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Salvage Robotic-Assisted Laparoscopic Radical Prostatectomy: A Single Institution, Five-Year Experience

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Abstract

Purpose—Salvage robotic-assisted laparoscopic prostatectomy (sRALP) is a treatment option for certain patients with recurrent prostate cancer (CaP) after primary therapy. Data regarding patient selection, complication rates, and cancer outcomes are scarce. Here, we report the largest, single-institution series to date of sRALP.

Methods—We reviewed our database of 4,234 patients who have undergone robotic-assisted laparoscopic prostatectomy at Vanderbilt University and identified 34 men who had surgery after failure of prior definitive ablative therapy. Each patient had biopsy-proven recurrent CaP and no evidence of metastases. The primary outcome measure was biochemical failure (BCF).

Results—The median time from primary therapy to sRALP was 48.5 months with a median PSA prior to sRALP of 3.86 ng/mL. Most patients had Gleason scores ≤ 7 on pre-sRALP biopsy, although 12 patients (35%) had ≥ Gleason 8 disease. After a median follow-up of 16 months, 18% had BCF. The positive margin rate was 26%, of which 33% had BCF following surgery. On univariable analysis, there was a significant association between PSA doubling time and BCF (hazard ratio [HR] 0.77, 95% confidence interval [CI] 0.60-0.99; p=0.049) as well as between Gleason score at original diagnosis and BCF (HR 3.49, 95% CI 1.18-10.3; p=0.023). There were two Clavien II-III complications: a pulmonary embolism and a rectal laceration. Post-operatively, 39% had excellent continence.

Conclusions—sRALP is safe, with many outcomes favorable to open, salvage radical prostatectomy series. Advantages include superior visualization of the posterior prostatic plane, modest blood loss, low complication rates, and short length of stay.

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Keywords

Prostate Cancer; Salvage Therapy; Robotics; Prostatectomy; Outcomes Assessment

Introduction

Prostate cancer remains the most common non-cutaneous malignancy in American men.[1] Rates of prostate cancer recurrence after attempted curative treatment range from 20-60% regardless of the mode of definitive local therapy performed.[2-4] It has been shown that up to 72% of patients with rising prostate specific antigen (PSA) after primary external beam radiation therapy (XRT) will have locally-recurrent disease.[5] The consequence of this local relapse is a dramatically elevated risk of distant metastasis and death.[6] Therefore, a significant number of patients with locally-recurrent disease may benefit from salvage therapy.

In select patients with clinical characteristics consistent with localized relapse, open salvage radical prostatectomy (SRP) has been shown to provide a biochemical recurrence-free survival rate of 48% and a metastasis-free survival rate of 83% at 5 years post-SRP in a large multi-institutional study.[7] Although long-term data is limited regarding the use of cryotherapy in the salvage setting, a recent comparison revealed superior overall survival with open SRP, despite adjustments for post-radiation biopsy Gleason score and PSA level.[8, 9] Nonetheless, SRP is performed relatively infrequently, which can be attributed in part to the technical challenges of the procedure.[10] Additionally, the historical morbidity of the procedure has been daunting, with rectal injury rates reported of over 15% in some series.[11, 12]

The rapid adoption of minimally-invasive radical prostatectomy in the United States has led to the exploratory use of robotic-assistance in the salvage setting at several institutions.[13-19] These series are relatively small and data regarding post-operative outcomes are limited. However, these studies suggest that salvage robotic-assisted laparoscopic prostatectomy (sRALP) is a feasible treatment option for qualified patients with recurrent prostate cancer after primary therapy.[14-19] Here, we report what is, to our knowledge, the largest single-institution series of sRALP with 5-year data on patient selection, complication rates, and cancer outcomes.

Methods

We reviewed our database of 4,234 patients who have undergone robotic-assisted laparoscopic prostatectomy at Vanderbilt University. From this group, we identified 34 men who underwent sRALP after failure of prior definitive therapy from 2006 to mid-2011. All patients had undergone previous local treatment with curative intent for localized prostate cancer. Initial treatments included: brachytherapy (n=13, 38%), external beam radiation therapy (XRT) (n=11, 32%), combined brachytherapy/XRT (n=6, 18%), and high-intensify focused ultrasound (HIFU) (n=4, 12%). Patients received a metastatic evaluation, including bone scan and/or CT scan as clinically indicated. Each patient underwent a biopsy to confirm recurrent prostate cancer and had no clinical evidence of metastatic disease at the time of consultation. The standard six-port transperitoneal technique was used during sRALP and all surgeries were performed at Vanderbilt University Medical Center. Pre-operative evaluation and post-operative follow-up were performed according to institutional protocol. There were no routine differences in pre-operative patient preparation for patients undergoing sRALP compared to standard RALP performed at our institution. The majority of sRALPs in this series (n=28, 82%) were performed by the senior author (JAS). As cancer-

control was our main concern, no intended nerve-sparing procedures were performed. Post-operative cystography was performed at the discretion of the provider.

An attending surgical pathologist evaluated all surgical specimens. Pathologic stage was assigned according to the 2010 American Joint Committee on Cancer guidelines and Gleason score was determined if possible. Clinical, pathological, and outcome data were analyzed and supplemented by medical record review and patient survey. Institutional Review Board approval was obtained for analysis and post-operative survey of this patient population. Patient-reported outcomes were obtained by chart review or phone survey of all patients at the time of analysis of this study.

The primary outcome measure was biochemical failure (BCF), which included both PSA persistence (PSA ≥0.1 ng/mL on initial post-sRALP PSA) and PSA recurrence (PSA ≥0.2 ng/mL with a subsequent confirmatory PSA >0.2ng/mL) post-sRALP. Duration of follow-up was the time from surgery to the date of death or last clinic visit.

We evaluated clinical variables, including: age, race (white vs. non-white), and body mass index; and pre-initial treatment variables, including: PSA and Gleason sum at original diagnosis along with type of initial local treatment. Post-initial treatment variables were also assessed, including: PSA nadir, pre-sRALP PSA, pre-sRALP biopsy Gleason sum, clinical stage, pre-sRALP hormone therapy status, and American Society of Anesthesiology Physical Status classification score (ASA). We also evaluated operative characteristics, pathologic stage and Gleason sum, pathologic node status, peri-operative complications—which were graded according to the Clavien system—and patient-reported potency (defined as erections sufficient for intercourse) and continence measures (pads per day).[20] Due to limited information, PSA doubling time (PSADT) was calculated using a two-point method which has been previously validated.[21]

Statistical Analysis

Exploratory univariable analyses were performed using a Cox proportional hazards model to assess the correlation between clinicopathologic variables and BCF. Multivariable analyses were not appropriate due to the limited number of events. All analyses were conducted with STATA data analysis software (College Station, TX, version 11).

Results

The median age of the cohort was 66.5 years (interquartile range [IQR] 57.9-69.9 years) and median follow-up was 16.1 months after sRALP (IQR 8.4-31.8 months). Tables 1 and 2 provide the distribution of patients by clinical and pre-operative oncologic characteristics. Median PSA at primary diagnosis of prostate cancer was 5.6 ng/mL (IQR 5.2-8.0 ng/mL) and the majority of men had Gleason 6 disease at the time of original diagnosis. Median PSA nadir after primary treatment was 0.9 ng/mL (IQR 0.5-1.4 ng/mL) and the median time from primary therapy to sRALP was 48.5 months (IQR 28.9-70.8 months) with a median PSA prior to sRALP of 3.86 ng/mL (IQR 2.41-5.07 ng/mL). Median pre-operative PSADT was 10.1 months (IQR 5.4-13.9 months). At the time of local recurrence, patients were distributed across Gleason scores and most were clinical stage T1c (56%) or cT2a (27%).

Operative Results

Median time of surgery was 176 minutes (IQR 159-191 minutes) and 94% of patients were discharged on the first post-operative day. No patients required conversion to open surgery. Table 3 provides the distribution of patients by peri-operative characteristics. Lymphadenectomy was performed at the discretion of the surgeon and the majority of patients (n=29, 85%) underwent bilateral pelvic lymphadenectomy. Of the five patients who

did not undergo lymphadenectomy, four had Gleason ≤ 7 disease while one had Gleason 8 disease. Two had prior bilateral inguinal hernia repairs with mesh, two had combined brachytherapy/XRT, and all had extensive fibrosis. There were two major complications—a pulmonary embolism (Clavien grade II) and a rectal laceration in a patient with pT4 disease which required repair and colostomy diversion (Clavien grade IIIb). Three bladder neck contractures (BNC) were managed with office cystoscopy and dilation. Five anastomotic leaks noted on post-operative cystogram required prolonged catheterization.

Pathologic Results and Biochemical Outcomes

Table 4 reports the distribution of pathologic characteristics. Most patients had Gleason 6 or 7 disease and were stage pT2 on pathologic analysis, although 9 patients (26%) had Gleason 8-10 disease and 16 (47%) were stage ≥pT3 on final pathology. Nine patients (26%) had positive surgical margins—seven of these were located at the prostatic apex (78%). On univariable analysis, there was a significant association between PSADT and BCF (hazard ratio [HR] 0.77, 95% confidence interval [CI] 0.60-0.99; p=0.049) as well as between Gleason score at original diagnosis and BCF (HR 3.49, 95% CI 1.18-10.3; p=0.023). Overall margin status was not associated with BCF (HR 3.15, 95% CI 0.63-15.7; p=0.162), although the association between apex margin status and BCF approached statistical significance on univariable analysis (HR 4.25, 95% CI 0.85-21.3, p=0.079).

Five patients (15%) had biochemical persistence post-sRALP and one patient (3%) had biochemical recurrence at 16.5 months post-sRALP. In all, six patients (18%) had BCF after a median follow-up of 16 months. Four patients (12%) have required salvage hormonal therapy. Two patients (6%) had clinical recurrence of disease as demonstrated by bone scan and one patient (3%) died of disease at 14 months after sRALP.

Functional Outcomes

Table 5 provides the distribution of patients by functional outcomes. Twelve patients (39%) achieved excellent urinary continence, defined as 0-1 pads per day at time of last follow up, although 12 patients (35%) had follow-up of less than one year. An additional eight patients (26%) reported incontinence that required 2-3 pads per day. One patient was incontinent preoperatively and remained incontinent post-operatively. Five patients underwent artificial urinary sphincter placement for persistent incontinence. Functional outcomes could not be obtained on one patient. Pre-operative potency was generally poor in this cohort and only 7 patients (21%) were potent pre-operatively without the assistance of medication. Of the 17 patients able to attain erections with or without pharmacologic assistance pre-operatively, 5 patients (29%) were successfully able to obtain erections sufficient for penetration with additional therapy beyond phosphodiesterase-5 inhibitors post-operatively.

Discussion

Our data suggest that sRALP is a safe and compelling alternative to open SRP and may offer some advantages. In particular, low rates of BNC, short length of stay, and low EBL appear to be favorable when compared to open SRP series. There was a statistically significant association between BCF and Gleason score at original diagnosis of prostate cancer as well as PSADT on univariable analysis. As a result, careful patient selection is critically important. When viewed in conjunction with patient factors such as life expectancy and pre-sRALP PSA, our results suggest that those with slow PSADT and low-grade disease at original diagnosis are most likely to benefit from sRALP.

Recurrence of prostate cancer after primary non-extirpative therapy remains a significant dilemma, with biochemical failure rates that range from 20-60% after long term follow-

up.[2-4, 22] Therefore, a large proportion of patients are potential candidates for salvage therapy. Of the currently available salvage treatments, the largest experience has been with open SRP. Compared to salvage cryotherapy open SRP appears to provide superior cancer-control, although comparisons are difficult due to variable selection criteria between salvage series.[8] Of note, salvage series using third and fourth-generation cryotherapy devices have shown promising early and intermediate results, although long-term oncologic results are pending.[9, 23] Despite the excellent oncologic outcomes of open SRP in appropriately selected patients, it remains a rarely-performed procedure.[4] While limited life-expectancy and concern for advanced disease certainly contribute to the 2% SRP-rate observed by Agarwal *et al.* in the CaPSURE® database, the substantial historical morbidity of SRP has been an important reason to avoid this treatment.[4, 24] It is notable that the morbidity of open SRP has decreased in recent series.[25] Several authors cite an improved understanding of surgical technique as well as the enhanced delivery of more modern radiation techniques as a basis for the improved outcomes found in contemporary open SRP series.[26-28] Nonetheless, given the potential for improved visualization and decreased blood loss with the robotic platform, experienced centers have begun to utilize this approach for SRP.[16-18] To date, there are only several small case series in the published literature and data regarding patient selection, complication rates, and cancer outcomes are sparse.[14-19]

Although we are relatively early in our experience with sRALP, many of our outcomes compare favorably to contemporary open SRP series. With 16 months of median follow-up, 6 patients (18%) had BCF, the majority of whom had biochemical persistence after sRALP. This underscores the importance of appropriate patient selection and also emphasizes the need for improved methods to detect systemic disease. Additionally, the statistically significant association between BCF and PSADT as well as Gleason score at original diagnosis likely represents a proxy for disease aggressiveness. These factors may facilitate patient selection, along with previously cited parameters, such as pre-SRP PSA and pre-SRP biopsy Gleason score.[7, 28, 29]

Given the reasonably high rate of advanced disease present on pathologic examination in this series, we achieved a relatively low rate of positive margins (26%), which were largely at the prostatic apex. Three patients (33%) with positive margins developed BCF and although our series was underpowered to evaluate the effect of overall margin status on BCF, the association between apex margin status and BCF approached statistical significance. Margin status is reported to be a predictor of BCR after radical prostatectomy and also has been found to be predictive of BCR in the salvage setting.[29, 30] While comparisons are difficult given heterogeneity between series, positive margin rates in the published sRALP series have ranged from 13-50%.[15-19] In a multi-institutional series of 15 patients, Chauhan *et al.* reported a 13% positive margin rate, although after a median 4 months of follow-up, 40% of the patients in this series developed a detectable PSA.[18] In two other sRALP series, Boris *et al.* and Eandi *et al.* report positive margin rates of 27% and 28%, respectively, which is concordant with our series.[16, 17] These early data for margin rates after sRALP are congruent with contemporary open SRP series, which have ranged from 11-33%.[7, 28, 29]

The majority of our functional outcomes are comparable to contemporary open SRP series. Erectile function post-operatively was poor, although most patients had impaired erectile function pre-operatively. Many were not interested in post-operative impotence treatment (21 patients, 64%). High rates of impotence have been a consistent finding in other sRALP series.[16-18] The short follow-up of our series and others may underestimate true return to potency, but even in modern SRP series with long-term follow up, potency rates remain low.[25, 26, 28] Although the continence rate of 39% (0-1 pads per day) in this analysis is less than some rates reported in contemporary open series, 35% of our patients have follow-up of

less than one year.[26-28] This suggests continued improvement for a proportion of men in our series. The anastomotic stricture rate of 9% compares favorably to open series, with BNC rates after SRP reported as high as 22-30%.[26, 27] Further potential advantages of sRALP include low EBL—no patients required perioperative transfusion—and short length of stay (94% discharged on first post-operative day).

Although our series is in its infancy, we feel the improved visualization afforded by robotic-assistance allows an easier and safer dissection of the posterior plane, which is often obliterated in patients with prior local therapy. This is reflected by our low rectal injury rate (3%), with the only rectal injury occurring in a patient with unrecognized pT4 disease. In an effort to improve posterior visualization, we frequently will not perform ligation of the dorsal vein and will completely free the lateral margins of the prostate to allow full mobilization of the prostate. This maneuver appears to improve visualization of the posterior prostatic apex, which is often the most adherent post-radiation, particularly after brachytherapy. Despite this improved visualization, salvage surgery of the prostate remains technically demanding and prior experience in the performance of radical prostatectomy is recommended.

Our findings should be interpreted within the context of several limitations, such as the small sample size, incomplete information for some patients, and relatively short follow-up. Given the low number of patients with BCF, a multivariable analysis was not feasible, and the results of the univariable analysis are therefore exploratory in nature. Additionally, this is a single-institution study and our data may not be generalizable. Despite these limitations, this series does add important information in support of sRALP as an attractive alternative to open SRP for recurrent prostate cancer after failed primary therapy.

Conclusions

In the largest, single-institution experience to date, sRALP appears to be safe, with outcomes comparable or favorable to open, salvage radical prostatectomy series. Primary advantages are the improved visualization of the posterior prostatic plane, decreased development of anastomotic stricture, low complication rates, low blood loss and short length of stay. Although salvage surgery for locally-recurrent prostate cancer is challenging, a high proportion of patients after sRALP have encouraging early oncologic results. Further follow-up is required to determine the continued efficacy of this procedure.

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Abbreviations and Acronyms

sRALP	Salvage robotic-assisted laparoscopic prostatectomy
CaP	Prostate Cancer
BT	Brachytherapy
XRT	External beam radiation therapy
BCF	Biochemical PSA failure
HR	Hazard ratio

CI	Confidence interval
SRP	Salvage radical prostatectomy
HIFU	high-intensify focused ultrasound
PSA	prostate-specific antigen
ASA	American Society of Anesthesiology Physical Status classification system
PSADT	PSA doubling time
IQR	Interquartile range

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Table 1

Distribution of patients by clinical characteristics

Characteristic	n	%
All	34	
Age		
≤60 years	12	35%
61-70	14	41%
>70	8	24%
Race		
White	32	94%
Non-white	2	6%
ASA class		
2	16	47%
3	18	53%
BMI		
21-25 kg/m^2	7	21%
25.1-30 kg/m^2	20	59%
>30 kg/m^2	5	15%
Pre-operative Erectile Function		
Impotent	17	50%
Potent with pharmacologic assistance	10	29%
Potent	7	21%
Pre-operative Hormone Therapy		
Yes	4	12%
No	30	88%

Percentages may not add up to 100% due to missing data.

Table 2

Distribution of patients by pre-operative oncologic characteristics

Characteristic	n	%
All	34	
PSA at Primary Diagnosis		
<4.0ng/ml	1	3%
4.0-10.0ng/ml	20	59%
>10.0ng/ml	4	12%
Gleason Score at Primary Diagnosis		
6	15	44%
7	9	26%
≥8	1	3%
Pre-operative Local Therapy		
Brachytherapy	13	38%
XRT	11	32%
Brachytherapy/XRT	6	18%
HIFU	4	12%
PSA Doubling Time		
<3.0 months	1	3%
3.0-8.9 months	11	32%
9.0-14.9 months	11	32%
>15 months	5	15%
PSA at sRALP		
<4.0ng/ml	17	50%
4.0-10.0ng/ml	15	44%
>10.0ng/ml	2	6%
Pre-operative Biopsy Gleason Score		
6	13	38%
7	8	24%
≥8	12	35%
T Clinical Stage		
T1	22	65%
T2	10	29%
≥T3	2	6%
Time to sRALP		
<24 months	3	9%
24-36 months	11	32%
37-48 months	3	9%
49-60 months	6	18%
>60 months	11	32%

Percentages may not add up to 100% due to missing data.

Table 3

Distribution of patients by peri-operative characteristics

Characteristic	n	%
EBL		
≤100ml	13	38%
101-250ml	17	50%
>250ml	4	12%
Lymphadenectomy		
Yes	29	85%
No	5	15%
Length of Stay		
1 day	32	94%
2 days	1	3%
>2 days	1	3%
Complications		
Clavien I	11	32%
Clavien II	1	3%
Clavien III	1	3%
Rectal Injury		
Yes	1	3%
No	33	97%
Pulmonary Embolism		
Yes	1	3%
No	33	97%
Bladder Neck Contracture		
Yes	3	9%
No	31	91%
Anastomotic Leak		
Yes	5	15%
No	29	85%
Febrile Urinary Tract Infection		
Yes	3	9%
No	31	91%

Table 4

Distribution of patients by pathologic characteristics

Characteristic	n	%
pTstage		
pT2a	6	18%
pT2b	1	3%
pT2c	11	32%
pT3a	2	6%
pT3b	13	38%
pT4	1	3%
Gleason Score		
6	3	9%
7	17	50%
≥8	9	26%
Pathologic Node Status		
N+	0	0%
N-	29	85%
Nx	5	15%
Margin Status		
Positive	9	26%
Negative	25	74%
Bladder Neck Invasion		
Present	1	3%
Absent	33	97%
Seminal Vesicle Invasion		
Present	12	35%
Absent	22	65%
Extra-capsular Extension		
Present	13	38%
Absent	21	62%
Calculated Tumor Volume		
≤3.0cc	9	26%
3.1-5.0cc	8	24%
5.0-9.0cc	10	29%
>9.0cc	7	21%

Percentages may not add up to 100% due to missing data.

Table 5

Distribution of patients by functional outcomes

Characteristic	n	%
Post-operative Continence		
0-1 ppd	12	39%
2-3 ppd	8	26%
>3 ppd	11	35%
Post-operative Erectile Function		
Impotent	26	79%
Potent with additional therapy	6	18%
Potent	1	3%
Post-operative Erectile Function if Potent Pre-operatively		
Impotent	12	71%
Potent with additional therapy	5	29%
Secondary Surgeries		
Artificial urethral sphincter (AUS)	4	12%
Implantable penile prosthesis (IPP)	1	3%
IPP/AUS	1	3%

Percentages may not add up to 100% due to missing data.