), Volumetric Modulated Arc Therapy (VMAT), with or without markers] and HIFU. We also reviewed the literature searching for the following key words: "prostate cancer", "active surveillance", "prostatectomy", " radiation therapy", "HIFU" and "costs". *Results:* In our Centre 360 patients with PCa were evaluated by PCU in 2015. During the same year we executed 500 prostate biopsy, among these, 146 pts were affected by low risk PCa. For partition of patients, according to chosen treatment modality, is described in Table I. The costs of every treatment are reported in Table II. *Conclusion:* RT represents the most frequent treatment modality for low risk PCa in Our Centre. The costs are intermediate between AS (considering the whole time of 7 years) and the robotic surgery (€8,000, €8,300 and €12,000, respectively). According to both literature and clinical experience of other centers, the RARP showed the highest costs. The literature review about HIFU did not evidence any study about the efficacy; consequently we focuses on costs only, which are inferior to other treatments, including RRP.

Table II. *Costs of every treatment modality.*

Treatment modality	Cost (€ per patient)
Active surveillance	
First year	1960.49
Seventh year (end of protocol)	8312.36
Radical prostatectomy (including hospital recovery)	
Open	5674.28
Robotic	9836.14
Radiation therapy	
3D-CRT without markers	6494.98
3D-CRT with markers	8978.63
IMRT without markers	6349.48
IMRT with markers	8833.55
V-MAT without markers	10000
V-MAT with markers	10000
HIFU (including and hospital recovery)	4427.18

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THE ROLE OF MAGNETIC RESONANCE OF PROSTATE IN PATIENTS WITH HIGH GRADE PROSTATIC INTRAEPITHELIAL NEOPLASM AND ATYPICAL SMALL ACINAR PROLIFERATION

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Introduction: Men diagnosed with High Grade Prostatic Intraepithelial Neoplasm (HGPIN) and Atypical Small Acinar Proliferation (ASAP) are usually counselled to undergo re-biopsy because of the variable risk of prostate cancer (PCa). Multiparametric Magnetic Resonance of the prostate (mpMRI) may offer an opportunity to verify the specific areas in the prostate and eventually to target subsequent biopsy in this group of patients. *Materials and Methods:* In our Centre, we use 1.5 T mpMRI incorporating a 16-channel surface coil. Two dedicated Uroradiologists evaluated the exams, which included T2-weighted, diffusion weighted and dynamic contrast enhanced imaging. The reports referred to PI-RADS 1.0 scoring system. We retrospectively analyzed the use of mpMRI in monitoring patients with previous diagnosis of HGPIN and ASAP since 2014 up to august 2016. Additionally, we compared our experience with literature data in Pubmed, searching for the key-words: "High Grade Prostatic Intraepithelial Neoplasm", "Atypical Small Acinar Proliferation", "Multiparametric Magnetic Resonance", "prostate" and "Biopsy". *Results and Discussion:* We identified a total of 10 pts, divided into 3 groups: a) 5 pts with HGPIN, b) 3 with ASAP and c) 2 with ASAP and HGPIN together. The characteristics of the patients were reported in Table I. According to literature (based on trials conducted with sextant techniques), 40% of men with ASAP are diagnosed with PCA on the first rebiopsy. Because no clinical variables are able to predict which men with ASAP are at higher risk, current guidelines suggest to perform re-biopsy in 3 to 6. PCa is found in the same sextant as original ASAP in 48% to 57% of cases but, in contrast, in the contro-lateral lobe of the prostate in 17%. However, because the exact biopsy location can only be estimated by conventional TRUS guidance, it is strictly operator-dependent. In this context, mpMRI is a promising technique for PCa detection , also because the exam is specifically validated in the setting of active surveillance. Additionally, this cohort of patients lays in the "Grey Zone PSA Level and prior negative biopsy" (PSA 2.5-10 ng/ml). *Conclusion:* These preliminary results suggest that mp-MRI could be a valid technique in order to refer or to avoid PBx in patients with diagnosis of HGPIN or ASAP.

Table I. *Division of groups of patients who executed Multiparametric Magnetic Resonance in order to follow-up ASAP and/or HGPIN in Sant'Anna Hospital, Como, Italy.*

Group A: HGPIN						
Pts	Age	First PSA	Nr PBx	N + cores	PiRADS	RM Utility
Pts 1	68	6.8	2	2	0	CTRL
Pts 2	68	4.89	4	1	2	CTRL
Pts 3	72	5.3	2	2	0	CTRL
Pts 4	77	4.26	1	1	0	CTRL
Pts 5	69	7.4	2	2	5	2nd PB: PCa. PiRADS 5 in the same region of PCa (right apex)
Group B: ASAP						
Pts 1	65	5.3	2		1	CTRL
Pts 2	77	3.95	2	1	5	1nd BX: PCa. PiRADS 5 in the same region of PCa
Pts 3	58	3.4	1	2	0	CTRL
Group C: ASAP + HGPIN						
Pts 1	59	7.4	2	HGPIN and ASAP in 1 in left apex	4 (left median and apex)	3 BX, negative
Pts 2	70	3.6	1	HGPIN (2 right lateral and apex) ASAP in right apex	0	CTRL

BX: Biopsy; CTRL, control; PCa, prostate cancer.

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METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC) PATIENTS LONG TERM RESPONDERS (LTR) TO THE A NEW AGENT (NA)-BASED SECOND LINE: CLINICAL OUTCOMES AND PROGNOSTIC FACTORS OF SUBSEQUENT TREATMENT WITH ANOTHER NA

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Background: Three NA [abiraterone acetate (AA), cabazitaxel (CABA), or enzalutamide (ENZ)] are able to significantly prolong their overall survival (OS) after docetaxel failure. A quote of pts can obtain a prolonged disease control over 12 months with a second line NA and it is unclear if a clinical benefit may result from a subsequent treatment with another NA. The present study is aimed to assess the clinical outcomes and prognostic factors of subsequent NA treatment in those pts LTR to a second line NA. *Patients and Methods:* We collected data of pts who received sequentially twoNAs after DOC. For each pt we recorded the clinical outcome of treatments received after DOC. We consider as LTR pts without progression over 12 months from the start of the NA second line. We assessed the independent prognostic value of a series of third-line baseline covariates, in terms of progression free survival (PFS) and OS by Cox regression analysis. *Results:* A consecutive series of 476 mCRPC pts received a NA-based second line: AA (261 pts), CABA (151), and ENZ (64): we identified 116 LTR pts (AA 71 – CABA 28 – ENZ 17). All pts received a subsequent NA-based third line: 27 received AA, 59 CABA, and 30 ENZ. Comparing the third-line outcomes of LTR and no-LTR pts, no statistically significant differences were observed in terms of both biochemical and objective response rate, and PFS, while LTR showed a statistically significant longer OS (median 18 *vs.* 11.4 mos; $p<0.0001$). The third line OS was statistically significant different ($p=0.01$) according to the sequence adopted (see Table).

Second line	Third line	Median third line OS
AA or ENZ	ENZ or AA	10.5
AA or ENZ	CABA	17.7
CABA	AA or ENZ	26.3

AA, abiraterone acetate; CABA, cabazitaxel; ENZ, enzalutamide.

At the multivariate analysis, performance status (PS) and the presence of visceral metastases were independent prognostic factors for PFS in third line, while PSA, PS and lactate dehydrogenase were independent prognostic factors for OS. *Conclusion:* In our experience, NA-based third line is active also in mCRPC LTR population with highest benefit in sequences with CABA and some factors may help in selecting patients with higher probability of achieving a disease control.

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PROGNOSTIC VALUE OF NEUTROPHIL–TO–LYMPHOCYTE RATIO (NLR) IN METASTATIC CASTRATIONRESISTANT PROSTATE CANCER (MCRPC) PATIENTS RECEIVING A NEW AGENT (NA)-BASED THIRD-LINE TREATMENT. FINAL RESULTS FROM A MULTICENTER ITALIAN STUDY

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Background: High NLR has been reported to be a poor prognostic indicator in both first and second mCRPC lines, while no information is available concerning this issue in pts treated in third line therapy. The present study is aimed to assess the possible relationship between third line clinical outcomes and NLR in a series of mCRPC pts treated with a NA [abiraterone acetate (AA), cabazitaxel (CABA), or enzalutamide (ENZ)] after the failure of docetaxel (DOC) and another NA. *Patients and Methods:* We collected data of pts who received sequentially two NAs after DOC in 38 Italian hospitals. For each pt we recorded the clinical outcome of all treatments received after DOC. Cox regression analysis was used to assess the independent prognostic value of a series of pretreatment covariates, in terms of overall survival (OS), comprising NLR. *Results:* A consecutive series of 476 mCRPC pts with bone (86%), nodal (56%) or visceral (15%) mets, was collected. All pts received a NA-based third line: 135 received AA, 221 CABA and 120 ENZ. Data on NLR were available for 398 pts (84%). In the univariate analyses, the NLR as a discrete variable dichotomized according to the Maximally Selected Log-Rank statistics (optimal cut-off: 3.66), was significantly associated with both OS and progression free survival (PFS), calculated from the third line start ($p<0.0001$). At the multivariate analysis, NLR, performance status, pain, hemoglobin, alkaline phosphatase, treatment with AA and with CABA were independent prognostic factors for PFS, while NLR, performance status, hemoglobin, PSA, and lactate dehydrogenase were independent prognostic factors for OS. In Kaplan-Meier analysis, the median OS from the start of third-line was higher (14.2 *vs*. 9.3 mos) in pts with NLR ≤3.1 compared to those with NLR >3.1 (log-rank; $p<0.0001$). Similarly, the median PFS was 5.5 and 3.8 (log-rank; $p<0.0001$) in pts with NLR ≤3.66 and >3.66, respectively. *Conclusion:* Our results, observed in the largest cohort of mCRCP pts treated with NA-based third line after DOC and another NA, confirms that NLR is an independent factor for PFS and OS also in this population.

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