Initial experience and cancer detection rates of office-based transperineal magnetic resonance imaging-ultrasound fusion prostate biopsy under local anesthesia

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Abstract

Introduction: We aimed to demonstrate feasibility and cancer detection rates of office-based ultrasound-guided transperineal magnetic resonance imaging-ultrasound (MRI-US) fusion (TFB) prostate biopsy under local anesthesia.

Methods: With institutional review board approval, records of men undergoing TFB in the office setting under local anesthesia were reviewed. Baseline patient characteristics, MRI findings, cancer detection rates, and complications were recorded. The PrecisionPoint Transperineal Access System (Perineologic, Cumberland, MD, U.S.), along with UroNav 3.0 image-fusion system (Invivo International, Best, The Netherlands) were used for all procedures. Following biopsy, men were surveyed to assess patient experience.

Results: Between January 2019 and February 2020, 200 TFBs were performed, of which 141 (71%) were positive for prostate cancer, with 117 (83%) Gleason grade group 2 or higher. A total of 259 of 265 MRI lesions were biopsied, with 127 (49%) positive overall. Prostate Imaging–Reporting and Data System (PI-RADS) 4–5 lesions were positive for prostate cancer in 59% of cases. The mean procedural time was 20 minutes, with a patient enter-to-exit room time of 54 minutes. There were no septic complications, no patients required post-procedure hospital admission, and all procedures were successfully completed. Seventy-five percent of patients surveyed reported complete resolution of pain at three days following the procedure.

Conclusions: Office-based TFB represents a viable approach to prostate cancer detection following prostate MRI. Larger-scale assessment is needed to categorize cancer detection rates more accurately by PI-RADs subset, patient selection factors, complication rate, and cost relative to TFB under anesthesia.

Introduction

The goals of prostate biopsy are simple: first, detection of clinically significant prostate cancer when present; and second, minimizing procedure-associated morbidity. Optimizing cancer detection rates has appropriately driven much of the evolution of prostate biopsy over the last few decades. Patient selection for biopsy remains the most important factor influencing likelihood of cancer diagnosis. More discerning use of screening, multiparametric magnetic resonance imaging (mpMRI), and the introduction of a variety of secondary tests (4K score, Prostate Health Index [PHI], and others) all hold potential benefits with regard to reducing unnecessary prostate biopsies.[1-3] Refining templates and sample number along with mpMRI have also played significant roles in enhancing cancer detection.[4] However, as a field, urology has been slow to meaningfully adjust biopsy technique with the objective of reducing procedure-associated morbidity. Morbidity of biopsy, specifically infection and sepsis, is one of the central reasons why the United States Preventative Service Task Force (USPSTF) and others have been critical of prostate cancer screening.[5]

Biopsy-associated infection, a long-recognized risk of the transrectal biopsy approach, is reported to occur at a rate 1–6%.[6-10] Urologists inevitably become familiar with such infections, which hold significant morbidity and even mortality for affected patients. Treatment of such infections is increasingly costly and problematic, particularly with the rise of fluoroquinolone-resistant and multidrug-resistant bacteria.[11] Iterations of single and dual drug antibiotic prophylaxis, rectal swab cultures, enemas of various types, formalin-dipped biopsy needle guns, among other methods, have all failed to adequately reduce the risk of transrectal prostate biopsy-associated sepsis.[12-15] One biopsy-associated death can essentially negate much of the benefit of prostate cancer screening, as the number needed to treat to prevent one death from prostate cancer is relatively high compared with other malignancies.

Transperineal prostate biopsies, while a small fraction of prostate biopsies performed, continue to gain traction, as many centers phase out transrectal biopsies altogether in an effort to eliminate biopsy-associated infection.[16-19] In addition, transperineal biopsy obviates the need for antibiotic prophylaxis in almost all patients, offering significant benefit in an era when antibiotic stewardship is critically important. However, perceived requirement for general anesthesia, cost, time, practice culture, questions of accuracy, and need for additional training and equipment have all have contributed to the lack of more universal adoption of transperineal biopsy. These perceptions are even more pronounced for performance of transperineal ultrasound-guided MRI-fusion-guided prostate biopsies (TFB). Currently, almost all TFB are performed under general anesthesia, using a template grid for planning biopsy location and alignment of the biopsy needle with the plane of the ultrasound array. The use of a large stepper, template grid, and general anesthesia each independently increase procedure-associated time, cost, setup complexity, and morbidity to the patient.[18]

The PrecisionPoint Transperineal Access System (Perineologic, Cumberland, MD, U.S.) employs a short transperineal access needle that snaps around a transrectal ultrasound probe, stabilizing the biopsy needle in the plane of the ultrasound array and minimizing the number of punctures through the perineum. This device facilitates performance of transperineal prostate biopsy in an office setting.[18] We set out to demonstrate that TFB with the transperineal access system features comparable accuracy to traditional transrectal fusion biopsy while also allowing for reasonable procedure time, low pain scores, and minimal infectious complications.

Methods

Patient preparation and positioning

Patients self-administered one sodium phosphate enema prior to biopsy to facilitate ultrasound visualization. No antibiotic prophylaxis was used in any patient. Patients were offered diazepam 5–10 mg as an oral sedative to be taken one hour prior to biopsy. Patients were placed in lithotomy using adjustable stirrups secured to a procedure table. Tape was used to elevate the scrotum off the perineum, and the perineal skin was prepped with 2% chlorhexidine in 70% isopropyl alcohol (ChloraPrep, Becton Dickinson, Franklin Lakes, NJ, U.S.).

MRI imaging preparation and imaging fusion platform

mpMRI was performed within the six months prior to biopsy. Prostate Imaging–Reporting and Data System (PI-RADS v2) designations were applied and lesions with PI-RADs 3–5 designation were marked by three core reading radiologists. PI-RADs 1 and 2 category lesions were not marked or biopsied. Marked images were then transferred to the Uronav 3.0 image-fusion software platform (Philips/In Vivo, Koninklijke Philips, The Netherlands).

Ultrasound and local anesthetic

The 8848 biplanar ultrasound probe with Flex Focus ultrasound (bK Ultrasound, Peabody, MA, U.S.) was chosen for the procedure based on compatibility with Uronav 3.0 image fusion software for TFB. Although not critical to the procedure, the probe has a low profile and a long linear transducer, facilitating early and continuous view of passing needles for the administration of local anesthesia and acquiring biopsies. The system's magnetic field generator was located just above the perineum. A probe tracker for the field generator was attached using a purpose-built accessory. Setup is portrayed in Figures 1–3.

Prior to ultrasound, the perineum is marked to designate two perineal access points, one on either side of midline approximately 1 cm anterior and lateral to the anal verge. Local anesthetic (1% lidocaine with 8.4% sodium bicarbonate, mixed 9:1) is then administered; 5 mL of the anesthetic are then injected at each of these two sites at the skin and subcutaneous tissue. Under transrectal ultrasound guidance with the linear transducer, additional anesthetic is administered on each side using a 20-gauge/6-inch spinal needle. A small amount is injected along the anticipated biopsy

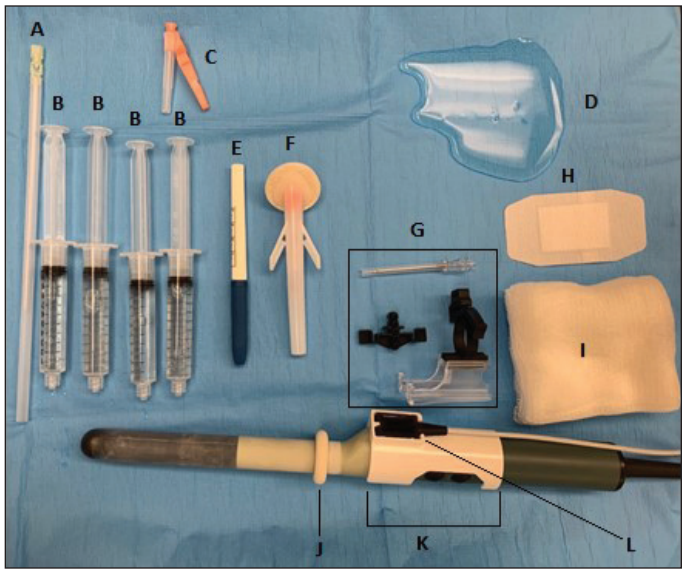

Figure 1. Setup/supplies for transperineal fusion biopsy. **(A)** 20-gauge 6" spinal needle; **(B)** 10 cc of 10:1 1% lidocaine mixed with 8.4% sodium bicarbonate; **(C)** 22 g needle; **(D)** surgical lubricant; **(E)** marking pen; **(F)** 2% chloraprep; **(G)** PrecisionPoint Transperineal Access System; **(H)** bandage; **(I)** 4x4 surgical dressing; **(J)** disposable probe cover; **(K)** tracker mount; **(L)** tracker for field generator. Probe pictured is the bK 8848 Biplanar Ultrasound Probe.

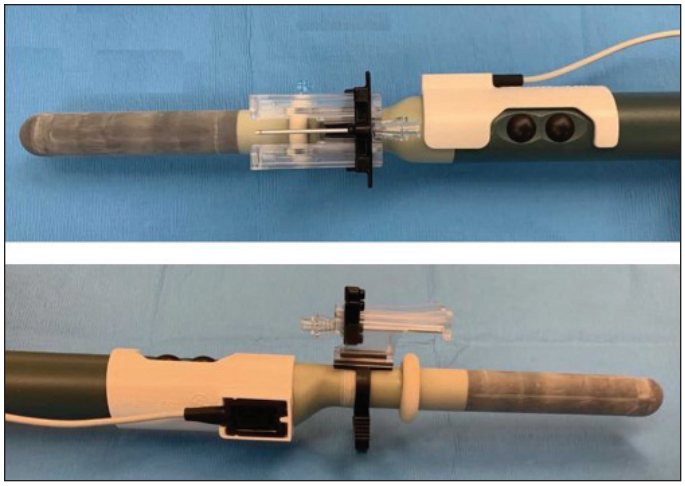

Figure 2. Biopsy probe setup. BK 8848 Biplanar Ultrasound Probe with PrecisionPoint Transperineal Access System and tracker for field generator attached.

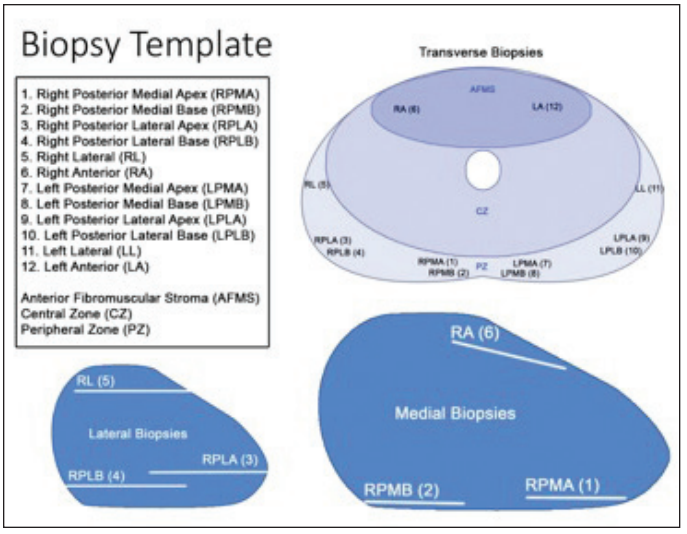

Figure 4. Transperineal biopsy template used in addition to any magnetic resonance imaging target lesions sampled.

needle tract and the majority bolus injected just beneath the endopelvic fascia into the pelvic floor musculature.

Ultrasound images for fusion are obtained by sweeping across the prostate in the sagittal plane from one lateral aspect of the prostate to the other. This is done prior to attaching the PrecisionPoint to the ultrasound probe to avoid unintentional collision between the access system and the perineum during the sweep.

Image fusion and biopsies

Once ultrasound images are obtained, 3D imaging calibration is performed. Orientation of the imaging, defining prostate boundaries, rotational adjustments in sagittal and transverse planes, and lesion localization are carried out. The PrecisionPoint is then attached and used in conjunction with the Uronav 3.0 MRI-US fusion imaging software platform to perform targeted biopsies of the MRI-detected lesions. The PrecisionPoint needle guide is a small, mobile, linear template that replaces the larger template grid used for TFB under anesthesia. The guide allows biopsies to be taken at variable distance away from the ultrasound and moves across the perineum with rotation of the probe. The Uronav 3.0 software contains a computer-generated map of the needle guide to designate which needle guide access point is best suited to a particular lesion location.

Target lesions detected on MRI were sampled with 2–3 needle core biopsies each. A 12-core biopsy was performed in addition to target biopsies using our own transperineal template (Figure 4). The PrecisionPoint access needle can be withdrawn and reinserted through any of the five access points on the needle guide to target a lesion or various biopsy template locations. The same skin puncture site can be used for the access needle at any point of the needle guide, limiting the number of skin punctures to only two for the entire procedure.

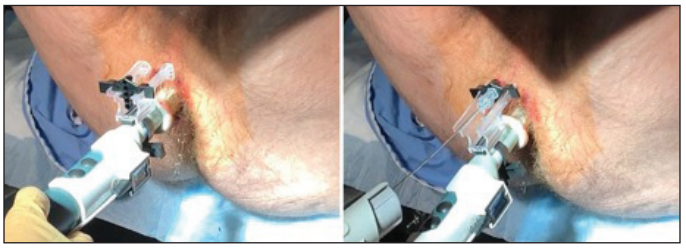

Figure 3. Patient and probe setup. **(Left)** Probe positioned in rectum with PrecisionPoint Access System attached and oriented, not yet inserted into transperineum. **(Right)** Probe positioned in rectum with PrecisionPoint Access System inserted into transperineum with core biopsy instrument.

Data collection

Charts of 200 sequential patients who had underwent TFB in-office between January 2019 to March 2020 were reviewed. Information regarding patient demographics, indication for biopsy, MRI results, pathological results, and outcome were gathered. Hospital and admission records were reviewed to assess for presentation following procedure. All patients were contacted via telephone following the procedure and asked to consent to a brief survey regarding their experiences with TFB in-office (Appendix available at *cuaj.ca*). Responses of those who were able to be reached and who consented were recorded.

Results

Between January 2019 and February 2020, 200 sequential patients underwent TFB in the office setting under local anesthesia as detailed above. Average age was 67 years (range

Table 1. Patient demographics	
Patient age at biopsy, years (range)	67 (50–83)
Prior biopsy	51%
5-ARI inhibitor usage	11%
Active surveillance	20%
Hypertension	36%
Diabetes	18%
Average PSA (range)	8.97 (2–33.7)
Average prostate size, cc (range)	52 (13–114)

Table represents demographics characteristics of patient population. Prostate size obtained from magnetic resonance imaging and PSA listed is from value closed to time of transperineal fusion biopsy. 5-ARI: 5-alpha reductase inhibitors; PSA: prostate-specific antigen.

44–87) with average prostate-specific antigen (PSA) of 7.89 (range 2–33.2) and average prostate size of 52 cc (range 10–235 cc). Additional demographic data is available in Table 1.

In addition to the MRI-detected abnormality, the primary indication for prostate biopsy was elevated PSA. There were a total of 265 PI-RADs lesions found on prostatic MRI; of these, 186 (70%) were PI-RADS 4–5 lesions (Table 2). Of the 200 biopsies performed, 141 (71%) were positive, with 117 (58.5%) being classified as Gleason grade group (GG) 2 or greater and 25 (12.5%) as GG 4 or greater (Table 3). Of the 259 MRI lesions biopsied, 127 (49%) were positive for prostate cancer (Table 2). Among the PIRAD 4–5 lesions, 110 of 186 lesions (59%) were positive. Regarding the systematic biopsies alone, 131 (65.5%) were positive, with 99 being GG 2 or greater. MRI targeted biopsy was positive in 111 biopsies, with 101 being GG 2 or greater. (Table 3).

An average of 36 mL of the local anesthetic was used; 67% of patients opted to receive diazepam orally. From 175 patients with complete time records available, mean time per procedure was 20 minutes. The mean time from patient room entry to room exit was 54 minutes. Time points improved after the first 50 TFBs were performed, with mean procedure time (timeout prior to procedure to completion of procedure) decreasing to 18 minutes from 21 minutes, and the mean room entry to exit time decreasing from 60 minutes to 50 minutes (Table 4).

Table 2. MRI lesion and targeted biopsy characteristics	
Total number of lesions	265
PI-RADS 2	6 (2.2%)
PI-RADS 3	73 (28%)
PI-RADS 4	135 (51%)
PI-RADS 5	51 (19%)
MRI lesions biopsied	259
MRI lesions not biopsied (PI-RADS 2)	6
MRI lesions positive	127 (49%)
PI-RADS 4 positive	69 (51%)
PI-RADS 5 positive	41 (80%)

Table provides information on MRI lesions based on PI-RADS v2. Positive biopsy is based on any cancer detected, including Gleason grade group 1 (Gleason grade 3+3). MRI: magnetic resonance imaging; PI-RADS: Prostate Imaging Reporting and Data System.

Table 3. Biopsy characteristics	
Total biopsies	200
Positive biopsies	141 (71%)
Gleason grade group ≥2 (overall)	117 (58.5%)
Gleason grade group ≥4 (overall)	25 (12.5%)
Systematic biopsy positive	131 (65.5%)
Systematic biopsy positive for grade group 1	32
Systematic biopsy positive for grade group ≥2	99
MRI targeted positive	111 (55.5%)
MRI targeted positive for grade group 1	10
MRI targeted positive for grade group ≥2	101
Systematic biopsy positive only	30
Systematic biopsy positive: grade group 1	18
MRI biopsy positive only	10

.Positive biopsies reflect pathology of at least Gleason grade group 1 (Gleason grade 3+3) or greater. Systematic refers to standard template biopsies as outlined in Figure 4 and MRI-targeted refers to core obtained through fusion biopsy. MRI: magnetic resonance imaging.

No narcotic pain medications were prescribed for any patient. A total of 165 (83%) patients were reached by nursing staff within 1–2 days, with 159 denying any significant complaints. The remaining six patients stated complaints of gross hematuria, increased urinary frequency, or perineal pain, with one patient receiving antibiotics for culture-positive urinary tract infection and the rest resolving without further intervention. There were no hospitalizations, emergency room visits at affiliated hospitals, or septic complications. No procedures were aborted for any reason.

Post-procedure telephone surveys were administered to each of the 200 patients in the cohort, with a completion rate of 38% (76/200). Mean pain score was 2.4/10 immediately following the procedure, with a decrease to 1.4/10 in the first three days following the procedure. Most patients (74%, 56/76) reported no pain following the third post-procedural day. Of all surveyed patients, 9% reported pain that affected their ability to perform their job and 7.9% reported pain affecting their ability to relax or enjoy activities. Urinary issues immediately following the biopsy were reported by 22%, the vast majority citing minor, self-limited hematu-

Table 4. Biopsy performance characteristics	
Mean procedure time	20±1 min (7–35)
Mean patient enter-to-exit time	54±2 min (23–93)
Mean procedure time, first 50 biopsies	21±0.5 min (15–27)
Mean procedure time, next 50 biopsies	18±0.4 min (8–30)
Mean patient enter-to-exit time, first 50 biopsies	60±2.4 min (43–85)
Mean patient enter-to-exit time, next 50 biopsies	50±3 min (39–85)
Mean 1% xylocaine: 8.4% NaHCO3 used 10:1	35±5 mL (20–40)
Patients using oral sedation	67%

Times are based on mean time calculations using all patients with complete time records (88%). Mean procedure time and patient enter-to-exit time for first 50 and next 50 biopsies are derived from a single practitioner data set. Patients using oral sedation most commonly used 5 mg oral diazepam taken prior to procedure.

ria. Thirty-six patients reported a prior history of transrectal prostate biopsy. Of these, 53% (19/36) reported less pain with the transperineal approach compared to their prior transrectal biopsy, with an additional 33% (12/36) reporting no significant difference between these procedures. Most respondents (89%, 32/36) reported they would encourage a friend or family member to undergo transperineal biopsy based on their experience.

Discussion

To our knowledge, while prior large-scale studies have assessed the feasibility of performing transperineal prostate biopsies in the office under local anesthesia, no studies have reported on the suitability of performing MR-US fusion biopsies under local anesthesia. As our practice has transitioned to the transperineal approach for all non-fusion prostate biopsies, we felt compelled to explore an in-office approach to TFB. An office-based TFB approach could avoid the additional time, morbidity, and cost associated with performance of biopsies under general anesthesia, assuming that the cancer detection rate was not compromised. The primary goals of this project included examination of the cancer detection rate and feasibility in terms of time and tolerance of TFB under local anesthesia using the PrecisionPoint Access System. The secondary goals of this study involved assessment of post-biopsy complications, particularly infectious complications.

To comparatively gauge our cancer detection rate, literature reporting on cancer detection with transperineal biopsy, transrectal MR-US fusion biopsy, and transperineal MR-US fusion biopsy was reviewed. Transperineal biopsies demonstrate a cancer detection rate of approximately 36–50%.[18-22] Cancer detection rates for transrectal MR-US fusion biopsies have been reported from 35–70%, while also stating an increased detection rate of clinically significant (Gleason score ≥3+4) and a decreased detection rate of lower Gleason grade prostate cancer.[23–25] In one of the largest prospective, investigator-blinded trials on MRI-fusion to date, Pokorny et al reported a detection rate of 69.7% with MRI-guided transrectal biopsy vs. 56.5% with transrectal-guided biopsy.[25] Additionally, using our unpublished, institution-specific data, we reviewed 706 transrectal fusion biopsies with an overall prostate cancer detection rate of 65%, with 47% of biopsies resulting in detection of Gleason GG 2 or greater cancer. Specific to TFBs, an overall prostate cancer-positive rate of 40–75% has been reported in the literature across a broad range of patients.[26-28] Thus, our detection rate of 71% compares favorably with prior estimates for both transrectal and transperineal fusion biopsies, as well as our own previous transrectal MR-US fusion data.

Biopsies targeting MRI-detected lesions demonstrated a 51% positive prostate cancer detection rate overall, with 59% of PI-RADS 4–5 lesions positive for prostate cancer. These results fall in the spectrum of prior reported cancer detection rates, with Mehralivand et al reporting a 58% prostate cancer detection rate for PI-RADS 4–5 lesions during fusion biopsy and Washino et al reporting an effective rate of 80% of PI-RADS 4–5 lesions containing prostate cancer.[29,30]

Large-scale retrospective studies have repeatedly demonstrated the low side effect profile of transperineal biopsies, particularly regarding infectious complications, when compared to transrectal biopsies.[11,16,17,19,20] Stefanova et al reported on the results of 1287 patients undergoing transperineal prostate biopsy in the office using local anesthesia reporting zero major complications or episodes of urosepsis.[20] Minor complications were relatively uncommon (1.9%), with temporary urinary retention representing the majority of minor complications. We report six minor complaints post-procedurally, with three patient reporting temporary increased urinary frequency that resolved without intervention or antibiotics, one patient reporting persistent perineal pain, and two patients with hematuria lasting approximately one week without needing transfusion or catheter placement.

To our knowledge, none of our patients presented to the emergency room or required additional visits to the office for postoperative complications. Telephone survey confirmed that this procedure was well-tolerated, with minimal complaints and pain that was rarely high enough to interfere with work or other activities.

Prior studies have noted a time of 10–15 minutes required from probe insertion to probe removal per transperineal biopsy, after the learning curve has been passed.[18,20,21] Mean procedural time for TFB in this series was modestly longer at 20 minutes per procedure. Procedural time for our most recent TFB procedures, however, has decreased to 18 minutes, demonstrating the improved efficiency of the procedure with relatively little experience. It is our expectation that time required per procedure will be further minimized as the procedure is refined and additional proficiency develops.

While mean total room time was long at 54 minutes, room time substantially improved after the first 50 biopsies to 50 minutes, an improvement of approximately 10%, and it is expectation that total time will continue to decrease as the support staff's familiarity with biopsy setup and workflow improves. The time required for TFB under local anesthesia is acceptable and makes the procedure feasible to incorporate into a routine office day.

Of note, the practitioners in this study performed TFB as part of a standard clinical day, seeing routine office patients in between TFB cases. As no procedures were aborted and all were successfully completed, we were not able to assess factors that may make patients unsuitable for the procedure. Other series of transperineal biopsy under local anesthesia have similarly not reported any significant number of patients unable to tolerate a transperineal biopsy procedure.[18-21]

Limitations

There are several important limitations to consider in the study. First, this report represents an initial small series to assess TFB under local anesthesia. As such, the ability to detect uncommon complications/events and ensure generalizability is limited.

Second, as most of the biopsies were performed by a single physician in an academic setting, intra-operator variability, overall generalizability, and time required to become proficient in this new technique are not able to be assessed. Additionally, the small sample size limits the ability to perform subgroup analyses, hampering the assessment of cancer detection rates across the spectrum of prostate size, PSA range, and PI-RADS interpretation.

Followup is limited to encounters — office calls, emergency room visits, and office visits — that occurred within the institution and those patients who consented to a telephone survey. While it is reasonable to conclude that most patients would contact the physician performing the procedure if concerned, it is possible that a minority of patients presented to outside emergency rooms and, as such, were not included when assessing complications. Additionally, survey questions comparing patient preference of modality is extremely limited, as most patients who had previously undergone transrectal biopsy had the procedure performed by a different physician, thus raising the issues of intra-operative variability.

However, to our knowledge, this is the first report detailing feasibility of TFB under local anesthesia, and we feel that the limitations will be overcome following the collection of a larger sample size.

Finally, it is our current practice to use both MRI and PSA density, as well as more traditional measures, such as digital rectal exam and PSA, to select patients for biopsy in order to reduce unnecessary biopsies. Such measures likely decrease the number of low-grade prostate cancers detected and may reduce the discrepancy between systemic and targeted biopsies.

Conclusions

TFB is feasible under local anesthesia in the office setting using the PrecisionPoint access system. This initial experience suggests cancer detection rates similar to TFB under general anesthesia using a template grid and transrectal MR-US fusion biopsy, but with potential advantages of lower morbidity and avoidance of antibiotic prophylaxis. Larger cohorts are required to determine consistency in cancer detection rates, factors influencing patient selection for TFB under local anesthesia, a generalizable learning curve, and complication rate.

Competing interests: The authors do not report any competing personal or financial interests related to this work.

This paper has been peer-reviewed.

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