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Participant-Reported Outcome Measures After Transrectal and Transperineal Prostate Biopsy in a Randomized Clinical Trial

Adrian J. Waisman Malaret, Paul J. Feustel, Fortis Gaba, et al.

Correspondence: Badar M. Mian (mianb@amc.edu).

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Study Need and Importance: Randomized studies comparing transrectal and transperineal prostate biopsies (under local anesthesia) have demonstrated essentially similar rates of cancer detection, infections, and other complications. There has been a lack of prospective studies of patient experience, which may become the key factor when counseling patients regarding biopsy approach. We analyzed patient-reported outcomes including pain, and urinary and erectile function from the ProBE-PC randomized trial comparing transrectal and transperineal biopsy.

What We Found: Over 96% of men completed the numerical rating pain scale demonstrating significantly higher mean pain scores at several steps of the transperineal procedure when compared with transrectal approach. More importantly, clinically significant pain (score ≥4) was significantly higher during transperineal biopsy at local anesthesia injection (37.9% vs 2.6%; odds ratio, 95% CI, 19.39, 6.57-10.28) and on the evening of the procedure (18.8% vs 11.2%; odds ratio, 95% CI, 1.84, 1.21-2.79; Figure). Clinically significant worsening International Prostate Symptom Score was more frequently reported after transperineal approach, compared with transrectal biopsy (28% vs 18%, $P = .009$). No difference was noted in the International Index of Erectile Function scores between the 2 procedures.

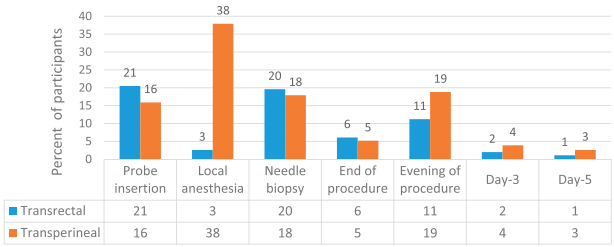

Figure. Patients with clinically significant pain (score ≥4) on numerical rating scale (range, 0-10) at different steps of the prostate biopsy procedures.

Limitations: We did not evaluate anxiety and embarrassment related to these biopsy procedures. Postbiopsy urinary and erectile functions were only assessed at 2 weeks post procedure and not at longer intervals. The study population consisted primarily of White men.

Interpretation for Patient Care: Transperineal prostate biopsy was associated with a noticeably higher rate of clinically significant pain and urinary dysfunction after the procedure. This information is clinically relevant for a contextualized discussion of trade-offs between the 2 procedures. These results are especially useful during patient counseling regarding prostate biopsy approach.

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Participant-Reported Outcome Measures After Transrectal and Transperineal Prostate Biopsy in a Randomized Clinical Trial

Adrian J. Waisman Malaret,[1] Paul J. Feustel,[2] Fortis Gaba,[1] Hasim Bakbak,[3] Jillian M. Egan Kelly,[1] Hugh A. G. Fisher,[1] Adrien N. Bernstein,[1] Ronald P. Kaufman Jr,[1] and Badar M. Mian[1]

[1]Department of Urology, Albany Medical Center, Albany, New York
[2]Department of Neuroscience and Experimental Therapeutics, Albany Medical College, Albany, New York
[3]Department of Urology, Koc University, Istanbul, Turkey

Purpose: Patient-reported outcome measures (PROMs) play a pivotal role when recommending medical interventions. There is a lack of prospective studies directly comparing PROMs after transrectal (TR-Bx) and transperineal prostate biopsy (TP-Bx). We conducted a prespecified comparative analysis of PROMs from the ProBE-PC randomized trial.

Materials and Methods: Eight hundred forty men were randomized to TR-Bx or TP-Bx under local anesthesia (LA). Participant-reported Numerical Rating Scale pain scores at various time points were collected, with score ≥ 4 defined as clinically significant pain. Prebiopsy and postbiopsy International Prostate Symptom Score (IPSS), IPSS-quality of life (QoL), and International Index of Erectile Function-5 were analyzed including minimum clinically important change in IPSS, IPSS-QoL, and International Index of Erectile Function-5 scores.

Results: Higher pain scores were reported by patients undergoing TP-Bx than TR-Bx at 3 time points: LA injection, evening of the procedure, and Day 3 ($P < .001$). Compared with TR-Bx, clinically significant pain was reported more frequently with TP-Bx during LA injection (3% vs 38%; odds ratio, 19.39; 95% CI, 6.57-10.28) and on the evening of procedure (11% vs 19%; odds ratio 1.84; 95% CI, 1.21-2.79). Increasing experience with TP-Bx between the first and later quartiles of participants did not influence pain scores. Findings were confirmed on adjusted multivariable analysis. Clinically important worsening of IPSS and IPSS-QoL was reported more frequently after TP-Bx than TR-Bx (28% vs 18%, $P = .009$, and 31% vs 22%, $P < .01$).

Conclusions: Compared with TR-Bx, higher rates and increased level of pain, as well as increased urinary dysfunction, were reported after TP-Bx. This information is clinically relevant during patient counseling regarding prostate biopsy procedures.

Key Words: prostate biopsy, pain, patient-reported outcomes

Clinically relevant outcomes after prostate biopsy include cancer detection, noninfectious complications, infectious complications, functional outcomes, and patient experience. Patient-reported outcome measures (PROMs) can provide a comprehensive evaluation of safety, efficacy, and patient experience after any procedure and, thus, inform clinical

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Statistical analysis: Waisman Malaret, Mian, Gaba, Faustel.
Supervision: Bernstein, Mian, Fisher, Egan Kelly, Kaufman.
Corresponding Author: Badar M. Mian, MD, Department of Urology, Albany Medical Center, 23 Hackett Blvd, Albany, NY 12208 (mianb@amc.edu).

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recommendations. Comparative assessment of cancer detection and complications after transrectal (TR-Bx) and transperineal (TP-Bx) have now been addressed through 3 large randomized clinical trials (RCTs) demonstrating minimal to no differences between the procedures.[1-4] However, the effect of the 2 biopsy procedures on various patient-reported outcomes such as pain, urinary function, and erectile function have not been studied in sufficient detail in a prospective manner.

TP-Bx is often performed under sedation or anesthesia as it is more painful because of the needle penetrating the skin, fascial, and muscle layers, several times, during the biopsy procedure. Recent studies, including RCTs, have demonstrated the feasibility of TP-Bx under local anesthesia (LA) resulting in recommendations to adopt this approach. Worsening of urinary symptoms is reported by 6% to 25% of patients after both TR-Bx and TP-Bx procedures.[5] While the risk of urinary retention after TR-Bx is low, TP-Bx has previously been associated with increased risk of urinary retention which is likely related to extensive, mapping biopsies and the use of general anesthesia. Postbiopsy erectile dysfunction of varying degrees is not infrequent and has been reported by up to 35% of patients after both biopsy procedures.[6,7]

Currently, there is a lack of studies directly comparing the effects of TR-Bx and TP-Bx under LA on PROMs. We conducted a comparative analysis of biopsy-related pain, urinary function, and erectile function after TR-Bx and contemporary TP-Bx under LA from the ProBE-PC randomized trial.

PARTICIPANTS AND METHODS

The study design, randomization, and prostate biopsy protocols for TR-Bx and TP-Bx have been detailed previously (Supplemental Table 1, https://www.jurology.com).[4,8] Briefly, men undergoing initial or repeat prostate biopsy for clinical suspicion of PCa at one of the affiliated centers were invited to participate in the study. Participants were randomly assigned 1:1 to either the TR-Bx or the TP-Bx procedure. Both procedures were performed in the office setting, using LA only. For TP-Bx, lidocaine 1%, 30 mL (15 mL per side) was injected into the perineal skin, levator muscles and periapical space, bilaterally. Both TR-Bx and TP-Bx MRI-targeted biopsy procedures were performed using UroNAV fusion platform. To ensure the onset of anesthetic effect, minimum interval of 3 minutes was required between LA injection and needle biopsy, for all procedures.

Outcome Measures

Validated instruments were used to measure patient-reported outcomes as follows: (1) for periprocedural pain assessment, the numerical rating scale for pain assessment (NRS; range 0-10); (2) for urinary function, the International Prostate Symptom Score (IPSS; range 0-35); (3) for urinary function's effect on quality of life (QoL), IPSS-QoL (range 0-6); and (4) for erectile function, the International Index of Erectile Function-5 (IIEF-5; range 5-25). Participants reporting NRS scores of ≥ 2 were categorized as having any pain (including mild pain) and NRS pain scores of ≥ 4 (moderate to severe pain) were categorized as having clinically significant pain (csPain).[9,10] The NRS pain score ≥ 4 has been identified as the threshold of tolerability and additional analgesic requirement because this level of pain can cause interference with postprocedure mood and activity level.[11] Minimal clinically important changes in IPSS, IPSS-QoL, and IIEF-5 scores were defined as ≥ 3, ≥ 1, and ≥ 4, respectively.[12,13] In addition to the overall mean scores, within-person change in the prebiopsy and postbiopsy functional scores were analyzed. Qualitative measure of self-reported symptoms was performed using the modified Transrectal Ultrasound–Guided Biopsy Questionnaire (TRUS-BxQ) after the procedures in both arms.[14]

Data Collection

Participants were asked to give a pain score at each step of the biopsy procedure including ultrasound probe insertion, LA injection, needle biopsy, and the end of procedure. In addition, participants completed the NRS pain scores at home on the evening of the procedure, on day 3 and day 5. Baseline IPSS, IPSS-QoL, and IIEF-5 questionnaire were completed a few weeks before the procedure. The postbiopsy IPSS, IPSS-QoL, IIEF-5, and the modified TRUS-BxQs were completed 2 weeks after the biopsy. The completed surveys were either mailed backed to the office or collected during postbiopsy clinic visit.

Statistical Analysis

Before analysis, data including baseline variables, pain, and functional outcomes were assessed for normality and homogeneity of variance. Continuous data are presented as median and quartiles for data with high skewness values ($>\pm 1$), including baseline characteristics and pain scores at different time points, while data with low skewness values ($<\pm 1$) are presented as mean and SD including IPSS, QoL, and IIEF scores. Owing to unequal variances, statistical testing for differences between groups is assessed by Welch t test or Mann-Whitney test. Categorical data are presented as frequencies and percentages. Because the pain scores were measured at multiple time points, Bonferroni correction to the P values was performed to adjust for multiple testing and the risk family-wise error. Differences in proportions, with 95% confidence limits, were estimated using

normal approximation. Multivariable logistic regression was used to assess relationships between dichotomous outcomes and continuous or categorical independent variables. Adjusted odds ratios (ORs) with 95% CI are reported from the multivariable model incorporating variables that could potentially influence the measured outcomes of pain, urinary function, sexual function, and QoL. These include age (in decades), BMI (per unit), presence of diabetes, postvoid residual, prostate volume (in mL), preprocedure analgesics, total biopsy cores taken, and procedural experience over time (measured as quartiles of enrolled participants). Statistical tests were performed with Minitab (v19) or R (4.3.0) with significance accepted at $P < .05$.

RESULTS

Of the 840 randomized participants, 782 underwent either TR-Bx (384) or TP-Bx (398) biopsy procedure. Baseline characteristics of the study participants are presented in Table 1. Prebiopsy use of acetaminophen was reported by 17% while the use of benzodiazepines or opioids was reported by 3%. The total number of biopsy cores were obtained, and the baseline rates of prebiopsy moderate to severe urinary and erectile dysfunction were similar.

Pain Assessment

The NRS pain scores were completed by nearly 96% of the participants. The pain scores at various time points are detailed in Table 2. Overall mean (SD) pain scores were higher in the TP-Bx group than the TR-Bx group at 3 time points: during LA injection (3.3 [1.8] vs 0.7 [1.2]; $P < .001$), on the evening of the procedure (2.0 [1.8] vs 1.5 [1.5]; $P < .001$) and on day 3 (0.7 [1.0] vs 0.4 [1.3]; $P = .001$). During ultrasound probe insertion, TR-Bx was associated with higher mean pain score (2.3 [2.0] vs 1.8 [1.7]; $P < .001$). Of note, following the Bonferroni correction for multiple testing, the differences in pain scores remained statistically significant. Proportion of men reporting any pain was significantly higher in the TP-Bx group than the TR-Bx group during LA injection (85.1% vs 16.9%; OR, 28.13 [95% CI, 1.70-18.98]), the evening of the procedure (61.0% vs 49.3%; OR, 1.61 [95% CI, 1.2-2.15]), and on day 3 (21.2% vs 14.6%; OR, 1.59 [95% CI, 1.08-2.32]).

Proportion of men reporting csPain was significantly higher in the TP-Bx group than the TR-Bx group during LA injection (37.9% vs 2.6%; OR 19.39 [95% CI, 6.57-10.28]) and on the evening of the procedure (18.8% vs 11.2%; OR, 1.84 [95% CI, 1.21-2.79]). Multivariable logistic regression analysis revealed TP-Bx as an independent predictor of csPain at 3 time points: during LA injection, on the evening of the procedure, and on day 3 (Supplemental Tables 2-8, https://www.jurology.com).

Table 1. *Baseline Characteristics of the Trial Participants*

Characteristics	Transrectal biopsy (n = 384)		Transperineal biopsy (n = 398)	
Age, median (IQR), y	66	(61, 70)	65	(60, 70)
Race, No. (%)[a]				
Asian	4	(1)	0	(0)
Black	19	(5)	28	(7)
Hispanic	1	(0.3)	0	(0)
White	358	(93)	367	(92)
Unknown	2	(0.5)	3	(0.8)
Family history of prostate cancer, No. (%)	110	(29)	98	(25)
BMI, median (IQR)	28	(25, 32)	28	(26, 32)
Diabetes, No. (%)	51	(13)	43	(11)
Anticoagulation, No. (%)	16	(4)	19	(5)
Antiplatelet, No. (%)				
Aspirin 81 mg	63	(16)	62	(16)
Aspirin 325 mg	52	(14)	42	(11)
Clopidogrel	4	(1)	7	(2)
Prebiopsy analgesics, No. (%)				
Acetaminophen	62	(16)	70	(18)
Opioids or benzodiazepines	10	(2)	13	(3)
PSA				
Median (IQR), ng/mL	7.0	(5.1, 10.3)	6.9	(5.0, 10.1)
>10 ng/mL, No. (%)	101	(26)	106	(27)
Prostate volume, median (IQR), mL	47	(35, 65)	47	(36, 65)
PSA density, median (IQR)	0.14	(0.09, 0.22)	0.14	(0.09, 0.23)
Digital rectal examination, No. (%)				
Abnormal	79	(21)	70	(18)
Normal	305	(79)	328	(82)
Clinical stage, No. (%)[b]				
T1c	305	(79)	328	(82)
T2	69	(18)	60	(15)
T3	9	(2)	10	(3)
Postvoid residual urine				
Median (IQR), mL[c]	15	(2, 47)	14	(2, 47)
>100 mL, No. (%)	38	(11)	38	(10)
IPSS score				
Median (IQR)[d]	7	(4, 13)	6	(3, 12)
Moderate-severe symptoms, No. (%)	106	(28)	124	(31)
IIEF-5 score				
Median (IQR)[e]	18	(4, 28)	17	(4, 27)
Moderate-severe symptoms, No. (%)	78	(21)	84	(21)
Prebiopsy mpMRI performed, No. (%)	372	(97)	378	(95)
Anterior tumor, No. (%)	128	(33)	125	(31)
Biopsy technique, No. (%)				
MRI targeted and systematic	287	(75)	295	(74)
Systematic only	97	(25)	103	(26)
Total cores taken, median (IQR)	13	(11, 13)	14	(12, 15)

Abbreviations: IIEF-5, International Index of Erectile Function-5; IPSS, International Prostate Symptom Score; mpMRI, multiparametric MRI.
Missing data: PSA level: 1 participant; postvoid residual: 6.5%; IPSS: 32%; IIEF: 35%; incomplete score sheets were not included.
[a] Race, as self-reported in each participant's electronic medical records.
[b] Clinical stages of prostate cancer: T1c, organ confined, detected through PSA screening; T2, palpable, organ confined; T3, palpable, extending past the capsule.
[c] Measured with a postvoid bladder scan.
[d] IPSS: 0 to 7, mild symptoms; 8 to 19, moderate symptoms; 20 to 35, severe symptoms.
[e] IIEF-5 score: 17 to 21, mild symptoms; 8 to 16, moderate symptoms; 5 to 7, severe symptoms.

Urinary Function

The effects of biopsy procedures on urinary and erectile functions are detailed in Table 3. The mean per participant increase in the postbiopsy IPSS after TP-Bx and TR-Bx was 1.2 and 0.3 ($P = .002$), respectively. Clinically significant worsening of IPSS after TP-Bx and TR-Bx was reported by 28% and 18% ($P = .009$), respectively. The mean per participant increase in the postbiopsy IPSS-QoL

Table 2. *Overall Pain Scores and Proportion of Participants Reporting Pain at Various Time Points During and After Prostate Biopsy Procedures*

Time points	Transrectal biopsy (n = 384)	Transperineal biopsy (n = 398)	*P* value and odds ratio (95% CI)[a] (transperineal relative to transrectal)
Probe insertion			
Overall pain score, mean (SD)[b]	2.30 (2.0)	1.8 (1.7)	< .001
Any pain, No. (%)[c]	226 (60.9)	189 (48.5)	.60 (0.45-0.81)
csPain, No. (%)[d]	76 (20.5)	62 (15.9)	.73 (0.51-1.08)
Response rate, %	97	98	
Local anesthesia administration			
Overall pain score, mean (SD)[b]	0.7 (1.2)	3.3 (1.8)	< .001
Any pain, No. (%)[c]	61 (16.9)	326 (85.1)	28.13 (1.70-18.98)
csPain, No. (%)[d]	11 (2.6)	145 (37.9)	19.39 (6.57-10.28)
Response rate, %	94	94	
Needle biopsy			
Overall pain score, mean (SD)[b]	2.2 (1.7)	2.0 (1.6)	.12
Any pain, No. (%)[c]	222 (62)	220 (57)	.81 (0.61-1.09)
csPain, No. (%)[d]	70 (19.6)	69 (17.9)	.90 (0.62-1.30)
Response rate, %	93	97	
End of procedure			
Overall pain score, mean (SD)[b]	1.0 (1.3)	0.9 (1.2)	.13
Any pain, No. (%)[c]	68 (23.0)	96 (29.4)	1.40 (0.69-2.84)
csPain, No. (%)[d]	22 (6.1)	20 (5.2)	.84 (0.45-1.57)
Response rate, %	95	98	
Evening of procedure day			
Overall pain score, mean (SD)[b]	1.5 (1.5)	2.0 (1.8)	< .001
Any pain, No. (%)[c]	176 (49.3)	233 (61.0)	1.61 (1.20-2.15)
csPain, No. (%)[d]	40 (11.2)	72 (18.8)	1.84 (1.21-2.79)
Response rate, %	94	96	
Day 3 after procedure			
Overall pain score, mean (SD)[b]	0.4 (1.0)	0.7 (1.3)	.001
Any pain, No. (%)[c]	52 (14.6)	81 (21.2)	1.59 (1.08-2.32)
csPain, No. (%)[d]	7 (2.0)	15 (3.9)	2.04 (0.82-5.07)
Response rate, %	93	95	
Day 5 after procedure			
Overall pain score, mean (SD)[b]	0.3 (0.9)	0.4 (1.0)	.13
Any pain, No. (%)[c]	21 (5.9)	37 (9.7)	1.72 (0.99-3.00)
csPain, No. (%)[d]	4 (1.1)	10 (2.6)	2.38 (0.74-7.65)
Response rate, %	95	94	

Abbreviations: csPain, clinically significant pain.
[a] *P* value is for the mean difference in overall pain scores (1-10) at each time point; odds ratios are for proportion of men experiencing pain at each time point.
[b] Numerical rating scale for pain assessment, range 0 to 10; higher score = more pain.
[c] Any pain: includes pain scores 2 to 10.
[d] csPain: includes pain scores 4 to 10.

score following TP-Bx and TR-Bx 0.4 and 0.1 (P = .002), respectively. Clinically significant worsening of IPSS-QoL was reported by 31% after TP-Bx and 22% after TR-Bx (P = .02). On multivariable logistic regression analysis, TP-Bx was an independent predictor of decline in IPSS and IPSS-QoL (Supplemental Tables 9-10, https://www.jurology.com).

Erectile Function

The postbiopsy mean IIEF score decreased minimally following both procedures, and the mean change in the score for individual participants was similar between TP-Bx and TR-Bx at −0.4 and −0.8 (P = .3), respectively. Clinically significant change in IIEF score after TR-Bx and TP-Bx was reported by a similar number of men (13% vs 13%). Multivariable logistic regression identified prebiopsy IIEF-5 as a predictor of clinically significant postbiopsy decrease in IIEF-5, but not the biopsy approach (Supplemental Table 11, https://www.jurology.com).

General Symptoms

Postbiopsy subjective symptoms from the modified TRUS-BxQ are summarized in Table 4. Noticing any hematuria was reported by 79% after TP-Bx and 69% after TR-Bx (P = .006). An episode of hematochezia was reported by 9% after TP-Bx and 18% after TR-Bx (P = .001). The hematospermia rates after TP-Bx and TR-Bx were similar at 28% and 30% (P = .6), respectively. General worsening of urination was noted by 23% and 16% (P = .02) in the TP-Bx and TR-Bx groups, respectively, while the rate of worsening erections was similar (9% vs 12%, P = .31).

DISCUSSION

Participant-reported outcomes analysis of men undergoing prostate biopsy in this randomized controlled study demonstrated some clinically significant differences between TR-Bx and TP-Bx procedures. Compared with TR-Bx, pain was reported more frequently, with higher mean pain scores and higher rate of csPain were reported after TP-Bx at several time points. Postbiopsy worsening of urinary function, including clinically significant worsening, was reported more frequently after TP-Bx. Similarly, urinary QoL declined more frequently after TP-Bx compared with TR-Bx while the decline in erectile function occurred at a similar rate after both procedures.

Previous reports, consisting mostly of observational cohort studies, have also noted that patients undergoing TP-Bx using LA experience higher level of pain. It is important to note that the timing of pain assessment, and the number of time points evaluated, vary significantly among the studies which can directly affect the reported outcomes. Guo et al[15] reported that 98% of men undergoing TP-Bx had clinically noticeable pain at some point during the procedure. In their study, mean NRS pain score was 4.0, and 15% of men required additional LA injections due to pain.[15] In a multicenter cohort study by Lopez et al,[16] the pain questionnaire was completed once, at 2 weeks after the procedure. Of 1218 patients, 37% reported some pain, and 27% responded that repeat TP-Bx would be a moderate to major problem due to pain.[16] Similarly, Marra et al[17] studied a cohort of 1008 men undergoing TP-Bx and reported that the maximal intraprocedural

Table 3. *Changes in the Urinary and Erectile Functions After Prostate Biopsy Procedures*

Variables	Transrectal biopsy (n = 384)	Transperineal biopsy (n = 398)	Mean between-group difference in postbiopsy scores (95% CI)	*P* value
Overall IPSS, mean (SD)[a]				
Prebiopsy	8.8 (6.6)	8.3 (6.9)		
Postbiopsy	9.1 (6.1)	9.5 (6.7)		
Increase in IPSS				
Within-person increase, mean (SD)	0.3 (2.7)	1.2 (3.5)	0.9 (0.32-1.40)	.002
Clinically significant increase, No. (%)[b]	41 (18)	81 (28)		.009
Response rate[c], %	66	67		
IPSS-QoL, mean (SD)[d]				
Prebiopsy	1.7 (1.3)	1.6 (1.3)		
Postbiopsy	1.8 (1.4)	2.0 (1.5)		
Increase in IPSS-QoL				
Within-person increase, mean (SD)	0.1 (0.9)	0.4 (1.0)	0.3 (0.10-0.43)	.002
Clinically significant increase, No. (%)[e]	48 (22)	86 (31)		.02
Response rate[c], %	64	65		
IIEF-5 score, mean (SD)[f]				
Prebiopsy	16.2 (11.2)	15.8 (10.8)		
Postbiopsy	15.4 (10.9)	15.2 (10.8)		
Decrease in IIEF-5				
Within-person decrease, mean (SD)	−0.8 (4.9)	−0.4 (4.3)	0.4 (−0.4 to 1.2)	.3
Clinically significant decrease, No. (%)[g]	31 (13)	32 (13)		.8
Response rate[c], %	62	63		

Abbreviations: IIEF-5, International Index of Erectile Function-5; IPSS, International Prostate Symptom Score; IPSS-QoL, International Prostate Symptom Score-quality of life.
[a] IPSS, range 0 to 35; higher score = worse symptoms.
[b] Clinically significant change in IPSS: ≥ 3 points.
[c] Only those participants with both the prebiopsy and postbiopsy score sheets from the same participant were included. Any score sheets with incomplete answers were excluded.
[d] IPSS-QoL score, range 0 to 6; higher score = worse symptoms.
[e] Clinically significant change in IPSS-QoL: ≥ 1 point.
[f] IIEF-5, range 5 to 25; lower score = worse symptoms.
[g] Clinically significant change in IIEF-5: ≥ 4 points.

mean pain score was 4.7, which had resolved by next assessment at 40 days. Myrga et al[18] evaluated pain during and immediately after biopsy procedures that were performed by experienced surgeons who exclusively performed either TR-Bx or TP-Bx procedures. In their multivariable model, receiving TP-Bx doubled the odds of having pain during the procedure compared with TR-Bx and 60% higher rate of moderate to severe pain in the TP-Bx group.[18] Furthermore, compared with TR-Bx, a doubling of the mean pain score was reported in the TP-Bx group by Myrga et al (1.6 vs 3.9) and by Guo et al[15] (2.0 vs 4.0). It is noteworthy that the aforementioned large studies reporting moderate to severe pain with TP-Bx were performed by surgeons with interest, expertise, and experience with this procedure, many of whom had converted solely to the TP-Bx approach. The published studies report variable learning curve for TP-Bx, ranging from 20 to 100 procedures. For the current study, the authors had moderate experience (>20 cases) with TP-Bx before the study, and all were uro-oncologists, with several years of experience with prostate imaging and targeted prostate biopsy. We also evaluated the effect of increasing experience with TP-Bx during the study period on the reported outcomes (eg, first quartile vs second to fourth quartile) and did not find any differences in outcomes.

Recently, limited information about biopsy-related pain has emerged from RCTs comparing TR-Bx and TP-Bx outcomes. Hu et al[19] reported pain scores immediately after the biopsy and at 7 days. During the biopsy procedure, both the mean pain scores (3.0 vs 3.6) and men experiencing severe pain (7% vs 12%) were significantly higher in the TP-Bx group. There was no difference in pain on day 7. Detailed pain assessment during other steps of

Table 4. *Participant-Reported General Symptoms After Prostate Biopsy Procedures*

Variable	Transrectal biopsy (n = 384)	Transperineal biopsy (n = 398)	*P* value
Noticed any blood in urine, No. (%)			
Yes	249 (69)	291 (79)	.006
No	108 (30)	79 (21)	
Response rate, %	93	93	
Noticed any blood with stool, No. (%)			
Yes	64 (18)	34 (9)	.001
No	293 (82)	330 (91)	
Response rate, %	93	92	
Noticed any blood in semen, No. (%)			
Yes	181 (70)	193 (72)	.6
No	77 (30)	75 (28)	
Response rate, %	67	67	
Did urination become worse, No. (%)			
Yes	43 (16)	67 (23)	.02
No	228 (84)	221 (77)	
Response rate, %	71	72	
Did erections become worse, No. (%)			
Yes	19 (9)	27 (12)	.3
No	189 (91)	197 (88)	
Response rate, %	54	56	

the procedure were not performed, and effects of biopsy procedures on voiding function and erectile function were not studied. An RCT by Ploussard et al, conducted for evaluation of cancer detection, assessed pain immediately after and the next day after biopsy.[3] The authors stated that there were no differences in pain or urinary function between the procedures; however, details such as pain scores or the proportion of men experiencing significant symptoms were not provided.

Other studies evaluating pain immediately after the procedure or at 7 to 40 days after the procedure have suggested that there are no differences in pain measures between TR-Bx and TP-Bx.[17-19] Pain assessment immediately after the procedures is not an appropriate time point since the anesthetic effect is at its peak at that time. Similarly, pain assessment performed after 7 to 40 days for a relatively minor procedure would not be expected to yield differences in pain because of the prolonged interval which can introduce recall bias.

In this study, pain assessment was conducted real time at multiple time points, including on the evening of the biopsy procedure which is a relevant time point because the anesthetic effect would have dissipated by that time. Patients in the TP-Bx group reported higher mean pain scores and higher rate of csPain on the evening of and 3 days after the procedures. The only time point where TR-Bx group reported a higher rate of mild pain (not csPain) was during ultrasound probe insertion, a finding that has been reported by other studies,[15,18] and is likely related to the shape of the needle guides. To reduce the biopsy-related pain, especially for TP-Bx, additional measures have been used including nitrous oxide inhalation, intravenous sedation, general anesthesia, and oral agents (hydrocodone, benzodiazepines). However, the benefits of such measures have to be reconciled with the increased cost, resource utilization, and workflow challenges.

Prostate biopsy-related worsening of urinary and erectile functions after both TR-Bx and TP-Bx has been reported in observational studies but direct comparison of the 2 procedures has been lacking. In a systematic review by Borghesi et al including primarily noncomparative studies, worsening of urinary function was noted by 6% to 25% of patients as well as a higher rate of urinary retention (2%-11%) after TP-Bx.[20] Urinary retention is likely related to the use of general anesthesia and excessive number of biopsy cores and is not expected with TP-Bx using LA. However, general anesthesia or sedation is often used for TP-Bx, suggesting that some risk of urinary retention may persist. Several cohort studies of TR-Bx and TP-Bx have reported the effect on erectile function that ranges from no change to a decline in 20% to 34%, depending on the methodology and timing of evaluation.[6,7,21] This study is unique for evaluating the overall change, and within-person change, in the urinary function and erectile function after both biopsy procedures. The urinary function worsened to a greater extent, and in more men after TP-Bx, with 56% relative increase in clinically significant worsening of IPSS, compared with TR-Bx. Similarly, 40% higher likelihood of significant decline in urinary-QoL was noted after TP-Bx compared with TR-Bx. The within-person differences in IIEF and clinically significant erectile dysfunction were similar (13% each) for TR-Bx and TP-Bx procedures. Other recently reported RCTs either did not study or did not report any details of the differential effects TR-Bx and TP-Bx on urinary and sexual functions.[3,19]

The results of 3 large RCTs comparing the 2 procedures have only demonstrated either no or minimal differences in cancer detection and complications rates. These results suggest that clinical equipoise is necessary, and as a result, the authors perform TR-Bx and TP-Bx at a 50:50 ratio in their clinical practice. Some clinicians have maintained their belief in the superiority of TP-Bx based on tertiary or speculative outcomes such as TR-Bx related burden of prophylactic antibiotics and side effects. In the absence of clear advantage for the primary or secondary outcomes, it is not infrequent in clinical practice to overweight tertiary features that may justify our preferred practice pattern. Regardless, current analysis provides actionable information about the trade-offs between various clinically relevant outcomes (cancer detection, complications, PROMs) that must be considered when discussing prostate biopsy procedures.

This study represents the first comprehensive analysis of PROMs after contemporary TR-Bx and TP-Bx under LA from a large, prospective RCT. The study is strengthened by its sample size, robust data collection, and a high rate of response from participants. Our detailed evaluation demonstrates a higher rate and a higher level of pain after TP-Bx at several time points during the procedure which is noticeable by the patients for up to 3 days after the procedure. This study has some limitations. The study design did not include an evaluation of anxiety and embarrassment experienced by the participants which are reported to occur at a higher rate during TP-Bx compared with TR-Bx.[18] This study population was not diverse, consisting mostly of white men. Finally, the postbiopsy urinary and erectile functions were not measured at multiple time points to evaluate the

timing for the resolution of reported differences in outcomes.

CONCLUSIONS

While both prostate biopsy procedures under LA are generally tolerable, csPain was reported more frequently after TP-Bx at multiple time points when compared with TR-Bx. A noticeable worsening of urinary function and urinary QoL was reported more frequently after TP-Bx. The trade-off between such patient-reported outcomes, diagnostic yield, and complications is clinically relevant during patient counseling regarding prostate biopsy procedures.

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EDITORIAL COMMENTS

A transperineal prostate biopsy (TP-Bx) approach has increased in adoption in urology practices due to its negligible infection risk even without prophylactic antibiotics, as well as potentially improved detection of anteriorly located tumors compared with transrectal biopsy (TR-Bx). However, with more recent trial, data show similar rates of cancer detection and infection between TR-Bx with targeted prophylaxis and TP-Bx.[1,2] Considering the clinical equipoise, patient experience during these

procedures is important for counseling for patients to choose the procedure approach.

In this clinical trial of patients randomized to TR-Bx or TP-Bx, the authors collected patient-reported outcomes measures (PROMs) pertaining to pain, urinary symptoms, and erectile function.[3] This study provides useful granularity through collection of PROMs at different time points in relation to biopsy. A significantly higher proportion of the TP-Bx group had clinically significant pain during initial administration of local anesthetic and the evening of the biopsy. The mean pain score was still significantly higher 3 days after TP-Bx but unlikely to be clinically meaningful by then.

More clinically significant worsening of urinary symptoms but not erectile function was also seen in the TP-Bx group. Of note, although erectile function was not significantly different between the groups, about a third of patients in both still reported a clinically significant decrease in International Index of Erectile Function-5 (IIEF-5) scores. International Prostate Symptom Score and IIEF-5 scores to assess these domains after biopsy were provided by at least 62% of patients, a robust rate given that PROMs are often plagued by low responses. While not assessed here, it would be interesting to see further longitudinal data as to whether urinary symptoms equalize across these 2 modalities, as well as if IIEF-5 scores return to baseline.

Overall, this study provides helpful data to counsel patients regarding benefits and risks of these 2 biopsy approaches, allowing for more nuance in shared decision-making.

Wesley H. Chou[1] and Sudhir Isharwal[1]
[1]Department of Urology, Oregon Health & Science University
Portland, Oregon

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Waisman Malaret et al[1] analyzed patient-reported outcome measures (PROMs) after transrectal (TR) and transperineal (TP) prostate biopsy from the ProBE-PC randomized trial. They found that the TP route was associated with higher rates and severity of pain and urinary dysfunction compared with the TR route.[1] While PROMs represent an integral part of patient care and most quality initiatives, PROM research has been limited by lack of standardization of the instruments/questionnaires used, recall bias, cognitive/literacy barriers, lack of responses, and lack of longitudinal follow-up, among other factors.[2] In this context, the authors are to be commended for their rigorous methodology and the comprehensive study design.

The proposed advantages of the TP route include lower infection rates and improved antibiotic stewardship. However, multiple randomized controlled trials found only minimal to no significant difference when compared with the TR approach. In a different study, the authors surveyed 49 men who received both biopsy approaches and found that, while more men favored the position and local anesthesia infiltration during the TR route, 61% would prefer a TP approach if they were to need another biopsy.[3] Therefore, despite the current study suggesting that the TR route is associated with more favorable PROMs, it remains difficult to predict which approach patients would prefer if they had experienced both procedures.

To conclude, it is imperative to recognize that PROMs may play a significant role in counseling patients about the pros and cons of each biopsy strategy. This study enables a better understanding of real-world patient experiences and helps set appropriate expectations—not only regarding the risks of infection or the detection of clinically significant cancer but also the anticipated pain, the risk and duration of urinary and erectile dysfunction, and the overall biopsy experience. These insights can enhance shared decision-making.

Ahmed A. Hussein[1]
[1]Department of Urology
Roswell Park Comprehensive Cancer Center
Buffalo, New York

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REPLY BY AUTHORS

We appreciate the very thoughtful editorial comments[1,2] on our recent study of patient-reported outcomes after transrectal and transperineal prostate biopsy procedures.[3] We agree with Chou and Isharwal[2] that clinical equipoise regarding efficacy and safety of 2 biopsy techniques further highlights the importance of measuring patient-reported outcomes. The randomized nature of this large sample size coupled with the high response rate across all outcome domains further strengthens the findings of this study. The increased level of patient-reported pain or discomfort and embarrassment during transperineal biopsy has been confirmed by other randomized and observational studies.[4,5]

A previous pilot study abstract referenced by Hussein[1] was an interesting exercise to determine whether patient preference of the biopsy procedure could be captured as part of the randomized trial. This required a cohort of men who had received both transrectal and transperineal biopsy procedures. After analysis, it became apparent that the survey response suffered from the phenomenon of "recency effect" (or recency bias) which has been reported in other areas of medical practice.[6] Patients tended to favor the more recent of the 2 biopsy procedures, regardless of the biopsy approach. The survey was further confounded by the fact that the initial (mostly transrectal) biopsies were performed elsewhere, while the more recent (mostly transperineal) biopsy was performed at our center.

The push to perform transperineal prostate biopsy under local, instead of general, anesthesia was primarily driven by the need to reduce the cost and increase the uptake of transperineal biopsy. Although the feasibility of this approach has been demonstrated, any yet-to-be-confirmed cost savings may come at the expense of patient experience.

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