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Original Research Paper

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COMPLICATIONS OF TRANSRECTAL ULTRASOUND-GUIDED 12-CORE PROSTATE BIOPSY- A 5-YEAR EXPERIENCE

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ABSTRACT **Objective:** The aim of our study was to estimate complication rates after 12-core TRUS-guided prostate biopsy for suspected carcinoma prostate following all recommended pre and post-procedural measures. **Material and methods:** This 5-year retrospective study included 69 patients, based on elevated serum PSA (≥4 ng/mL), abnormal digital rectal examination findings and/or mpMRI findings (PIRADS ≥3). All patients received prophylactic antibiotics and rectal enema prior to biopsy. Single-use disposable 18-G biopsy needle was used. Post-operative complications were recorded. **Results:** Minor complications were detected in 33.33%, including fever (1.45%), mild self-limiting hematuria (18.84%), rectal bleeding (4.35%) and urinary retention (20.75%). Serious complications which necessitated hospitalization occurred in 2 patients (2.89%) including urosepsis and hematuria with clot retention in the other. **Conclusion:** TRUS-guided prostate biopsy is safe for diagnosing prostate cancer with acceptable post-procedural complications when done taking all precautions.

KEYWORDS : TRUS, prostate biopsy, prostate cancer, PSA, mpMRI.

INTRODUCTION

Worldwide, prostate cancer (PCa) is the fourth most common cancer overall, the second most commonly diagnosed cancer among men and the fifth leading cause of cancer death among men [1]. In post-PSA (prostate specific antigen) era screening for PCa has gained acceptance due to favourable cancer-specific survival rates with early radical prostatectomy [2]. Prostatic biopsy remains the corner-stone of diagnosis of PCa. It is indicated in patients with elevated serum PSA levels, abnormal digital rectal examination (DRE) findings, or when mpMRI shows a high PIRADS score. Screening has increased the overall burden of patients undergoing prostatic biopsy.

TRUS-guided prostate biopsy is the most the most commonly employed technique of obtaining prostatic tissue for histopathology (HPE) [3] [4]. The advantages of the trans-perineal route especially with regard to sepsis have been reported in literature [5] but the procedure is technically more difficult, more time consuming and requires anesthesia. TRUS guided biopsy being an invasive procedure comes with its own set of complications like fever, hematuria, rectal bleed and acute urinary retention (AUR). Severe complications requiring hospitalization include septic shock, hematuria leading to clot retention or requiring transfusion, Fournier's gangrene, or myocardial infarction [6,7].

The aim of our retrospective study was to estimate complication rates after TRUS-guided prostate biopsy following strict pre and post procedural protocols.

MATERIAL AND METHODS

Inclusion and exclusion criteria

The study included 69 patients who underwent TRUS-guided prostate biopsy in the Department of Urology, AJ Institute of Medical Sciences and Research Centre, Mangalore between March 2018 and June 2023. The data for analyses was collected from patients' electronic, paper-based medical and radiological imaging records. The indications for biopsy were PSA ≥ 4 ng/mL with a palpable nodule / hard prostate on DRE. In patients with PSA >4 ng/mL and negative DRE, PIRADS score >3 on mpMRI findings was the indicative parameter for biopsy. Patients with raised serum PSA and/or abnormal DRE but had clinical suspicion of prostatitis or were radiologically diagnosed as prostatic abscess were excluded from study. 16 patients admitted with catheter for AUR were excluded for evaluation of post-procedure urinary retention as a complication.

Preparation for the biopsy

Patients on antiplatelet therapy were referred to the concerned physician and the drug was discontinued 5-7 days prior to biopsy. Urine culture was sent in all patients. All culture positive patients were treated with specific antibiotics before the biopsy. As antibiotic prophylaxis, all patients received prophylactic intravenous cefoperazone-sulbactum, 1.5 gms, 1 hour before the procedure and a second dose after 12 hours. Rectal enema was given to all patients, the night before biopsy. All patients were informed in detail about the procedure, its complications, and their written consent forms obtained.

Biopsy Technique

All procedures were performed under general anaesthesia. The operative area was cleaned using 10% w/v povidone iodine solution and disposable draping was used. All biopsies were performed under the guidance of standard gray-scale ultrasound- 7.5 MHz rectal probe. Single use disposable automatic biopsy gun with 18 G biopsy needle was used in all patients. 12-core biopsy specimens were obtained and sent to the pathology laboratory in specifically labelled (area-wise) bottles containing formalin. A soft rectal pack was placed in all the patients for two hours after procedure.

Analysis

All patients were studied for TRUS-guided prostate biopsy related complications viz. hematuria, infection (fever, urosepsis), rectal bleeding, vasovagal syncope. The incidence of AUR was considered only in pre-operatively non-catheterised patients. Positive urine culture/ diabetes mellitus, antiplatelet therapy and history of prior lower urinary tract

symptoms (LUTS) were considered as risk factors for infection, hematuria, and urinary retention respectively. The incidence rates of complications were investigated in different groups for each complication. The infection, hematuria and rectal bleeding groups were divided into sub-groups according to the severity of symptoms. All sub-groups were analysed for their association with risk factors. As descriptive statistics for continuous variables mean ± standard deviation, and for categorical variables, rates and percentages were used.

RESULTS

The mean age, mean serum total PSA concentration and mean prostate volume of the 69 patients were 67.3±7.35 years (49-84 years), 141.3±305.6 ng/mL (2.54-2000 ng/mL) and 50.71±24.02 cc (20-134 cc) respectively. The incidence of pre-operative risk factors which could contribute to post-operative complications are summarized in Table 1. The observed complications, and their frequencies are summarized in Table 2.

Table-1: Pre-operative risk factors for post-operative complications

Complications	Pre-operative risk factors	No. of patients	%
Infection	Positive urine culture	2/69	2.89%
	Diabetes mellitus	24/69	34.78%
Hematuria	Antiplatelet patient on therapy	14/69	20.29%
Urinary retention	Lower urinary tract symptoms	38/53	71.69%

Table 2: Observed post-operative complications

	Total n/N	%	Patients with Risk factors	%	Patients without Risk factors	%	P value
Infection	2/69	2.89	1/26	3.85	1/43	2.32	0.359
Mild -Fever	1/69	1.45	1/26	3.85	0/43	0	0.097
Severe - Urosepsis	1/69	1.45	0/26	0	1/43	2.32	0.218
Hematuria	14/69	20.29	4/14	28.57	10/55	18.18	0.195
Mild self-limiting	13/69	18.84	4/14	28.57	9/55	16.36	0.149
Severe - Clot retention	1/69	1.45	0/14	0	1/55	1.82	0.305
Rectal bleeding	3/69	4.35	1/14	7.14	2/55	3.64	0.284
Mild	3/69	4.35	1/14	7.14	2/55	3.64	0.284
Severe	0/69	0	0	0	0	0	
Urinary Retention (Mild)	11/53	20.75	9/38	23.68	2/15	13.33	0.2

Infectious complications were detected in 2/69 patients (2.89%), with similar rates of infection in patients with or without risk factors viz. positive urine culture or diabetes mellitus (p value 0.359). Similarly, statistically no difference was detected for both minor and serious infectious complications in the two sub-groups (p value 0.097 and 0.218 respectively).

Hematuria was detected in 14/69 patients (20.29%). The overall incidence was similar in patients with or without risk factors namely antiplatelet therapy (p value 0.195). Similarly, statistically no difference was detected for both minor and serious haematuria in the two sub-groups (p value 0.149 and 0.305 respectively). For rectal bleeding also statistically, no difference was detected in in the two groups (p value 0.284).

AUR occurred in 11/53 patients (20.75%), with similar rates in patients with and without risk factors (LUTS) (p value 0.2).

DISCUSSION

With the advent of serum PSA as a biomarker for PCa and the emergence of mpMRI/PIRADS as a valuable tool to assess the prostatic architecture in malignancy, the number of prostatic biopsies is on the increase. Being an invasive procedure, deploying a needle of significant bore through the perineum or the rectum, several complications could be encountered. TRUS-guided biopsy in particular, being directed through the rectum, naturally has a potential of inducing infective complications which may vary from mild fever to full blown septic shock [8]. The advantages of perineal biopsy to over-ride this particular complication have been impressed in several studies [9].

However perineal biopsy requires specialised experience, expertise and anesthesia besides adding to the cost. TRUS-guided biopsy on the other hand is easier to perform, may be done under sedation/LA, and is a more familiar procedure to the contemporary urologist. Complication rates of TRUS-guided and trans-perineal biopsies reported in literature are presented in Tables 3 and 4 respectively. This retrospective study was conducted to assess our own complication rates with TRUS-guided biopsy.

Earlier reports on TRUS-guided biopsy report higher incidence of infective complications, some of them of a serious nature with significant morbidity and mortalities. With the advent of better antibiotics and safety protocols, the incidence of sepsis has considerably reduced. Infective complication rates following TRUS-guided prostate biopsy, in various studies were reported between 0.8% to 6.6% vis-à-vis

1.16% to 3.36% via the trans-perineal route [10-17] [18-21]. Our own infection rate of 2.89% compares well with the incidence reported in the above studies.

Hematuria is the most frequently seen complication following TRUS-guided prostate biopsy. In various studies the incidence of mild hematuria and severe bleeding with clot retention was reported between 14.5% to 84% and 0.25% to 0.7% respectively. Hematuria following trans-perineal prostate biopsy, among various studies, were reported between 6.85% to 42.37% of all the cases. Our own incidence of hematuria was 18.18% of the cases which is comparable with the above figures.

Rectal bleeding following TRUS-guided prostate biopsy, among various studies, were reported between 1.3% to 39.6% of the cases. Rectal bleeding following trans-perineal prostate biopsy was naturally infrequent and incidence between 0 to 3.39% has been reported. Presence of haemorrhoids could be a significant cause of rectal bleed following trans-rectal biopsy. We had no patient with significant pile masses in our series and we encountered mild bleed in 4.35% of the cases. A soft rectal pack placed for 2 hours after biopsy was sufficient to control the bleed in all cases.

Urinary retention rates following TRUS-guided prostate and trans-perineal biopsy have been reported as 0.2% to 4.6% and 2% to 6.78% respectively by several authors. Our own incidence of AUR was 20.75% This is higher than the reported studies. The high percentage of our subjects with pre-operative LUTS (71.69%) and the general anaesthesia for the procedure could have contributed to this observation. Fortunately, all were self-limiting and voided well on catheter removal after 24 hours.

Hospitalization for serious complications following TRUS-guided prostate biopsy, among various studies, were reported between 0.4% to 2.9%. Our incidence of 2.89% included one patient with sepsis and another with clot retention requiring cystoscopy and fulguration of the bleeder.

Table 3. Complication of TRUS-guided prostate biopsies: literature data

Author	Cases	%					
		Hematuria	Hematosper mia	Rectal bleeding	Fever	AUR	Hospitalization
Djavan et al. [10]	1051	62	9.8	2.1	2.9	0.9	2.9
Rietbergen et al. [11]	1687	23.6	45.3	1.7	4.2	0.4	0.4
Rodriguez & Terris [12]	128	84	9.1	9.9	1.7	1.6	0.8
Önder et al. [13]	858	43	17.9		6.6	4.6	1.7
Raaijmakers et al. [14]	5802	22.6	50.4	1.3	3.5	0.4	0.5
Peyromaure et al. [15]	289	74.4	78.3	39.6			
Berger et al. [16]	5957	14.5	36.3	2.3	0.8	0.2	
Paul et al. [17]	405	72		29.3	2.2		

Limitation

The study is retrospective. The number of subjects is lower than ideal. Prospective observational studies with larger number of patients would provide more meaningful insights into safety of the procedure.

CONCLUSION

TRUS-guided prostate biopsy to diagnose PCa is a safe procedure when strict safety protocols are followed. Most of complications are minor and self-limiting. Infective complications are comparable with those of trans-perineal biopsy.

Table 4. Complication of Transperineal prostate biopsies: literature data

Author	Cases	Total No. (%)			
		Hematuria	Rectal	Fever	AUR
Tian et al., 2014, [18]	175	12 (6.85)	0	6 (3.42)	10 (5.71)
Yuan et al., 2014 [19]	59	25 (42.37)	2 (3.39)	2 (3.39)	4 (6.78)
Guo et al., 2015 [20]	173	33 (19.1)	0	2 (1.16)	NA
Tobias Kohl et al., 2021 [21]	550	212 (38.5)	NA	20 (3.6)	11 (2.0)

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