Micro-ultrasound transperineal prostate biopsy as an alternative to MRI-US fusion transrectal biopsy

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ABSTRACT

Introduction: ExactVu micro-ultrasound generates high-resolution images and promises to improve prostate biopsy performance, while transperineal prostate biopsy (TPB) has gained popularity due to its sterile technique. The aim of this study was to compare TPB using ExactVu to transrectal biopsy (TRB).
Methods: A retrospective analysis of patients who underwent TPB (n=306) using ExactVu or TRB (n=392) from 2019–2023 was performed. Clinical parameters were compared between the groups using Chi-squared. Putative predictors of cancer on biopsy and upgrading on radical prostatectomy were investigated using logistic regression.
Results: More transperineal than transrectal biopsy patients had a Prostate Imaging-Reporting and Data System (PI-RADS) 5 lesion (40% vs. 28%, p=0.001) and were biopsy-naive (53% vs. 39%, p<0.001). In patients with no previous diagnosis of prostate cancer, the clinically significant prostate cancer detection rate was higher in the TPB group (53% vs. 42%, p=0.01). Transperineal patients required fewer cores to obtain equal cancer detection rates (11±5 vs. 15±4 cores, p<0.01). Upgrading from grade group 1 to grade group ≥2 on radical prostatectomy was more common with TRB (9.1% vs. 2.1%, p=0.04). Urinary retention rate did not differ by biopsy type and two transrectal but no transperineal patients developed urosepsis.
Conclusions: TPB required fewer cores to obtain a similar clinically significant prostate cancer

KEY MESSAGES

- Micro-ultrasound transperineal biopsy (TPB) has a superior clinically significant prostate cancer (csPCa) detection rate in patients with no prior prostate cancer when compared to transrectal software fusion biopsy.
- Few patients undergoing TPB were upgraded to csPCa on radical prostatectomy.
- Complication rates after TPB were low, with no episodes of sepsis.

detection rate when compared to TRB. TPB had fewer complications and a low upgrade rate. This suggests that cognitive fusion TPB using ExactVu is an excellent alternative to software fusion TRB.

INTRODUCTION

Magnetic resonance imaging (MRI) targeted prostate biopsy has been widely adopted as it increases the detection of clinically significant PCa (csPCa, grade group (GG) ³2) while reducing identification of clinically indolent PCa (GG1) when compared to systematic biopsy.[1,2] Cognitive- and software guided- MRI-US fusion prostate biopsy techniques have been shown to be equivalent.[3] However, both are still often accompanied by systematic biopsies to minimize missed csPCa and access can be limiting.[3] New technologies are being evaluated to further improve the accuracy of MRI targeted biopsy and increase accessibility.

ExactVu micro-ultrasound (ExactVu Imaging Inc, Markham ON) is being evaluated as a such a technology as it provides high resolution images of the prostate.[4] Socarrás et al. assessed 194 patients who underwent ExactVu targeted transperineal biopsy (TPB) under spinal anaesthetic followed by MRI-US fusion and systematic biopsy.[4] The csPCa detection rate was not statistically different between ExactVu and software guided MRI-US fusion TPB (24% vs. 28%), suggesting that ExactVu could be a promising alternative to MRI-US fusion biopsy. Similar findings have been reported by multiple small observational studies comparing ExactVu and MRI-US fusion TRBs.[5,6]

In addition to improving the detection rate of csPCa with prostate biopsy, there is increasing focus on reducing associated complications. The TPB sterile technique likely decreases the risk of sepsis while maintaining a comparable if not superior PCa detection rate with improved sampling of the anterior and apical zones.[7,8] Thus, interest in TPB under local anaesthetic is becoming a popular alternative to transrectal biopsy (TRB).

While ExactVu guided cognitive TPB may be a valuable office-based tool to improve csPCa detection rate and decrease sepsis rates, evidence for this is lacking. Therefore, the objective of this study was to compare PCa detection rate, upgrade rates, and complication rates between office-based TPB using ExactVu and TRB. We hypothesize that office-based TPB using ExactVu will perform similarly to software fusion TRB.

METHODS

Population and variables

After obtaining IRB approval (H24-03139), a retrospective review of all patients at our tertiary centre who underwent TPB and a consecutive cohort of patients who underwent TRB from 2019 to 2023 was performed. This included both patients on active surveillance and those without a previous diagnosis of PCa. Patients without a pre-biopsy prostate MRI were excluded (supplemental figure 1).

Demographic, clinicopathological, and outcome data were collected from electronic medical records. Biopsy findings were categorized by presence of any PCa or csPCa (defined as ISUP grade group (GG) ³2) and using the National Comprehensive Cancer Network risk groups.

Multiparametric MRI was used at our centre. TPBs were performed by one of two urologists (MG, MM) under local anaesthetic in office using cognitive fusion with the ExactVu

microultrasound (Exact Imaging, Markum ON). A sample ExactVu image from our centre can be seen in Figure 2 of Vassallo et al.'s 2025 review.[9] TPB patients received 3 days of twice daily oral Ciprofloxacin prophylaxis until 2022, at which time our centre switched to a single dose 500mg oral Keflex. TRBs were performed by radiologists under local anesthetic utilizing an 8-9 MHz endorectal ultrasound and the UroNav© (Philips) system software for MRI-US fusion in the hospital radiology department. Three days of either 500mg twice daily oral Ciprofloxacin or 3g once daily oral Fosfomycin antibiotic prophylaxis were used for TRB.

Statistical analysis

Patients were grouped based on biopsy technique (TRB or TPB). Clinical parameters including previous biopsy status, prostate volume, prostate MRI findings (PI-RADs score, number and location of lesions), and prostate biopsy results were compared using the Mann Whitney-U test for continuous variables and Chi-squared or Fisher's exact test for categorical variables. PSA was presented as a median due to significant outliers and compared using the Median test. These methods were also used to compare post-biopsy complications, PCa treatment, and rate of grade upgrade between TPB and TRB. If a patient underwent radical prostatectomy (RP), the pathological findings of the prostatectomy specimen were compared to those of the prostate biopsy to calculate the upgrade rate.

Multivariable analysis using logistic regression was performed to identify risk factors for PCa or csPCa on biopsy and upgrade at time of RP. Variables included biopsy approach (TPB vs. TRB), PSA, prostate size, PI-RADs score, and previous biopsy. Subgroup analyses were also performed excluding patients on active surveillance and assessing anterior versus posterior MRI lesions. Patients with missing data were excluded from multivariable analyses. A p-value of < 0.05 was considered significant and all statistical analysis was conducted with SPSS-v.25 (IBM Corp. Armock, NY, USA).

RESULTS

A total of 698 patients were included in the analysis, of which 392 underwent TRB and 306 TPB. Mean follow up was 18±13 months. As shown in Table 1, the sample's median PSA was 8.0ng/ml, with a mean prostate volume of 57cc, and 36% of men were on active surveillance. A larger proportion of the TPB than TRB cohort had PI-RADs 5 (40% vs. 28%, respectively) and peripheral zone lesions (79% vs. 64%, respectively). Most patients in the TPB group had a targeted biopsy only (73% TPB vs. 5.7% TRB), while TRB patients were more likely to have a combined targeted and systematic prostate biopsy (88% TRB vs. 25% TPB, $p < 0.001$). This corresponded to a mean of 11±5 biopsy cores taken during TPB and 15±4 cores for TRB ($p < 0.001$).

Table 2 demonstrates that overall PCa and csPCa detection rates were 72%, and 48%, respectively. In a subgroup analysis of biopsy naïve patients, the TPB cohort had a significantly higher csPCa detection rate than TRB (59 vs. 48%, $p < 0.05$). The same was true when patients on active surveillance were excluded (csPCa detection rate 53 vs. 42%, $p < 0.05$). Although not statistically significant, TRB detected more GG1 PCa (28% vs. 21%) and fewer GG5 cancers (9.2% vs. 14%). PCa detection rates by biopsy approach are stratified by PI-RADs score in Figure 1. Complications were uncommon, but 2 patients undergoing TRB developed urosepsis requiring hospitalization and IV antibiotics (Clavien Dindo Grade 2). ER visits occurred in 4 TPB and 12 TRB patients, while 4 TPB and 6 TRB patients went into urinary retention (Clavien Dindo Gade 1-2).

Of the patients who underwent RP (Table 3), 96% had csPCa on RP pathology. GG5 cancers were more common in the TPB than TRB group (30% vs. 12%). Upgrade to ^{3}GG2 occurred in 9.1% of TRB patients compared to only 2.1% of TPB patients (p = 0.04).

Biopsy method was not a risk factor for PCa or csPCa in a multivariable analysis (p = 0.9, n = 639), even when patients on active surveillance or with a previous biopsy were excluded (p = 0.5, n = 404 and p = 0.4, n = 275, respectively). Additionally, biopsy method was not a risk factor for upgrading at time of RP. This remained true in subgroup analyses looking at anterior versus posterior MRI lesions although only 139 patients with PCa / csPCa and 68 patients who underwent RP were included due to missing data. A further subgroup analysis was done looking at only patients with targeted or combined systematic and targeted biopsies with no difference in outcomes (p = 0.7, n = 478).

DISCUSSION

MRI-targeted TPB improves PCa diagnosis while limiting associated sepsis risk, but access is limited and systematic biopsies are often added to avoid missing csPCa.[7] Micro-ultrasound allows clinicians to correlate real time high resolution ultrasound images with MRI regions of interest, possibly enhancing cognitive fusion targeted biopsies and even identifying PCa missed on MRI review.[6] In fact, a recent randomized control trial by Kinnaird et al. showed that micro-US guidance alone is non-inferior to software fusion MRI-guided biopsy.[10] Our results support the utility of micro-US by demonstrating high detection rates for csPCa with ExactVu cognitive TPB. Additionally, there were no episodes of urosepsis with TPB and an equally low rate of urinary retention compared to TRB.[11]

Our study found a PCa detection rate of 72% and csPCa detection rate of 51% for PI-RADs 3-5 lesions, which is on the higher end of published literature.[12–14] There were no significant differences in PCa detection rates between TPB and TRB groups in our study, which was mirrored in Uleri et al.'s 2023 systematic review comparing MRI-targeted TPB and TRB.[14] Uleri et al. demonstrated a significantly higher csPCa detection rate for TPB, which was congruent with the trend seen in our biopsy naïve patients and those not on active surveillance, although not statistically significant on multivariable analysis. Through subgroup analyses, Uleri et al. attributed the difference to a higher detection rate of anterior and apical lesions with TPB.[14] Unfortunately, our study had missing data with regards to lesion location, so subgroup analyses were limited.

Overall, our population had a low rate of post-biopsy complications. Previous literature, including the PREVENT trial, has suggested that TPB decreases risk of urosepsis compared to TRB.[8,15,16] In fact, Castellani et al.'s meta-analysis demonstrated that TPBs can be done without prophylactic antibiotics after it demonstrated no difference in infectious complications in 3,662 men undergoing TPB with or without antibiotic prophylaxis.[17] The ProBE-PC trial, on the other hand, failed to show a difference in the infection rate in 718 men randomized to TRB with antibiotics or TPB without antibiotics, with a letter to the editor stating that an adequately powered comparative trial would require 3,938 patients in each arm to identify a difference in urosepsis rates.[15,18] Our study was also underpowered to demonstrate a difference, but did identify 2 cases of urosepsis in men undergoing TRB and none in the TPB cohort. All patients in our received antibiotic prophylaxis, but as this evidence evolved, TPB patients were stepped down to a single dose of Keflex while TRB patients remained on Ciprofloxacin or Fosfomycin. TPB has been associated with a higher rate of urinary retention, which was not seen in our study where retention rates were equal between groups.[11] However, previous studies assessing TPB have utilized general anesthesia and/or performed saturation biopsies with a greater number of

cores retrieved, both of which elevate the risk of urinary retention.[19] TPBs in our study were done under local anaesthetic and had fewer cores taken, likely reducing morbidity.

Upgrade rates to csPCa on RP were low in all patients. Given that very few patients in our study underwent RP for GG1 PCa, a second analysis was done assessing upgrading to ≥GG3 with no significant differences between groups. Our results were comparable to Ahdoot et al.'s study comparing transrectal MRI-targeted, systematic, and combined biopsies in 2,103 men.[20] They found that 6.7% of combined biopsies were upgraded to ≥GG3 on RP, corresponding to our TRB upgrade rate of 8.8%. Our TPB group underwent primarily targeted biopsy with an upgrade rate of 14%, again mirroring Ahdoot et al.'s targeted biopsy upgrade rate of 18.3%. This suggests that TPB using ExactVu cognitive fusion is an accurate diagnostic technique.

Our study is limited by its retrospective nature and cohort size that is not large enough to compare rare events such as post biopsy urosepsis. Our cohorts were heterogenous due to referral patterns, with a higher rate of previous negative biopsy in the TRB group. However, subgroup analyses were done assessing biopsy naïve patients with similar results. The TPB group also had more PI-RADs 5 lesions than the TRB group. Therefore, detection rates were displayed stratified by PI-RADS score. Furthermore, our broad inclusion criteria and wide catchment area as a tertiary referral centre make our results more generalizable with the caveat that the specialized care available at our centre likely enhances outcomes. Our study is limited in that it compares two different biopsy approaches and two different imaging techniques as all TPBs at our centre are done with ExactVu which is not available for use for TRBs. Our study was limited by missing data, so that we were unable to perform accurate subgroup analyses looking specifically at apical or anterior tumours. Finally, we did not account for improvement in PCa detection rate with operator experience as ExactVu was new to our centre in 2019.

CONCLUSIONS

The csPCa detection rate with cognitive fusion TPB using ExactVu was not statistically different than with TRB even though 73% of TPB were targeted while 88% of TRB were combined targeted and systematic. Few patients undergoing TPB were upgraded to csPCa on radical prostatectomy, and complication rates were low with no episodes of sepsis after TPB. This suggests that TPB using ExactVu is a safe and effective alternative to software fusion TRB, which can be used to improve accessibility. Further research is warranted to validate these findings.

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FIGURES AND TABLES

Figure 1. Detection of prostate cancer on transrectal versus transperineal biopsy stratified by PI-RADs lesion. Blue bars represent transrectal biopsy patients, while grey bars represent transperineal biopsy patients. PI-RADs 3–5 lesions are shown separately and then combined. Figure 1A demonstrates the detection rate of any prostate cancer, while 1b includes only clinically significant prostate cancer (GG2+) and 1c includes only GG1 prostate cancer. GG: grade group; PI-RADS: Prostate Imaging-Reporting and Data System.

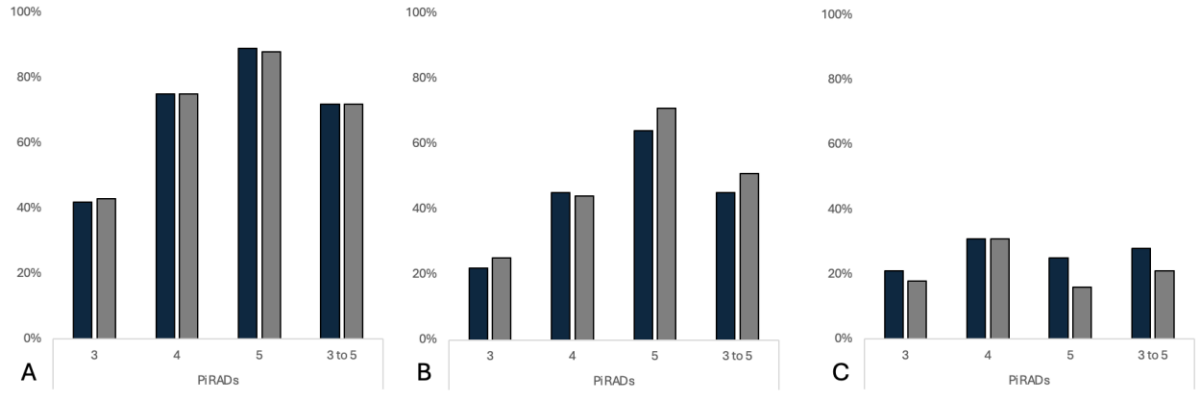

Table 1. Basic clinical parameters					
		TRB (n, %)	**TPB (n, %)**	**Total (n, %)**	**p**
Previous biopsy	None	153 (39%)	161 (53%)	314 (45%)	
	Negative	93 (24%)	41 (13%)	134 (19%)	
	Positive	144 (37%)	103 (34%)	247 (36%)	<0.001
cT Stage	T1	53 (75%)	162 (67%)	215 (69%)	
	T2	14 (20%)	65 (27%)	79 (25%)	
	T3	3 (4.2%)	10 (4.1%)	13 (4.1%)	
	T4	1 (1.4%)	6 (2.5%)	7 (2.2%)	0.629
PSA (median ± IQR)		8.0±6	8.8±7	8.4±6	0.125
Prostate volume (mean ± SD)		57±31	53±26	55±29	0.188
Number of lesions on MRI (mean ± SD)		1.4±0.7	1.5±0.8	1.4±0.7	0.800
PI-RADS (maximum)	2	6 (1.6%)	10 (3.7%)	16 (2.4%)	
	3	88 (23%)	40 (15%)	128 (20%)	
	4	186 (48%)	113 (42%)	299 (46%)	
	5	106 (28%)	107 (40%)	213 (33%)	0.001
Lesion location	Transition zone	126 (33%)	53 (20%)	179 (28%)	
	Peripheral zone	246 (64%)	211 (79%)	457 (71%)	
	Central zone	10 (2.6%)	2 (0.8%)	12 (1.9%)	<0.001

Lesion location 2	Anterior	38 (63%)	52 (37%)	90 (45%)	
	Posterior	22 (37%)	88 (63%)	107 (55%)	0.001
Lesion location 3	Apex	116 (34%)	85 (33%)	201 (34%)	
	Apex to mid	34 (10%)	21 (8.1%)	55 (9.2%)	
	Mid	119 (35%)	93 (36%)	212 (36%)	
	Mid to base	15 (4.5%)	26 (10%)	41 (6.9%)	
	Base	53 (16%)	33 (13%)	86 (15%)	0.085
Maximum lesion size (mean ± SD)		1.6±0.8	1.6±0.8	1.6±0.8	0.812
Biopsy type	Systematic only	15 (6.1%)	9 (2.9%)	24 (4.4%)	
	Targeted only	14 (5.7%)	222 (73%)	236 (43%)	
	Both	216 (88%)	75 (25%)	291 (53%)	<0.001
Number of cores taken (mean ± SD)		15±4.3	11±4.6	13±5.0	<0.001

IQR: interquartile range; MRI: magnetic resonance imaging; PI-RADS: Prostate Imaging-Reporting and Data System; PSA: prostate-specific antigen; SD: standard deviation; TRB: transrectal biopsy; TPB: transperineal biopsy.

Table 2. Prostate biopsy results

		TRB (n, %)	**TPB (n, %)**	**Total**	**p**
ISUP grade group	Negative biopsy	103 (27%)	81 (27%)	184 (27%)	
	1	105 (28%)	62 (21%)	167 (25%)	
	2	81 (21%)	64 (21%)	145 (21%)	
	3	39 (10%)	30 (10%)	69 (10%)	
	4	19 (5.0%)	20 (6.7%)	39 (5.7%)	
	5	35 (9.2%)	43 (14%)	78 (11%)	0.158
NCCN risk group	Low	69 (25%)	50 (22%)	119 (24%)	
	Intermediate	147 (52%)	106 (47%)	253 (50%)	
	High	65 (23%)	69 (31%)	134 (27%)	0.165
PCa detection rate	All patients	281 (72%)	219 (72%)	500 (72%)	1.000
	AS excluded	159 (64%)	134 (66%)	293 (65%)	0.623
	Biopsy naïve	104 (68%)	118 (74%)	222 (71%)	0.266
	AS only	50 (100%)	39 (100%)	89 (100%)	1.000
csPCa detection rate	All patients	175 (45%)	157 (51%)	332 (48%)	0.093
	AS excluded	103 (42%)	108 (53%)	211 (47%)	0.013
	Biopsy naïve	73 (48%)	95 (59%)	168 (54%)	0.045
	AS only	47 (86%)	37(97%)	84 (97%)	1.000
Complications	ER visit	12 (3.2%)	4 (1.3%)	16 (2.3%)	0.132
	Sepsis	2 (0.5%)	0 (0%)	2 (0.3%)	0.505

	Retention		6 (1.6%)	4 (1.3%)	10 (1.5%)	1.000
Management	GG1	Active surveillance	80 (80%)	57 (93%)	137 (85%)	
		Radical prostatectomy	12 (12%)	3 (4.9%)	15 (9.3%)	
		Radiation	4 (4.0%)	1 (1.6%)	5 (3.1%)	
		Other*	4 (4.0%)	0 (0%)	4 (2.5%)	0.113
	≥GG 2	Active surveillance	17 (9.8%)	9 (5.9%)	26 (8.0%)	
		Radical prostatectomy	103 (60%)	112 (73%)	215 (66%)	
		Radiation	47 (27%)	20 (13%)	67 (21%)	
		Other*	6 (3.5%)	12 (7.8%)	18 (5.5%)	0.002

*Included systemic therapy, focal therapy, and clinical trials. AS: active surveillance; csPCa: clinically significant prostate cancer; ER: emergency room; GG: grade group; ISUP: International Society of Urological Pathology; NCCN: National Comprehensive Cancer Network; PCa: prostate cancer; TRB: transrectal biopsy; TPB: transperineal biopsy.

Table 3. Pathologic outcomes of patients who underwent radical prostatectomy

		TRB (n, %)	**TPB (n, %)**	**Total**	**p**
GG	1	4 (3.5%)	1 (1.0%)	5 (2.3%)	
	2	52 (46%)	48 (46%)	100 (46%)	
	3	32 (28%)	19 (18%)	51 (24%)	
	4	9 (8.0%)	5 (4.8%)	14 (6.5%)	
	5	13 (12%)	31 (30%)	44 (20%)	0.003
NCCN risk group	Low	1 (0.9%)	1 (0.9%)	2 (0.9%)	
	Intermediate	68 (61%)	60 (55%)	128 (58%)	
	High	42 (38%)	48 (44%)	90 (41%)	0.703
Clinically significant PCa		106 (94%)	103 (99%)	209 (96%)	0.067
Concordance between biopsy and RP	Same GG	62 (55%)	58 (56%)	120 (55%)	
	Downgraded	27 (24%)	18 (17%)	46 (21%)	
	Upgraded	24 (21%)	28 (27%)	52 (24%)	0.394
Upgrade to ≥GG3	All patients	10 (8.8%)	14 (14%)	24 (11%)	0.285
	AS excluded	5 (7.8%)	12 (18%)	17 (13%)	0.080
	Biopsy naive	2 (4.7%)	10 (17%)	12 (12%)	0.053
% of GG1–2 biopsies upgraded to ≥GG3	All patients	17%	29%	23%	0.387
	AS excluded	22%	48%	35%	0.057
	Biopsy naive	18%	48%	38%	0.139

Upgrade to csPCa (≥GG2)	All patients	10 (9.1%)	2 (2.1%)	12 (5.8%)	0.038
	AS excluded	3 (4.9%)	1 (1.6%)	4 (3.3%)	0.619
	Biopsy naïve	2 (5.0%)	1 (1.9%)	3 (3.2%)	0.575
% of GG1 biopsies upgraded to ≥GG2	All patients	92%	67%	87%	0.371
	AS excluded	75%	100%	80%	1.000
	Biopsy naïve	100%	100%	100%	1.000

AS: active surveillance; GG: grade group; NCCN: National Comprehensive Cancer Network; PCa: prostate cancer; RP: radical prostatectomy; TRB: transrectal biopsy; TPB: transperineal biopsy.