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Original Research Article

A Hospital Based Evaluation of the Safety and Feasibility of Transrectal Ultrasound (TRUS) Guided Free-Hand Transperineal Prostate Biopsy under Local Anesthesia (LA) for Suspected Prostate Cancer

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Abstract:

Aim: We assessed the safety and feasibility of transrectal ultrasound (TRUS) guided free-hand transperineal prostate biopsy under local anesthesia (LA) for suspected prostate cancer.

Methods: The present study was conducted at department of Urology for a period of 18 months. Total 50 patients were included in the study. Informed consent and patient information sheet were explained in detail to the study subjects prior to their enrolment.

Results: The mean age of the patients was 69.4 ± 8.72 years, median PSA 14.56 ng/mL (4.17–672) and prostate size 44cc (16–520). Of 50 patients, PIRADS 3, 4, and 5 lesions in mpMRI were found in 15 (30%), 15 (30%) and 20 (40%) patients, respectively.

Conclusion: Freehand TRUS-guided transperineal prostate biopsy by coaxial needle technique under LA is a safe, feasible procedure with good tolerability, high CDR, and minimal complications, particularly no urosepsis. In developing countries like India, this approach has a potential to avoid economic burden due to general anesthesia and management of post biopsy urosepsis. It shows excellent patient tolerability while minimizing complications.

Keywords: Prostate Cancer, Local Anaesthesia, Transperineal Biopsy.

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Introduction

Systematic transrectal ultrasound-guided biopsy of the prostate (TRUS biopsy) is recommended by several international guidelines as the investigation of choice for PCa detection. Moreover, transperineal prostate biopsy (TPPBx) has gained popularity with the introduction of multiparametric magnetic resonance imaging (mpMRI) in the detection of PCa.[1] In local practice settings, patients are required to purchase nonstandard equipment such as a brachytherapy stepping unit and grid for template-guided biopsy or a Precision Point device or CamPROBE for freehand probe-mounted TPPBx before prostatic biopsy. Freehand TPPBx with a coaxial needle technique under local anesthesia (LA) offers an alternative to probe-mounted freehand or template-guided techniques in the diagnosis of PCa. TPPBx technique can be easily performed under LA in an office setting; compared with template-guided counterparts, it is less painful, [2] more cost-effective [3] and associated with a lower admission rate and lower bed occupancy.

The diagnosis of prostate cancer requires a prostatic biopsy. Transrectal ultrasound (TRUS)-guided 12 core systematic prostate biopsy through transrectal approach is the current standard of care. [4] Multiparametric magnetic resonance imaging (mpMRI) helps in the identification of clinically significant lesion (s) in patients suspected to have prostate cancer. [5] It also aids in targeting the lesions during biopsy by various methods such as in bore guidance, MRI-TRUS software-assisted fusion, and cognitive fusion biopsies. However, owing to the variable size of prostate, accessing all areas and representative samples from the whole prostate gland is difficult. [6]

Historically, transperineal needle biopsy without image guidance was first done by Ferguson and Barringer which was not accepted widely due to

very low yield of malignancy. [7] In 1954, Kaufman tried transperineal biopsy under transrectal finger guidance with an accuracy rate of 88%. [8] With the demonstration of clinically useful TRUS imaging of prostate by Watanabe et al. in 1974, transrectal approach for prostate biopsy gained popularity. [9] Transperineal prostate biopsy resurfaced after the study by Stewart et al. in 2001, which revealed the limitations of transrectal approach in saturation biopsy setting as persistent false negative rates and under sampling of anterior prostate. [6]

With the ease of access to all sectors of prostate and high yield of biopsy, transperineal approach gained attention in previous biopsy negative patients. [10] Over a period of time, transrectal approach was replaced by transperineal route across many centers in the world due to extremely low or no urosepsis. [11]

We assessed the safety and feasibility of transrectal ultrasound (TRUS) guided free-hand transperineal prostate biopsy under local anesthesia (LA) for suspected prostate cancer.

Methods

The present study was conducted in the Department of urology, Multiple Hospital for a period of 18 months. Total 50 patients were included in the study. Informed consent and patient information sheet were explained in detail to the study subjects prior to their enrolment.

Inclusion criteria were patients with (i) raised PSA, normal DRE, and positive mpMRI findings [lesions with Prostate Imaging-Reporting and Data System version 2.1 (PIRADS) score ≥3] (ii) normal PSA, abnormal DRE and positive mpMRI findings (iii) raised PSA, abnormal DRE and positive mpMRI findings (iv) negative mpMRI (i.e., PIRADS ≤2) and high clinical suspicion of prostate cancer. Exclusion criteria were patients with (i) active urinary tract infection (UTI), (ii) coagulation abnormalities, and (iii) previous prostate biopsies. Patients who fulfilled the above criteria were consecutively enrolled in the study and data were collected.

Study Procedure

Detailed counseling of the patients about the procedure and its possible complications was done and informed consent obtained prior to their enrolment. Basic blood investigations, coagulation profile, urine routine, and urine culture were done. mpMRI of prostate was done for all patients prior to biopsy and representative line diagrams showing different sectors (medial, lateral, anterior, posterior) in relation to apex, mid gland, base, and seminal vesicles (SVs) were drawn with lesions marked for cognitive guidance. Oral laxative was given (Dulcolax 2 tablets) the night before biopsy for adequate rectal emptying.

Patient Position and Local Anesthesia

Transperineal biopsy was done as a daycare procedure under local anesthesia (LA) (2% lignocaine solution) in the operating room. Single dose of third-generation cephalosporin (Cefaperazone plus sulbactum 3 g) was given as a preoperative prophylactic antibiotic after test dose 30 min before the procedure. The patient was positioned in dorsal lithotomy and perineal skin was prepared with chlorhexidine solution. The skin and subcutaneous tissue just anterior to the anal opening was infiltrated with 2% lignocaine. TRUS probe (ARIETTA 60 HITACHI diagnostic ultrasound system Biplanar transrectal probe CC41R1) installed with PRECISION POINT DEVICE (Precision Point™ BXTAccelyon) and loaded with Coaxial biopsy needle (BARD Truguide 13-gauge × 7.8 cm C1410A) was used. 2% Lignocaine jelly was applied per rectally and TRUS was done for visualizing the entire prostate gland and SVs. Stab incisions were made on either side of midline in the perineum at the probable site of coaxial needle passage.

Using real-time ultrasound images, 22-gauge Chiba needle was inserted coaxially and 2% lignocaine infiltrated along the muscular plane and the space of Allaway (between prostatic apical capsule and pelvic floor muscle). [12]

Preliminary Transrectal Ultrasound and Magnetic Resonance Imaging Cognition

The critical step in this technique is the preliminary TRUS examination of prostate and MRI cognitive fusion. As anatomy of prostate varies with patients, proper visualization of SVs, peripheral zone, transitional zone, central zone, and urethra is vital. The prostate is divided into anterior, mid, and posterior sectors with each sector subdivided into medial and lateral zones based on Ginsburg protocol. [13]

In case of larger prostates, basal sectors were also added. MRI images were correlated with TRUS and the lesions with PIRADS score ≥3 were cognitively marked as targets.

Biopsy Technique

Biopsy was done using Bard® Mission™ Disposable Core Biopsy Instrument 18 G × 25 cm - Semi-Automatic 1825 MS. Using real-time TRUS imaging, biopsy needle was inserted coaxially to reach just distal to the intended area and fired. TRUS probe was manipulated to access different areas of prostate gland. Representative cores from each sector, three cores from the target lesion and in case of more than one target lesion, three cores from each target were taken. The number of biopsy

cores were tailored based on the size of the prostate.

Pathological Analysis

Biopsy cores were sent in separate containers marked for each sector and target areas if present. A dedicated Uropathology laboratory analyzed the biopsy specimens, and the detailed reports were given. Tumor type, location, Gleason grade, biopsy core length, number of positive cores, percentage of the core involved, perineural invasion, and lymphovascular invasion are reported.

Outcome Measures and Data Collection

Basic demographic, clinical, and imaging data were collected preoperatively. Outcome measures assessed intraoperatively include procedure time (wheel-in to wheel-out), pain score by visual analog scale (VAS), and complications if any. Immediate postoperative complications such as hematuria and acute urinary retention were documented. Patients were discharged on 3-day course of oral cephalosporins with an information sheet explaining possible adverse events and when to seek medical attention. They were followed up after 3 days and enquired for complications such as fever, UTI, hematochezia, and hematospermia. Pathology reports in detail were documented and correlated with target lesions. Further follow-up of the patient for any complications was done telephonically in a month period.

Statistical Analysis

Data were collected as per methodology and the statistical analysis was carried out using SPSS software version 20.0. (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.) Descriptive analysis results were expressed as mean, median, range, and standard deviation based on their distribution. Categorical variables were expressed in percentage. Odds ratio (OR) was calculated for the association of PIRADS score with malignancy. "P" value was considered statistically significant if <0.05.

Results

Table 1: Demographic and perioperative data

Parameters	
Sample Size (n)	50
Age (Mean ± SD)	69.4 ± 8.72
PSA (Median)	14.56 (4.18-66.4)
Prostate Volume (Median)	44 (16-52)
Procedural time (Median)	20 (15-40)
Number of cores biopsied (Median)	20 (12-38)

The mean age of the patients was 69.4 ± 8.72 years, median PSA 14.56 ng/mL (4.17–672) and prostate size 44cc (16–520).

Table 2: Cancer detection rate

Parameters	Overall, n	Gleason grade group 1, n	Gleason grade group 2, n	Gleason grade group 3, n	Gleason grade group 4, n	Gleason grade group 5, n
All cases (n=50)	38	3	16	20	8	2
PIRADS 3 (n=15)	10	3	4	4	0	0
PIRADS 4 (n=15)	12	0	4	6	4	0
PIRADS 5 (n=20)	18	0	8	10	6	3

Of 50 patients, PIRADS 3, 4, and 5 lesions in mpMRI were found in 15 (30%), 15 (30%) and 20 (40%) patients, respectively.

Discussion

Urosepsis is a dreadful and potentially life-threatening complication, especially with the emergence of multi-drug resistant bacterial strains. [14] A recent study by Johansen et al. has shown alarming rise of urosepsis rate of up to 10% after transrectal biopsy. [15] Transperineal prostate biopsy report more closely represents the disease found at radical prostatectomy specimen and improves preoperative risk stratification. [16] Furthermore, MRI – cognitive fusion transperineal prostate biopsy is technically easy without a steep learning curve. [17]

The mean age of the patients was 69.4 ± 8.72 years, median PSA 14.56 ng/mL (4.17–672) and prostate size 44cc (16–520). Of 50 patients, PIRADS 3, 4, and 5 lesions in mpMRI were found in 15 (30%), 15 (30%) and 20 (40%) patients, respectively. The

overall CDR in our study was 75% which is higher compared to the previous studies, [18,19,20] that can be due to relatively higher PSA levels and relatively larger lesion size in our study. The higher CDR can also be attributed to the prebiopsy mpMRI and the inclusion of both MRI targets and systematic cores in the biopsy which are strongly recommended by the European Association of Urology guidelines based on the results of Cochrane meta-analysis and MRI-FIRST trial. [21,22] In the studies by Guo et al. and Huang et al., the malignancy yield was low (35.3% and 45% respectively), as only systematic cores were taken during biopsy. [19,20] The study by Marra et al. revealed CDR of 53.8% in mpMRI targeted biopsy alone which was increased by 17.3% on adding systematic cores.

The CDR of Wetterauer et al. was low (64.5%) when compared to our study in spite of taking systematic plus targeted biopsy and the probable reason could be the inclusion of re-biopsy/≥2 prior biopsy. [23] Bass et al. showed a good CDR of 78.4% by MRI targeted biopsy without systematic cores and they used stepper grid to localize the lesions which has a higher chance of retrieving cores from peri-target areas. [24] However, a recent study by Urkmez et al. showed equivalent cancer yield for freehand biopsy when compared to grid-based biopsy. [25]

The detection of clinically significant cancer was very high (28/30) and the two cases of clinically insignificant cancers had PIRADS 3 lesions. This finding of high yield of clinically significant cancer and fewer insignificant cancers in prebiopsy MRI targets was similar to the study by Ahmed et al.[26] In addition, our results similar to the study by JW Seo et al. proved that higher the PIRADS score, more are the chances of detecting malignancy from the lesion. [27] Furthermore, patients with high clinical suspicion of cancer but PIRADS 2 lesions in MRI on biopsy were found to be negative for malignancy.

None of our patients had UTI or urosepsis. This concurred with a recent population-based study of 73,630 patients by Berry et al. showing a lower incidence of septic complications in trans perineal route compared to transrectal biopsy. [28] The traditional indication of using transperineal approach of prostate only for saturation biopsy in previously biopsy negative patients is slowly changing. The economic burden due to post biopsy infections and the need for better prevention has been documented. [29] In developing countries like India, the healthcare expenses in managing a complication can be higher than the procedure itself. Various centers across world have started using transperineal prostate biopsy as the standard of care, completely switching over from transrectal approach.

All the biopsies were done by single surgeon, experienced in transrectal and transperineal prostate biopsy. Hence, the high yield of the biopsy may be attributed to the surgeon's experience and knowledge of prostate imaging. However, adequate training and mpMRI proficiency may help beginners breach the learning curve more rapidly. Other limitations are low sample size and absence of prospective comparison with transrectal biopsy group, which are recommended in further studies.

Conclusion

Freehand TRUS-guided transperineal prostate biopsy by coaxial needle technique under LA is a safe, feasible procedure with good tolerability, high CDR, and minimal complications, particularly no urosepsis. In developing countries like India, this approach has a potential to avoid economic burden due to general anesthesia and management of post biopsy urosepsis. It shows excellent patient tolerability while minimizing complications.

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