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COMPREHENSIVE PROSPECTIVE COMPARATIVE ANALYSIS OF OUTCOMES BETWEEN OPEN AND LAPAROSCOPIC RADICAL PROSTATECTOMY CONDUCTED IN THE YEARS 2003 TO 2005

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Abstract

Objectives—To compare in a non-randomized prospective fashion the oncological, functional and morbidity outcomes after laparoscopic (LRP) and retropubic (RRP) radical prostatectomy.

Material and Methods—Between January, 2003 and December, 2005, 1430 consecutive men with clinically localized prostate cancer, underwent radical prostatectomy, 612 LRP and 818 RRP. Surgical approach was selected by the patient. Preoperative staging, respective surgical techniques, pathologic examination and follow-up were uniform. Functional outcome was measured by patient-completed health related quality of life questionnaire.

Results—Positive surgical margin rates (11%) and freedom from progression (median followup: 18 months) were comparable between LRP and RRP (hazard ratio (HR) 0.99 for LRP vs RRP, $p=0.9$).

We found no significant association between operation type and time to postoperative potency (HR 1.04 for LRP vs. RRP; 95% C.I. 0.74, 1.46; $p=0.8$). LRP patients were less likely to become continent than RRP patients. (HR 0.56 for LRP vs. RRP; 95% C.I. 0.44, 0.70; $p<0.0005$).

LRP was associated with lesser blood loss (315 ml (SD186) vs. 1267 ml (SD 660)), and overall transfusion rate (3% vs. 49%). No significant difference was noted in cardiovascular, thrombo-embolic and urinary complications. Emergency room visits and readmissions were higher after LRP (15% vs. 11% and 4.6% vs. 1.2% respectively).

Conclusions—In our institution and during the study period, LRP and RRP provided comparable oncological efficacy. LRP was associated with less blood loss and transfusion rate, and higher postoperative hospital visits and readmission rate. While the recovery of potency was equivalent, that of continence was superior after RRP.

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Keywords

prostate neoplasm; pathology; laparoscopy; surgery

Introduction

The laparoscopic approach to performing radical prostatectomy is widely used to treat clinically localized prostate cancer. Great enthusiasm followed the initial surge of laparoscopy and its potential advantages such as the relatively lower blood loss, the magnified visualization and the ease of accessibility to the depth of the pelvic anatomy. The aspiration has been that given the above advantages, laparoscopic radical prostatectomy (LRP) will be equal to other approaches in terms of oncological efficacy, and surpass them with regards to short-term morbidity, postoperative convalescence and eventually functional outcomes.

The technique is established and well beyond the transition from the initial learning experience to a more mature phase. Therefore comparative trials with other matured surgical approaches or modalities are reasonable and could provide evidence to either support or negate the respective hypothetical advantages of one technique over the other, and would serve as benchmark for further improvements.

Certainly, a randomized trial is the best study design to compare outcome after an operation such as radical prostatectomy, whereby the goals of completely excising the cancer with the least impact possible on urinary continence and sexual potency are often competing aims. Such a well-designed trial which has yet to be conducted remains methodologically difficult to accomplish. By default, level (IIa) type evidence becomes the next best study design to be used to evaluate the performance of LRP against other surgical approaches.

The present study is a nonrandomized prospective analysis (level IIa) of outcomes between open and laparoscopic radical prostatectomy performed consecutively during the years 2003 to 2005, at the same institution and by surgeons dedicated to the surgical treatment of localized prostate cancer. This study allows a comparison of the principal quality endpoints indicators (oncological outcome, urinary and sexual function) and secondary quality endpoints indicators (hospital stay, transfusion rate and complication profile).

Material and Methods

Patient population

This is an institutional review board approved prospective non-randomized study of 1430 consecutive men with clinically localized (cT1 – cT3a) adenocarcinoma of the prostate who underwent a radical prostatectomy at Memorial Sloan- Kettering Cancer Center (MSKCC) between January 2nd, 2003, and December 31st, 2005. 612 patients were operated on by one of two surgeons through a laparoscopic approach (one surgeon performed 502 (82%) and the other 110 (18%) of the laparoscopic cohort) and 818 patients were operated on by one of two surgeons through an open retropubic approach (one surgeon performed 508 (62%) and the other 310 (38%) of the open cohort).

Preoperative treatment planning

The choice of surgical approach was patient driven. Patients interested in a specific approach or surgeon, were seen according to their choice; those undecided were offered a consultation with either or both open and laparoscopic surgeons and treated according to their choice. All patients were made aware of the existence of both approaches.

All surgeons used a uniform preoperative evaluation and risk assessment. Preoperative clinical parameters including patients' age, body mass index (BMI), 2002 TNM clinical stage, preoperative PSA, Gleason sum on prostate biopsies were prospectively recorded.

Results from clinical staging, PSA level, Gleason sum, biopsy data, endorectal coil MRI findings and the patient's preoperative potency status along with the Kattan's nomogram predicted disease risk¹ were taken into consideration while carefully planning the surgery.

Surgical technique

LRP was performed using modifications of the previously described Montsouris technique². One modification involved the apical dissection, with transection of the urethra at the end of the prostatectomy once the neuro-vascular bundles have been dissected off the apex and completely freed. Furthermore, intra-operative gross examination of the specimen before completion of the urethrovesical anastomosis was systematically done³. The retropubic radical prostatectomy (RRP) was performed according to the technique previously described⁴. Whatever the surgical approach, neuro-vascular bundle preservation was prospectively recorded by the surgeon immediately after completion of each case, using the same preservation assessment scale in both groups. In all cases, the specimen was macroscopically examined by the surgeon and fresh frozen sections were obtained depending on the intraoperative assessment, and additional tissue was accordingly resected.

Indications and anatomical limits of Pelvic lymph node dissection (PLND)

In the LRP group between January 1, 2003 and January 31, 2005 the Partin Tables predicted probability of pelvic lymph node invasion was used to decide on the indication for PLND⁵. Patients with a predicted lymph node invasion 1% did not undergo a node dissection, those with a probability > 1% underwent a PLND limited to the external iliac nodal group. This strategy was changed on February 1st, 2005, whereby all patients regardless of their risk stratification underwent a standard PLND including the external iliac, hypogastric and obturator fossa nodal groups. In the RRP group all but 23 patients in the study underwent a standard PLND.

Pathological examination

Prostate biopsy specimens on all patients were reviewed by the genitourinary pathology team. Only the MSKCC biopsy reading was taken in consideration in the study. The radical prostatectomy specimen was coated with India ink to delineate the surgical margins then fixed in 10% formalin. Prostate and seminal vesicles were step sectioned transversely at 3–4 mm intervals. The prostate's most apical tissue was sectioned in the sagittal plane. Specimens were examined for the following variables: Gleason sum, pathological stage, seminal vesicle invasion, bladder neck invasion and extraprostatic extension. A positive surgical margin (PSM) was defined as presence of cancer at the inked margin of resection in the radical prostatectomy specimen, regardless of whether additional tissue was resected or not.

Urinary and sexual function assessment

Considered for this analysis are the subset of men enrolled in an IRB approved health-related quality of life study which prospectively assesses clinical outcomes and changes from baseline by means of questionnaires assessing urinary and sexual functions, completed at home by the patient every three months postoperatively for 48 months and mailed back to the data management office. Patients were considered continent when they replied that they do "not experience any leakage or are pad free". Those wearing an occasional pad or any protective material were not considered continent. Patients were considered potent, when

they reported in the questionnaire that they are able to have erections hard enough for penetration “much more than half of the time”, “almost always” or “always”. Those who replied having erections hard enough for penetration “about half of the time”, “much less than half of the time”, “never” or “no sexual activity”, were considered impotent. This assessment did not discriminate against the use of phosphodiesterase 5 inhibitors.

Morbidity assessment

Intraoperative (blood loss, operative time) and inpatient data (hospital stay, postoperative complication) were prospectively recorded. All documented patients phone calls, nursing notes, emergency room or urgent care center visits, rehospitalizations and reoperations within 30 days postoperatively, were reviewed and recorded. Complications were graded according to the MSKCC surgical secondary events grading scale (Table 1). Low molecular weight heparin was used in LRP patients only, and was started prior to surgery and continued daily until discharge.

Statistical method

We used a logistic regression model to predict PSM by type of surgery, with nomogram pre-operative probability of organ-confined disease as a covariate. To calculate the predicted probability of PSM with increasing surgical experience, we created logistic regression models separately for LRP and RRP with PSM as the dependent variable and number of prior cases performed within the study time as the predictor. We adjusted for possible changes in disease severity by using PSA, pathological Gleason and pathologic stage as covariates. Multivariable Cox proportional hazards regression was used to evaluate the difference in biochemical recurrence, defined as a PSA >0.1 ng/ml and rising or initiation of hormonal therapy, by surgery type. We adjusted for preoperative PSA, surgical margin status, and pathologic stage and grade. The recurrence-free probability was estimated using Kaplan-Meier methods.

We compared lymph node status among patients treated after February 1, 2005 (251 LRP patients and 220 RRP patients), since prior to that date most LRP patients had limited or no PLND.

We examined postoperative continence in 193 LRP and 222 RRP men enrolled in our questionnaire based prospective quality of life study; postoperative potency was evaluated in the subset of 132 LRP and 164 RRP men who were potent preoperatively. Multivariable Cox proportional hazards regression was used to evaluate the difference in time to postoperative continence and potency by surgery type. For continence we adjusted for age and for potency we adjusted for age and nerve sparing status (none/unilateral vs bilateral).

We evaluated morbidity variables in 692 RRP and 484 LRP patients treated before July 2005, as patient charts were retrospectively reviewed to this date. Differences in morbidity by operation type were assessed using t-test for continuous variables and exact methods for categorical variables. All analyses were conducted using Stata 9.0 (Stata Corp., College Station, TX).

Results

Pre and intra-operative clinical parameters

Preoperative clinical parameters—Table 2 shows preoperative characteristics of the LRP and RRP groups. The RRP group had slightly more aggressive cancers as reflected by a difference in pre-operative probability of organ confined disease (median 63% vs. 55% for LRP and RRP respectively).

Intra-operative techniques—The extent of neurovascular bundle preservation was similar between surgery groups: 88% bilateral preservation for the LRP group vs. 91% for the RRP group, 6% vs. 6% for the unilateral preservation, 5% and 3% respectively for the bilateral neurovascular bundle resection rate ($p=0.2$ by exact methods).

Principal Quality indicators

Oncological outcome

Pelvic lymph node dissection: We examined lymph node dissection and lymph node metastasis in 251 LRP and 220 RRP patients treated after February 2005. The median number of lymph nodes retrieved after a standard PLND was comparable between surgical techniques (13 after LRP and 12 after RRP). The overall lymph node metastasis rate was 7% in both groups (Table 3).

Positive surgical margins rate

The overall PSM rate was 11%, and was similar between surgical groups (Table 3). Figure 1 shows the predicted probability of a PSM for each approach against the preoperative probability of organ confined disease. For both approaches, the risk of PSM increased as the severity of disease increased. With adjustment for preoperative risk of organ confined disease, we found no significant difference in PSM by surgical procedure (odds ratio (OR) 1.16 for LRP vs RRP, 95% C.I. 0.79, 1.69, $p=0.4$).

The predicted probability of a PSM by surgeon experience is shown in Figure 2. After LRP there was a statistically significant decrease in the overall rate of PSM over time (OR 0.84 per 100 patients treated; 95% C.I. 0.72, 0.98; $p=0.03$); this relationship remained statistically significant in the subset of patients with organ confined disease (OR 0.67 per 100 surgeries completed; 95% C.I. 0.50, 0.91; $p=0.009$), but not for patients with non organ confined disease (OR 0.62 per 100 surgeries completed; 95% C.I. 0.24, 1.60; $p=0.3$). On the contrary, the rate of PSM remained stable in the overall patient sample who received RRP (OR 1.05 per 100 surgeries completed; 95% C.I. 0.95, 1.15; $p=0.4$), as well as in the subset with organ confined disease (OR 1.07 per 100 surgeries completed; 95% C.I. 0.84, 1.36; $p=0.6$) and with non organ confined disease (OR 1.15 per 100 surgeries completed; 95% C.I. 0.76, 1.75; $p=0.5$). Note that estimates of PSM probability cannot be compared between groups in figures 2 – 4 because, in this analysis, risk adjustment was within group only. The interaction term between surgical experience and procedure was statistically significant ($p=0.02$), demonstrating that PSM rate changed only in the LRP group.

Biochemical recurrence data (BCR)

In total, there were 97 recurrences: 29 and 68 among LRP and RRP patients, respectively. The median follow-up for recurrence-free patients was 1.5 years overall and comparable between surgical groups (1.5 years for LRP and 1.6 years for RRP). The Kaplan-Meier recurrence-free probability by technique is shown in Figure 3. With adjustment for preoperative PSA, surgical margin status, and pathologic stage and grade, there was no significant difference in recurrence by surgical technique (hazard ratio (HR) 0.99 for LRP vs RRP; 95% C.I. 0.62, 1.59; $p=0.9$). However, given the short length of follow-up, confidence intervals are wide.

Functional Outcomes

This assessment is limited to 415 patients enrolled in our questionnaire based prospective quality of life study. Preoperatively, 99% ($n=400/404$) were continent and 73% ($n=296/405$) were potent. These rates were similar in the surgical groups (Table 2).

Urinary Continence—120/193 LRP and 184/222 RRP patients were continent at last follow-up. The median followup for those incontinent was 23 months. At 12 months postoperatively, the probability of recovery of continence was lower after LRP (48%; 95% C.I. 41%, 55%, respectively) than RRP (75%; 95% C.I. 69%, 81%) (Figure 4). With adjustment for age, operation type was significantly associated with time to postoperative continence. Patients who had LRP were less likely to become continent when compared to those who had RRP during the study period (HR 0.56 for LRP vs RRP; 95% C.I. 0.44, 0.70; $p<0.0005$).

Sexual Function—In the subset of patients who were potent preoperatively, 73/130 LRP and 96/164 RRP were potent at last follow-up. Nerve sparing status was bilateral in 232 (78%), unilateral in 14 (5%), none in 4 (1%), and unknown in 46 (16%). The median follow-up for those impotent was 23 months. At 12 months postoperatively, the recovery of sexual function was comparable between LRP and RRP during the study period. With adjustment for age and nerve sparing status, there was no significant difference in recovery of postoperative potency by technique (HR 1.04 for lap vs. open; 95% C.I. 0.74, 1.46; $p=0.8$) (Figure 5).

Morbidity

The morbidity profile of 1176 patients treated before July 1, 2005 is shown in Table 4. The mean operative time was longer for LRP compared to RRP (mean 199 and 188 min., respectively, $p<0.0005$). The estimated intraoperative blood loss was much less for LRP compared to RRP (mean 315 and 1267 ml, $p<0.0005$). Fourteen patients (3%) in the LRP group were transfused versus 338 patients (49%) in the RRP group ($p<0.0005$); of the latter, 233 (34%) received autologous blood only, 67 (10%) received both autologous and nonautologous and 38 patients (5.5%) received nonautologous blood only.

The mean hospital stay was on average 1.3 nights shorter for men who received LRP compared to RRP (mean 2.0 and 3.3 nights, respectively, $p<0.0005$); emergency room or urgent care center visits within the first 30 days postoperatively were noted in 75 patients (15%) after LRP and 75 patients (11%) after RRP ($p=0.02$); of these, 22 (4.6%) LRP patients were readmitted versus 8 patients (1.2%) in the RRP group ($p=0.001$). The most common cause of emergency room or urgent care center return visits was lower extremities edema. The reoperation rate was 1.9% after LRP and 0.4% after RRP; the cause of reexploration in 6 of the 9 patients reoperated after LRP was postoperative bleeding, as it is our policy to promptly explore patients diagnosed with postoperative bleeding after LRP rather than pursue conservative management. Venous thromboembolic, cardiac and urologic complications were low and comparable in both groups (Table 5). One patient in the RRP group died of a postoperative myocardial infarction.

Discussion

In the last three decades the surgical treatment of prostate cancer has undergone a number of innovations, including the anatomical radical prostatectomy which allowed a remarkable improvement in the recovery of sexual function⁶, followed by the use of the laparoscopic approach^{7, 8}, a technique that was quickly adopted by many centers in Europe^{9–12}, while in the United States, laparoscopy with the assistance of a telemanipulated robotic arms is gaining popularity¹³. The striking point in this surgical evolutionary process is the wide acceptance of new techniques based on either hypothetical benefits or extrapolated proven advantages from other surgical operations such as cholecystectomy¹⁴. After thousands of radical prostatectomies performed either laparoscopically or with robotic assistance, retrospective comparisons in given centers to open surgery have concluded that the results

are comparable if not superior^{15–17}. Based on the critical review of the published literature, such conclusions cannot be drawn as inadequacies in the methodological design preclude comparative analyses and certainly do not prove superiority of one surgical technique over the other¹⁸.

If a well designed randomized clinical trial is the best methodology to answer whether laparoscopic or laparoscopically assisted robotic radical prostatectomy provide superior oncological, functional and morbidity outcomes than open retropubic radical prostatectomy, its feasibility is hindered primarily by the surgeon factor. Men newly diagnosed with clinically localized prostate cancer are often counseled on the different therapeutic options available to them; those who elect to have surgery choose not only their treatment modality but also the approach and, most importantly, their surgeon. Few surgeons are equally proficient in both surgical techniques and are willing to offer randomly the two options. Even if this were possible, the surgeon factor would overwhelm the technique factor.

The present nonrandomized prospective study demonstrates that biases can be introduced by the patients at this very initial level. For unclear reasons, the RRP group had slightly higher tumor grades, clinical and pathological stages. Perhaps, as clinicians we inherently introduce our own biases at this level while counseling men with prostate cancer. Other possible factors could be the available patient educational materials which may influence men with prostate cancer to choose one approach over the other based on the aggressiveness of their disease. This can somewhat be offset by a risk adjusted reporting of oncological outcome, found herein comparable between RRP and LRP with regards to positive surgical margins and short-term biochemical recurrence rates. The positive surgical margin rate over the study period remained stable in the RRP experience, while that of LRP underwent a significant decrease over the study period, indicating that the procedure and therefore the results continued to evolve during the study and that we are comparing a well established operative technique, to a relatively newer technique where the maturity process is still ongoing, despite the considerable experience of the surgeons. Furthermore, this finding highlights the importance of three concepts: the integration of quality assurance in surgery, the inexactitude of associating the learning curve to a specific number of operations performed and finally improvement overtime needs to be taken in consideration whenever a new surgical technique is compared to the existing gold standard.

With regards to the functional outcomes, the recovery of sexual function is equivalent after LRP and RRP. Only men who were able to consistently achieve penetration (more than half of the time or always) were considered potent in this analysis. The recovery of urinary continence as defined by “no leak” and “no pad” on patient self-reported questionnaire was higher after RRP than after LRP. Although the present study found a difference in recovery of urinary continence, generalization of this finding must be prudent, first because this study is more of a comparison of surgeons and their technique than a pure comparison of surgical technique, and second because this study was conducted during the year 2003 to 2005: the difference in recovery of urinary continence was an unexpected finding of our analysis. We suspect this to be related to an extensive apical dissection. Based on these results, we have instituted a “quality assurance” process to identify potential modifications in our LRP technique; their impact on the continence is being evaluated.

LRP was associated with a significantly lower intraoperative blood loss, and transfusion rate and hospital stay, however, the unscheduled postoperative return visits and hospital readmissions after discharge were higher after LRP. Nevertheless the morbidity and postoperative complication profile appears overall comparable between the two surgical approaches.

Conclusion

In our institution and during the years 2003–2005 study period, laparoscopic and retropubic radical prostatectomy provided equivalent perioperative morbidity results, laparoscopic approach being associated with lesser blood loss and transfusion rate but higher postoperative hospital visits and readmission rate. While the recovery of continence was higher after retropubic radical prostatectomy, potency was comparable in both groups.

The two approaches seem to provide similar short-term oncological results regardless of the preoperative risk of the prostate cancer

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Figure 1. Predicted probability of positive surgical margins by preoperative risk, by operation type, with 95% confidence intervals. Black lines: RRP; Gray lines: LRP.

Figure 2.

Predicted probability of positive surgical margin by surgeon experience, separately for lap and open, with adjustment for preoperative PSA and pathologic stage and grade. Estimates of PSM probability cannot be compared between groups as risk adjustment was within group only. Black lines: RRP; Gray lines: LRP.

Figure 3. Kaplan-Meier recurrence-free probability by operation type. Black lines: RRP; Gray lines: LRP.

Figure 4. Cumulative incidence of continence by operation type. Black lines: RRP; Gray lines: LRP.

Figure 5. Cumulative incidence of overall potency by operation type. Black lines: RRP; Gray lines: LRP.

Table 1

Memorial Sloan-Kettering Cancer Center Surgical Secondary Events Grading Scale

Complication Grade	Description
1	Oral medication / bedside care
2	Intravenous Medication / Minor Bedside Surgical Procedure
3	Interventional Radiology / Endoscopy / Operation / Intubation
4	Chronic Disability / Major Organ Resection
5	Death

Table 2

Patients preoperative characteristics stratified by surgical approach.

	RRP N=818	LRP N=612
Age at surgery (years)	59 (54, 64)	60 (55, 65)
Preoperative PSA (ng/ml)	5.3 (4.1, 7.3)	5.3 (4.0, 7.5)
Clinical stage		
T1	535 (65%)	428 (70%)
T2	283 (35%)	184 (30%)
Biopsy Gleason grade		
6	474 (58%)	389 (64%)
7	228 (28%)	150 (25%)
8	17 (2%)	8 (1%)
Unknown	99 (12%)	65 (11%)
Preoperative probability of organ-confined disease (%) *	55 (38, 67)	63 (49, 67)
Continent preoperatively **	214 (99%)	186 (99%)
Potent preoperatively **	164 (75%)	132 (71%)

* Not available for 126 RRP and 128 LRP patients.

** For 222 RRP and 193 LRP patients enrolled in our questionnaire based prospective quality of life study

Table 3

Pathological characteristics stratified by surgical approach

	RRP N=818	LRP N=612
Pathologic Gleason grade		
6	312 (38%)	230 (38%)
7	427 (52%)	344 (56%)
8	67 (8%)	32 (5%)
Unknown	12 (1%)	6 (1%)
Positive surgical margins		
Negative	724 (89%)	543 (89%)
Positive	92 (11%)	69 (11%)
Unknown	2 (0.2%)	0 (0%)
Seminal vesical invasion		
Absent	755 (92%)	580 (95%)
Present	51 (6%)	23 (4%)
Unknown	12 (1%)	9 (1%)
Extraprostatic extension		
Absent	548 (67%)	446 (73%)
Present	262 (32%)	160 (26%)
Unknown	8 (1%)	6 (1%)
Lymph node involvement*		
Absent	203 (92%)	231 (92%)
Present	15 (7%)	18 (7%)
Not evaluated	2 (1%)	2 (1%)
Number of nodes evaluated*		
Median (IQR)	12 (8, 16)	13 (8, 17)
Range	1, 48	2, 35
Number of positive nodes when lymph nodes were involved*		
Median (range)	1 (1, 2)	1 (1, 4)

* For patients treated after February 1, 2005 (220 RRP and 251 LRP)

Table 4

Morbidity Profile for 1176 patients treated before July 1, 2005

	RRP N=692	LRP N=484	P Value**
Mean operating room time (minutes) (n=946)	188 (SD 41)	199 (SD 47)	<0.0005
Mean estimated blood loss (cc) (n=1070)	1267 (SD 660)	315 (SD 186)	<0.0005
Mean length of stay (days) (n=465)	3.3 (SD 1.2)	2.0 (SD 1.5)	<0.0005
No. transfused (%)	338 (49%)*	14 (3%)	<0.0005
ER return visit	75 (11%)	75 (15.5%)	0.02
Reoperation	3 (0.4%)	9 (1.9%)	0.03
No. readmitted (%) (n=1162)	8 (1.2%)	22 (4.6%)	0.001

* Includes autologous and/or nonautologous transfusion

** P values were determined using t-tests for continuous variables and exact methods for categorical variables.

Table 5

Venous thromboembolic events, cardiovascular and genitourinary complications in 692 RRP and 484 LRP patients treated before July 1, 2005

Complication	RRP	Grade	LRP	Grade
No. with DVT and/or PE (%)	5 (0.7%)	3	4 (0.8%)	3
MI	1 (0.1%)	5	1 (0.2%)	2
A-Fib	11 (1.6%)	2	3 (0.6%)	2
Syncope	8 (1.2%)	2	0	-
Urinary retention	14 (2%)	2	6 (1.2%)	2
Bladder neck Contracture	10 (1.4%)	3	2 (0.4%)	3
Urethral Stricture	3 (0.4%)	3	1 (0.2%)	3
Ureteral injury	2 (0.3%)	3	1 (0.2%)	3