Initial transperineal prostate biopsy experience at a high-volume center

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Introduction: *Transperineal prostate biopsy (TPBx) allows for prostate cancer detection with fewer infectious complications when compared to transrectal prostate biopsy (TRUSBx). We evaluated the initial experience of a single physician with no prior TPBx exposure, compared to TRUSBx and MRI/US fusion biopsy (MRIBx) performed by experienced physicians.*

Materials and methods: *All consecutive patients undergoing prostate biopsy (June 2019-March 2020) were included. Patient discomfort, procedural time, clinically significant cancer detection rates (csCDR) and 30-day complications were compared between TPBx, TRUSBx and MRIBx.*

Results: *A total of 303 patients underwent biopsy. Comparing TPBx to TRUSBx to MRIBx, median pain scores during the anesthetic block were 4 versus 2 versus 3 (p = 0.007) respectively, and not statistically different during the rest of the procedure. Median time of biopsy was 11, 7.5 and 12 minutes respectively. csCDR were 38%, 29.8%, and 43.6% (p = 0.12) respectively. The combined transrectal groups (n = 211) had nine complications including two sepsis events. The TPBx group (n = 92) had no 30-day complications.*

Conclusions: *TPBx was well tolerated in the office setting with similar levels of discomfort for all aspects of the procedure compared to transrectal approach. Learning curve for TPBx showed rapid improvement in procedural time within the first 15 cases with an average procedure time of 9 minutes thereafter. Similar rates of csCDR were found between the groups and TPBx had significantly fewer infectious complications than standard transrectal technique.*

Key Words: prostate cancer, prostate biopsy, transperineal prostate biopsy, learning curve, infectious complications

Introduction

In 2020, over one million prostate biopsies were performed in the United States resulting in over 190,000 men diagnosed with prostate cancer with over 33,000 deaths.[1] The vast majority of these biopsies were performed via transrectal ultrasound guidance, which is associated with infectious complication rates as high at 7% and sepsis rates as high as 3.1%.[2] Prophylactic antibiotics used to decrease the infectious risk associated with transrectal ultrasound guided prostate biopsy (TRUSBx) have likely contributed to the rise of fluoroquinolone-resistant bacteria, potentially driving both an increase in septic complications and the need for broader antibiotic coverage.[3-5] In addition to patient morbidity, the cost of these infectious complications can range from $8,672-$19,100 per admission, representing a considerable burden to the health system.[6]

Transperineal prostate biopsy (TPBx) offers an alternative method to diagnose prostate cancer with significantly lower rates of sepsis (0.0%-0.1%) and comparable rates of cancer detection with a superior sampling of the anterior prostate.[7-9] Despite these advantages, widespread adoption of the TPBx technique has been slow in the United States, attributed to the need for anesthesia, concern about patient tolerability, and a slow learning curve with freehand biopsy techniques.[10-12] We sought to evaluate the initial real world experience of transperineal prostate biopsy for an early adopter, evaluating patient tolerability, procedure duration, cancer detection rates and 30-day complications.

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Materials and methods

Patient characteristics and data collection

After obtaining institutional IRB approval, prostate biopsy and pain scores were prospectively collected for all patients undergoing prostate biopsy at a single institution between June 2019 and March 2020. One provider performed only TPBx during this period on all patients referred to his clinic. The other three providers performed either TRUSBx or MRI/US fusion biopsy (MRIBx). Patient selection for biopsy approach was random based on workflow of the clinic. In other words, no clinical data including PSA, prostate size, biopsy history or infection risk were considered when determining patient biopsy approach.

Patient characteristics, including age, race, digital rectal exam (DRE) (normal or abnormal), PSA level, prostate size and prior biopsy status were collected. During the procedure, patients were asked to verbally rate their pain level, using a 10-point numerical rating score (NRS), at the time of probe insertion, infiltration of local anesthesia, biopsy, and after the procedure. Pathology reports were collected and recorded according to Gleason grade group classification. Clavien-Dindo classification was used to rate all 30-day complications.

Biopsy technique

Patients underwent either standard 12-core sextant TRUSBx, freehand TPBx using a 10-sector mapping template, or MRI-US fusion targeted and systemic biopsy using UroNav US fusion device by one of four practicing urologists.

TRUSBx was performed by three physicians using BK Force Flex 400 exp system and 8808e biplane probe. Antibiotic prophylaxis was given in the form of ciprofloxacin 500 mg or intramuscular ceftriaxone 1 g in men with risk factors for fluoroquinolone resistance (prior biopsy, recent antibiotic use, prior sepsis, recent hospitalization, known resistance) in accordance with AUA guidance.[2] All patients underwent preprocedural sodium phosphate enema. Local anesthesia was performed with a prostatic nerve block by injecting 10 cc of 1% lidocaine into the junction of the seminal vesicle and prostate base. A standard 12-core sextant biopsy with or without the addition of two additional transition zone biopsies were obtained using an 18-gauge disposable Bard biopsy needle.

MRI-US fusion biopsy was performed by two surgeons with the same preparation as standard TRUSBx. Multiparametric MRI of the prostate was performed on either 1.5 or 3 Tesla MRI, either with or without an endorectal coil. Lesions were classified using standard prostate imaging reporting and data system (PI-RADS) version 2. Regions of interest defined as PI-RADS 3-5 lesions were outlined by radiology for fusion biopsy. Fusion biopsy was then performed using the UroNav fusion system with 2-4 cores per lesion taken followed by a systematic 12-core biopsy.

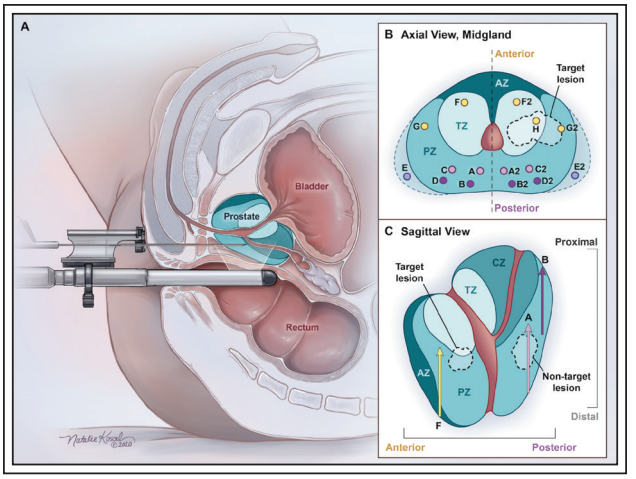

Figure 1. A) Transperineal prostate biopsy using PrecisionPoint access system **B)** Axial 10-sector template [A-posterior medial distal; B-Posterior medial proximal; C-posterior lateral distal; D-posterior lateral proximal; E-base; F-anterior medial; G-anterior lateral; H-target lesion biopsy (not performed in series)] **C)** Sagittal depth of biopsy.

TPBx was performed by a single surgeon with no prior experience with transperineal approach. The first 12 procedures were performed under general anesthesia. All subsequent procedures were performed in-office with local anesthesia. Patients were provided with a single dose of oral cephalexin pre-procedure. No pre-procedure enema was administered. Patients were positioned in the dorsal lithotomy position. Using a biplane probe with linear sagittal array (BK 8848), and the PrecisionPoint access system, a perineal and apical block was performed by injecting 30 cc of 1% lidocaine into the subcutaneous tissues and proximal and distal to the levator muscle. A series of 14 specimens were taken using a modification of the Barzell's template using 10-sector targeting with additional cores taken in the posterior medial and posterior lateral sectors,[13] Figure 1.

Statistical analysis

The distribution of continuous variables were visually inspected; PSA, prostate size and pain scores were visibly left skewed while patient age was normally

TABLE 1. **Demographics and complication rates**

	TPBx	TRUSBx	MRIBx	p value
N	92	94	117	
Age (mean (SD))	64.7 (8.0)	64.0 (6.5)	65.1 (7.3)	0.58
PSA (median [IQR])	6.7 [4.9, 10.4]	7.0 [4.8, 9.8]	7.5 [5.3, 10.2]	0.63
Mean prostate size (cm^3)	43.6	53.1	53.6	0.28
Purpose (n (%))				0.006
Cancer screening	80 (87.0)	81 (86.2)	84 (71.8)	
Active surveillance	12 (13.0)	13 (13.8)	33 (28.2)	
DRE (n (%))				0.16
Normal	77 (83.7)	67 (71.3)	95 (81.2)	
Abnormal	15 (16.3)	27 (28.7)	22 (18.8)	
Complication (n (%))				0.053
Grade I	-	2 (2.1)	5 (4.3)	
Grade II	-	-	2 (1.7)	

TPBx = transperineal prostate biopsy; TRUSBx = transrectal prostate biopsy; MRIBx = MRI/US fusion biopsy; PSA = prostate-specific antigen; DRE = digital rectal exam

distributed. Hence, median PSA, prostate size and pain scores were compared between groups using the Kruskal-Wallis test while patient age was compared between groups using ANOVA. Categorical variables (biopsy purpose, DRE status, cancer detection) were compared between groups using the chi-square test, and complications were compared between groups using Fisher's exact test. Statistical analysis was performed in R.[14] Procedure time was fit using least squares regression without weighting with a single-phase exponential decay equation of the form: $Y = (Y_0 - \text{Plateau}) * e^{(-K*X)} + \text{Plateau}$. Outliers were identified and removed using the ROUT method with coefficient 1%.[15] Best-fit values are reported with 95% confidence intervals.

TABLE 2. **NRS pain scores during biopsy procedure and procedural time**

All patients	**TPBx**	**TRUSBx**	**MRIBx**	**p value**
N	80	67	94	
Probe insertion (median (IQR) minutes)	2 (0-4)	3 (1.5-4.8)	3 (1.1-4.9)	0.06
Anesthetic block	4 (2-6)	2 (1-4)	3 (1-4)	0.007
Biopsy	3 (1-5)	2 (0-4)	2.5 (1-4)	0.11
Post-procedure	0 (0-2)	0 (0-1)	0 (0-1.3)	0.20
Procedural time (median time (min) (IQR))	11 (9-13.3)	7.5 (6-11)	12 (11-14)	< 0.001
Patients with ≥ 1 prior biopsy	**TPBx**	**TRUSBx**	**MRIBx**	**p value**
N	21	38	81	
Probe insertion (median NRS score (IQR))	1.5 (0-4)	3 (1.5-5)	3 (1.5-5)	0.01
Anesthetic block	4 (2-6)	2.5 (1-4)	3 (1-4.1)	0.02
Biopsy	3 (1-4)	2 (0-4)	2 (1-4)	0.36
Post-procedure	0 (0-2)	0 (0-1)	0 (0-1.5)	0.15
Procedural time (median time (min) (IQR))	11 (9-13)	7.5 (6-11)	12 (11-14)	< 0.001

NRS = numeric rating scale; TPBx = transperineal prostate biopsy; TRUSBx = transrectal prostate biopsy; MRIBx = MRI/US fusion biopsy

Results

A total of 303 consecutive patients underwent prostate biopsy; 92 patients underwent TPBx, 94 patients underwent standard TRUSBx, and 116 patients underwent MRIBx. Mean patient age was similar between the groups (TPBx 64.7, TRUSBx 64.0, MRIBx 65.1, p = 0.58). Median PSA was also similar (TPBx 6.7, TRUSBx 7.0, MRIBx 7.5, p = 0.63). No significant difference in mean prostate size was noted between the groups (TPBx 43.6, TRUSBx 53.1, MRIBx 53.6, p = 0.28). The most common indication for biopsy was cancer screening, accounting for 87% of TPBx, 86.2% of TRUSBx, and 71.8% of MRIBx (p = 0.006), while active surveillance accounted for the remainder. An abnormal DRE was noted in 16.3% of TPBx, 28.7% of TRUSBx, and 18.8% of MRIBx patients (p = 0.16), Table 1.

Patient pain scores were recorded during each step of the procedure for TPBx (n = 80), TRUSBx (n = 67), and MRIBx (n = 94). Median pain score during probe insertion was 2 (TPBx, IQR 0-4) vs. 3 (TRUSBx, IQR 1.5-4.8) versus 3 (MRIBx, IQR 1.1-4.9) respectively (p = 0.06). Pain during the anesthetic block was 4 (2-6) versus 2 (1-4) versus 3 (1-4) (p = 0.007). Pain during biopsy was 3 (1-5) versus 2 (0-4) versus 2.5 (1-4) (p = 0.11). Pain in the post-procedural period was 0 for all groups with IQR 0-2 versus 0-1 versus 0-1.3 respectively (p = 0.20). Subanalysis of pain scores for patients with at least one prior prostate biopsy is also shown with similar results, Table 2.

Median procedural time, measured from the time of probe insertion to the time of probe removal, for TPBx was 11 minutes (IQR 9-13.3). Median procedural time for TRUSBx was 7.5 minutes (IQR 6-11). Median procedural time for MRIBx was 12 minutes (IQR 11-14), Table 2.

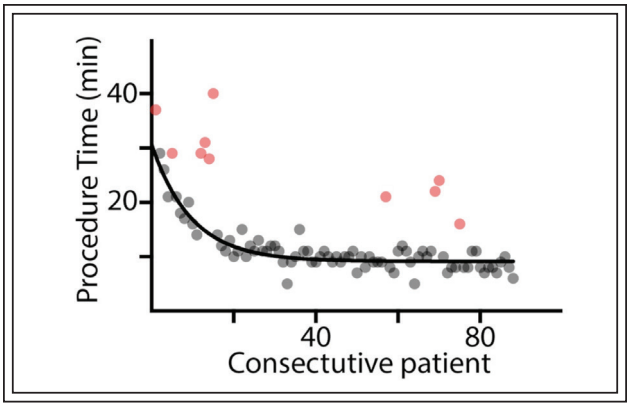

Figure 2. Learning curve for transperineal prostate biopsy

To get an understanding of how quickly proficiency with TPBx was achieved by a single provider, procedure time was modeled using a single-phase exponential decay fit by least squares regression. It took between 6 and 7 patients to drop the procedure time in half. Approximate procedure time was 9 minutes once the provider had achieved proficiency, Figure 2.

Clinically significant cancer detection rates (csCDR), defined as Gleason grade group 2 or greater, were 38% for TPBx, 29.8% for TRUSBx, and 43.6% for MRIBx (p = 0.12). When assessing only patients undergoing a diagnostic biopsy (i.e. excluding patients on active surveillance), csCDR were 38.8% for TPBx, TRUSBx 30.9%, and MRIBx 41.7% (p = 0.33), Table 3.

TABLE 3. **Cancer detection rates**

All patients	**TPBX**	**TRUSBx**	**MRIBx**	**p value**
N	92	94	117	
No cancer (%)	31 (33.7)	50 (53.2)	39 (33.3)	
Gleason group ≥ 1	61 (66.3)	44 (46.8)	78 (66.7)	0.005
Gleason group ≥ 2	35 (38.0)	28 (29.8)	51 (43.6)	0.12
Screening biopsy only (excluding AS)	**TPBX**	**TRUSBx**	**MRIBx**	**p value**
N	80	81	84	
No cancer	26 (32.5)	42 (51.9)	34 (40.5)	
Gleason group ≥ 1	54 (67.5)	39 (48.1)	50 (59.5)	0.04
Gleason group ≥ 2	31 (38.8)	25 (30.9)	35 (41.7)	0.33

TPBx = transperineal prostate biopsy; TRUSBx = transrectal prostate biopsy; MRIBx = MRI/US fusion biopsy

No 30-day complications were reported in the TPBx group. In the TRUSBx group, two patients had Grade I complications including an emergency department visit for rectal bleeding with syncope without transfusion and an isolated episode of diarrhea lasting 3 days. In the MRIBx group, seven patients had complications. Five patients had Grade I complications including four episodes of urinary retention requiring catheterization and one episode of rectal bleeding without transfusion. The remaining two patients suffered post-biopsy sepsis. In total, 9/211 patients who underwent transrectal approach suffered a complication (4.3%) with two episodes of sepsis (0.9%), Table 1.

Discussion

TRUSBx has been considered the standard for detection of prostate cancer since Hodge et al introduced the sextant biopsy template in 1989.[16] This has remained mostly unchanged in the United States despite infectious complications. Various approaches to limit infectious complications have been described including augmented antibiotic prophylaxis, pre-procedure rectal culture directed prophylaxis, needle disinfection during the biopsy, and iodine enema.[17-20] However, none have been as effective as avoiding the fecally contaminated transrectal route.[12]

The transperineal approach allows for similar cancer detection but improved infectious complications.[21-23] The reluctance to change practice is often attributed to the assumption that TPBx is more challenging for the physician, and more painful for the patient. The American Urological Association states in the core curriculum that TPBx is "more difficult to perform under local anesthesia and unfamiliar to most urologists''.[24] While prior studies have focused on the diagnostic capabilities and complication rates of TPBx, to our knowledge, we are the first to report a direct comparison of TPBx, TRUSBx, and MRIBx with regards to patient tolerability, procedure duration, cancer detection rates, and 30-day complications. Additionally, our study is unique in that it captures the initial experience of an early adopter with no prior transperineal biopsy experience.

Early reports using the PrecisionPoint system have shown low rates of patient discomfort.[25,26] Procedural pain levels were similar between the groups, with the exception of the anesthetic block being 1-2 points less comfortable for TPBx ($p = 0.007$), and probe insertion being one point less comfortable for the transrectal groups ($p = 0.06$). On an exploratory subanalysis, we also found that previous biopsy status did not affect reported pain levels, Table 2.

The difference in pain during anesthetic block could be related to the location of the injection in TPBx, which is performed over a larger area encompassing the perineal skin, soft tissue, levator musculature and apical prostate compared to standard periprostatic block in TRUSBx. Positioning may explain the difference in pain during probe insertion, as the transperineal biopsy is performed in the dorsal lithotomy position, which may relax the perineal musculature and external anal sphincter. While our data highlights a statistical difference between the groups during anesthetic block and probe insertion, we suspect that this does not correlate to a clinically significant difference in pain experienced between approaches. We do however find this useful for patient counseling, as we can now that during TPBx, 75% of patients will experience no pain worse than a 6/10 during a brief anesthetic block, and no pain worse than 4/10 during the biopsy, Table 2.

When comparing procedure duration we found that our median time of 11 minutes (IQR 9-13.3) during TPBx is comparable to the time reported by Ristau et al who reported mean TPBx time of 11.2 minutes.[8] TPBx was slower than standard TRUSBx with median time of procedure 7.5 minutes (IQR 6-11), and faster than MRIBx with median time of procedure 12 minutes (IQR 11-14) ($p =< 0.001$). However, as evident in the Figure 2, the true procedural duration after proficiency is achieved is likely close to 9 minutes, Table 2.

To understand the learning curve for TPBx for a first-time user, we used a single-phase exponential decay fit by least squares regression. This model showed a rapid decline in procedure time, with an approximate procedural time of 9 minutes once proficiency was achieved. Notably, the first 12 biopsies were performed in the operating room under sedation before transitioning to an in-office procedure with only local anesthesia for the remainder of patients undergoing TPBx.

The overall cancer detection rate in our study for TPBx was 66.3% while clinically significant cancer detection was 38%. These rates are comparable to other studies that found 41.9%-61% cancer detection and 16.1%-40.3% for clinically significant cancer detection.[7,8,25,27] No statistically significant difference in csCDR was noted between the groups in this study, Table 3. Although not sufficiently powered to prove a negative finding, by not detecting a difference between groups for csCDR we feel that this adds to the literature to support the non-inferiority of TP biopsy to standard TRUS biopsy.

No 30-day complications occurred in the TPBx cohort during the duration of this study. Surprisingly, of the 94 patients who underwent TPBx, none had

post-op urinary retention. However, Veselina et al previously reported urinary retention rates of 1.6% in a cohort of 1,287 free hand TPBx performed in the office, so this is not entirely unexpected.[7] Additionally, mean prostate size was not significantly different between the groups suggesting that size was not a confounding variable in post-procedural urinary retention. Nine of two-hundred eleven (4.3%) patients undergoing a transrectal prostate biopsy incurred a complication, with 7/9 (78%) of these complications being Grade I. Two patients developed post-biopsy sepsis requiring multi-day hospital admission and intravenous antibiotics despite a program of augmented antibiotic prophylaxis and pre-procedural enema. The rate of sepsis in our transrectal group was 0.9%, which is on the low-end of the published range from 0.9%-4.2%.[28,29] Notably, one of the two patients who developed sepsis had a prior biopsy, Table 1.

One strength of this study is that it follows the initial experience of a provider with no prior exposure to TPBx technique who achieved procedural efficiency and duration 9 minutes after only approximately 15-20 cases. When comparing the equivalent rates of cancer detection with that of TRUSBx, performed by physicians in this study with high-volume biopsy practices, we suggest that even during the early stages of TPBx adoption, diagnostic accuracy is not sacrificed.

We acknowledge the non-randomized nature of this study introduces the limitation of selection bias. However, the surgeon performing TPBx did so on all patients referred for biopsy, and if selection bias was present, we believe it would most strongly affect cancer detection, which showed no significant difference and was not the main focus of this study. Our population had a high proportion of Caucasian patients (> 90% in all cohorts), which may affect the generalizability to other non-Caucasian patient populations with regard to cancer detection rates.

Conclusion

We found that TPBx was a well-tolerated procedure with a similar level of discomfort to TRUSBx and MRIBx approaches. The learning curve for TPBx was short with proficiency achieved after approximately 15-20 biopsies. Cancer detection rates between TPBx and standard approaches were comparable. Finally, we found that TPBx is safe with no 30-day complications occurring in 92 consecutive biopsies. TPBx is a safe and tolerable means for in-office diagnosis of prostate cancer with a short learning curve and similar cancer detection to standard approaches even in its earliest stages of adoption.

Disclosure

No physician or staff in this study were compensated by PrecisionPoint or any other company. We have no financial disclosures to report. □

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