Safety and feasibility of freehand transperineal prostate biopsy under local anesthesia: Our initial experience

Ananthakrishnan Sivaraman*, Vasantharaja Ramasamy, P. Aarthy, Vinoth Sankar, P. B. Sivaraman

Department of Urology, Uro-Oncology and Robotic Surgery, Chennai Urology and Robotics Institute, Chennai, Tamil Nadu, India
*E-mail: ananthsiv@gmail.com

INTRODUCTION

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. Multimodality imaging helps in the identification of clinically significant lesion(s) in patients suspected to have prostate cancer. 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.

TRUS guided transrectal biopsy breaches the rectum to reach the genitourinary tract, making the procedure a clean-contaminated one. Septic complications and the

ABSTRACT

Introduction: With the emergence of multidrug-resistant organisms causing urosepsis after transrectal biopsy of prostate, the need for an alternative approach has increased. We assessed the safety and feasibility of transrectal ultrasound (TRUS) guided free-hand transperineal prostate biopsy under local anesthesia (LA) for suspected prostate cancer.

Materials and Methods: This prospective study was conducted from July 2019 to December 2020 in which patients with elevated prostate-specific antigen (PSA) and/or abnormal digital rectal examination underwent magnetic resonance imaging-TRUS cognitive fusion transperineal prostate biopsy (target and systematic) using coaxial needle. Demographic, perioperative, and outcome data of 50 consecutive patients were analyzed.

Results: The mean age of the patients was 69.6 ± 7.61 years, median PSA 13.55 ng/mL (4.17–672) and prostate size 45cc (16–520). Prostate Imaging–Reporting and Data System (PIRADS) 2, 3, 4, and 5 lesions were found in 2, 12, 12, and 24 patients, respectively. Average procedure duration was 20 min (15–40 min) and number of cores ranged from 12 to 38 (median 20). Forty out of fifty (40/50) patients experienced only mild pain with visual analog scale ≤2.

Histopathological examination showed adenocarcinoma, benign prostatic hyperplasia, and chronic prostatitis in 41, 5, and 4 patients respectively with 82% cancer detection rate (CDR). Over 95% of cases showed clinically significant cancer (International Society of Urological Pathology class ≥ 2) and 91.7% of patients with PIRADS score 4/5 and 66.7% with PIRADS score 3 had malignancy. Three patients developed complications (two hematuria, one urinary retention), both were managed conservatively and none had urosepsis.

Conclusions: Free-hand transperineal prostate biopsy by coaxial needle technique under LA is safe and feasible with good tolerability, high CDR, and minimal complications particularly reduced urosepsis.
morbidty associated are not uncommon following this procedure and hence an alternative approach to prostate biopsy is needed. Difficulty in accessing anterior zone and apical region of prostate is a known drawback in the transrectal approach. [4] 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. [5] In 1954, Kaufman tried transperineal biopsy under transrectal finger guidance with an accuracy rate of 88%. [6] With the demonstration of clinically useful TRUS imaging of prostate by Watanabe et al. in 1974, transrectal approach for prostate biopsy gained popularity. [7] 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. [8] With the ease of access to all sectors of prostate and high yield of biopsy, transperineal approach gained attention in previous biopsy negative patients. [9] 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. [10] In a recent study by Urkmez et al., freehand transperineal prostate biopsy technique compared to grid-based biopsy showed similar cancer detection rate (CDR), reduced anesthesia needs, and lower acute urinary retention rate. [10] In this study, we evaluated the safety and feasibility of freehand TRUS-guided transperineal prostate biopsy as an alternative to the transrectal approach.

MATERIALS AND METHODS

Study population
This was a single institutional prospective study conducted from July 2019 to December 2020 (18 months). Institutional Ethics Committee approval (IEC No: CURI/IEC/02/05/2019) was obtained before initiation of this 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
Preoperative workup
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 (PrecisionPoint™ BXTAccelyon) and loaded with Coaxial biopsy needle (BARD Truglide 13-gauge × 7.8 cm C1410A) as shown in Figure 1 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) [11] [Figure 2].

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

![Figure 1: (i) ARIETTA 60 HITACHI diagnostic ultrasound system Biplanar transectal probe (CC41R1) installed with PRECISION POINT DEVICE (PrecisionPoint™-BXTAccelyon) and loaded with Coaxial biopsy needle (BARD Truglide 13-gauge × 7.8 cm (C1410A) (A) aerial view, (B) lateral view (ii) PRECISION POINT DEVICE loaded with Coaxial biopsy needle (A) end-on view, (B) lateral view]
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 [12] [Figure 3]. 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 as shown in Figure 4 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 [Figure 5]. 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.

**RESULTS**
The demographic, perioperative, and follow-up data sets were collected prospectively. Table 1 depicts the

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**Figure 2:** Infiltration of local anaesthesia (a) Trans rectal ultrasound (TRUS) image sagittal and axial view (white arrow – infiltration given in the “Space of Allaway” i.e., between prostatic apical capsule and pelvic floor muscle, yellow arrow – needle tract) (b) TRUS probe with 22-gauge Chiba needle inserted via coaxial needle

**Figure 3:** MRI-TRUS cognitive fusion (I and II) MRI line diagram - sagittal and axial showing sectors (purple-anterior, blue-mid, red-posterior, green-basal). (III) TRUS sagittal and axial images. (IV) probe manipulation (A) apex-depress/withdraw probe, (B) Midgland - raise/insert probe, (C) Base - Insert further from midgland. (V) Urethra (A) MRI line diagram (B) TRUS images (yellow). SV = Seminal vesicle, AFS = Anterior fibromuscular stroma, TZ = Transitional zone, CZ = Central zone, PZ = Peripheral zone, U = Urethra, MRI = Magnetic resonance imaging, TRUS = Transrectal ultrasound

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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.
demographic and perioperative data of the study population. Of 50 patients, PIRADS 2, 3, 4, and 5 lesions in mpMRI were found in 2 (4%), 12 (24%), 12 (24%) and 24 (48%) patients, respectively. The median target lesion size of suspected lesion on MRI was 12 mm (range 7–23 mm). Forty out of 50 (80%) experienced only mild pain with VAS ≤2. Histopathological examination showed adenocarcinoma prostate, benign prostatic hyperplasia, and chronic prostatitis in 41 (82%), 5 (10%), and 4 (8%) patients respectively with high CDR of 82%. The distribution of Gleason grade group versus PIRADS score is shown in Table 2. Out of 41 cases of malignancy, 39 (95.12%) cases showed clinically significant cancer (International Society of Urological Pathology class ≥2), and remaining 2 cases were clinically insignificant cancer (ISUP class <2). Over 91% of patients with PIRADS score 4 or 5 and 66.7% of patients with PIRADS score 3 showed malignancy. The odds of having malignancy in PIRADS 4 or 5 lesions was five times more than in PIRADS 3 lesions (OR 5.5, \( P = 0.033 \), 95% confidence interval 1.02–29.6). Around 84% of patients had abnormal DRE and all of them had malignancy. Of all patients, only 3 developed complications after procedure (two had hematuria, one had acute urinary retention and none presented with either hematospermia or hematochezia) [Table 2].

**DISCUSSION**

Urosepsis is a dreadful and potentially life-threatening complication, especially with the emergence of multi-drug resistant bacterial strains.[29] A recent study by Johansen et al. has shown alarming rise of urosepsis rate of up to 10% after transrectal biopsy.[20] An alternative procedure with low risk of sepsis and negligible exposure to bacterial flora needs to adopted. The need for a strict hospital policy for antibiotic usage and check on resistance patterns to reduce urosepsis cannot be overemphasized. A large series by Stefanova et al. showed transperineal biopsy under LA was as tolerable as transrectal approach.[21] In comparison with transrectal approach, transperineal route has the benefit of superior detection of anterior and apical lesions.[22,23] Transperineal prostate biopsy report more closely represents the disease found at radical prostatectomy specimen and improves preoperative risk stratification.[24] Furthermore, MRI – cognitive fusion transperineal prostate biopsy is technically easy without a steep learning curve.[25]

The demographic and clinical data such as age, prostate volume, number of cores biopsied were in concordance with previous studies as mentioned in Table 1. Median PSA (13.55 ng/ml) was higher in our study which can be attributed to more prevalence of high-risk cancers at diagnosis in India.[26] The median procedure time was 20 min, slightly high compared to the previous studies as mentioned in Table 1, which can be attributed to our learning curve. Seven out of 8 patients with normal DRE but positive MRI findings were found to have malignancy in the targeted biopsy. This finding concurs with previous studies regarding the need of MRI in all patients prior to biopsy regardless of DRE findings to decide on biopsy, target the lesion, and for early detection of prostate cancer.[27,28]
Tolerability

In our study, majority (33/50) of the patients had VAS of 1/10, and no one required conversion to general anesthesia (GA) for pain, inferring that the need of GA for a transperineal approach can be replaced by an optimal periprostatic block. Table 3 reveals that in most other studies the patients experienced only mild pain with median VAS ≤2 except in the study by Marra et al. They used multiple puncture technique for the biopsies in contrast to our coaxial needle technique which might be the probable reason for high pain score.\(^{[13]}\) Usage of coaxial needle plays a major role to reduce pain by avoiding multiple punctures. The loose areolar tissue beneath the perineal skin allows easy manipulation of coaxial needle to access all areas of prostate through single skin puncture on either side of midline. This evidence was supported by the randomized study comparing biopsy...
with and without coaxial needle by Babaei Jandaghi et al. and another study by Novella et al., showing lower pain score and shorter procedure time with the use of coaxial needle.\[31,32\]

**Cancer detection rate**

The overall CDR in our study was 82% which is higher compared to the previous studies,\[13,14,18,29,30\] 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.\[33,34\] 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.\[14,18\] 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.\[13\] The above data also substantiates the need of targeted plus systematic biopsy of whole gland as standard of care. 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.\[29\] 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.\[30\] However, a recent study by Urkmez et al. showed equivalent cancer yield for freehand biopsy when compared to grid-based biopsy.\[18\]

The detection of clinically significant cancer was very high (39/41) 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.\[35\] In addition, our results [as shown in Table 2] 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.\[36\] Furthermore, patients with high clinical suspicion of cancer but PIRADS 2 lesions in MRI on biopsy were found to be negative for malignancy.

**Complications**

Only 3 out of 50 patients had complications postbiopsy and none were more than Grade 2 Clavien-Dindo classification.\[36\] Two patients had hematuria, both subsided with conservative management (Clavien-Dindo Grade 1). Similar to previous studies as shown in Table 3, hematuria was the predominant complication.\[13,14,18\] Although freehand biopsy has chance of injuring urethra causing hematuria, proper visualization of urethra in TRUS avoids trauma. However, in lesions close to the urethra especially in apex of prostate, as seen one of our cases it is difficult to avoid inadvertent injury while firing biopsy gun. One patient in our study had acute urinary retention postprocedure for which he was catheterized (Clavien-Dindo Grade 1). A trial without catheter was successful after starting alpha blockers. Acute urinary retention once thought to be common after transperineal biopsy was rarely seen as in several recent studies.\[13,18,29,30\] This could be attributed to the change of technique from grid-based to freehand biopsy.

### 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)   | 41 (82)        | 2 (4)                        | 13 (31)                     | 16 (39)                    | 8 (19)                     | 2 (4)                      |
| PIRADS 3 (n=12)    | 8 (66.7)       | 2 (25)                       | 3 (37.5)                    | 3 (37.5)                   | 0                          | 0                          |
| PIRADS 4 (n=12)    | 11 (91.7)      | 0                            | 3 (27.3)                    | 5 (45.4)                   | 3 (27.3)                   | 0                          |
| PIRADS 5 (n=24)    | 22 (91.7)      | 0                            | 7 (31.8)                    | 8 (36.4)                   | 5 (22.7)                   | 2 (9)                      |

PIRADS = Prostate imaging-reporting and data system

### Table 3: Procedural outcomes

| Parameters               | Our study | Wetterauer et al.\[29\] | Huang et al.\[18\] | Marra et al.\[12\] | Bass et al.\[30\] | Guo et al.\[14\] |
|-------------------------|-----------|-------------------------|--------------------|-------------------|------------------|------------------|
| Sample size (n)         | 50        | 400                     | 130                | 279               | 181              | 173              |
| Pain score (VAS), median (IQR) | 1 (0-6) | 2 (0-8)                 | 3 (2-4)            | 5 (3-7)           | 1 (0-2.4)        | 4 (1-6)          |
| Overall, n (%)          | 41 (82)   | 258 (64.5)              | 58 (45)            | 150 (53.8)        | 142/181 (78.4)   | 61 (35.3)        |
| In PIRADS 3, n (%)      | 8/12 (66.7) | 14/31 (45.1)       | NR                 | 34.9              | 27/62 (43.5)     | NR               |
| In PIRADS 4, n (%)      | 11/12 (91.7) | 107/172 (62.2)     | NR                 | 51.7              | 63/87 (72.4)     | NR               |
| In PIRADS 5, n (%)      | 22/24 (91.7) | 59/63 (93.7)       | NR                 | 75                | 90/94 (95.7)     | NR               |
| Hematuria n (%)         | 2 (4)     | 0                       | 7 (5.3)            | 191 (72.6)        | 0                | 33 (19.8)        |
| Urinary retention, n (%)| 1 (2)     | 4 (1)                   | 4 (3)              | 2 (0.7)           | 1/181 (0.05)     | NR               |
| UTI, n (%)              | 0         | 0                       | 3 (2.2)            | 0                 | 0                | 0                |
| Urosepsis               | 0         | 0                       | 0                  | 0                 | 0                | 0                |
| Hematospermia, n (%)    | 0         | 0                       | 0                  | 0                 | 0                | 0                |
| Hematochezia            | 0         | 0                       | NR                 | 142 (54.2)        | NR               | 0                |

NR = Not recorded, IQR = Interquartile range, PIRADS = Prostate Imaging-Reporting and Data System, VAS = Visual analog scale, UTI = Urinary tract infection.
as documented in the recent study by Urkmez et al. (10% vs. 1% respectively). No patient required readmission for any complication.

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 transperineal route compared to transrectal biopsy. Single-dose of prophylactic third-generation cephalosporin was given as per our protocol, even that was omitted in a study by Wetterauer et al. showing no urosepsis postbiopsy. These results validate transperineal prostate biopsy as a clean procedure which can be used to evade the morbid septic complications of transrectal approach.

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 postbiopsy infections and the need for better prevention has been documented. 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.

Limitations and recommendations
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. We used PRECISION POINT DEVICE for maintaining coaxial needle and TRUS probe in alignment, but any stabilizer to maintain the alignment can be used or it can even be done without any stabilizing device (in case of experts in image-guided biopsy).

CONCLUSIONS
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 postbiopsy urosepsis.

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Conflicts of interest
There are no conflicts of interest.

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