Robotic-assisted laparoscopic versus open salvage radical prostatectomy following radiotherapy

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Introduction: *To describe immediate perioperative outcomes of robot-assisted laparoscopic salvage radical prostatectomy for recurrent cancer following radiation therapy, and compare outcomes to a contemporary open surgical cohort.*
Materials and methods: *A total of 39 patients underwent salvage radical prostatectomy with pelvic lymphadenectomy (20 robotic, 19 open) for local recurrence following radiation therapy at a single institution between 2007 and 2011. Intraoperative parameters, postoperative complications, and oncological outcomes, were recorded. Wilcoxon rank-sum test and Fisher's exact test were used for comparison of continuous and categorical variables respectively. Mean values of numeric variables are reported with standard deviation.*
Results: *The cohorts were similar with respect to age, ethnicity, and American Society of Anesthesiologists Score classification. Estimated blood loss was lower in the robotic group versus the open group (381.3 mL versus 865.0 mL, p = 0.001). There was no difference in the rate of intraoperative complications, postoperative Clavien ≥ 3 complications (30% versus 15.7%), anastomotic leak (40% versus 42.1%), or wound infection (0% versus 15.7%) in the robotic and open groups. Mean node yield (10.4 versus 11.8), positive surgical margins (15.0% versus 15.7%), and undetectable prostate-specific antigen rate (78% versus 60%) were also similar between the robotic and open groups.*
Conclusions: *Robotic salvage prostatectomy appears to have no significant difference to the open approach with respect to safety and surgical quality as measured by complications, node yield and surgical margins in this retrospective single-institution series.*

Key Words: prostatic neoplasms, radiotherapy, salvage therapy, prostatectomy

Introduction

Radiation therapy is a common treatment for clinically localized prostate cancer.[1] It has been demonstrated that an estimated 10% of low risk and up to 60% of high risk prostate cancer patients will experience biochemical recurrence (BCR) after definitive radiation therapy, with a subgroup of these being organ-confined, localized recurrences.[2] Curative options for men with locally recurrent prostate cancer after radiation therapy include salvage radical prostatectomy and cryotherapy.[1] Although both salvage radical prostatectomy and cryotherapy can be curative, they are underutilized due to the substantial morbidity associated with salvage local therapy.[3] The majority of men are treated with systemic androgen deprivation therapy (ADT), but this is not curative and is associated with adverse effects including cardiovascular disease, impact on bone mineral density, and quality-of-life.[4-7]

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Salvage radical prostatectomy is a technically demanding operation. Postoperative complications including urine leak, injury to the rectum, and urinary incontinence are more common than in primary radical prostatectomy,[8] and this may contribute to the underuse of this potentially curative treatment option. While robot-assisted laparoscopic radical prostatectomy has enjoyed broad adoption across the United States for primary treatment of prostate cancer, few series of robotic salvage radical prostatectomy have been published.[9-12] None of the published series has a contemporary open surgical cohort for comparison and thus little is known about the relative merits of the robotic approach in the salvage setting. Our objective was to assess the safety and surgical adequacy of robotic salvage prostatectomy with respect to contemporary open salvage radical prostatectomy.

Materials and methods

Following Institutional Review Board approval, we retrospectively identified all patients who underwent salvage radical prostatectomy with pelvic lymphadenectomy and vesicourethral anastomosis following primary radiotherapy at a single institution between 2007 and 2011 (n = 39). An additional 8 patients underwent open salvage prostatectomy with planned urinary diversion rather than vesicourethral anastomosis and were excluded from the analysis. Between 2007 and 2011, our center averaged 208 open and 477 robotic prostatectomies per year, with our salvage open series representing 1.5% of the total number of open cases and our salvage robotic series representing 0.6% of all robotic prostatectomies. Patients with BCR after radiation therapy, as defined by ASTRO criteria,[13] who were felt to be potential candidates for salvage therapy underwent metastatic evaluation. If the patients were clinically node-negative and without evidence of distant metastatic disease, TRUS-guided biopsy of the prostate was performed. Patients did not receive MRI imaging of the pelvis to assist in biopsy or pre-surgical staging.

Demographic data including age, gender, ethnicity, body mass index (BMI), and American Society of Anesthesiologists Score (ASA) were collected. Pre-radiotherapy serum prostate-specific antigen (PSA), clinical tumor stage, and initial Gleason sum were collected. Variables also included radiotherapy year, modality, use of hormonal therapy or chemotherapy, and PSA nadir. Prior local salvage therapy, PSA prior to salvage prostatectomy, and post-radiotherapy biopsy Gleason score were also collected. Operative parameters included procedure performed (open or robot-assisted), lymphadenectomy, EBL, and duration of surgery. Intraoperative and postoperative complications within 90 days were rigorously recorded and scored according to the Clavien-Dindo system.[14] Pathology parameters included American Joint Committee on Cancer Tumor Node and Metastasis (TNM) stage, grade, and surgical margin status. Bladder neck contracture at any point in follow up was recorded. When available, data was abstracted regarding urinary and erectile symptoms before and after salvage prostatectomy. However, preoperative voiding symptoms were not systematically recorded using a validated instrument. All patients were felt to have a mobile prostate on physical exam, as a fixed prostate was felt to indicate surgically unresectable cT4 disease.

Robotic procedures were performed in a transperitoneal fashion using a 4 arm da Vinci S or Si HD Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA, USA) with two assistant ports. All patients had a standard pelvic lymphadenectomy with limits as follows: bifurcation of the common iliac artery (proximal), external iliac artery (lateral), bladder (medial), inguinal ligament (distal), and hypogastric vessels/pelvic floor (posterior). Patients were not randomized to treatment arms. The decision to use an open or robotic approach was determined by joint decision-making between the surgeon and the patient. One surgeon, tends to favor open surgery for thin patients, an acknowledged selection bias. There were four surgeons in this series who performed both open and robotic surgery. Follow up was individualized according to disease stage and comorbid disease. Duration of follow up was calculated from date of surgery to date of last follow up or death. A portion of patients returned to their primary providers for follow up care. Wilcoxon rank-sum test and Fisher's exact test were used for comparison of continuous and categorical variables respectively. Mean values of numeric variables are reported with standard deviation. A value of $p < 0.05$ was considered statistically significant.

Results

Demographics and baseline variables

Between 2007 and 2011, 39 patients were treated with salvage radical prostatectomy with pelvic lymphadenectomy and vesicourethral anastomosis for recurrent disease following primary radiotherapy. Of these, 20 (51%) had a robot-assisted laparoscopic approach. Median follow up was 16.8 months (95% CI 14.6-26.3). The robotic and open cohorts were similar with respect to age, ethnicity, and ASA classification. The robotic group had a higher mean BMI (34.0 versus 28.6, p = 0.004), Table 1.

TABLE 1. **Patient characteristics**

	Robotic (n = 20)	**Open (n = 19)**	**p value**
Mean age (years)	66.0	66.0	1
Ethnicity	n (%)	n (%)	
White	11 (55%)	13 (68%)	
Black	3 (15%)	4 (21%)	
Hispanic	5 (25%)	2 (11%)	
Other	1 (5%)	0	
Body mass index	34 ± 5.6	28.6 ± 5.0	0.004
ASA			0.204
2	2 (10%)	6 (32%)	
3 or 4	18 (90%)	13 (68%)	

ASA = American Society of Anesthesiologists Physical Classification System

The robotic and open groups were alike with regards to pre-radiotherapy oncologic parameters including mean PSA (12.1 versus 10.1 ng/mL, p = 0.545), as well as clinical stage, and biopsy Gleason sum. There was no significant difference in radiotherapy modality, subsequent mean PSA nadir (0.38 versus 0.7, p = 0.116), or PSA prior to salvage prostatectomy (p = 2.97 versus 4.51, p = 0.094) between the robotic and open groups, Table 2.

TABLE 2. **Pre and post-radiotherapy characteristics**

	Robotic (n = 20)	**Open (n = 19)**	**p value**
Mean pre-radiation PSA (ng/mL)	12.1 ± 15.5	10.1 ± 10.9	0.545
Pre-radiation biopsy Gleason sum	n (%)	n (%)	0.155
6	3 (15%)	6 (32%)	
7	10 (50%)	10 (53%)	
8	2 (10%)	1 (5%)	
9	4 (20%)	0	
Unknown	1 (5%)	2 (11%)	
Pre-radiation clinical stage			0.992
cT1	11 (55%)	12 (63.1%)	
cT2	4 (20%)	4 (21%)	
cT3	3 (15%)	3 (15.7%)	
Unknown	2 (10%)	0	
Primary therapy			0.899
EBRT or proton	13 (65%)	11 (57.8%)	
Brachytherapy or brachytherapy/EBRT	7 (35%)	8 (42.1%)	
Mean PSA nadir (ng/mL)	0.38 ± 0.37	0.70 ± 0.60	0.116
Mean Pre-SRALP PSA	2.5 ± 2.4	4.5 ± 3.1	0.021
Post-radiation biopsy Gleason sum	n (%)	n (%)	0.58
7	4 (20%)	8 (42.1%)	
8	4 (20%)	4 (21%)	
9	2 (10%)	3 (15.7%)	
10	1 (5%)	0	
Unknown/unable to be determined	9 (45%)	4 (21%)	

Prior to undergoing salvage prostatectomy, several patients in the robotic (n = 3) and open (n = 2) groups had failed other salvage therapies including EBRT, cryotherapy, aborted prostatectomy at another institution, and intraprostatic injection of an investigational agent. In addition, one patient in each group had received salvage systemic chemotherapy prior to salvage prostatectomy. In the robotic and open groups, a subset of patients was treated with hormonal therapy prior to salvage surgery (8 versus 4, p = 0.301). For a number of patients, a Gleason score was not able to be determined from the post-radiotherapy biopsy. There was no difference in pre-salvage biopsy tumor grade between the open and robotic groups, and all patients had either intermediate or high grade disease. Prior to surgery, erectile dysfunction was universal among patients undergoing robotic salvage prostatectomy, and present in all but 3 patients undergoing open salvage prostatectomy.

Surgery, pathology and complications

The duration of surgery (303.3 minutes versus 291.5 minutes, p = 0.855) was similar between the robotic and open cohorts, Table 3 and Table 4. EBL was significantly lower in the robotic group (381.3 mL versus 865.0 mL, p = 0.001). There was no difference in the rate of intraoperative complications between the robotic and open groups. Two patients in the open group had a rectal injury. There were no rectal injuries in the robotic group. One patient in the robotic group who was morbidly obese and had prior mesh ventral hernia repair had an enterotomy during adhesiolysis that required primary repair. No robotic patient had conversion to open prostatectomy.

TABLE 3. **Surgery, pathology and complications**

	Robotic (n = 20)	**Open (n = 19)**	**p value**
Mean surgery duration (minutes)	303.3 ± 73.1	291.5 ± 60.1	0.855
Mean estimated blood loss (mL)	381.3 ± 303.4	865.0 ± 616.4	0.001
Mean length of stay (nights)	3.2 ± 1.6	3.6 ± 2.3	0.838
Pathologic stage	n (%)	n (%)	0.374
pT2	6 (30%)	9 (47.3%)	
pT3	14 (70%)	10 (52.6%)	
Pathologic Gleason sum	n (%)	n (%)	0.694
6	0	0	
7	6 (30%)	7 (36.8%)	
8	2 (10%)	0	
9	7 (35%)	9 (47.3%)	
10	0		0
Unable to be determined	5 (25%)	3 (15.7%)	
Positive surgical margin	3 (15%)	3 (15.7%)	0.709
Seminal vesicle involvement	8 (40%)	8 (42.1%)	0.851
Positive nodes	3 (15%)	2 (10.5%)	0.951
Mean nodes retrieved	10.4 ± 5.7	11.8 ± 4.9	0.303
Intraoperative complications	1 (5%)	2 (10.5%)	0.963
Postoperative complications within 90 days			
Mean number of complications	1.1 ± 1.0	1.8 ± 1.6	0.158
Any complication	14 (70%)	15 (78.9%)	0.785
Any ≥ Clavien 3 complication	6 (30%)	3 (15.7%)	0.501
Anastomotic leak	8 (40%)	8 (42.1%)	0.848
Wound infection	0	3 (15.7%)	0.212
Bladder neck contracture*	5 (25%)	5 (26.3%)	0.999

*bladder neck contracture was assessed at any point in follow up (i.e., not limited to 90 days)

TABLE 4. **Summary of complications**

	Adverse event	Robotic Minor (Clavien Grade I-II)	Robotic Major (Clavien Grade III-IV)	Open Minor (Clavien Grade I-II)	Open Major (Clavien Grade III-IV)	Total n (%)
Procedural	Anastomotic leak	5	3	7	1	16 (28.6)
	Rectal injury				2	2 (3.5)
	Repair small bowel enterotomy		1			1 (1.8)
	Urinary retention			1		1 (1.8)
	Rectofistula				1	1 (1.8)
	Lymphocele	1			1	2 (3.5)
	Gross hematuria	2	2			4 (7.1)
	Penile/Voiding pain		1			1 (1.8)
CV	Stemi/NSTEMI	1				1 (1.8)
	DVT or PE	1		1		2 (3.5)
	Anemia	2				2 (3.5)
ID	Urosepsis				1	1 (1.8)
	Urinary tract infection	1		9		10 (17.9)
	Wound infection			3		3 (5.4)
	Balantitis			1		1 (1.8)
GI	Ileus	1		2		3 (5.4)
MSK	Flare of chronic back pain			1		1 (1.8)
	Neuropathy			1		1 (1.8)
	Pelvic pain	1		2		3 (5.4)
Total		15 (27%)	7 (13%)	28 (50%)	6 (10%)	56 (100%)

CV = ; ID = ……………;
GI = ………………; MSK = ……………

Length of stay, (3.2 days versus 3.6 days, p = 0.838), pathologic stage (p = 0.374), grade (p = 0.694) and rate of seminal vesicle involvement (p = 0.851) were similar. Mean lymph node yield (10.4 versus 11.8, p = 0.303) and the rate of positive nodes (15% versus 10.5%, p = 0.951) were also comparable. There was no difference in positive surgical margin rate in the robotic versus open cohorts (15% versus 15.7%, p = 0.709).

Rigorously recorded postoperative complications within 90 days of surgery were common in both the robotic and open groups (70% versus 78.5%, p = 0.785). There was no difference in the mean number of complications per patient between the cohorts (1.1 versus 1.8, p = 0.158), or in the rate of Clavien ≥ 3 complications (30% versus 15.7%, p = 0.501). In particular, the robotic and open groups had similar rates of anastomotic leak (40% versus 42.1%, p = 0.848) and wound infection (0% versus 15.7%, p = 0.212). Occurrence of bladder neck contracture at any point in follow up was also similar between robotic and open patients (25% versus 26.3%, p = 0.999).

Continence was defined as being dry without use of pads. Incontinence was characterized according to the number of pads used per day and included mild (1 pad), moderate (2-3 pads), and severe (4 or more pads, or treatment with incontinence surgery). Few patients achieved continence or had only mild incontinence, with one and three patients in the robotic and open groups, respectively. All other patients had severe incontinence at most recent follow up or were treated with incontinence surgery such as artificial urinary sphincter. This is comparable to other case series.[15]

Oncologic outcomes

Rates of achieving an undetectable PSA were similar between the robotic and open groups (78% versus 60% p = 0.307). With limited follow up, there was no difference in recurrence free survival (RFS) between the two groups. The median RFS was 9.5 months in the robotic group and was not reached in the open group (p = 0.142). Seven patients in each arm resumed hormonal therapy (p = 0.999).

Discussion

We report perioperative outcomes of salvage robot-assisted laparoscopic radical prostatectomy for local recurrence following radiation therapy. In this single institution series, it appears that salvage robot-assisted laparoscopic radical prostatectomy is equivalent to the open approach with respect to safety and surgical quality.

This represents the first series of salvage robot-assisted laparoscopic radical prostatectomy with a contemporary open comparator, Table 5.

A notable benefit of the robotic approach in our series was lower EBL. This mirrors what is known for primary robotic radical prostatectomy.[18] The lower blood loss may be related to tamponade of venous bleeding by pneumoperitoneum.[19] Other potential benefits, such as reduced length of stay, faster convalescence, and fewer complications were not observed in our series, though a larger, multicenter series may be better able to detect small differences. In addition, these cases represent the initial robotic salvage cases performed at the institution and further refinements in technique may lead to improved outcomes.

We did not anticipate that the robotic approach would lead to improved functional outcomes in terms of erectile dysfunction or incontinence. Urinary incontinence after salvage radical prostatectomy is felt to reflect damage to the external sphincter due to radiotherapy. Loss of the bladder neck during radical prostatectomy unmasks this injury resulting in incontinence. The approach to radical prostatectomy, open or robotic, would be unlikely to alter this outcome. In addition, patients undergoing salvage radical prostatectomy have an eight fold increased probability of incontinence (47.0 versus 5.8) than those undergoing standard radical prostatectomy.[20] Erectile dysfunction was nearly universal prior to salvage surgery in our cohort, which is a similar finding to other series.[10,21] This, coupled with the high rate of locally advanced disease, informs our practice to perform non-nerve sparing salvage surgery.

Complications, which were rigorously tallied and classified according to the Clavien-Dindo system, were common. There was no statistically significant difference in the frequency or spectrum of complications between the robotic and open groups. While the sample sizes are too small to make any determinations about differences in the rate of rectal injury between the two groups, it is notable that there were no rectal injuries in the robotic cohort. There were two rectal injuries with

TABLE 5. **Comparison of published salvage series**

	Kaouk et al[16]	Boris et al[17]	Eandi et al[9]	Strope et al[15]	Chauhan et al[12]	Kaffenberger et al[10]	Yuh et al[11]	MDACC
Patients (n)	4	11	18	6	15	34	51	20
Age (year)	NR	64.9	67	NR	62	66.5	68	66
Initial PSA (ng/mL)	12.8	5.2	6.8	9.3	6.9	5.6	5.27	6.3
Lymph node involvement (%)	0	18%	6%	0	7%	0	6%	15%
Lymph node yield (n)	NR	5.6	NR	NR	6	NR	22	10.4
Positive margin (n, %)	2 (50%)	3(27%)	5 (28%)	1(16%)	2 (13%)	9 (26%)	16 (31%)	3 (15%)
Bladder neck contracture (n, %)	0	1 (9)	3 (18%)	1 (16%)	1 (7%)	3 (9)	1 (3%)	5 (25%)
Rectal injury (n, %)	0	0	0	0	0	1 (3)	1 (3%)	0
Blood loss (cc)	117	113	150	280	75	NR	175	275
Length of stay (days)	2.7	1.4	2	2	1	1	2	3
Surgery duration (minutes)	125	183	156	356	140	176	179	295
Follow up (months)	5	21	18	15	5	16	36	17

N = number of patients; NR = not reported; PSA = prostate-specific antigen; BCR = biochemical recurrence; MDACC = MD Anderson Cancer Center the open approach. In our experience, the robot permits satisfactory dissection of the prostate off the rectum with excellent visualization. With additional experience and a larger sample size, it is possible that the robotic approach might be associated with less frequent rectal injury, although we are unable to reach this conclusion with the data at hand.

With relatively short follow up, little can be gleaned regarding the relative merits of robotic compared to open salvage prostatectomy with regards to oncologic outcomes. Both the open and robotic groups had acceptable positive margin rates that compare favorably to other published series, which had varying rates of 13%-50%.[9-11,17] Rates of achieving undetectable PSA were also similar. The two groups had similar RFS and use of postoperative ADT. In addition, node yield and rate of node positivity was similar between the two groups, suggesting equivalence with regards to lymphadenectomy.

This analysis is not without limitations and we are cautious not to overstate our conclusions. The retrospective design is accompanied by potential selection bias that may be reflected in the lower BMI observed in the open cohort. There may be other biases that are unmeasured. We have limited data about the radiation treatment that the patients received. In addition, retrospective assessment of complications may underestimate the true incidence of postoperative complications. Also, the relatively small sample size may have adversely impacted the ability to detect differences between the two groups. Our short follow up impairs our ability to assess cancer outcomes and urinary continence, which may improve over time. We did not use validated instruments to assess urinary incontinence and erectile dysfunction in these patients, though this was not a central purpose of this paper.

Conclusions

Robotic salvage prostatectomy appears to have no significant difference to the open approach with respect to safety and surgical quality as measured by rate of complications and positive margins in this retrospective single-institution series, the only published series of robotic salvage prostatectomy with a contemporary open comparator. □

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