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ORIGINAL PAPER

Morbidity following transperineal prostate biopsy: Our experience in 8.500 men

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Summary *Introduction: To evaluate clinical complications following transperineal prostate biopsy in 8.500 patients.*

Materials and methods: From January 2000 to January 2022, 8,500 men (median age: 62.8 years) underwent transperineal prostate biopsy; since 2011, 1,850 patients were submitted to mpMRI and in the presence of a PI-RADS score ≥ 3, a transperineal targeted biopsy was added to systematic prostate biopsy (4 cores). All patients underwent antibiotic prophylaxis (2000-2011: levoxacin 500 tablet; 2012-2022: 2 grams intravenous of cefazolin). Among 8.500 men 1.350 (15.8%) vs. 4.520 (53.3%) vs. 2.630 (30.9%) underwent 12 vs. 18 vs. > 24 needle cores, respectively. The prostate biopsy-related complications were evaluated within 20 days from prostate biopsy; the number of patients who needed hospital admission or emergency department visit (EDV) was recorded.

Results: Prostate cancer was found in 3.150/8.500 (37.1%) patients; overall, hospital admission and EDV were equal to 1.5% and 8.9% and the side effects were directly correlated with the number of needle cores resulting equal to 17.4% (12 cores), 38.7% (18 cores) and 55.3% (> 24 cores) (p = 0.001). Hospital admission and EDV in men who underwent 12 vs. 18 vs. > 24 cores occurred in 1.5% and 7.4% vs. 1.4% and 8.7% vs. 1.7% and 10.6% (p > 0.05), respectively.

Conclusions: Clinical complications following transperineal prostate biopsy involved 35.9% of the patients but only 1.5% of them required hospital admission; urinary tract infection with fever was the most frequent cause of hospital recovery (33.4% of the cases), but none of the patients developed sepsis.

KEY WORDS: *Prostate cancer; Transperineal prostate biopsy; Prostate biopsy; Complications; Sepsis.*

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INTRODUCTION

Prostate cancer (PCa) is the most frequent tumor diagnosed in men with about 2 million procedures carried out in the *United States* and *Europe* every year (1). Although it has an overlapping detection rate for PCa with respect to transrectal procedure, transperineal biopsy is recommended as the first-choice technique for diagnosis of prostate cancer owing to lower rates of post-procedural sepsis in comparison with transrectal approach (2-4). Although the use of targeted antibiotic therapy obtained by rectal swab culture and rectal preparation with povidone-iodine decrease the risk of infections and/or sepsis after transrectal prostate biopsy, it remains higher than after transperineal approach because of bacterial resistance to antibiotics (5). In fact, in case of transrectal biopsy the risk of complications requiring hospital admission ranges from 0.1% to 2.5% (6) being in most of the cases secondary to *urinary tract infection* (UTI), fever or sepsis. In addition, transperineal prostate biopsy improves the detection of *clinically significant prostate cancer* (csPCa) located in the anterior zone of the gland especially in men submitted to repeated biopsies or enrolled in *Active Surveillance* (AS) protocols (7, 8).

In this study, the clinical complications following prostate biopsy in 8.500 patients submitted to transperineal approach in more than twenty years of clinical practice have been retrospectively evaluated.

MATERIALS AND METHODS

From January 2000 to January 2022, 8.500 men aged between 38 and 96 years (median age: 62.8 years) underwent prostate biopsy under the suspicion of PCa. The indications for biopsy were: abnormal digital rectal examination, PSA >10 ng/mL or PSA values between 4.1-10 ng/ml, and 2.6-4 ng/ml with Free/Total PSA < 25% and < 20%, respectively; moreover, 175 men enrolled in AS protocol underwent scheduled repeated biopsies. Since 2011, 1.850 patients were submitted to mpMRI for initial (1.100 cases) and repeated (750 cases) procedure; 5.550 (65.3%) *vs.* 2.950 (34.7%) men underwent initial vs. repeated prostate biopsy. After institutional review board and ethical committee approval were granted the informed consent was obtained from all individual partecipants included in the study. In the presence of a *Prostate Imaging-Reporting and Data System-version* 2 (PI-RADS) score ≥ 3, a transperineal mpMRI/TRUS fusion targeted biopsy (TPBx: 4 cores for each suspicious area) was added to systematic prostate biopsy (8, 9). All mpMRI examinations were performed using a 1.5 or 3.0 Tesla scanner (*ACHIEVA 3T; Philips Healthcare Best, the Netherlands*) equipped with: a 16-channel phased-array coil placed around the pelvic area with the patient in the supine position, a multi-planar turbo spin-echo T2-weighted, an axial diffusion weighted imaging and an axial dynamic contrast enhanced MRI.

All the data were collected using the START criteria (10).

In the case of initial or repeated procedure an extended (ePBx: 12-18 cores) vs. a saturation transperineal biopsy (SPBx: 24 cores) was done (9). From 2002 to 2009

No conflict of interest declared.

prostate biopsy was performed under local anesthesia (2% lidocaine 10-20 mL) and from 2010 to 2022 under sedation; SPBx was always performed under sedation in surgery room. The patients underwent antibiotic prophylaxis assuming one tablet of levofloxacin (500 mg daily) for 3 days beginning the day before biopsy from 2000 to 2011; from 2012 to 2022 the patients underwent a single intravenous dose of 2 grams of cefazolin. In men with previous endocarditis or with artificial cardiac valve a single dose of penicillin plus aminoglycoside was administered before biopsy. Anticoagulant drugs (i.e., dicumarol) were stopped 5-7 days before biopsy and replaced with a daily dose of low molecular weight of heparin.

Prostate biopsy was performed transperineally (8, 10) using a freehand technique, a tru-cut 18 gauge needle (*Bard; Covington, GA*) and a GE Logiq 500 PRO and P6 ecograph (*General Electric; Milwaukee, WI*) supplied with a biplanar transrectal probe (5-6.5 MHz); the TPBx was performed transperineally using using a Hitachi 70 Arietta ecograph, (*Chiba, Japan*) supplied with a bi-planar transrectal probe (8). The prostate biopsy scheme at 12, 18 or > 24 cores included 3 *vs.* 6 *vs.* 12 cores in the posterior zone of each lobe (apex, middle zone and base of the gland) beginning parasagittally to reach the outer edges of the gland (lateral margins); in case of repeated procedure the biopsy included 2-4 cores in the transition and anterior zone (9, 11, 12). Among 8.500 men 1.350 (15.8%) *vs.* 4.520 (53.3%) *vs.* 2.630 (30.9%) were submitted to 12 *vs.* 18 *vs.* 24 or more needle cores, respectively. In detail, 1.150/1.850 (62.1%) men submitted to mpMRI underwent TPBx combined with systematic biopsy for PI-RADS score 3 lesions (625 cases: 54.4%) *vs.* 4 (370 cases: 32.1%) *vs.* 5 (155 cases: 13.5%); over time, the use of mpMRI in clinical practice allowed to reduce the number of needle biopsy cores performed during prostate biopsy.

Clinical (comorbidities, drug therapy, risk factors) and laboratory data were collected from each patient's medical record; overall, 6.595/8.500 (77.5%) patients utilized alpha blockers.

Overall prostate biopsy-related complications were evaluated within 20 days from prostate biopsy when the histological report was given; moreover, number of patients who needed hospital admission or *emergency department visit* (EDV) was recorded. The patients without clinical complications following prostate biopsy did not undergo additional clinical evaluation. Definition of *urinary tract infection* (UTI) was given by presence of fever, positive urine culture and/or leucocytosis without bacteremia; moreover, in case of fever greater than 38.5°C the presence of bacteremia was investigated by blood culture. All patients were prospectively evaluated with the 5-item version of the *International Index of Erectile Function* (IIEF-5) at time zero and at 1, 3 and 6 months from prostate biopsy (13). The Clavien-Dindo grading system for the classification of biopsy complications was used (14).

For statistical analysis the t Student's - test was used; a p value < 0.05 was considered statistically significant.

Results

Overall, PCa was found in 3.150/8.500 (37.1%) patients, *high grade prostatic intraepithelial neoplasia* (HGPIN) in 209 (2.4%), *atypical small acinar proliferation* (ASAP) in 102 (1.3%) and normal parenchyma in 5.039 (59.2%); 2.135 (67.8%) and 2.310 (73.3%) out 3,150 with PCa had a PSA < 10 ng/mL and a T1c clinical stage, respectively. Detection rate for csPCa (15) increased with the use of mpMRI (PI-RADS ≥ 3) reducing the risk of overdiagnosis in comparison with systematic prostate biopsy (17 *vs.* 28%). Overall, clinical parameters and histological findings in presence of PCa diagnosed at initial or repeat biopsy are listed in Table 1. Overall, hospital admission and EDV were equal to 1.5% (129/8.500) and 8.9% (755/8.500); moreover, clinical complications of men submitted to 12 *vs.* 18 *vs.* > 24 cores are listed in Table 2. Overall, side effects following prostate biopsy occurred in 40.5% (3,441/8,500) of the patients (5.8% of them had two or more symptoms); in detail, overall complications were directly correlated with number of needle cores resulting equal to 17.4% (235 cases), 38.7% (1.751 cases) and 55.3% (1.455 cases) in patients who underwent 12 *vs.* 18 vs. > 24 cores (p = 0.001), respectively.

Hospital admission and EDV in men who underwent 12 *vs.* 18 *vs.* > 24 cores occurred in 1.5% (21/1.350) and 7.4% (100/1.350) *vs.* 1.4% (63/4.520) and 8.7% (395/4.520) *vs.* 1.7% (45/2.630) and 10.6% (280/2.630) (p > 0.05), respectively.

Overall, the most frequent biopsy complication that needed hospital admission vs. EDV was UTI (73 cases: 0.8%) *vs.* acute urinary retention (435 cases: 5.1%), respectively (Table 2). UTI with fever greater than 38.5° C was the most frequent cause (43 men: 33.3%) of hospital recovery. In all the 43 men admitted to hospital for UTI the blood culture was negative and a double antibiotics therapy was administered (penicillin plus aminoglycoside for 5 days) acquiring a complete remission of

Table 1.

Clinical characteristics and results in 8.500 patients (pts) who underwent 12, 18 and ≥ 24 needle cores as an initial or repeat transperineal prostate biopsy.

Scheme of biopsy	**12 cores pts = 1.350**			**18 cores pts = 4.520**			**≥ 24 cores pts = 2.630**		
Number of biopsies	**1st**	**2nd**	**3d**	**1st**	**2nd**	**3d**	**1st**	**2nd**	**3d**
Number of patients	1.350	-	-	3510	870	140	195	1978	457
Median number of cores (range)	12 (10-15)			18 (16-21)			28 (24-38)		
Median age (years; range)	68.2 (40-85)			61.8 (49-78)			63.2 (48-76)		
	number of pts			**number of pts**			**number of pts**		
PSA ≤ 2.5 ng/mL (F/TPSA ≤ 15%)	71	-	-	84	-	-	5	-	-
PSA 2.6-4 ng/mL (F/TPSA ≤ 20%)	195	-	-	185	55	-	35	90	-
PSA 4.1-10 ng/mL (F/TPSA ≤ 25%)	599	-	-	2479	97	-	65	1030	232
PSA > 10 ng/mL	485	-	-	1462	158	-	72	841	260
Abnormal DRE	190	-	-	150	58	-	18	44	16
Median prostate weight (grams)	47 (24-94)			58 (23-128)			63 (20-209)		
RESULTS	**%**			**%**			**%**		
Prostate cancer (PCa)	39.8	-	-	47.5	13.7	-	48.6	28	9.3
Gleason score (median)	7.3	-	-	7.2	6.4	-	6.75	6.3	6
Clinically insignificant PCa	2	-	-	8.7	34.4	-	18.3	36.8	38
PCa ≤ 10 ng/mL	54.	-	-	68.2	77.8	-	77.8	63	66.7
Clinical stage T1c	53.4	-	-	74.3	81.8	-	76	93	92

DRE: digital rectal examination; F/T: percentage of free/total PSA; Clinically insignificant PCa: ≤ 2 positive cores with percentage of cancer ≤ 50% and Gleason score 6 (Grade group 1) .

Table 2.
Complications following transperineal prostate biopsy in 8.500 patients (pts) submitted to 12 vs. 18 vs. ≥ 24 needle cores.

Complications	12 cores * 1.350 pts	vs	18 cores ** 4.520 pts	vs	≥ 24 cores ° 2.630 pts
Hematuria	101 (7.4%)		352 (8.4%)		235 (8.9%)
Urethrorrhagia	28 (2.1%)		75 (1.6%)		60 (2.2%)
Hemospermia	105 (10.7%)		915 (20.2%)		785 (29.8%)
Acute urinary retention	48 (3.5%)		285 (6.3%)		270 (10.2%)
Prostatitis	7 (0.5%)		29 (0.6%)		21 (0.8%)
Sepsis	-		-		-
Orchiepidymitis	6 (0.4%)		18 (0.4%)		16 (0.6%)
Urinary tract infection	16 (1.2%)		30 (0.6%)		16 (0.6%)
Perineal hematoma	5 (0.3%)		20 (0.4%)		18 (0.7%)
Vagal syndrome	9 (0.9%)		-		-
Erectile dysfunction** (6 months from biopsy)	3 (0.2%)		15 (0.3%)		10 (0.3%)
Fever	7		12		24
Systemic adverse events***	1 (0.07%)		-		-
Hospital admission (within 20 days)	21 (1.5%)		63 (1.4%)		45 (1.7%)
Emergency department visit (within 20 days)	100 (7.7%)		395 (8.7%)		280 (10.6%)

** Prostate biopsy performed under local anesthesia (*) or sedation (°); **Transient Erectile dysfunction resolved within 3-6 months from biopsy; ***Acute cardiac ischemia.*

symptoms and fever within 3 days; moreover, 3/43 (7%) patients had a positive urine culture for gram negative bacteria after the double antibiotics administration.
Only two patients with gross hematuria needed blood transfusion and all men with urinary retention had catheters removed within 7 days.
Among each complication, only hemospermia significantly correlated with the number of needle cores resulting equal to 36.5% (960/2.630) *vs.* 11.8% (160/1.350) (p = 0.001) in patients submitted to more than 24 *vs* 12 cores, respectively; moreover, urinary retention was most frequent in patients with a higher prostate weight who underwent SPBx (Table 1). Biopsy complication rate that needed hospital admission vs EDV was superimposable in presence (1.2 *vs.* 8.9%) and absence of PCa (1.3% *vs.* 9.3%). Hospital recovery occurred a median of 2 days (range: 1-3) after prostate biopsy for a median duration of 3 days (range: 2-6), moreover, EDV was performed within 3 days (range: 1-7) from the procedure. Complication rate was superimposable in patients submitted to prostate biopsy under local anesthesia office performed (2.105 cases) vs. sedation in surgery room (6.495 cases); from 2000 to 2022 UTI resulted superimposable and equal to 0.6% (2002) *vs* 0.9% (2022), respectively, moreover, nobody had sepsis or needed recovery in intensive care unit.
Finally, among the patients who needed hospital admission 69 (53.4%) and 60 (46.8%) were assigned a grade II and I of the Clavien-Dindo complications scale (14), respectively; moreover, all patients submitted to EDV had a grade I.

Discussion

The latest EAU guidelines strongly recommend to perform transperineal approach to reduce the risk of sepsis (1) suggesting a single dose of antibiotic (i.e., cefazolin) (2) for the antibacterial prophylaxis. Infections are well-established adverse events after transrectal prostate biopsy; asymptomatic bacteriuria, febrile UTI, acute bacterial prostatitis, orchitis, epididymitis, and urinary sepsis represent the broad spectrum of possible infectious complications. Medical comorbidities (particularly diabetes or metabolic syndrome) and older age are independent predictors increasing the risk of infections and sepsis; a previous history of prostatitis, antibiotics within 6 months before prostate biopsy, and non-adherence to antibiotic prophylaxis or resistence to antibiotics (i.e., quinolone) represent other risk factors (16, 17). Whether a repeated biopsy protocol, including those done in AS, could increase the risk of infection is unclear; *Loeb et al.* (18), reported a cumulative increase in the risk of having a complication where each additional biopsy was associated with a 1.7-fold increase in overall hospitalizations, and a 1.7-fold increase in serious infectious complications. Clinical complications and hospital admissions following transrectal prostate biopsy have increased during the last years primarily due to an increasing rate of infections (9); *Carignan et al.* (20) in 5.798 submitted to transrectal prostate biopsy demonstrated an increased incidence of infections from 0.52% in 2002-09 to 2.15% in 2010-11 secondary in the 52% of the cases to pathogens (*Escherichia Coli* in the 75% of the cases) resistant to ciprofloxacin especially in patients with diabetes, chronic obstructive pulmonary disease and in those hospitalized during the precedent month. *Loeb et al.* (21) in a random sample of Medicare participants in *Surveillance, Epidemiology and End Results* (SEER) regions from 1991 to 2007 found that prostate biopsy was associated with a 2.65-fold increased risk of hospitalization secondary to infections within 30 days compared to the control population; men who were hospitalized for infectious complications had a 12-fold higher 30-day mortality rate in comparison to those who were not. The use of targeted antibiotic therapy obtained from rectal swab culture combined with rectal preparation using povidone-iodine decrease the risk of infections and/or sepsis in men submitted to transrectal biopsy (22); recently, *Dai et al.* (23) reported clinically fewer infections (1.9% vs. 2.9%) in men managed with targeted antibiotic prophylaxis, although the difference was not statistically significant (p = 0.53).
Transperineal prostate biopsy in comparison with transrectal approach reduce number of infections and reset sepsis rate (0-0.2%) (24), given the avoidance of bacterial contamination which is common during transrectal access (25). *Miller et al.* (26) compared side effects following transrectal and transperineal biopsy showing a superimposable incidence of clinical complications (19.8 *vs.* 22.2%) but a sepsis rate equal to 1.2 *vs.* 0%, respectively. In a recent meta-analysis including 90 randomized controlled trials (16.941 participants) *Pradere et al.* (27) showed that transperineal biopsy was associated with significantly reduced infectious complications as compared to transrectal biopsy; on the contrary, no difference in infectious complications/hospitalization was found for number of biopsy cores, periprostatic nerve block, number of injections for periprostatic nerve block, needle guide type, needle type and rectal preparation with enema. In addition, in

a systematic review and meta-analysis on 37.805 men submitted to transperineal biopsy *Spyridon et al.* (28) showed that incidence of sepsis was similar in the patients who received antibiotics or not (0.05 *vs* 0.08%; p = 0.2) underlining the safety of the procedure.

In our series, to our knowledge the first that evaluated transperineal prostate biopsy complications in a so high number of patients of a single center (8.500 cases), overall hospital admission and EDV were equal to 1.5% (129/8.500) and 8.9% (755/8.500). Overall, side effects following prostate biopsy occurred in 40.5% (3.441/8.500) of the patients (5.8% of them had two or more symptoms); in detail, side effects were directly correlated with number of needle cores resulting equal to 17.4% (235 cases), 38.7% (1.751 cases) and 55.3% (1,455 cases) in patients who underwent 12 *vs.* 18 *vs.* > 24 cores (p = 0.001), respectively. Hospital admission and EDV in men who underwent 12 *vs.* 18 *vs.* > 24 cores occurred in 1.5% (21/1.350) and 7.4% (100/1.350) *vs.* 1.4% (63/4.520) and 8.7% (395/4.520) *vs.* 1.7% (45/2.630) and 10.6% (280/2.630) (p > 0.05), respectively.

Overall, the most frequent biopsy complication that needed hospital admission vs. EDV was UTI (73 cases: 0.8%) vs. acute urinary retention (435 cases: 5.1%), respectively; 43/73 (59%) men with UTI had fever greater than 38.5°C, but nobody developed sepsis or needed recovery in resuscitation department. Erectile dysfunction following prostate biopsy was restored within 3-6 months irrespective of the number of needles cores obtained.

Some limitations and considerations of the present study deserve mention. First, we don't know if a greater percentage of patients developed complications after our evaluation performed 20 days from prostate biopsy. Second, some cases of UTI could be missed because no additional clinical evaluation were required in absence of urinary symptoms. Third, the reduction of needle cores following the introduction in clinical practice of mpMRI could reduce prostate biopsy complications. Finally, our data refer in the majority of the cases to procedures performed under sedation, but the same biopsy protocol could be office-performed under local anesthesia (29, 30).

Conclusions

Clinical complications following transperineal prostate biopsy involved 35.9% (3.050/8.500) of the patients but only 1.5% (129/8.500) of them required hospital admission; UTI with fever was the most frequent cause of hospital recovery (33.4% of the cases), but none of the patients developed sepsis. Finally, number of needle cores (12 *vs.* 18. *vs.* > 24) significantly correlated with increased onset of side effects, but did not significantly increased hospital admission or EDV.

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