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MP-2.01

Hospital volume and its relationship to positive surgical margins at radical prostatectomy

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Introduction and Objective: It is well understood that in the treatment of prostate cancer with surgery, positive surgical margin (PSM) status varies between institutions and there is mounting evidence that high volume surgeons and centres obtain better oncological results. However, larger studies recording PSM for radical prostatectomy are from large centres of excellence and not on a population level. The aim of our study was to establish the province-wide PSM rate for pathological stage T2 and T3 disease prostate cancer and assess the overall and regional based PSM rates based on surgical volume.

Materials and Methods: A random audit of pathological reports from the Ontario Cancer Registry in Ontario, Canada, was analyzed for PSM status among patients undergoing radical prostatectomy in 2005 and 2006. Data were collected from 43 hospitals. The sampling consisted of a total of 1583 radical prostatectomies, representing around 60% of the provincial total. Pathological stage T2 and T3 were considered as this is a more homogenous group. Regression analysis was performed to assess volume-margin associations.

Results: The province-wide surgical PSM rate for pathological stage T2 disease had a median of 32% while T3 had a median of 38%. Regional rates of PSM for T2 ranged from 0% to 100% among a total of 43 regions (Fig. 1). The volume of radical prostatectomies ranged from 2 to 67 per region. There was no significant correlation between volume and PSM with T2 disease (R = –0.2207, $p \leq 0.155$).

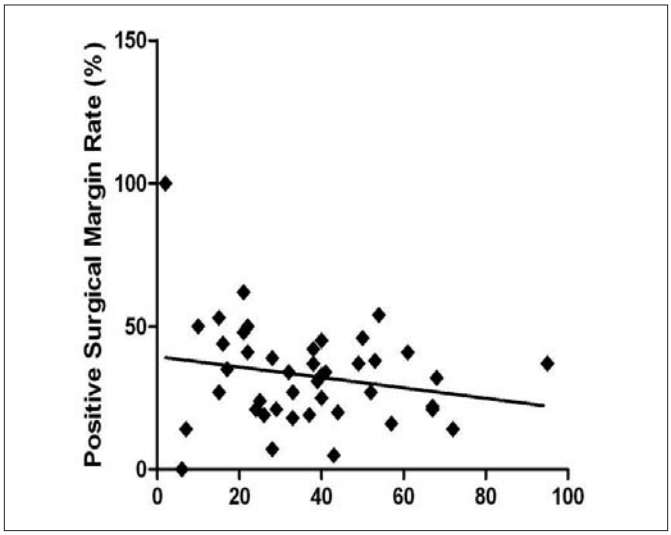

Fig.1. Ontario Cancer Registry: positive surgical margin rate for radical prostatecomies for pathological T2 stage disease 2005/06, by hospital.

Conclusion: The province-wide PSM rate for pathological stage T2 disease prostate cancer undergoing radical prostatectomy is higher than published centres of excellence. Although larger volume centres did better; results were not statistically significant which contradicts previously published data. Factors such as individual surgeon, patient selection, pathological processing and interpretation may explain differences.

MP-2.02

Mature results of a randomized phase II study of OGX-011 in combination with docetaxel/prednisone versus docetaxel (DOC)/prednisone in patients with metastatic castration resistant prostate cancer (CRPC)

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Introduction and Objective: Clusterin is a cytoprotective chaperone protein associated with CRPC progression. OGX is a 2′-methoxyethyl antisense that potentiates chemotherapy in xenografts and inhibits clusterin expression in clinical studies. The primary objective was to determine the PSA response rate (RR) of combination DOC and OGX-011. Progression-free survival (PFS) and overall survival (OS) were secondary end points.

Materials and Methods: Patients received DOC 75 mg/m^2 q3w + OGX 640 mg IV weekly + prednisone (A) or DOC + prednisone (B) in a randomized phase II design. Planned sample size was 40/arm: Arm A the hypotheses (PSA RR < 40% v. > 60%) could be tested at 10% β and 10% α, Arm B the true PSA RR could be estimated with half-width of the 90% CI < 13% if PSA RR = 40%.

Results: Eighty-two patients (41/arm) were randomized from 09/05 to 12/06. All patients are off therapy and 49 have died. Baseline characteristics were similar in each arm: median age 69 (49–87), PSA greater than 100 µg/L in 51%, Hgb 100 g/L or greater in 98%, alk phos greater than ULN in 44%, LDH greater than ULN in 36%, ECOG performance status (PS) 0:1 in 51%:49%, bone/lymph node/visceral metastases in 69%/50%/28%. Median cycles for A and B were 9 and 7. Adverse events with OGX included fatigue, fever, rigors, diarrhea and rash. Mean serum clusterin change on day 1 cycle 2 was –18% in A and +8% in B ($p = 0.0005$). PSA RR was 58% (A) and 54% (B). PSA declines at 12 weeks of any/> 30%/> 50% was observed in 87%/65%/45% (A) and 68%/58%/34% (B). PSA/objective disease progression as best response occurred in 0%/4% (A), and 3%/17% (B). PFS for A and B was 7.3 (5.3–8.8) and 6.1 (3.7–8.6) months. Median OS for A and B was 27.5 (19.2–∞) and 16.9 (12.7–26.0) months (HR 0.60 [0.34–1.06], $p = 0.07$). Variables predictive of OS on multivariate analysis: PS 0 versus 1 ($p = 0.0002$), presence of visceral metastasis ($p = 0.006$) and treatment assignment (HR 0.54 [0.29–0.97], $p = 0.04$).

Conclusion: The PSA RR in both arms met criterion for further study. OGX reduced serum clusterin and OS appears superior with DOC/OGX. This combination warrants further evaluation.

MP-2.03

Impact of positive surgical margins after radical prostatectomy differs by disease-risk group

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Introduction and Objective: The prognostic value of positive surgical margins (PSM) following radical prostatectomy (RP) remains controversial. While most studies suggest that PSM has a negative impact on disease outcomes, other reports indicate that its prognostic value depends on the pathological features of the disease. We evaluated the relationship between PSM and biochemical progression based on several clinicopathological features.

Materials and Methods: We analyzed data from 1268 patients who underwent RP for clinically localized prostate cancer at our centre between 1992 and 2008 and did not receive any neoadjuvant or adjuvant treatment. Using survival analysis, we examined the relation of age, pretreatment PSA, pathological T-stage, RP Gleason score, disease risk groups (Low: PSA < 10 ng/mL and Gleason 6 or less, Intermediate: PSA 10–20 ng/mL and Gleason = 7, High: PSA > 20 or Gleason 8 or more) and the surgical margin status (PSM versus negative surgical margins [NSM]) to biochemical progression-free survival (BPFS).

Results: At a median follow-up of 79 months, the overall BPFS for all stages and disease risk groups was significantly better for patients with NSM compared with those with PSM, 93.8% versus 79.9%, respectively (log rank p value < 0.001). The low-risk disease group did significantly better than intermediate and high-risk groups in terms of BPFS, 89% versus 65% and 31%, respectively (log rank test comparing risk groups $p < 0.001$). This difference remained significant in multivariate Cox regression analysis independent of T stage and surgical margin status. However, there was no significant difference in BPFS between PSM and NSM in the low-risk group 94.9% versus 99.6%, respectively ($p = 0.53$) in contrast to intermediate- and high-risk groups.

Conclusion: Patients with PSM have a higher risk of biochemical progression than those with NSM in intermediate and high risk prostate cancer. However, in low risk disease, PSM and NSM had similar favourable outcomes. This suggests that patients with low risk disease even with PSM might be candidates for expectant management and salvage therapy only with disease progression, sparing the majority from unnecessary treatment, side effects and costs.

MP-2.04

Does nerve-sparing radical prostatectomy increase the risk of positive surgical margins and biochemical progression?

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Introduction and Objective: Since the introduction of nerve-sparing radical prostatectomy (NSRP), concerns about the increased risks of positive surgical margins (PSM) and biochemical progression (BP) have been raised. While some reports showed an increased risk of PSM and BP with NSRP, others found no such relationship. In this study we examined the relationship of NSRP to PSM and BP using a large, mature data set.

Materials and Methods: We analyzed data from 776 patients who underwent RP for clinically localized (stage T1/T2) prostate cancer at our centre between 1997 and 2008, who did not receive either neoadjuvant or adjuvant treatment and for whom surgical records detailed the type of nerve-sparing approach used. We evaluated their clinical and pathological features and the relationship between nerve sparing, surgical margin status and BP using multivariate survival analysis.

Results: Five hundred and thirty-four patients (68.8%) underwent NSRP and 242 patients (31.2%) had non-NSRP performed. In a multivariate analysis, patients who underwent non-NSRP had a higher pathological stage (OR 2.37, 95% CI 1.54–3.65, $p < 0.001$) and a higher baseline PSA (OR 1.06, 95% CI 1.02–1.09, $p < 0.001$). The rates of PSM in NSRP were 14.0% compared with 17.3% in non-NSRP ($p = 0.27$). With a median follow-up of 41 (mean 48.6, range 3–178) months, biochemical progression-free survival adjusted for stage, grade and PSA was 92% for the NSRP group compared with 88% for non-NSRP (log rank p value = 0.21).

Conclusion: After adjustment for pathological factors, a nerve-sparing approach does not appear to increase the risk of positive surgical margins and biochemical progression in men who undergo RP. However, this is best confirmed in a randomized trial of similar patients.

MP-2.05

A prospective longitudinal study of the effects of androgen deprivation therapy on cognitive function in men with prostate cancer

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Introduction and Objective: To prospectively examine changes in cognitive function over time in men on androgen deprivation therapy (ADT) compared with controls.

Materials and Methods: Three separate groups matched for age and education, were tested longitudinally for cognitive function; PC patients starting continuous ADT ($n = 77$), PC patients not receiving ADT (PC controls [$n = 85$]) and healthy controls ($n = 83$). A battery of neuropsychological tests, examining 7 cognitive domains was administered at baseline (before ADT treatment), 6 months and 12 months later. Mean scores at baseline were compared using ANOVA, and change scores between baseline and 12 months were analyzed using mixed effects linear regression models, adjusted for age and education.

Results: The mean age and education level of the patients overall was 68.9 years and 15.7 years, respectively. All 3 cohorts had similar cognitive scores at baseline other than in 1 test of Working Memory. Adjusted for age and education, Attention and Processing Speed, Visuospatial ability, and Visual Memory scores did not significantly differ from baseline to 12 months ($p > 0.05$) for the cohorts. At 12 months, compared with healthy controls, ADT patients had significantly improved on the longest digit span forward and backward (Immediate and Working Memory) ($p < 0.05$). Androgen deprivation therapy patients also improved on card rotations, colour naming (Executive Function) ($p < 0.05$) and the controlled oral word association fluency test (Language Fluency) ($p < 0.05$). Compared with healthy controls, PC controls had only improved on the longest digit span forward (Immediate Memory) at 12 months ($p < 0.05$).

Conclusion: Preliminary results indicate that most cognitive domains do not appear to be impacted by 12 months of ADT use. The results also suggest a slight improvement, rather than decline, in 2 tests of executive function, one of working memory and one of language fluency. These results should provide some reassurance to clinicians and patients.

MP-2.06

Prognostic value of capsular incision at radical prostatectomy

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Introduction and Objective: Surgical margins (SMs) are an important predictor of outcome following radical prostatectomy (RP). Their significance in patients with otherwise organ-confined disease is however more controversial. In this study we evaluate the impact of capsular incision (CI) on patient outcome.

Materials and Methods: Between 1985 and 2008, 8046 consecutive patients were treated with RP at the Ottawa Hospital and Memorial Sloan-Kettering Cancer Center. Patients were divided into 4 pathological categories. Group 1 (CI group) = SM positive (p), ECE negative (n); Group 2 = SMn, ECEn; Group 3 = SMn, ECEp; Group 4 = SMp, ECEp. Estimates of recurrence-free survival were generated with the Kaplan–Meier method. Recurrence was defined as a PSA greater than 0.2 ng/mL and rising or the postoperative use of adjuvant radiation or hormones. Cox proportional hazards regression was used to estimate the hazard ratio (HR) for recurrence controlling for pretreatment PSA, RP date, RP Gleason sum, seminal vesicle invasion and lymph node involvement.

Results: Median follow-up was 39.9 months. The 5-year recurrence-free probability after RP for the CI group was 73% (95% CI 68–78). This was

not only inferior to patients with SMn and ECEn (log rank $p < 0.0001$) but also to those with SMn and ECEp (log rank $p < 0.0001$) (Fig. 1). In multivariate analysis patients with CI had a 2.5 times increased hazard of recurrence relative to those with SMn and ECEn ($p < 0.0001$). The CI group also had a 1.5 times increased hazard of recurrence relative to those patients with SMn and ECEp ($p = 0.015$).

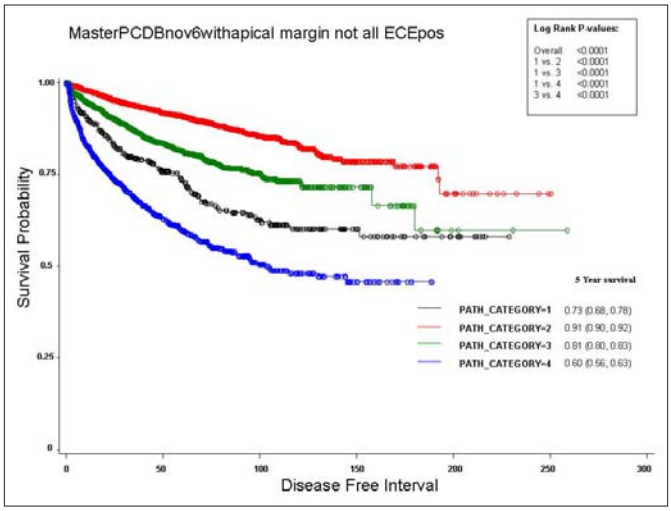

Fig.1.

Conclusion: Capsular incision has a significant impact on patient outcome following RP. Patients who otherwise would have organ-confined disease, will be made to have a higher probability of recurrence than those with completely resected extraprostatic disease. Limiting capsular incision is therefore of utmost importance and is an important quality indicator of RP.

MP-2.07

Investigational study for the treatment of localized (T1c/T2a) prostate cancer with high intensity focused ultrasound in Canada

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Introduction and Objective: Failure rates for radiation and surgery for localized prostate cancer are real and the associated morbidity remains significant. High intensity focused ultrasound (HIFU) is a novel minimally invasive, out-patient procedure for prostate cancer. This Canadian pilot study evaluates the ability of HIFU to treat prostate cancer demonstrating biochemical response, while assessing short-term clinical outcomes.

Materials and Methods: Patients were prospectively enrolled between August 2007 and July 2008. Inclusion criteria for the study was primary treatment for organ-confined prostate cancer (T1c/T2a), Gleason scores 6 or less, prostate total volumes less than 50 mL, PSA 15 ng/mL or less, negative bone scan, ≤ 3 positive biopsy cores. Follow-up occurred at 3-month intervals, and included the EPIC score (Q #1–4), the IPSS score, the IIEF score, and PSA measurements. Early and late complications were reported.

Results: There were 29 patients treated by 5 urologists. Mean age was 60 (range 46–75) years. Clinical stage T1c was found in 28/29 patients (T2a in 1 patient). Mean pretreatment prostate volume was 29 (range 14.5–40.2) mL. Two patients initially did not follow-up. Descriptive statistics for PSA, EPIC, IPSS and IIEF are reported in Table 1. Early complications included 24 minor catheter-related issues (i.e., blockage or reinsertion for retention) and 5 other complications (infection, bleeding). There were no reported cases of serious complications such as fistulae or bladder neck contractures. Late complications included requirement for prolonged catheterization (> 21 d, $n = 13$) and cystoscopy ($n = 3$). Post-HIFU, 8/27 (30%) patients required PDE5i for erectile dysfunction compared with 4/29 (13.8%) pre-HIFU.

Table 1. MP-2.07. Descriptive statistics for PSA, EPIC, IPSS and IIEF

	PSA, ng/mL			EPIC, score/19			IPSS, score/35			IIEF, score/25		
Time, mo	*n*	Median	Range	*n*	Mean	Range	*n*	Median	Range	*n*	Mean	Range
0	29	4.94	0.76–9.3	29	18.5	14–19	29	5.9	0–24	29	22.0	5–25
3	24	0.15	0.02–4.81	25	16.8	10–19	24	9.5	0–29	24	11.4	3–24
6	15	1.08	0.09–3.31	14	17.4	12–19	15	8.4	1–31	15	12.5	1–25
9	5	1.26	0.09–2.12	7	18.0	15–19	8	6.9	1–14	8	16.4	1–25

Conclusion: In the short term, HIFU treatment for organ-confined prostate cancer appears effective and safe. Although some patients have worrisome PSA parameters, this could be related to residual benign prostatic tissue. Incidence of erectile dysfunction, incontinence and serious adverse outcomes are very encouraging. Further studies are required to examine long-term outcomes of HIFU.

MP-2.08

Recurrent localized prostate cancer after radiotherapy treated with salvage high intensity focused ultrasound in a phase II trial

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Introduction and Objective: The majority of patients with radio-recurrent prostate cancer are currently treated with hormonal therapy. The aim of this study was to evaluate the efficacy and safety of high intensity focused ultrasound (HIFU) as a salvage treatment for recurrent prostate cancer after radiotherapy (either external beam radiotherapy or brachytherapy).

Materials and Methods: From April 2006 to August 2008, as part of a prospective phase II study, 40 patients with recurrent prostate cancer after radiotherapy have been treated with the Sonablate 500. All patients had staging studies and prostatic biopsies to confirm the presence of local disease. The majority of patients were external beam radiotherapy (EBRT) failures (33 patients), with the remainder being brachytherapy failures (7 patients). Patients have had follow-up at 21, 45, 90 and 180 days. Adverse event data was collected prospectively, and graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) Version 3. Health-related quality of life (HRQoL) was assessed using the SF-36. Repeat prostatic biopsy was performed at 6 months according to study protocol, irrespective of serum PSA.

Results: The mean age was 68 years, mean preoperative PSA was 3.8 ng/mL, mean prostatic size was 25 mL, and mean IPSS was 7.9. Mean length of hospital stay was 1 day. Repeat prostatic biopsy at 6 months, performed so far in 31 patients, has been negative in 68% of patients. There were no deaths in this series. There have been 2 cases (5%) of urethrorectal fistula; one of which required surgical correction. No patient has required surgical intervention for incontinence. Other complications have included urinary retention in 7.5%, urinary tract infection in 10% and urinary incontinence in 2.5%. Three patients (7.5%) have required transurethral resection of the prostate (TURP). No fecal incontinence has been reported. No statistically significant difference in HRQoL was noted between baseline and day 180.

Conclusion: Salvage HIFU in this phase II study has shown a negative biopsy rate of 68% and an acceptable toxicity rate, opening the possibility of a new minimally invasive treatment for radiotherapy failures.

MP-2.09

2D versus 3D transrectal ultrasound (TRUS) for repeat prostate biopsies (RPBx): quantitative comparison of accuracy and efficiency

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Introduction and Objective: 3D TRUS may be superior to 2D TRUS for

accurate guidance and recording of prostate Bx. Patients undergoing RPBx after a prior negative Bx or finding of atypical small acinar proliferation (ASAP), might benefit most from these hypothesized improvements, as previous Bx core locations can be viewed in 3D and used to guide a RPBx. However, the superiority of 3D over 2D TRUS for RPBx accuracy has not been demonstrated clinically. We have developed a patient-based TRUS prostate Bx simulator and used it to quantify 2D and 3D TRUS for RPBx.
Materials and Methods: 3D TRUS prostate images were collected from 7 patients and were incorporated into a TRUS Bx simulator. Movement of the simulator TRUS probe within a mock pelvis, dynamically slices the patient's 3D TRUS image, to produce realistic 2D or 3D TRUS views of the prostate. Five residents and 5 experts performed 12-core RPBx on each prostate using preplanned targets (representative of prior Bx locations). Participants alternated use of 2D or 3D TRUS to perform RPBx on 6 prostates. The 7th prostate was reserved for practice. For each pass of the needle, the efficiency or time per biopsy was recorded and the 3D distance between the needle core and the RPBx target was measured.
Results: Repeat prostate biopsies performed using 3D TRUS were significantly more accurate ($p < 0.01$) than those performed using 2D TRUS with Bx errors of 0.86 (standard deviation [SD] 0.47) mm and 3.68 (SD 2.60) mm, respectively. Based on biopsy probability curves experts using 2D TRUS had a 30% chance of missing a prior Bx target volume of 0.5 mL, while using 3D TRUS the probability was less than 1%. Biopsy accuracy was not significantly different between experts and residents using 2D or 3D TRUS; however, experts were significantly faster than residents using 2D (34, SD 15, s v. 68, SD 29, s) and 3D TRUS (30, SD 14, s v. 45, SD 16, s). Accuracy and efficiency did not vary between anatomical regions of the prostate for either modality.
Conclusion: We have demonstrated and quantified the improvement of 3D over 2D TRUS for repeat prostate biopsy using a clinically realistic Bx simulator. This work supports clinical utilization of 3D TRUS to determine improvement in cancer detection, especially in patients undergoing RPBx.

MP-2.10

Operator is an independent predictor of detecting cancer at transrectal ultrasound guided prostate biopsy

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Introduction and Objective: We sought to investigate whether interoperator differences exist in the setting of cancer detection for transrectal ultrasound guided prostate biopsy (TRUS BX). Our secondary aim was to investigate if a learning curve exists should a difference in cancer detection be noted.
Materials and Methods: We reviewed our prospective database on 8822 TRUS BX performed at our institution (Princess Margaret Hospital, Toronto, Ont.; 2000–2008). We limited our analysis to men presenting for first TRUS BX ($n = 5164$). Biopsies are performed by radiologists with 4 having performed more than 175 procedures. Patients underwent systematic biopsy with additional sampling of visible suspicious lesions. The odds ratio (OR) for detecting cancer in TRUS BX was calculated for likely independent prognostic variables, including the individual radiologist. We also examined rates of biopsy positivity in increments of 50 and compared first and last 100 procedures. One radiologist (AT) having performed the most biopsies (75%) was considered the referent for cancer detection. Univariate and multivariate logistic regression modelling was used to determine significant covariates with $p < 0.05$ deemed relevant.
Results: Prostate cancer was detected among 2498 men who underwent TRUS BX (48.4%). Number of biopsies performed among the 4 operators were: 191, 460, 645 and 3868 with cancer detection rates being 52.9%, 43.0%, 44.8% and 49.4%, respectively ($p = 0.009$). Other significant covariates ($p < 0.001$; Table 1**)** included prostate-specific antigen level, identification and biopsy of ultrasonographically suspicious lesions, nodule on digital rectal examination, smaller prostate volume and increasing patient age. Operator was a significant multivariate predictor of cancer detection (OR 0.68–0.91, $p = 0.004$) No learning curve was detected with biopsy rates consistent throughout the series.

Table 1. MP-2.10

Operator	AT (reference)	B	C	D	*p* value
Proportion of prostate cancer overall					
Total biopsies, *n*	3453	585	412	179	0.02
Cancer positive, *n*	1751	271	182	98	
Cancer positive, %	50.7	46.3	44.2	53.1	
Cancer positive: first 100 compared to last 100 biopsies					
First 100, %	49.0	46.0	42.0	52	0.12
Last 100, %	50.8	46.4	44.9	54.4	
Cancer positive: ultrasound negative and PSA ≤ 10 ng/mL ($n = 2177$): first 100 compared to last 100 biopsies					
n	1612	265	215	85	0.49
First 100 biopsies, %	33	28	26	41.2	
Last 100, %	34.3	33.3	33.0	—	

Conclusion: Although the volume of TRUS BX previously performed does not appear to influence positive biopsy rate, significant differences exist among various operators. These data suggest that multiple individuals performing prostate biopsy may have significant impact on quality of patient care. Further research is encouraged to identify the cause of these differences.