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Urology

TO EVALUATE THE COMPLICATIONS OF TRUS GUIDED PROSTATE BIOPSY: A PROSPECTIVE OBSERVATIONAL TERTIARY CARE CENTER STUDY

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ABSTRACT The most common non-cutaneous cancer in United States is prostate cancer, And also, the second most common cause of cancer-related death . The recommended methods for screening of prostate cancer are prostate specific antigen (PSA) test and rectal examination. But prostate needle biopsy is necessary to make the diagnosis. Prostate biopsies were originally done with either digitally guided or trans-perineal biopsy trucut. But with the development of trans rectal ultrasound, all trucut biopsies have been replaced by trans rectal ultrasound (TRUS)-guided prostate biopsy . Majority of the prostate biopsy related complications are mild and self-limited but sometimes it could be severe and life threatening. Infection, bleeding, and urinary retention are the most common complications after prostate biopsy. Among Infectious complications, mild fever, febrile UTI, and sepsis are common. The aim of the study was to assess the complications following TRUS guided prostate biopsy. **Methodology :** Our study was a prospective study done in department of urology , Governement Medical College , Kozhikode in patients undergoing TRUS guided prostate biopsy. Patients with suspected carcinoma prostate are subjected to TRUS guided prostate biopsy and followed up for complications. All patients underwent detailed history and physical examination. Co-morbidities were assessed if any, especially diabetes mellitus. Study variables were pain , fever , hematuria , hematochezia , urinary retention and urosepsis. **Results :** The most common complication was hematuria , followed by fever. Positive pre-biopsy urine culture and diabetes mellitus are risk factors which should be looked into before planning prostate biopsy.

KEYWORDS : TRUS guided prostate biopsy , complications

INTRODUCTION

The most common non-cutaneous cancer in United States is prostate cancer, an approximate 241,000 cases diagnosed in 2012. And also, the second most common cause of cancer-related death[1]. The recommended methods for screening of prostate cancer are prostate specific antigen (PSA) test and rectal examination. But prostate needle biopsy is necessary to make the diagnosis. Prostate biopsies were originally done with either digitally guided or trans-perineal biopsy trucut. But with the development of trans rectal ultrasound, all trucut biopsies have been replaced by trans rectal ultrasound (TRUS)-guided prostate biopsy[2].

Majority of the prostate biopsy related complications are mild and self-limited but sometimes it could be severe and life threatening. Infection, bleeding, and urinary retention are the most common complications after prostate biopsy. Among Infectious complications, mild fever, febrile UTI, and sepsis are common[3-6]. Recently, there is an increase in hospitalisation rate due to infectious complication following prostate biopsy[7]. Multiple factors could be responsible for recent trends. Bacterial resistance to fluoroquinolones and the lack of standard regimen for antimicrobial prophylaxis before prostate biopsy apparently the most common factors[8-11].

This is a prospective study, designed to evaluate the complications of TRUS guided prostate biopsy.

AIM

The aim of the study was to assess prospectively, the complications following trans rectal ultrasound (TRUS) guided prostate biopsy.

OBJECTIVES

Primary objective of the study was to assess urosepsis requiring hospitalisation.

Secondary objective was to assess the occurrence of other complications following biopsy of prostate. These include-

- Fever
- Hematuria
- Hematochezia
- Urinary retention
- Pain or discomfort

METHODOLOGY

Design And Duration Of Study

A prospective observational study design carried out at our institute for a period of 12 months.

Approval of Institutional Review Board and Ethics Committee was obtained.

Inclusion Criteria

- Raised serum prostate specific antigen (PSA >4.0 ng/ml) or
- Abnormal digital rectal examination (DRE) or
- Both
- Outside biopsy report suggestive of prostate cancer but no slides/blocks available for review

Exclusion Criteria

- Patients refused to give consent
- Patients started on prophylactic antibiotics more than 3 days prior to biopsy

All consecutive patients under evaluation of suspected carcinoma prostate were included in the study. All patients underwent detailed history and physical examination. Co-morbidities were assessed if any, especially diabetes mellitus. Detailed medication history including steroid, insulin, anti-coagulation medication, antiplatelet drugs was taken. If patient was on Warfarin, it was decided to change to either unfractionated heparin (UFH) or low molecular weight heparin (LMWH) with an appropriate time of bridge therapy before proceeding for prostate biopsy. Similarly, if patient was taking antiplatelet drug like Clopidogrel, it was planned to discontinue for 7 days at least prior to biopsy.

All patients were asked to give urine sample for culture & sensitivity on prior visit. If urine culture was negative, 2 doses of Ciprofloxacin tinidazole combination were given before doing biopsy and continued for 2 more days. But if culture was positive, patients received antibiotics for 3days prior to biopsy and were continued for total of 7 days according to sensitivity.

An information sheet was provided to all patients and those who consented to take part, were included in the study.

Peri prostatic nerve block was given to all patients before TRUS guided prostate biopsy. 5ml of Injection Lignocaine 2% (v/v) mixed with 5ml of normal saline and injected 5ml each on both sides. 22 gauge 17cm long spinal needle was used for this purpose.

Standard 12- Core prostate biopsy done in each patient and samples were labelled properly according to site and side of the prostate and

sent for pathology

Outcomes

Primary outcome was to assess urosepsis requiring hospitalisation. Secondary outcome was to assess the incidence of other complications following TRUS guided prostate biopsy. These include-

- Fever
- Hematuria
- Hematochezia
- Urinary retention
- Pain or discomfort

All patients' data including follow up, up to 7 days, were prospectively recorded, including duration of hospitalisation including intensive care unit (ICU), if required.

Outcome Definitions

- Sepsis: SIRS with documented or clinically high suspicion of infection (SIRS includes - temperature ≥38^{0}C or <36^{0}C; heart rate >90 beats/minute; respiratory rate >20 breaths/minute or respiratory alkalosis; WBC >12,000 or <4000 or immature forms >10% in case of normal range of total WBC)[6]
- Infection – Any fever post biopsy more than 37.5^{0}C
- Gross hematuria – Visible blood in urine
- Hematochezia – Blood noticed in stool
- Urinary retention – Unable to pass urine after biopsy
- Pain or discomfort – Assessed with visual analogue scale

Sample Size Calculation

A target sample size of 95 was calculated using a precision of 4% and 90% desired confidence level for the infection related complications. This was carried out assuming an average incidence of infection related complication of up to 6%. This incidence was arrived at after a comprehensive literature review for this statistics.

$$n = \frac{4 p \times q}{d^2}$$

p = 0.06

q= 1-p = 0.94 d= 0.004

Statistical Analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS®) version 18 (IBM Corporation, USA).

Frequencies and percentages are used represent the categorical variables. eg; age, prostate volume etc.

Descriptive statistics are used to represent continuous variables, eg; mean standard deviation.

Chi square test and Fisher's exact test were used to find the relationship between two variables.

p value < 0.05 was considered as statistically significant.

The results are represented graphically using Bar charts and tables.

Ethical Concerns

The study protocol submitted to Institutional Ethics Committee, Government Medical College Kozhikode for approval. After explaining the details regarding the study , an informed consent obtained from participants. Confidentiality after data is maintained.

RESULTS

A total of 95 patients underwent TRUS guided prostate biopsy for suspected carcinoma prostate on the basis of raised PSA or abnormal rectal examination during study period. The demographic characteristics of the patients are given in Table 1. The mean age of patients was 67.4 years. Diabetes and hypertension were the most common associated co- morbid illnesses, being seen in over 48% of the patients. Some of these patients had both diabetes mellitus as well as hypertension as co-morbidities.

Table 1: Demographic Characteristic (n=95)

Age (yrs) (SD)	67.4 (9.6)
Prostate size (cc) (SD)	24.07 (13.29)
PSA (ng/ml)	76
Co- morbidity	
• DM	20
• HT	26
• CAD	02
• COPD	02
• Post CVA	01
• CKD	01

Clinical Presentation

Most common presentation of these patients was lower urinary tract symptoms. During evaluation, they were suspected to have prostate cancer either an abnormal rectal finding or raised PSA. At our institution, we do not do screening for prostate cancer. Therefore the number biopsies performed during the study period was quit small as compared to any other studies where they do routine screening for prostate cancer. Some patients have more than one clinical presentations eg; having LUTS and came with a report of raised PSA (done elsewhere).

Pathological Features Of Prostate Biopsy

Among all the patients who underwent TRUS guided prostate biopsy, only 70 patients were diagnosed as adenocarcinoma prostate, rest of them did not show evidence of malignancy on biopsy tissue. Majority of non-malignant pathology specimen were reported as benign prostatic hyperplasia, focal mild inflammation or chronic prostatitis. Majority of cases had higher Gleason's score on biopsy. 63% of patients had Gleason's score >7 and peri-neural invasion was seen in more than 81% of patients. Table 2 shows details of pathological features of prostate biopsy.

Table 2: Pathological Features Of Prostate Biopsy

Adenocarcinoma prostate	70 (73.7%)
Gleason score	50 (71.4%)
• >7	
• 7	8 (11.4%)
3+4=7	10 (14.28%)
4+3=7	2 (2.8%)
• <7	
Peri-neural invasion	35 (50%)

Patients with GS >7, PSA >20, T3 and above on cross sectional imaging or presented with bony pain underwent bone scan. Total of 60 patients had undergone bone scan, out of which only 42 patients did show evidence of osseous metastasis.

Pain During Prostate Biopsy

Pain during TRUS biopsy prostate was minimal in majority of patients. On visual analogue scale (VAS), it was 2 or less in 84% patients as shown in Table 4.

Table 3: Visual Analogue Scale VAS (n=95)

2 or less	80 (84%)
More than 2	15 (16%)

Complications Following Prostate Biopsy

Only six patients developed low grade fever after biopsy which subsided with antipyretics. None of them required hospital admission. Out of these 6 patients, two patient's pre biopsy urine culture was positive, two had sterile culture and one had contaminants in urine sample. Those two patients in whom urine samples were positive, they received appropriate duration of antibiotics before and after procedure according to culture sensitivity.

Another 71 years of age gentleman with multiple co-morbidities, developed urosepsis and septic shock after prostate biopsy. His pre-biopsy urine sample grew two organisms for which he was on antibiotics for 3days according to sensitivity pattern. Despite of this, patient developed features suggestive of sepsis and was hospitalised. The antibiotic was upgraded as the patient's condition deteriorating. He was kept in ICU for 2 days. The urine and blood culture sent before upgrading the antibiotic did not grow any organism. Total duration of hospitalization was 12 days.

Twenty five patients noticed mild hematuria post biopsy which settled in one or two days. Only three patients had several episodes of gross hematuria lasted for more than 2 days which ultimately resolved on its own. None of them required catheterization or bladder wash.

Two patients were catheterised after prostate biopsy as they were having urinary retention. Trial voiding were successful after 1 week.One patient was catheterised post biopsy due to sepsis.

Eight patients noticed blood in stool after biopsy which settled on its own.

Incidence of hematospermia after prostate biopsy was not assessed in this study population. Table 5 summarizes the complications of Prostate biopsy.

Table 4: Complications Following Prostate Biopsy (n= 43)

Minor Complications		
• Low grade fever	6	(6.3%)
• Hematuria < 2 days	25	(26.3%)
• Hematochezia	8	(8.4%)
Major Complications		
• Sepsis	1	(1.05%)
• Hematuria > 2 days	2	(2.1%)
• Urinary retention	2	

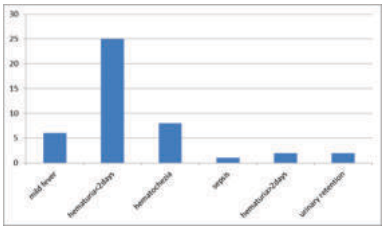

Fig.1: Complications Following Prostate Biopsy

Among all the patients, 25 of them had positive urine culture. Five of them were on perurethral catheter. E. coli was the most common organism found. Most of these urine samples grew single organism. Five urine samples grew 2 organisms and one sample grew three organisms. Most of these multiple organism urine samples were from patients who were on per urethral catheter. Pattern of micro-organisms seen on urine culture samples were shown in Figure 1.

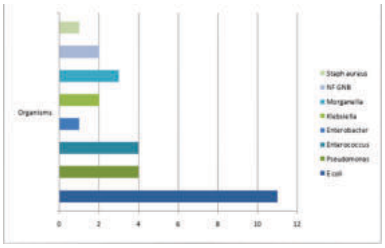

Fig2: Positive Urine Culture Samples, Showing Different Organisms

Antimicrobial Resistance Pattern Among Positive Urine Culture Samples

There were twenty five patients in whom pre-biopsy urine culture was positive. Urinary organisms were found resistant to one or more of the eight most common antimicrobial agents used. Organisms were most frequently resistant to Cefpodoxime in our study. Seven patients' cultures were resistant to Co-trimoxazole and Nitrofurantoin. Only three urine culture samples were resistant to Ciprofloxacin. Reason for apparently low resistance to Ciprofloxacin was because sensitivity for this antimicrobial was not checked in 70% of urine samples. See Figure 10 for detail below.

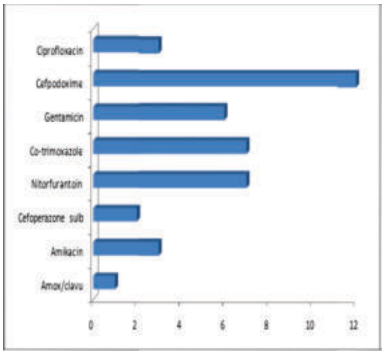

Fig.3: Antimicrobial Resistance Patterns Of Pre Biopsy Urine Cultures

Subgroup Analysis

Table 5: Relationship Of Urine Culture With Infection

Urine culture	Rate of infection (%)	p Value
Positive	5/25 (20.0%)	0.040
No growth or contaminants	3/70 (4.2%)	

Relationship Of Urine Culture With Infection

As shown in Table 5, patients with positive urine cultures had more infection as compared to the other group where urine culture was either no growth or contaminants. There was a statistically significant association of positive urine culture with rate of infection.

Table 6: Relationship Of Urine Culture With Hematuria

Urine Culture	Incidence of hematuria	p Value
Positive	7/25 (28%)	0.939
No growth or contaminants	18/70 (25.7%)	

In both groups almost equal number of patients had hematuria. There was no association found between urine culture and incidence of hematuria. See Table 6

Table 7: Risk Of Infection In Diabetics

Diabetes mellitus	Incidence of infection (%)	p Value
Present	2/20 (10%)	0.626
Absent	5/75 (6.6%)	

In our study, it was found that diabetic patients had more incidence of infection compared to non-diabetics. But the association of diabetes and incidence of infection did not reach to a statistical significance as shown in Table 7.

Association Of Infection With Indwelling Urethral Catheter

Table 8: Risk Of Infection With Indwelling Catheter

Per urethral catheter	Rate of Infection (%)	p value
Catheter	0/10 (0%)	1.000
No catheter	6/85 (7%)	

In our study, ten patients were on catheter prior to prostate biopsy. There was no infection noted in this group following biopsy. Six patients in non catheter group had infection (7%). This increase incidence of infection in no catheter group did not reach statistical significance (p = 1.000). Table 8.

DISCUSSION

Trans rectal ultrasound guided prostate biopsy has remained the gold standard to diagnose prostate cancer. Biopsy related complications are not uncommon. Majority of the complications are mild and self-limited but sometimes it could be severe and life threatening. Infection and bleeding from urethra and rectum are the most common complications following prostate biopsy. Some recent studies have reported increasing trends of hospitalisation following prostate biopsy due to infection related complications.

To reduce the incidence of infection following biopsy, there were many prophylactic regimens including oral as well as intravenous antibiotics recommended by various studies[12,13]. In our study, two doses of oral Ciprofloxacin plus tinidazole was given just before TRUS biopsy in those in whom urine culture showed no growth or contaminants and continued for 2 more days. Otherwise patients received 3 days of antibiotic course before biopsy and continued for total of seven days according to culture and sensitivity.

Rectal cleansing with povidone-iodine and enema plus antibiotics has been explored by various studies with controversial conclusions. Some studies say that it reduces infectious complications but few of them conclude no difference in complications[14-16]. However, Cochrane review has concluded that risk of bacteraemia was reduced with enema plus antibiotics when compared with antibiotics alone but risk of fever or infection was similar in both groups[6]. We have used oral dulcolax at bedtime prior night to prostate biopsy.

Loeb S et al have identified various risk factors for infectious complications. These include; Co-morbidities like Diabetes, COPD, Heart valve, benign prostate enlargement, recent urogenital infection, Recent antibiotics, hospitalization, presence of a catheter, positive prebiopsy urine culture etc.[17]In our study , the risk factors identified were Diabetes mellitus, per urethral catheter and positive urine cultures.

Prophylactic antibiotic before prostate biopsy is being used by all

centres but the particular antibiotic, dose and duration varies widely among centres. However, most studies showed no significant benefit if duration is more than 24hours[18,19,20]. At our centre, we utilised 2 doses of Ciprofloxacin tinidazole combination prior to biopsy and continued for 2 more days.

Febrile UTI following prostate biopsy is common. Reported incidence rate of infection in different studies is around 3%[22,23]. In our study, only one patient had febrile UTI which progressed to sepsis and required hospitalisation despite of being on antibiotics prior to procedure.

Incidence of fever reported in literature is about 3% to 3.5%[26,30]. Our study had reported fever in 6% of patient, higher than reported in previous studies.

Hospitalisation rate in our study was 1.05% similar to other studies in which it was 0.6% to 1.7%[16]. But other studies have reported incidence of hospitalisation of 3.1% to 3.06%[22]. Another study reported increase in hospitalisation rate from 1% to 4.1% from 1996 to 2005[24].

Hematuria is very common complaint following TRUS biopsy of prostate. Its incidence varies in literature from 10-84%[21,24,25]. There are various definitions of hematuria in different studies (visible blood, need for catheterisation or hospitalisation, also duration of hematuria). In a cohort study, incidence of hematuria was reported as 65.8%, but bothersome hematuria was only 6.2%[25]. Our study reported hematuria in 26.3% patients. But bothersome hematuria which lasted for more than 2 days was noted in only 2.1% patients. None of these patients required any intervention and it subsided on its own. A large prospective study on prostate cancer screening had reported prolonged hematuria (>3 days) in 22.6% and it was correlated with prostate volume[26]. We could not assess this association in our study population as the number patient in our study was quit small as compared to ERSPC study where approximately 6000 persons participated. There are studies which had evaluated relationship of hematuria with number of biopsy cores, size of the biopsy needle etc. and showed conflicting results. We did not evaluate these factors in present study.

Incidence of hematochezia ranged from 1.3% and 45%. Studies had shown that incidence of bleeding increases with increased number of prostate biopsy cores and anticoagulative drugs[27]. Our study did show incidence of rectal bleeding around 8.4%. A very low incidence rate as compared to previously reported in various studies. This could be due to smaller needle size used for biopsy and proper patient evaluation before biopsy. In most of the cases of rectal bleeding, if patients are counselled properly regarding rectal bleeding and hematuria, it is of little consequence. It is very rare to see massive rectal bleeding and could be fatal. No such massive hematochezia noted in our study. Rectal bleeding was noted in few patients in our study but it was self limiting.

Hematospermia was noted in almost all studies following prostate biopsy. Its incidence varied from as low as 1% to as high as 93%[29]. Gradually it declined over several weeks. Studies have reported anxiety and reduced sexual activity associated with hematospermia which resolved after about eight ejaculations. ERSPC study showed hematospermia in 50.4%[26]. Our study population included majority of patients above 60 years of age. And almost all of them did not have intercourse for a long time, either because of decreased libido or due to other socio-economic reasons.

TRUS guided prostate biopsy causes significant amount of pain. Therefore some form of analgesia is mandatory now. One study noted that TRUS biopsy prostate was associated with significant pain and discomfort as well as anxiety. This has resulted in reluctance to subsequent biopsy, among those it was required[25]. There are other factors affecting pain during biopsy like rectal compliance, volume of prostate and number of prostate biopsy cores. Left lateral decubitus position during biopsy was found to have slightly less pain, although the difference may not be clinically significant. Various types of anaesthesia/analgesia were described for prostate biopsy. Among them, peri prostatic nerve block (PPNB) is safe and effective procedure. We performed prostate biopsy in left lateral decubitus position and injected 2% Lignocain 5ml diluted with 5ml of normal saline as PPNB. It was very effective in reducing pain during biopsy and majority of our patients (84%) did not have clinically significant pain (based on VAS ≤2).

Risk of urinary retention following TRUS-Biopsy prostate is very small (0.2% to 1.7%). Number of cores taken during biopsy has no correlation with incidence of retention of urine. One study had assessed factors directly linked to retention of urine, includes volume of prostate, ratio of transition zone to total prostate volume and a higher IPSS score[3,26,28]. In our study, only two patient had retention following prostate biopsy.

Overall, the risk of mortality is very low following prostate biopsy. Some studies have reported it less than 1%[7,24]. There was no death in our study.

The subgroup analysis of our study showed that patients with positive urine cultures had increased rate of infection compared to other group with sterile urine culture or contaminants. It was statistically significant. Increased rate of infection among culture positive patients is self explanatory. However, all such patients received a course of antibiotics according to culture and sensitivity, started on 3 days prior to biopsy and then continued for 5 -7 days. Observation from this study suggests that it would have been ideal to complete the course of antibiotic and document a sterile urine culture before proceeding for biopsy.

Another important correlation was made between diabetes and incidence of infection. Although it was not statistically significant, but it was noticed that in diabetic patients incidence of infection was higher. It is a well established risk factor for increase incidence of infection after biopsy[23,31,32].

Patients with indwelling urethral catheter prior to biopsy had low incidence of infection when compared with other group who were voiding, although it was not statistically significant in this study. It could be explained as some of the patients who were voiding but had significant post void residue and that could have contributed to increased incidence of infection. Unlike them, patients who were on urethral catheter, had a decompressed system and hence less to develop infection system. However, indwelling catheter itself leads to colonisation of bacteria and that may cause infection following any urological procedure.

Results of various publications on complication of biopsy are shown in Table 10. Caution must be exercised during comparisons with other studies due to differences in population, sample size, biopsy core, and different definitions of complication as well as follow-up. The incidences of hematuria and hospital admission rates are comparable with published studies. Incidence of fever was higher in our study. Thorsten H. Ecke et al had very low rate of gross hematuria (6.5%). This could be because their definition of gross hematuria was including only those who complained of persistent gross hematuria of more than 2 weeks after biopsy[33].

Table 10: Review Of Recently Published Studies

Investigator	Year	No.	Biopsy cores	Enema	AB	Fever (%)	Hosp (%)	Hematuria (%)	Retention (%)
Djavan	2001	1015	8	NA	Yes	3.0	NA	15.9	2.6
Raaij-makers	2001	5802	6-7	No	Yes	3.5	0.5	22.6	0.4
Thorsten H.	2008	336	12	Yes	Yes	1.8	0.6	6.5	0.3
Present study	2022	95	12	No	Yes	6.3	1.05	26.3	2.1

AB = antibiotics; hosp = hospitalization; NA = not available

CONCLUSION

Trans rectal ultrasound guided prostate needle biopsy is safe for diagnosing prostate cancer. The most common complication was hematuria in 26.4% of cases, followed by low grade fever. Incidence of sepsis requiring hospitalisation was very low in our study. Increased incidence of infection in patients with positive urine culture suggests that treatment of infection and documentation of negative urine culture before biopsy may be wiser. Positive 7pre-biopsy urine culture and diabetes mellitus are risk factors which should be looked into before planning prostate biopsy.

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