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Association between number of prostate biopsies and patient-reported functional outcomes after radical prostatectomy: implications for active surveillance protocols

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Abstract

Purpose—Men with prostate cancer who progress on active surveillance (AS) are subject to multiple prostate biopsies prior to radical prostatectomy (RP). Our objective was to evaluate whether the number of preoperative prostate biopsies affects functional outcomes after RP.

Materials and methods—We identified men treated with RP at our institution between 2008 and 2011. At 6 and 12 months post-operatively, patients completed questionnaires assessing erectile and urinary function. Men with preoperative incontinence or erectile dysfunction or who did not complete the questionnaire were excluded. Primary outcomes were urinary and erectile function at 12 months postoperatively. We used logistic regression to estimate the impact of number of prostate biopsies on functional outcomes after adjusting for demographic and clinical factors.

Results—We identified 2,712 men treated with RP between 2008 and 2011. Most men (80%) had 1 preoperative prostate biopsy, 16% had 2, and 4% had at least 3. On adjusted analysis, erectile function at 12 months was not significantly different for men with 2 (OR 1.25; 95% CI 0.90, 1.75) or 3 or more (OR 1.52; 95% CI 0.84, 2.78) biopsies, compared to those with 1. Similarly, urinary function at 12 months was not significantly different for men with 2 (0.84, 95% CI 0.64, 1.10) or 3 or more (0.99, 95% CI 0.60, 1.61) biopsies compared to those with 1.

Conclusions—We did not find evidence that more preoperative prostate biopsies adversely affected erectile or urinary function at 12 months following RP.

Keywords

radical prostatectomy; transrectal ultrasound prostate biopsy; erectile dysfunction; urinary incontinence

PURPOSE

Prostate cancer is the most prevalent non-cutaneous malignancy among men in the United States, largely as a result of the widespread use of prostate-specific antigen (PSA) screening.¹ Due to aggressive screening practices, many men are diagnosed with low-risk cancers that would otherwise have been undetected and do not require aggressive treatment.² This has led to increased acceptance of active surveillance (AS) for properly selected patients.³

All AS protocols include periodic prostate biopsies every 1 to 4 years to monitor for disease progression.^{4–11} Treatment with curative intent is generally recommended when a repeat biopsy demonstrates grade or volume progression or there is an increase in clinical stage. Other than prostate biopsy, there are currently no markers or tests that reliably detect the presence of disease or disease progression. Thus, with the growing popularity of AS and its reliance on periodic biopsy, the numbers of patients on AS who have had multiple prostate biopsies is increasing.

Prostate biopsies cause local tissue trauma that can result in inflammation,¹² disruption of the prostatic vasculature,¹³ and injury to the periprostatic nerves, especially when directed peripherally towards the neurovascular bundles.¹⁴ As a result, prostate biopsies are associated with infection, hematuria, transient lower urinary tract symptoms (LUTS) and erectile dysfunction (ED).¹⁵ However, there is no known association between number of AS biopsies and long-term progression of LUTS or worsening erectile function during AS.^{16, 17}

Approximately one third of men ultimately progress on AS, half of whom select treatment with RP.^{4, 5, 7, 9, 10, 18, 19} Depending on the surveillance protocol, patients who progress will have a minimum of 2 preoperative biopsies, but often more. While patients on AS are subject to multiple biopsies, so to are approximately 20% of RP patients who require 2 or more biopsies prior to reaching a tissue diagnosis.²⁰ Although many patients who undergo RP have had multiple prostate biopsies, the impact of number of preoperative biopsies on urinary and erectile function after RP is understudied. We hypothesized that men with more preoperative prostate biopsies have worse postoperative urinary and erectile function.

MATERIALS AND METHODS

This study was approved by the Memorial Sloan Kettering Cancer Center institutional review board.

Cohort

At our institution, patient data is prospectively collected and entered into a secure database. Our study cohort comprised men who had open or minimally-invasive radical prostatectomy for prostate cancer between 2008 and 2011 and did not receive radiation or hormonal therapy in the 12 months following surgery.

Primary Outcomes

All patients completed a validated web-based survey assessing self-reported erectile, urinary and bowel function as well as global quality of life.²¹ Surveys were administered preoperatively and at regular intervals postoperatively. The erectile function domain consists of 6 questions from the International Index of Erectile Function (IIEF-6).²² We defined good erectile function as an IIEF-6 summary score of ≥ 22 (range 1–30, higher scores indicating better erectile function). The urinary function domain consists of 5 questions assessing stress and urgency urinary incontinence as well as urinary bother. We defined good urinary function as a urinary domain summary score of ≥ 17 (range 0–21, higher scores indicating better urinary function). Our primary outcomes were good urinary function at 6 and 12 months and good erectile function at 12 months after surgery. We elected not to analyze erectile function at 6 months since relatively few men are potent at that time.

Surveys completed between 10 and 14 months postoperatively were used to define 12-month outcomes. If there were no erectile or urinary function data between 10 and 14 months, but patients reported being continent or potent in an earlier survey, the result was carried forward to the 12-month time point. If there were no erectile or urinary function data between 10 and 14 months, but patients reported incontinence or erectile dysfunction at a later survey, it was assumed that they were not functional at 1 year. Any survey completed between 4 and 8 months postoperatively was used to define the 6-month urinary function outcome in a similar fashion.

Statistical Analysis

We used logistic regression to estimate the impact of number of preoperative prostate biopsies on postoperative urinary function at 6 and 12 months and on erectile function at 12 months. The primary exposure was number of preoperative prostate biopsies (1 vs 2 vs ≥ 3). The standard technique for transrectal ultrasound-guided prostate biopsy at our institution involves obtaining 14 cores from the apex, mid, base, and transitional zone using an 18-gauge needle. The full model adjusted for demographic and clinical characteristics that may be associated with postoperative functional outcomes. Covariates comprised age (continuous), smoking status (never vs former vs current), and presence of cardiovascular comorbidities (arrhythmia, cardiovascular disease, diabetes, hyperlipidemia, hypertension and peripheral vascular disease), preoperative PSA, clinical tumor stage, and biopsy Gleason sum. All comorbidities were self-reported on a preoperative questionnaire. We did not have data to assess the impact of post-biopsy infectious complications on post-operative functional outcomes, although this is a rare complication at our institution.²³ Furthermore, since a post-biopsy infection is likely on the causal pathway between prostate biopsy and functional outcomes, including it within our model would eliminate the possibility of finding a significant association with the main effect.

As a sensitivity analysis, we evaluated whether the number of biopsies was associated with any change in postoperative erectile function score or urinary function score. We fit linear regression models with the dependent variables IIEF-6 summary score at 12 months postoperatively and urinary domain summary score at 6 and 12 months postoperatively, each

entered as continuous variables. The primary exposure and all covariates in the linear regression models were identical to those used in the logistic models.

We performed 2 pre-specified subgroup analyses. First, since patients with high-risk disease may be less likely to receive optimal nerve sparing, we repeated our primary analyses after excluding high-risk patients, according to the D'Amico classification.²⁴ Second, we examined the impact of number of biopsies within 3 years of surgery on postoperative functional outcomes. We hypothesized that men with multiple biopsies spaced out over many years were more likely to have good postoperative urinary and erectile function compared to men with multiple biopsies in a shorter time interval. All statistical analyses were conducted using STATA 12.0 (StataCorp, College Station, TX).

RESULTS

We identified 2,712 men who met study criteria. After excluding men who had incontinence and ED at baseline ($n = 25$) and men who had missing postoperative functional assessments at 6 or 12 months ($n = 605$), 2,082 men remained available for analysis. All had RP, were continent or potent preoperatively and had completed questionnaires to evaluate functional outcomes. The analytic cohort used to evaluate continence comprised 1,813 men who had data on urinary function at 6 and 12 months postoperatively. The analytic cohort used to evaluate erectile function comprised 1,249 men who had data on erectile function at 12 months postoperatively.

Patient characteristics are shown in table 1. Median patient age was 61 (interquartile range [IQR] 55–66), 10% had diabetes, and 44% were former or current smokers. The majority (80%) of men had a single preoperative prostate biopsy; however, 16% had 2 and 4% had at least 3. Of the patients with at least 3 biopsies, 58 (64%) had 3, 15 (17%) had 4, and 17 (19%) had 5 or more.

Among the men used to assess urinary function, 62% (95% CI 60–64%) had good urinary function at 6 months, and 69% (95% CI 67–72%) had good urinary function at 12 months. Among the men in the analytic cohort used to assess erectile function, 35% (95% CI 32–37%) had good erectile function at 12 months.

On logistic regression, the number of biopsies was not significantly associated with urinary or erectile function after adjusting for patient characteristics (table 2). Compared to men with 1 preoperative biopsy, there was non-significant higher odds of having good erectile function at 12 months for men with 2 (OR 1.25, 95% CI 0.90–1.75, $p = 0.2$) or at least 3 (OR 1.52, 95% CI 0.84–2.78, $p = 0.2$) biopsies. The odds of having good urinary function at 12 months was non-significantly lower for men with 2 (OR 0.84, 95% CI 0.64–1.10, $p = 0.2$) and at least 3 (OR 0.99, 95% CI 0.60–1.61, $p > 0.9$) prior biopsies compared to men who had a single biopsy.

At 12 months the median IIEF-6 summary score was 12 (IQR 5–24) and the urinary function domain summary score was 19 (IQR 16–21). At 6 months the median urinary function domain summary score was 18 (IQR 15–20). Using multivariable linear regression, we did not observe a difference in IIEF-6 summary score at 12 months according to number of

preoperative biopsies (table 3). However, men with 2 biopsies had significantly lower urinary function scores at 6 ($\beta = -0.69$; 95% CI -1.30 to -0.07 ; $p = 0.028$) and 12 ($\beta = -0.79$; 95% CI -1.36 to -0.22 ; $p = 0.007$) months compared to men with a single biopsy.

While statistically significant, the differences in urinary function scores are unlikely of clinical significance. At 12 months, the urinary function score for a man with 2 prior biopsies is less than 1 point lower than for a man with a single biopsy on a 22-point scale. Likewise, the confidence interval likely excludes clinically meaningful differences. Moreover, the 12-month urinary function estimate was sensitive to a small number of outlying observations ($n = 22$) with high residuals. Repeating the linear regression without these outliers demonstrated that men with 2 biopsies did not have significantly different urinary function scores compared to men with 1 ($\beta = -0.23$; 95% CI -0.75 – -0.29 ; $p = 0.4$). We also note that the p-values for 12-month urinary function score need to be interpreted in the context of multiple testing.

The percentages of patients with 1, 2, and 3 or more biopsies within 3 years of surgery were 83% ($n = 1,724$), 14% ($n = 301$), and 2.7% ($n = 55$), respectively. Only 2 patients did not have any biopsies within 3 years of surgery. In our subgroup analysis, we reached similar conclusions when considering only the number of biopsies performed within 3 years of surgery and after excluding high-risk patients (data not shown).

DISCUSSION

In this large institutional cohort of men with prostate cancer treated with RP, we did not observe a significant association between the number of prostate biopsies and erectile or urinary function at 12 months postoperatively. These findings were similar when we excluded high-risk patients and restricted the cohort to men who received all biopsies within 3 years of surgery. Although we did observe some statistically significant differences in urinary function score when analyzed as a continuous variable, these were sensitive to outlying observations and were unlikely to be clinically meaningful differences.

Our findings contrast to those from a prior study of 73 men with prostate cancer treated with robotic-assisted radical prostatectomy.¹³ The authors investigated the impact of 1 versus 2 preoperative biopsies on recovery of erectile and urinary function, as defined by 2 questions from the IIEF and number of pads used, respectively. There was no statistical difference in continence at 3 and 6 months or potency at 3 months, although patients with multiple biopsies were less likely to be potent at 6 months (57% vs 80%, $p = 0.03$) compared to patients with 1 prior biopsy. These findings should be interpreted with caution given the small sample size, use of short-term functional outcomes, and the highly selected patient cohort treated by a single experienced surgeon. In our larger cohort treated by multiple surgeons using open and minimally-invasive approaches, we did not observe an association between number of preoperative biopsies and long-term patient-reported functional outcomes following RP.

These observations support the practice of AS using periodic surveillance biopsies and expand upon the findings from 2 recent studies that compared functional outcomes between

men with low-risk prostate cancer who had immediate RP to men who had delayed RP following disease progression on AS. Satkunasivam et al. observed that men who had immediate RP (n = 112) and men who had deferred RP after 2 or 3 biopsies on AS (n = 41) had rates of erectile function (29% vs 42%, p = 0.18) and urinary continence (90% vs 94%, p = 0.4) that were not significantly different at a median of 3.5 years (IQR 2.6–4.7) postoperatively.²⁵ Similarly, van den Berg et al. found that men who had deferred prostatectomy after initial treatment with AS (n = 29) had similar or better self-reported urinary and sexual functional outcomes at 6 months postoperatively compared to men who had immediate RP (n = 363).²⁶ Each group had similar rates of periprostatic fascial preservation and nerve sparing, but it was unknown how many biopsies the patients on AS had.

Prostate biopsy can cause damage to or inflammation of the periprostatic nerves, prostate and bladder neck, leading to transient ED and LUTS in many patients.¹⁵ Our main hypothesis was based on the theory that more prostate biopsies lead to inflammation and fibrosis from repeated tissue trauma. In fact, one study retrospectively reviewed surveillance biopsies from 56 men on AS who did not have symptoms of prostatitis and found that most biopsies had mild or moderate chronic inflammation.¹² With more prior biopsies, there was a small but significant increase in chronic inflammation (p = 0.04).

Despite these findings, repeated biopsies do not appear to impact long-term erectile function while on AS.^{16, 27} In one cohort, 342 men on AS were followed for a median of 3.5 years (IQR 2.3–5) and had a median of 5 per-protocol biopsies (IQR 3–6). Among men who were potent at baseline, the IIEF-6 score decreased by 1.5 points per year (95% CI 0.9–2.2) for the first 4 years on AS.¹⁶ This small, gradual decrease over time was similar regardless of the number of surveillance biopsies and likely reflected expected changes in an aging population.

Similarly, more biopsies are unlikely to impact long-term urinary function for men on AS.^{17, 28} One hundred twenty-three men completed an International Prostate Symptom Score (IPSS) questionnaire at baseline and again while on AS.²⁸ After an average of 2.3 surveillance biopsies, the mean IPSS score was not significantly different between baseline and follow-up (7.6 vs 8.5, p = 0.18) and there was no difference according to number of surveillance biopsies. Similarly, 291 men with a median of 3 (IQR 2–4) prior biopsies completed at least 2 IPSS questionnaires while on AS.¹⁷ Most men had stable or improved LUTS over time, although LUTS worsened in 25% of patients. On multivariable analysis, the total IPSS change was not significantly associated with number of prior biopsies.

Our study is not without limitations. The indications for preoperative biopsies included persistently elevated PSA with prior negative biopsies in addition to men on AS who had per-protocol surveillance biopsies. However, we do not believe these differences impacted surgical technique or postoperative patient-reported outcomes. We report status of urinary and erectile function at 12 months, although some patients may see improvement beyond 12 months. If the number of biopsies were associated with a longer time to functional recovery, our models may have inappropriately failed to detect a difference. Still, urinary and erectile function at 12 months is strongly predictive of longer-term outcomes.²⁹ Finally, 30% to 60%

of men in published AS series received at least 3 per-protocol biopsies; however, only 4% of our cohort had 3 or more preoperative biopsies, and it is thus possible that our study was underpowered.^{6, 8, 10, 30} With a larger proportion of men with 3 or more biopsies, we may have been able to detect a clinically meaningful difference in functional outcomes according to number of biopsies.

As AS gains acceptance as primary therapy for properly selected men, it is likely that more patients will progress to RP after having multiple biopsies. To date, there are no studies that have investigated the impact of number of surveillance biopsies on the oncologic efficacy of delayed curative treatment. However, men who require multiple biopsies to reach a prostate cancer diagnosis are not at increased risk of postoperative biochemical recurrence, and patients who have deferred RP after progressing on AS have similar oncologic outcomes to those who have immediate RP.^{18–20, 25} With the addition of our findings, the use of periodic surveillance biopsies for men on AS appears to be safe and to be unlikely to lead to adverse outcomes for men who eventually require RP.

CONCLUSIONS

In a large cohort of men with prostate cancer who had RP, we did not observe an association between the number of preoperative prostate biopsies and patient-reported urinary or erectile function at 12 months postoperatively. These findings support AS protocols that use periodic prostate biopsies to monitor for disease progression and help mitigate concerns regarding any adverse effects caused by multiple prostate biopsies on surgical outcomes.

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Abbreviations and Acronyms

AS	active surveillance
ED	erectile dysfunction
IIEF-6	International Index of Erectile Function
IPSS	International Prostate Symptom Score
LUTS	lower urinary tract symptoms
PSA	prostate-specific antigen
RP	radical prostatectomy

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Table 1

Cohort demographic and clinical characteristics.

Characteristic	N (%)
Median age (IQR)	61 (55, 66)
Race	
White	1,767 (85%)
Nonwhite	263 (13%)
Unknown	52 (3%)
Comorbidities	
Diabetes	199 (10%)
Hypertension	877 (42%)
Hyperlipidemia	993 (48%)
Cardiovascular disease	155 (7%)
Peripheral vascular disease	15 (1%)
Arrhythmia	95 (5%)
Smoking status	
Never	1,170 (56%)
Former	708 (34%)
Current	204 (10%)
Preoperative PSA (N = 2,042)	5.0 (3.7, 6.9)
Clinical T stage	
T1c	1,380 (66%)
T2	627 (30%)
T3	57 (3%)
Unknown	18 (1%)
Clinical Gleason score	
6	901 (43%)
7	989 (48%)
8	158 (8%)
Unknown	34 (2%)
D'Amico risk group	
Low	774 (37%)
Intermediate	986 (47%)
High	276 (13%)
Unknown	46 (2%)
Number of preoperative prostate biopsies	
1	1,668 (80%)
2	324 (16%)
3	90 (4%)
Surgical approach	
Open	798 (38%)
Laparoscopic	539 (26%)

Characteristic	N (%)
Robotic	745 (36%)

IQR, interquartile range; PSA, prostate-specific antigen

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Multivariable analyses predicting the presence of good postoperative erectile function (IIEF-6 ≥ 22) and urinary function (urinary domain summary score ≥ 17) based on number of preoperative prostate biopsies, adjusted for age, presence of arrhythmia, cardiovascular disease, diabetes, hyperlipidemia, hypertension, peripheral vascular disease, and smoking status.

Table 2

	Erectile function (12 months) N = 1,249			Urinary continence (6 months) N = 1,813			Urinary continence (12 months) N = 1,813		
	OR	95% CI	p-value	OR	95% CI	p-value	OR	95% CI	p-value
Number of preoperative biopsies			0.2			0.4			0.4
1	ref	ref		ref	ref		ref	ref	
2	1.25	0.90, 1.75		0.90	0.69, 1.16		0.84	0.64, 1.10	
3	1.52	0.84, 2.78		0.76	0.48, 1.20		0.99	0.60, 1.61	

OR, odds ratio; CI, confidence interval

Table 3

Multivariable linear regression predicting postoperative IIEF-6 score and urinary function score. The β coefficient indicates the difference in IIEF-6 and urinary function scores for each increase in number of biopsies, adjusting for age, presence of arrhythmia, cardiovascular disease, diabetes, hyperlipidemia, hypertension, peripheral vascular disease, and smoking status.

	IIEF-6 score (12 months) N = 965			Urinary function score (6 months) N = 1,330			Urinary function score (12 months) N = 1,381		
	β	95% CI	p-value	β	95% CI	p-value	β	95% CI	p-value
Number of preoperative biopsies			0.3			0.068			0.020
1	ref	ref		ref	ref		ref	ref	
2	1.12	-0.46, 2.70		-0.69	-1.30, -0.07	0.028	-0.79	-1.36, -0.22	0.007
3	1.20	-1.66, 4.06		-0.52	-1.57, 0.54	0.3	0.19	-0.79, 1.18	0.7

CI, confidence interval