

(clinical T-stage, PSA and Gleason score) (AUC=0.685; 95%CI 0.630 to 0.736; $p<0.0001$) in the prediction of HRR. *Conclusion:* The biopsy laterality as replacement of clinical T stage contributes significantly to improve the value of NCCN criteria for predicting subjects at HRR.

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EVALUATION OF POSTOPERATIVE RADICAL CYSTECTOMY COMPLICATIONS: A MODIFIED CLAVIEN CLASSIFICATION SYSTEM ANALYSIS

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Introduction: The modified Clavien classification system has been proposed to classify and grade complications in general

surgery and in the last years it is increasingly becoming a popular method in urology. Aim of our study was to evaluate the applicability of the modified Clavien classification system (CCS). *Patients and Methods:* A consecutive series of patients with primitive or recurrent bladder cancer treated with radical cystectomy from April 2011 to August 2011 at eleven academic centres in Europe were evaluated for complications occurring up to the end of the first postoperative month. Variables analyzed for each patient were: age, sex, asa score, anticoagulation therapy, type of diversion, operation time, preoperative hydronephrosis and BMI All complications were prospectively recorded and classified according to the modified CCS. Results were presented as complication rates per grade. Chi-square and Kruskal Wallis tests and binary logistic regression analysis were used for statistical analysis. *Results:* 194 patients were prospectively enrolled. Mean age was 57.8±12.7 years; mean BMI was 21.5±2.3 Kg/m². Mean bladder tumors size was 3.6±3.7 cm, mean number of bladder lesions was 2±2. All patients underwent radical cystectomy. Urinary diversion consisted in orthotopic neobladder in 44 patients (23%), ileal conduit in 89 patients (46%) and ureterocutaneostomy in 61 patients (31%). Mean operative time was 307±55 minutes. Mean hospital stay was 14.5±2.4 days. 185 complications were recorded in 123 patients. Overall perioperative morbidity rate was 63%. Most of them were not serious and were classified as Clavien type I (51 cases; 27.5%) or II (91 cases, 49%). Higher grade complications were observed: Clavien type IIIa in 15 cases (8%), IIIb in 18 cases (10%); IVa in 5 cases (3%), IVb in 2 cases (1%) and V in 3 cases (1.5%). Reoperation rate was 8% (16 patients) for severe wound infection (4 patients), urinary anastomosis leakage (4 patients) and ileal perforation or occlusion (7 patients). Patients who underwent ileal conduit urinary diversion presented a higher rate of CCS type I complications (58%) when compared to other urinary diversions ($p=0.034$). No significant association was found between Age, BMI, ASA score, anti-coagulant treatment, preoperative hydronephrosis, operative time, hospital stay and CCS type I or ≥IIIb complications. Patients with CCS complications type II and IIIa presented a significant longer operative time and hospital stay in univariate and multivariate analysis ($p=0.01$) (Table I).

Table I.

	CCS type II			CCS type IIIa		
	Yes	No	p	Yes	No	P
Operative time (m)	338±108	294±111	0.000	379±126	309±109	0.031
Hospital stay (day)	16.8±5	12.9±5	0.000	20.4±9.3	14.29±6.2	0.021

Discussion and Conclusion: The modified CCS represents a practical and easily applicable tool that may help urologists to classify the complications of radical cystectomy and urinary diversion in a more objective and detailed way. In our experience, using this CCS tool, radical cystectomy is associated with a higher morbidity (63%), an 8% reoperation rate and a 1.5% of mortality. Ileal conduit urinary diversion has a higher rate of type I complications. Longer operative time and longer hospital stay are associated with a higher risk of post operative complications.

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UPDATE OF THE SIURO-PRIAS-ITA PROJECT, THE ITALIAN EXPERIENCE IN THE PRIAS INTERNATIONAL COLLABORATIVE STUDY ON ACTIVE SURVEILLANCE

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Introduction and Background: Active Surveillance is being validated worldwide as an alternative to radical treatment (surgery, radiotherapy and brachytherapy) for low risk prostate cancer (PC). The aim of the study is to deal with the issue of overdiagnosis resulting from PSA based opportunistic screening, limit overtreatment potentially indolent PC and avoid therapy-induced side-effects. On these assumptions the SIURO-PRIAS-ITA project started enrolment in PRIAS (Prostate Cancer Research International: Active Surveillance), the international study on observational strategy in low risk prostate cancer patients coordinated by the Erasmus University Medical Center in Rotterdam, in December 2009. *Patients and Methods:* Eligibility criteria for SIURO-PRIAS-ITA: PSA 10 ng/ml, Gleason Score 6 or Gleason 3+4 in over 69 yr men with <10% positive cores, T1c or T2, PSA density 0.20, max 2 positive bioptic cores (<10% positive cores in case of saturation biopsy), biopsy samples according to the volume (8 for 0-40, 10 for 40-60 and 12 for >60 ml), pathologic review of diagnostic biopsy. At inclusion extensive information on the disease, comorbidities, education, habits are collected and three questionnaires administered: IPSS, IIEF and FACTP. Despite the well known problems of misinterpretation of PSA values, biopsy-induced sequelae and biopsy-resulting false negative/positive reports, follow-up is still based on PSA every 3 months, clinical evaluation every 6 months, evaluation of PSA doubling time (DT), rebiopsy at 12, 48 and 84 months and possible extra biopsy (*i.e.* if PSA DT between 3 and 10 years). Exit criteria: 3 yr PSA-DT, upsizing and/or upgrading at the rebiopsy (Gleason 3+4 is accepted in over 69 yr men with <10% positive cores). *Results:* From December 2009 to March 2012, 255 patients from 8 Italian centers entered the study; mean age was 65.6 years (min 49 max 80); iPSA was <3 ng/mL in 10.6 % patients, between 3 and 6 ng/ml in 54.5%, between 6 and 8 in 27% and >8 in 7.9%. 222 patients are still on protocol with a median follow-up of 16.6 months (min 2 max 39); 33 discontinued active surveillance based on protocol or personal decision. Reasons for discontinuation were upgrading at rebiopsy in 4 cases, upsizing in 9 and upgrading plus upsizing in 5, PSA DT <3 years in 2 cases, other causes in 2 cases (a patient on follow-up for bladder cancer in a center not participating in SIURO-PRIAS-ITA was erroneously prescribed hormonal therapy; a patient could not stop anticoagulants and repeat biopsy), personal choice in 11 patients. *Discussion and Conclusion:* Active Surveillance is proving an acceptable alternative for patients with low risk PC, which might harbour an indolent PC and thus overtreatment and treatment induced toxicities can be avoided. Unfortunately, the definition of