

Original Article

Transrectal ultrasound guided prostate biopsy performed by supervised junior and senior residents is safe and does not result in inferior outcomes

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Abstract: Purpose: To compare transrectal ultrasound guided prostate biopsy (TRUSBx) cancer detection and complication rates between residents at different levels of training and attending physicians at a single academic center. Methods: We performed a retrospective review of consecutive series of 623 men undergoing TRUSBx from June 2014 to February 2017. The procedure was performed either by resident physicians under direct supervision by an attending physician or by an attending physician. In total, junior residents, senior residents and attending physicians performed 244, 212, and 167 biopsies, respectively. Prostate cancer detection, 30-day complications, and 30-day hospitalizations rates were the outcomes of interest. We performed multivariable logistic regression analysis to identify predictors of these outcomes and examined the hypothesis that TRUSBx performed by trainees would not be associated with inferior outcomes. Results: There was no statistically significant difference in patient populations between the three groups when stratified by age, BMI, Charleston co-morbidity index, aspirin use, PSA level and palpable nodule on DRE. Prostate cancer was detected in 43.8% of the biopsies and there was no difference in detection rates ($P = 0.53$), Gleason score ($P = 0.11$), number of positive cores ($P = 0.95$), 30-day hospitalization ($P = 0.86$), and 30-day complication rates ($P = 0.67$) between TRUSBx performed by trainees and attending physicians. Conclusions: TRUSBx performed by residents and attending physicians yielded equivalent rates of cancer detection with no significant difference in 30-day complications or 30-day hospitalizations rates. There was no difference in outcomes between junior and senior residents suggesting that with adequate faculty supervision, it is safe for trainees at all levels to perform prostate biopsies.

Keywords: Transrectal ultrasound, prostate cancer, biopsy, resident training

Introduction

Transrectal ultrasound guided biopsy (TRUSBx) of the prostate is an increasingly common procedure in the urology office. Approximately one million prostate biopsies are performed annually in the United States and it is a critical component of urological residency training [1]. TRUSBx is the standard procedure for histological detection of prostate cancer, but is invasive and can lead to various complications such as rectal bleeding, hematuria, acute urinary retention, urinary tract infection, and hematospermia [2]. Given the learning curve and potential for complications, there is a growing public concern over the safety of trainee involvement in patient care at academic medical centers [3].

Several studies have evaluated the impact of a urology resident's level of training on prostate biopsy quality and patient comfort. Resident performed biopsies were associated with higher levels of pain with the procedure when compared to staff urologists [4]. However, cancer detection rates were comparable between junior and senior residents, especially when PSA was greater than 10 ng/ml [5, 6]. Nevertheless, there still exists a paucity of data examining residents' complication and cancer detection rates when compared to staff surgeons. To assess for safety and quality in the performance of TRUSBx, we measured prostate cancer detection and complication rates following TRUSBx by trainees and faculty urologists.

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Materials and methods

Data source

We conducted a retrospective cohort analysis of consecutive patients who underwent TRUSBx from June 2014 to February 2017 at the William S. Middleton Memorial Veterans Hospital (VA). All patients within the time period were included and none were excluded in the final analysis. This project was performed in accordance with institutional regulations for quality improvement projects and therefore deemed exempt from IRB review.

Study population

Via shared decision making, patients with either elevated PSA and/or abnormal findings on a digital rectal exam (DRE) underwent TRUSBx. Digital rectal examination was performed at the time of TRUSBx to document if any nodules were present. TRUS was used to determine prostate volume measurements. A 12-core TRUSBx was obtained using the standard sextant approach as described by McCullough [7] and extra cores were obtained when clinically indicated. The biopsies were performed on an outpatient basis using Flex Focus 800 BK Ultrasound machine (Analogic, Peabody, MA, USA).

The standard prophylactic antimicrobial regimen at our institution includes 2 doses of 500 mg oral ciprofloxacin. High risk patients [8], were given 1 gm of ceftriaxone in lieu of the standard antimicrobial protocol. Patients were instructed to self-administer an enema the morning before arrival. Verbal and written instructions were provided to patients to go to the emergency department or call the VA triage line if they noticed any fevers, chills, inability to void, or severe bleeding. Additionally, patients were queried for current use of platelet inhibitors or anticoagulant use at baseline. If the patient could not come off their aspirin, TRUSBx was performed with the patient on aspirin 81 mg but no other anticoagulants or antiplatelet therapy was allowed. Patients were also counseled to stop any over the counter vitamins or herbal supplements before biopsy.

Prostate biopsies were performed by either a resident or an attending depending on the daily schedule. Scheduling into attending or resident

procedure grids was done at random by a non-clinical administrative clerk. Senior urology residents were in their third year of urology training and junior urology residents were in their first year of urology training. All residents had appropriate graduated faculty supervision with the faculty in the room during the procedure and appropriate hands-on faculty guidance when needed.

Predictors and measures

Clinical and pathologic characteristics were collected via a detailed EHR review including patient baseline demographics such as age, body mass index (BMI), Charlson comorbidity index (CCI), medications use, and PSA levels. Time of year was also analyzed as July to December which correlates with the residents' first two-month rotation through the VA and January to June correlated with the residents' second rotation through the VA. The VA rotation accounts for the majority of the residents' prostate biopsy experience in our residency training program.

Outcomes of interest

The primary outcome measure was cancer detection rates stratified by experience (junior resident, senior resident, or attending). Secondary outcome measures included 30-day hospitalizations and 30-day complications also stratified by level of experience. We defined complications as any deviation from normal post biopsy activities including any unprompted phone calls to the triage line, outpatient medical intervention, emergency room visits, or hospitalizations within 30 days of their prostate biopsy. Complications were further categorized into infectious, bleeding, or other. Infectious complications were defined clinically with or without positive urine culture; which also included patients that were treated with empiric antibiotics by providers outside of our department.

Statistical analysis

Categorical data were compared using Pearson's chi squared test while continuous variables were compared using two-tailed ANOVA analysis across the three groups stratified by junior resident, senior resident, and attending urologist. Multivariable logistic regression was

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Table 1. Baseline demographics of cohort stratified by level of trainee

	Junior Resident	Senior Resident	Attending	P-value
Total, n (%)	244 (39.1)	212 (34.0)	167 (26.8)	-
Age, median (IQR)	67.1 (63.9-69.4)	67.3 (64.7-69.3)	66.4 (62.9-68.9)	0.083
BMI, median (IQR)	30 (26.6-32.7)	29.5 (27-32.7)	30.5 (27.6-33.7)	0.16
CCI, n (%)				0.34
0-1	178 (72.9)	160 (75.4)	117 (70.0)	-
2-3	56 (22.9)	37 (17.4)	39 (23.3)	-
> 3	10 (4.1)	15 (7.0)	11 (6.5)	-
Aspirin use, n (%)	100 (40.9)	93 (43.8)	78 (46.7)	0.51
Time of year, n (%)				0.49
July-December	130 (53.2)	109 (51.4)	96 (57.4)	-
January-June	114 (46.7)	103 (48.5)	71 (42.5)	-
Pre-biopsy PSA, median (IQR)	6.5 (5.1-9.9)	6.75 (5.1-10.2)	7 (5.3-10.3)	0.73
Prostate volume (mL), median (IQR)*	40 (30-55)	40 (29-58)	42 (28.9-57)	0.997
Palpable prostate nodule, n (%)	45 (18.6)	43 (20.3)	41 (25.4)	0.24

*Volume from transrectal ultrasound.

performed to identify if level of experience was associated with ability to detect prostate cancer adjusting for patient age, aspirin use, time of academic year, PSA, and prostate nodule. In the subset of patient's diagnosed with prostate cancer, we performed an additional multivariable logistic regression to identify if level of experience was associated with ability to detect Gleason Score ≥ 7 prostate cancer adjusting for similar co-variables. Finally, multivariable logistic regression was performed to identify if level of experience was associated with post-procedure 30-day complications in the entire cohort. All tests were 2-sided with $P < 0.05$ denoting statistical significance. Statistical analysis was performed using Stata (version 14, College Station, TX).

Results

Baseline cohort characteristics

Six hundred twenty-three prostate biopsies were retrospectively analyzed at the William S. Middleton Memorial Veterans Hospital (VA). The characteristics of the study cohort stratified by level of trainee are presented in **Table 1**. Of the 623 prostate biopsies, 244 biopsies were performed by junior residents, 212 biopsies by senior residents, and 167 by attending urologists. There was no difference in patient demographics including patient's age, BMI, CCI distribution, aspirin use, PSA value, prostate volume obtained from ultrasound, and pres-

ence of nodule on DRE between the three groups.

The pathological findings of the prostate biopsies as well as 30-day hospitalizations and complications are summarized in **Table 2**. Prostate cancer was detected in 43.8% of all biopsies and were comparable across the three groups: 44.9% in biopsies performed by attending physicians, 45.4% in biopsies performed by junior residents and 40.5% in biopsies performed by senior residents ($P = 0.53$). Analysis of positive biopsies, when stratified by Gleason score, showed no difference in proportion of pathologic findings between junior residents, senior residents or attending urologists. Interestingly, attending urologists obtained proportionally more Gleason 6 biopsies compared to junior residents ($P = 0.032$), but not to senior residents ($P = 0.19$). Overall, 30-day hospitalization and 30-day complication rate was 2.4% and 12.5% respectively; there was no difference based on the level of training ($P = 0.86$ and $P = 0.67$ respectively).

Predictors of cancer detection and complications

Multivariable logistic regression analysis identifying predictors of prostate cancer detection are shown in **Table 3**. Operator experience and patient aspirin use were not associated with prostate cancer detection. Conversely, patient's age (OR 1.06, 95% CI 1.02-1.09; $P = 0.001$)

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Table 2. Outcomes of prostate biopsy stratified by level of trainee

	Junior Resident	Senior Resident	Attending	P-value
Biopsy positive, n (%)	111 (45.4)	86 (40.5)	75 (44.9)	0.53
Gleason score, n (%)				0.11
6	29 (26.3)	27 (31.4)	31 (41.3)	-
7	56 (50.9)	36 (41.8)	34 (45.3)	-
8-10	25 (22.7)	23 (26.7)	10 (13.3)	-
Positive cores, n (%)				0.95
1	30 (27.0)	21 (24.4)	18 (24.0)	-
2-4	45 (40.5)	35 (40.7)	34 (45.3)	-
> 4	36 (32.4)	30 (34.8)	23 (30.6)	-
30 Day Hospitalization, n (%)	5 (2.05)	6 (2.83)	4 (2.4)	0.86
30 Day Complication, n (%)	27 (11.0)	29 (13.6)	22 (13.1)	0.67
Infection	5	0	3	-
Bleeding	13	20	11	-
Other	9	9	8	-

Table 3. Multivariable logistic regression analysis identifying independent predictors for the detection of prostate cancer or detection of Gleason Score ≥ 7 prostate cancer in subset of patients diagnosed with prostate cancer

	Detection of Any Prostate Cancer			Detection of Gleason Score ≥ 7 prostate cancer		
	Odds Ratio	95% CI	P-Value	Odds Ratio	95% CI	P-Value
Experience			-			-
Attending	Ref.	Ref.	-	Ref.	Ref.	-
Senior resident	0.78	0.50-1.21	0.27	1.56	0.76-3.20	0.22
Junior resident	1.03	0.67-1.56	0.91	2.22	1.11-4.45	1.11
Age	1.06	1.02-1.09	0.001	1.04	0.98-1.10	0.21
Aspirin use			-			-
No	Ref.	Ref.	-	Ref.	Ref.	-
Yes	1.09	0.78-1.53	0.78	2.22	1.26-3.93	0.006
Time of academic year			-			-
1 st 6 months	Ref.	Ref.	-	Ref.	Ref.	-
2 nd 6 months	1.48	1.06-2.07	0.021	1.00	0.57-1.74	0.997
PSA at time of biopsy	1.008	0.997-1.02	0.14	1.03	0.989-1.08	0.14
Prostate nodule			-			-
No	Ref.	Ref.	-	Ref.	Ref.	-
Yes	2.75	1.81-4.17	< 0.001	0.047	0.001-1.89	0.11

and palpable nodule on DRE (OR 2.75, 95% CI 1.81-4.17; $P < 0.001$) were predictors of a biopsy positive for prostate cancer. Interestingly, biopsy in the second half of the academic year (OR 1.48, 95% CI 1.06-2.07; $P = 0.02$) was associated with increased odds of prostate cancer detection. Furthermore, analysis of only biopsies showing clinically significant Gleason ≥ 7 disease, aspirin use was the sole predictor of detecting prostate cancer ($P = 0.006$).

Finally, multivariable logistic regression analysis identifying independent predictors of

30-day post-biopsy complications were performed and summarized in **Table 4**. CCI, experience level, and time of academic year, were not associated with differences in complications.

Discussion

Prostate cancer represents the fifth leading cause of cancer death in men worldwide, accounting for 6.6% of cancer mortality [9, 10]. Given the prevalence of prostate cancer, urology residents have historically been taught early in their training to perform supervised TRUS-

Table 4. Multivariable logistic regression analysis identifying independent predictors for the detection of post-procedure 30-day complications in all patients

	Odds Ratio	95% CI	P-Value
Experience			-
Attending	Ref.	Ref.	-
Senior resident	0.96	0.53-1.77	0.91
Junior resident	0.74	0.40-1.36	0.33
Age			-
Time of academic year			-
1 st 6 months	Ref.	Ref.	-
2 nd 6 months	1.01	0.97-1.06	0.62
Charlson-comorbidity index			-
0-1	Ref.	Ref.	-
2-3	0.97	0.53-1.77	0.91
> 3	0.21	0.027-1.56	0.13

guided prostate biopsies [3]. Nevertheless, many patients express reservation when having a resident perform procedures. Urology residents, when appropriately supervised, have previously been shown to achieve similar levels of patient comfort and morbidity when performing many office-based procedures including cystoscopy and vasectomy [11, 12]. The aim of this study was to compare prostate cancer detection rates and outcomes between residents and attendings when performing prostate biopsy and to assess possible safety concerns of TRUBx when performed by trainee physicians.

The overall prostate cancer detection rate in this study is approximately 44%; this compares favorably to other studies utilizing similar methodology ranging from 25-47% [6, 13-16]. Our results have demonstrated several important findings. There were no differences in prostate cancer detection rates between junior or senior residents and staff urologists. Patient age, nodule on DRE, and procedure during 2nd half of year was associated with positive biopsy findings. The 2nd half of the year phenomenon we observed is interesting and suggests there might be an element of experience driving this, but there could also be unmeasured patient factors that we were not able to account for.

The largest single institution study comparing prostate cancer detection rates between train-

ees and experienced consultants was done in 690 patients in Hertfordshire, UK [4]. Interestingly, significant differences were found between junior trainees and consultants (47% vs 64%), but not between senior trainees and consultants (59.6% vs 64%). Even though in our study we found no differences between the three groups, this discrepancy may rather reflect an initial learning curve with use of the ultrasound probe and biopsy needle, as we have also shown that the second half of the academic year correlated with a positive cancer detection. Another study examining operator experience and TRUSBx detection rate was done in 170 patients with PSA between 4 and 10 ng/ml [6]. Four cohorts (corresponding to year 1 to year 4 of resident training) were compared, but no significant differences were observed. Despite the limited sample size, it provides additional evidence that detection rate may not be compromised with trainee involvement as was noted in our larger study. There are variations in TRUS prostate biopsy techniques such as ultrasound probe configurations, core number, core length, and needle size that can impact cancer detection rate [13, 17, 18]. However, these differences in techniques were controlled in our study as all biopsies were standardized. Outside of the initial learning curve, it is likely that other sources of variation like individual differences in technique, rather than operator experience, may account for variations in TRUSBx outcomes. To further this point, Lawrentschuk *et al.* examined prostate cancer detection rates among four experienced urologists at the same institution with a median cohort of 514 patients per operator [19]. There were significant differences in the cancer detection rates even when performed in the same setting using identical equipment.

To our knowledge, the only study examining complication rates between trainees and faculty urologists while performing TRUSBx was conducted by Tadtayev *et al.* which reported an overall complication rate of 3.8% that was comparable among consultants, senior and junior trainees (3.6%, 3.2%, and 5.4% respectively) [5]. We also found no significant difference in 30-day complication and 30-day hospitalization rates based on level of experience in our study. The incidence of complications regarding infection, excess bleeding, and readmission

rates was consistent with previously reported studies [20, 21]. It has been reported that many of the patients with more severe complications requiring hospitalization are due to infectious causes. Furthermore, it has been shown that antimicrobial resistance, in particular to fluoroquinolones, may play a larger role in postoperative fevers and sepsis; rather than subtle variations in biopsy technique [22, 23]. Adherence to AUA's best practice guidelines on antimicrobial prophylaxis and targeted antibiotic prophylaxis based on risk factors may help clinicians reduce the rates of severe complications after TRUSBx and it is likely this play a larger role than operator experience.

It is not clear whether hesitation by patients towards resident operated TRUS prostate biopsy is due to the perceived technical skills of resident physicians or other factors such as communication skills and biases. In Yancy *et al.* patient satisfaction rates were compared between resident physicians and attending physicians at a university clinic. Of note, patients in resident-staffed clinics were more likely to be African American, male, have lower socioeconomic status, and lower physical and mental health scores on the short form 12 survey [24]. However, even after controlling for patient characteristics, resident physicians achieved lower patient satisfaction compared to attending physicians. They concluded that these differences may be attributed to experienced doctors' personal manner and respect toward the patient. Interpersonal skills training is a continuous and critical component of medical education and can play a role in patient's perceived quality of care.

There are several limitations in this study. This was a single institution study. Inter-institutional differences in urological training include the amount of supervision and introduction with TRUS-guided prostate biopsies, biopsy tools/techniques, and patient volume. Secondly, surgeons from each cohort contributed varying number of biopsies; thus, individual differences in learning speed and technique were not accounted for. Finally, procedure related findings such as patient comfort, procedure duration, and post-biopsy pain medication requirements were not examined. Prospective multi-institutional studies are warranted to further affirm our findings.

In conclusion, prostate biopsy performed by trainees have similar prostate cancer detection rates compared to faculty urologists without increased complications. There was no difference in rates of complications or hospitalization between junior, senior residents and attending physicians, suggesting that with adequate faculty supervision, it is safe for trainees at all levels to perform prostate biopsies. Communication of these findings with patients may alleviate their concerns and can provide residents with ample opportunity to hone these skills before graduating.

Disclosure of conflict of interest

None.

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