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# The Role of Early Adopter Bias for New Technologies in Robot Assisted Laparoscopic Prostatectomy

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**Purpose:** We determined the potential influence of an early adopter bias in patients undergoing robot assisted laparoscopic prostatectomy.

**Materials and Methods:** We compared baseline demographic, clinical and health related quality of life characteristics of patients undergoing 3 different surgical procedures for clinically localized prostate cancer following the introduction of robot assisted laparoscopic prostatectomy at our institution. Patients included in this analysis were participating in a prospective health related quality of life study using the SF-12® and Expanded Prostate Cancer Index Composite validated questionnaires.

**Results:** Of 402 patients 159 (39%) underwent robot assisted laparoscopic, 144 (36%) underwent radical perineal and 99 (25%) underwent radical retropubic prostatectomy. There were no statistically significant associations between procedure type and patient age ( $p = 0.267$ ), race ( $p = 0.725$ ), number of medical comorbidities ( $p = 0.490$ ), income ( $p = 0.056$ ) and level of education ( $p = 0.495$ ). Mean prostate specific antigen was  $5.9 \pm 3.3$ ,  $7.3 \pm 5.5$  and  $5.7 \pm 5.0$  ng/ml for robot assisted laparoscopic, radical perineal and radical retropubic prostatectomy, respectively ( $p = 0.030$ ). The proportion of robot assisted laparoscopic, radical perineal and radical retropubic prostatectomy patients with a final Gleason score of 4-6 was 55%, 45% and 39%, respectively ( $p = 0.037$ ). The proportion of robot assisted laparoscopic, radical perineal and radical retropubic prostatectomy patients with stage T2 disease was 91%, 68% and 80%, respectively ( $p = 0.001$ ). Statistically significant associations of higher income and education with higher baseline health related quality of life scores were seen in the sexual and physical domains (each  $p < 0.01$ ).

**Conclusions:** We failed to find evidence of an early adopter bias for patients undergoing robot assisted laparoscopic prostatectomy. Nevertheless, observational studies comparing robot assisted laparoscopic prostatectomy to radical perineal and radical retropubic prostatectomy should account carefully for patient baseline characteristics to allow meaningful comparisons of surgical outcomes.

*Key Words: prostate, prostatectomy, selection bias, robotics, outcome assessment (health care)*

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Since its introduction in July 2000, RALP has been strongly promoted and readily adopted by academic and private practice urologists as a minimally invasive alternative to traditional open procedures.<sup>1,2</sup> It was estimated that 10% of prostatectomies in the United States were performed with robotic assistance in 2004. Some groups predicted that the RALP market share would be 25% in 2006.<sup>1</sup> In addition to technical advantages such as motion scaling, decreased tremor and improved visualization, early

studies suggested more favorable outcomes with regard to estimated blood loss, length of hospital stay, continence, erectile function and HRQOL outcomes.<sup>2-5</sup> At our institution we found that RALP results in urinary and sexual HRQOL outcomes that are comparable to those of RPP and RRP.<sup>6</sup> To date most studies of the therapeutic effectiveness of RALP have been observational and provided low levels of supporting evidence. A particular concern is the potential for selection bias. If patients who elect RALP are not comparable at baseline to those who elect older techniques, differences in outcomes may not be attributable only to procedure type.

According to research on the adoption of new technologies there is an early adopter phenomenon, in which the first adopters of a product are risk takers who enjoy the privilege of trying something new. These early adopters tend to be younger, more educated and more affluent than the average consumer.<sup>7</sup> In the absence of randomized, controlled trials comparing the efficacy of RALP to that of other techniques the early adopter phenomenon could be a source of selection bias in early outcomes studies. Indeed, in this era of direct to

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consumer marketing of medical innovations, and easy and relatively free access to medical information on the Internet many patients now present to urologists inquiring about specific therapies. To determine if early adopter bias could impact outcomes at our institution we performed a detailed comparison of demographic, clinical and HRQOL characteristics in our initial cohort of RALP patients and contemporaneous patients undergoing the more established techniques of RPP and RRP.

## MATERIALS AND METHODS

Patients undergoing RALP, RPP or RRP for clinically organ confined prostate cancer between January 2001 and February 2006 at Duke University Medical Center who agreed to participate in an ongoing Institutional Review Board approved prospective prostatectomy outcomes study were included in the analysis. Baseline demographic variables collected were patient age, race, household income and educational level. Disease variables included number of comorbidities, preoperative PSA, pathological prostate size, prostatectomy Gleason score and final tumor stage. Before surgery all patients completed the EPIC, version 8.2000, which is a validated patient self-assessment questionnaire. Responses were used to calculate summary HRQOL scores at baseline in 4 disease specific domains, including urinary, sexual, bowel and hormonal. Mental and physical component scores were calculated from the SF-12 validated survey of general well-being included in the EPIC questionnaire. Based on studies suggesting that an SD of 0.3 to 0.5 represents a clinically meaningful change, clinically significant differences were defined as greater than 10 points for EPIC scores and greater than 5 points for SF-12 scores.<sup>8,9</sup> Patients included in this analysis underwent RALP, RPP or RRP performed by 1 of 2, 3 or 5 experienced attending surgeons, respectively, at our academic tertiary care referral center. Selection of surgical approach was based on surgeon and patient preference. RALP cases in this study encompass our initial experience in robotic surgery.

Statistical data analysis was performed using SPSS®, version 12.0. One-way ANOVA and chi-square analysis were used to test for differences in continuous and categorical variables, respectively. Additional subgroup analyses were performed to compare the first 50 RALP patients to those undergoing RPP or RRP. Nonparametric Kruskal-Wallis analysis was used to test for differences in domain scores. All statistical testing was 2-sided with  $\alpha = 0.05$ .

## RESULTS

Of the 522 consecutive radical prostatectomy candidates seen by participating surgeons during the study period 402 (77%) agreed to participate. Of these patients 159 (39%) underwent RALP, 144 (36%) underwent RPP and 99 (25%) underwent RRP. Table 1 lists patient clinical characteristics. There was no statistically significant difference in patient age at surgery in the RALP, RPP and RRP groups (mean  $\pm$  SD age  $58.4 \pm 6.5$ ,  $60.2 \pm 8.0$  and  $59.7 \pm 6.9$  years, respectively,  $p = 0.267$ ). Racial distributions among prostatectomy types were also similar with 80% to 85% of patients

TABLE 1. Patient clinical characteristics

Clinical Characteristic	No. RALP (%)	No. RPP (%)	No. RRP (%)	p Value
Age (y):				
Younger than 55	40 (25.0)	33 (22.9)	25 (25.3)	0.267
55–64	90 (56.9)	70 (48.6)	48 (56.8)	
Older than 64	29 (18.1)	41 (28.5)	6 (18.5)	
Totals	159	144	99	
Race:				
White	135 (84.9)	117 (81.3)	83 (83.8)	0.725
Black	19 (11.9)	20 (13.9)	10 (10.1)	
Other	5 (3.1)	7 (4.9)	6 (6.1)	
Totals	159	144	99	
Tobacco use:*				
Yes	10 (6.3)	21 (14.6)	8 (8.1)	0.044
No	148 (93.7)	123 (85.4)	91 (91.9)	
Totals	158	144	99	
Reported comorbidities:				
0	92 (57.9)	74 (51.4)	61 (61.6)	0.490
1	44 (27.7)	49 (34.0)	28 (28.3)	
2 or Greater	23 (14.5)	21 (14.6)	10 (10.1)	
Totals	159	144	99	

\* One patient (0.6%) in the RALP group elected not to answer.

identifying themselves as white and 10% to 14% identifying themselves as black per group ( $p = 0.725$ ). The number of reported comorbidities, including diabetes, myocardial infarction, stroke, amputation, peripheral vascular disease, chronic obstructive pulmonary disease, gastric ulcers, renal disease, depression, seizures, or alcohol or drug problems, was not statistically different among the 3 procedures ( $p = 0.490$ ). However, there was a trend toward fewer comorbidities in the RRP group compared to the RALP and RPP groups. There was a statistically significant difference in tobacco use with RPP patients having the highest rate and RALP patients having the lowest (14.6% vs 6.3%,  $p = 0.044$ ). Distributions of these demographic variables remained similar when analysis was limited to the first 50 RALP patients.

Table 2 lists the socioeconomic characteristics of our study population. No significant differences were seen in relationship status with 90% of all patients living with a spouse or partner ( $p = 0.838$ ). In terms of employment status 56% to 61% of patients were employed full-time, while 30% to 38% were unemployed or retired ( $p = 0.611$ ). The distribution of educational level was also similar among the 3 procedure groups ( $p = 0.495$ ), although there was a slight predominance of college and graduate degrees in the RRP cohort. Similarly there was no statistically significant difference in annual household income distribution among the groups, although there was a predominance of patients whose household income was \$100,000 or more in the RRP group compared to that in the RALP and RPP groups (41% vs 32% and 23%, respectively,  $p = 0.056$ ). When examining only the first 50 RALP patients, the distributions of these socioeconomic variables remained similar.

Table 3 lists the disease characteristics of our study population. Statistically significant differences across all 3 prostatectomy types were noted for all variables tested. Mean preoperative PSA was significantly higher in the RPP cohort at  $7.3 \pm 5.0$  ng/ml compared to  $5.9 \pm 3.3$  and  $5.7 \pm 5.0$  ng/ml in the RALP and RRP cohorts, respectively ( $p = 0.030$ ). Prostatectomy Gleason scores were statistically lower in the

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