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PATHOLOGICAL OUTCOMES IN PATIENTS CANDIDABLE FOR ACTIVE SURVEILLANCE TREATED WITH RADICAL PROSTATECTOMY. ARE THEY REALLY LOW RISK PATIENTS?

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Aim of the study
Over-diagnosis and over-treatment are potential side effects of PSA screening policies for prostate cancer (PCa). Active surveillance (AS) has evolved as an alternative to active treatment in case of low-risk PCa, to minimize side effects. Several protocols of AS has been proposed, based on standardized clinical parameters such as Prostate Cancer Research International Active Surveliance (PRIAS) criteria. Nevertheless in patients in AS the real pathological stage remains unknown. The aim of our study is to retrospectively make out the pathological stage in a multicenter cohort of patients who had undergone radical prostatectomy (RP) meeting the preoperative PRIAS criteria.

Materials and methods
Out of 923 patients recruited for minimally invasive RP between December 2009 and February 2013 in 5 Italian urological centers, 144 (15.6%) would have met the PRIAS criteria modified (clinical stage T1c/T2, PSA < or =6). The pathological features of these low risk patients have been investigated.

Results
The preoperative patients' characteristics are shown in table 1. Out of 144 patients included, 89 (61.8%) underwent laparoscopic RP and 55 (38.2%) robot-assisted RP. At pathological evaluation, Gleason score upgrade was reported in 40.9% of patients; 47 (32.6%), 11 (7.6%), 1 (0.7%) patients showed RP Gleason sum 7, 8 and 9, respectively. 15 (10.4%) and 4 (2.7%) patients had T3a and T3b pathological stage respectively. One patient showed lymph node invasion. 31 patients (20.9%) had positive surgical margins, of these 11 (35.5%) were multifocal. The positive surgical margin rate for pT2 and pT3 disease was 16.8% and 52.6%, respectively.

Discussion
AS is a well established standard approach for low risk localized prostate cancer. However, probably due to the poor reproducibility of the clinical tools, significant diseases can be under-diagnosed or missed. Analysing the pathological features on definitive specimens, some of these low risk patients demonstrated a migration in to intermediate or high risk groups according to D'Amico classification. Despite the preoperative estimated low risk of these patients, the rate of positive surgical margins was not negligible, particularly in pT3 stage.

Conclusions
Notwithstanding some preoperative criteria can define patients affected by PCa as low risk patients, at the pathological evaluation some of these revealed intermediate-high risk disease. So, based on our data, patients candidated to AS should be carefully counseled on possible disease understaging.

Table 1. Preoperative characteristics of patients

CHARACTERISTICS (n=144)	
Age, yr, median (IQR)	65 (60-69)
Preoperative PSA level, ng/ml, median (IQR)	5.3 (3.95-6.87)
Biopsy Gleason score, %	
<6	17.4
=6	82.6
Clinical stage, %	
T1c	70.1
T2a	13.2
T2b	11.1
T2c	5.6
Positive cores, no. (%)	
1	45.1
2	54.9
Number of patients meeting PRIAS criteria in each centre, median (IQR)	28 (22-44)

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SIURO-PRIAS-ITA PROJECT: UPDATE OF THE ITALIAN EXPERIENCE IN THE PRIAS INTERNATIONAL STUDY

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Aim of the study
Active Surveillance (AS) is being confirmed worldwide as an alternative to radical treatment (Prostatectomy/ Radiotherapy/Brachytherapy) for low risk prostate cancer (PCa). The aims of AS are to deal with the issue of overdiagnosis resulting from PSA based opportunistic screening, to limit overtreating of potentially indolent PCa and to avoid/delay therapy-induced side effects. Based these assumptions, in December 2009 the SIUrO-PRIAS-ITA project started including PCa patients in PRIAS (Prostate cancer Research International: Active Surveillance), the international study coordinated by the Erasmus University Medical Center in Rotterdam. We here report on the SIUrO-PRIAS-ITA experience.

Materials and methods
Eligibility criteria are iPSA≤10ng/ml, Gleason Score≤6 or Gleason 3+4 in>69 years old with60 ml), pathologic review of diagnostic biopsy. Follow-up is based on PSA every 3 months, clinical evaluation every 6 months, evaluation of PSA doubling time (PSA DT), re-biopsy at 12, 48 and 84 months and possible extra biopsy (if PSA DT is between 3 and 10 years). Exit criteria are PSA DT≤3 year, upgrading or upsizing at the re-biopsies. Active Treatment Free Survival (ATFS) was assessed using Kaplan-Meier survival analysis.

Results
From December 2009 to April 2013, 378 patients from 8 Italian centres entered SIUrO-PRIAS-ITA. Figure 1a shows enrolment grouped by centre. Mean age at diagnosis was 67 years (SD=7 yrs), mean PSA was 5.4 ng/ml (SD=1.9 ng/ml) and mean volume was 53 cc. The mean number of total cores sampled in the diagnostic biopsy was 15 (min 8– max 40), 95% of patients had clinical stage equal to T1c and 73% reported one positive core at diagnostic biopsy. 283/378 patients are still on AS protocol with a median follow up of 18 months (min 2 months – max 40 months). 95 patients discontinued AS based on protocol or personal decision; reasons for discontinuation are reported in Figure 1b. ATFS at two years follow up is 67% (Fig 1c).

Discussion
AS is proving an acceptable alternative to radical therapies for patients with low risk PCa, who might harbor an indolent PCa thus avoiding overtreatment and treatment induced toxicities. Unfortunately, the definition of indolent cancer is still cloudy and it is still not possible to distinguish between aggressive PCa, which needs immediate treatment, and non aggressive PCa. For this reason AS should be carried on within protocols with well defined criteria for inclusion, follow up management and discontinuation.

Conclusions
The follow up phase should be organized according to a precise scheme to guarantee high standard of care and switch to therapy, should any modification in the clinical situation occur. Every effort should be made to systematically check adherence to the protocol criteria and limit the number of patients lost at follow up.

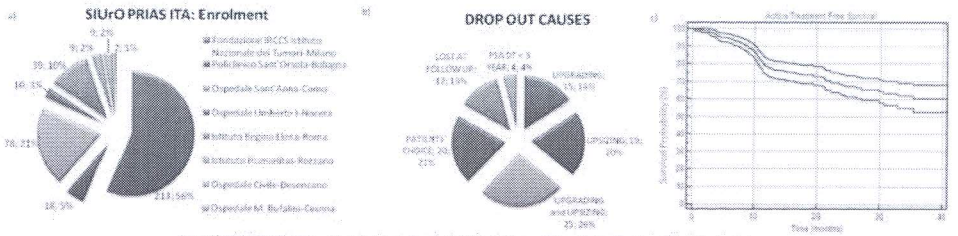

Figure 1: PRIAS SIUrO -ITA enrolment grouped by Centre (a), exit causes (b) and Active Treatment Free Survival (c)