

Robot-assisted laparoscopic radical cystectomy with extracorporeal urinary diversion: Initial experience and outcomes

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ABSTRACT

Introduction: Open radical cystectomy (ORC) is the most common surgical approach for invasive carcinoma of the urinary bladder, but robot-assisted radical cystectomy (RARC) has recently gained popularity. There is limited data from the Indian subcontinent on RARC. The aim of this study was to assess the perioperative, pathological, and oncological outcomes of RARC and follow-up in our initial 63 cases.

Materials and Methods: A retrospective analysis of prospectively maintained data of 63 RARC procedures performed in our tertiary care institute from July 2006 to January 2016 was done. All patients underwent RARC with extracorporeal urinary diversion. We analyzed perioperative parameters, length of hospital stay, pathological and oncological outcomes, and rate of complications. Follow-up data were analyzed for disease recurrence and survival.

Results: The mean age of the patients was 58 years. The mean American Society of Anesthesiologists (ASA) score was 1.66. Mean operative time was 348.6 min and mean blood loss was 868.2 ml. Mean hospital stay was 10.4 days (± 5.4 days). 42.8% patients had pT2 disease, 49.2% pT3, 1.58% pT1, and 6.34% had pT4 disease. Mean lymph node yield was 12.4 (3–25). One patient had positive surgical margins. Twenty-four patients had postoperative complications of which four were major complications (Clavien-Dindo 3 or higher). At a median follow-up of 60 months (range: 3–108 months), 11 patients were lost to follow-up 10 patients developed metastasis, out of which 4 died. Four had recurrence, two died and two are receiving chemotherapy.

Conclusion: This study shows the feasibility and safety of RARC. The operative time, blood loss, return of bowel activity and hospital stay were higher than those reported in the literature but may reflect the learning curve.

INTRODUCTION

Radical cystectomy is the standard treatment for muscle-invasive non-metastatic carcinoma urinary bladder.^[1] It is an extensive surgical and reconstructive procedure with a long operative time and a prolonged postoperative recovery, with significant associated morbidity and mortality.^[2] Open radical cystectomy (ORC) provides excellent oncological control and long-term disease-free survival.^[3] ORC is associated with significant intraoperative blood

loss, postoperative pain and prolonged hospital stay.^[4] Although ORC is still the most common approach, minimally invasive approaches have also gained popularity and are routinely performed in many high volume centers with encouraging results. Laparoscopic radical cystectomy described initially in the 1990s,^[5–7] was associated with prolonged operative time and required surgical expertise. After the introduction of robotics in urology, robot-assisted radical cystectomy (RARC) has become a feasible and safe alternative to ORC as comparative studies have shown benefits of the minimally invasive approach such as less

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postoperative pain, early bowel movements and recovery, without compromising oncological outcomes.^[8-12] In 2003 Menon *et al.* reported the first experience with the minimally invasive approach of RARC.^[13] We report our initial experience of RARC in 63 cases with intra- and post-operative outcomes. To the best of our knowledge, there is no data in the literature from the Indian subcontinent on the outcomes of RARC with long-term follow-up.

MATERIALS AND METHODS

A total of 63 RARC procedures were performed in our tertiary care institute from July 2006 to Jan 2016 for muscle-invasive carcinoma urinary bladder. These were retrospectively analysed from a prospectively maintained database. The preoperative parameters assessed were patient age, gender, body mass index (BMI), clinical stage of the disease, age-adjusted Charlson comorbidity index (ACCI), and the American Society of Anesthesiologists (ASA) score. All patients underwent routine laboratory investigations which included hemogram, renal function, liver function tests, Chest X-ray and a computed tomographic (CT) imaging of the abdomen and pelvis or Magnetic resonance urographic (MRU) imaging in case of deranged renal functions. Two patients received preoperative neoadjuvant chemotherapy. Table 1 shows patients' details. The selection of the robotic versus an open approach was made primarily at the surgeon's discretion and was determined by the patient's overall health status- specifically with regard to the ability to tolerate the pneumoperitoneum and steep Trendelenburg position associated with the robotic approach. Patients with large volume disease, history of previous pelvic surgery, or radiation therapy were excluded from the robotic

approach. The decision of the type of urinary diversion was individualized according to patients' age, preferences, compliance, and extent of disease. Intraoperative parameters included the duration of total operative time, blood loss, and intraoperative complications.

Postoperatively, patients were assessed for time to nasogastric (NG) tube removal, time to oral intake, abdominal drain removal, other postoperative complications, and hospital stay. Pathological outcomes assessed were pathological stage, margin status, total number of lymph nodes removed, and positive lymph nodes for tumor deposits. Patients with high-risk disease according to the surgical pathologic examination (Stage pT3, pT4, or lymph node-positive disease) were subjected to adjuvant chemotherapy. The decision on the surgical approach performed for each patient was not randomized.

The six-port transperitoneal approach was used in all the cases with two ports for robotic arms, one for camera and three ports for assistants. Robot was docked (da Vinci S Surgical System) with the patient in 30° trendelenburg position. Bilateral standard lymph node dissection was done with superior limit up to common iliac bifurcation in all patients. Cystectomy began with the dissection and identification of ureters as they crossed over the iliac arteries. Ureters were dissected toward the bladder and clipped with a Hem-o-lok clip. Lateral dissection was performed next, branches from the anterior division of internal iliac artery to bladder were identified and clipped, and further mobilization done till the endopelvic fascia. In female patients, the dissection was done between the rectum and the vagina in the cul-desac. In men, the dissection began in the plane behind the seminal vesicles, Denonvilliers' fascia was opened and pre-rectal fat was identified. Both vasa were identified and clipped. The anterior dissection was accomplished via a parietal peritoneal inverted-U-shaped incision incorporating the urachus. The bladder was then dropped, the space of Retzius defined, and the puboprostatic ligaments exposed. The endopelvic fascia and puboprostatic ligaments were incised followed by dorsal vein complex ligation with absorbable suture. The urethra was divided. The robot was undocked and the specimen was retrieved through a lower midline incision. All the urinary diversions were performed extracorporeally.

The ileal loop was isolated on its mesentery approximately 15–20 cm proximal to ileocecal junction and bowel continuity restored with end-to-end two layered anastomosis. Ureteroileal anastomosis was performed over 8-Fr feeding tubes by Bricker's technique. The distal end of the conduit was fashioned as a stoma at a previously marked site on the abdominal wall. All neobladders were made extracorporeally. Complications were recorded as per the Clavien-Dindo classification.^[14]

Table 1: Patient details

Age (years) [Mean (range)]	57.98 (40-74)
Male	61
Female	2
BMI (mean)	26.24
Normal (<25)	19
Overweight (25-29)	37
Obese (30-39.9)	7
ASA (mean)	1.66
ACCI	
0-2	15
≥3	48
Clinical stage	
Tis	0
Ta	0
T1	1
T2	29
T3	29
T4	4
Diversion	
Conduit	56
Neobladder	3
Ureterostomy	4
Neoadjuvant chemotherapy	2

BMI=Body mass index, ASA=American Society of Anesthesiologists, ACCI=Age-Adjusted Charlson Comorbidity Index

RESULTS

The mean age of the patients was 58 years (40–74 years) with 61 males and 2 females [Table 1]. The mean ASA score was 1.66. The mean BMI (kg/m²) was 26.2. The patients were divided into three groups according to the BMI. Normal weight, BMI <25 (*n* = 19), overweight, BMI 25–29 (*n* = 37) and obese, BMI 30–39.9 (*n* = 7). A total of 48 patients had ACCI score of ≥3. Most of the patients had T2 (29) and T3 (29), disease, while 4 patients had T4 and 1 patient had T1 disease. Fifty-six patients underwent ileal conduits, 4 had ureterostomies and 3 patients underwent neobladder reconstruction. In terms of intraoperative parameters [Table 2], the mean total operative time was 348.6 min (±64.3 min) which included a mean console time of 140.6 min, and mean blood loss was 868.2 ml (±622.7 ml). Meantime for NG removal was 3 days and for bowel activity 3.4 days. The mean hospital stay was 10.4 days (±5.4 days). Intraoperative complications occurred in only one patient (external iliac artery injury), for which the procedure was converted to ORC.

In terms of pathological outcomes [Table 3], 42.8% (27) patients had pT2 disease and 49.2% (31) had pT3 disease. One patient had pT1 and 4 patients had pT4 disease. The median lymph node yield was 12.4 (range: 3–25). Eight lymph nodes were found positive in five patients. The distribution of positive lymph nodes were 1/9, 2/12, 3/16, 1/10, and 1/7, respectively, in five patients. Patients with tumor stage T3 or more, or node-positive disease underwent adjuvant chemotherapy. In total, 35 patients received adjuvant chemotherapy, consisting of Gemcitabine and Cisplatin for 6 cycles. One patient had positive surgical urethral margins (pT2N0).

Table 2: Surgical outcomes

Mean blood loss (ml)	868.24±622.73
Mean total operating time (min)	348.64±64.31
Mean console time (min)	140.63±28.2
Mean time for NG removal (days)	3
Mean time of bowel activity, flatus (days)	3.4
Mean in hospital stay (days)	10.47±5.47

NG = Nasogastric

Table 3: Pathological outcomes

	<i>n</i> (%)
p stage	
pT0	0
ptis	0
pT1	1 (1.58)
pT2	27 (42.85)
pT3	31 (49.20)
pT4	4 (6.34)
Lymph nodes	
Yield (median)	12.4 (3-25)
Positive	8
Margin status	
Positive	1

A total of 24 (38%) patients had postoperative complications [Table 4] which were classified as per modified Clavien-Dindo classification. The majority were minor complications, mostly prolonged ileus and wound infection (Clavien-Dindo class 1, 22.2%, and class 2, 9.5%) Four patients had major complications in postoperative period (one patient had Clavien-Dindo class 3, 1.5%; two had class 4, 3.1%; and one had class 5, 1.5%). One patient had intestinal obstruction; the other three had cardiopulmonary complications. One of the above patients died of massive myocardial infarction during postoperative hospital stay. No definite correlation could be seen between the postoperative complications and BMI of the patients, although ACCI directly affected the complication rates [Table 4].

We further analyzed the cohort into first 30 and next 33 cases. For first 30 and the next 33 cases, respectively, mean blood loss was 918.8 ml and 822.28 ml, mean total operative time was 357.4 min and 340.68 min, mean console time was 152.05 min and 130.26 min, and mean hospital stay was 11.07 days and 9.94 days. The surgeries were performed by different surgeons with variable experiences over a period of time. There was a decreasing trend in all the parameters such as blood loss, operative time; and hospital stay, particularly in the console time and blood loss. Mean lymph node yield was 11.6 and 13.2, respectively.

Oncological outcomes on follow-up

Out of 63 patients, 11 patients were lost to follow-up after various periods of follow-up. At a median follow-up of 60 months (range: 3–108 months), two patients have completed 9-year follow-up (both T2N0) and 20 patients have completed 5 years or more. One patient (T3N2) expired after readmission within 30 days of surgery for chest infection and sepsis. Ten patients developed metastasis, out of which 4 died (T4N1, T4N0, T3N1, T2N0) of metastatic disease. Four patients had a recurrence, two died and two are receiving chemotherapy. Out of these two patients receiving adjuvant chemotherapy, one patient was lost to follow-up after 15 months, and the other patient died of metastatic disease after 23 months. Both the patients had negative surgical margins. The overall disease-free survival rate in our study at a median follow-up of 60 months was 69.2%.

DISCUSSION

Our initial experience with robotic approach for radical cystectomy has shown acceptable outcomes. The oncological outcome depends on many factors, but the factors related to surgical techniques are the surgical margin status and the lymph node yield, regardless of the lymph nodes being positive or not.^[15] The accepted lymph node yield is >10 lymph nodes and rate of positive surgical margins <10% for all cases and <15% for bulky disease (pT3-T4).^[15,16] Our lymph node yield was slightly less than the recommended parameters, but we could achieve excellent results with

surgical margin status, 1.58%. Results from the International Robotic Cystectomy Consortium (IRCC) showed an overall positive surgical margin status in 35 (6.8%) out of a total of 513 patients. The rates were 1.5% or less for pT2, 8.8% for pT3, and 39% for pT4.^[17]

Our mean operating time was 348.6 min ± 64.3 min, with a mean console time of 140.63 min. Our operating time is longer than the time described in literature for RARC, which varies from 252 to 618 min.^[7,18-22] The mean blood loss in our study was 868.2 ml ± 622.73 ml, which is also higher than what is described in literature.^[18,19] Guru *et al.*, in their initial 7 cases reported mean blood loss of 335 ml.^[23] Other retrospective series mentioned above have shown mean blood loss ranging from 250 to 700 ml [Table 5]. We believe that apart from this being our initial experience with RARC, a proportionately higher number of T3 disease cases has contributed to the long operating time and blood losses. Studies have shown a significant decrease in operating time and increase in lymph node yield with increasing surgeon experience.^[24]

Our mean time to NG removal was 3 days and mean time for bowel movement (flatus) 3.4 days. However, in our last 10 cases, we have been removing NG at a mean of 2 days and bowel activity has come down to 3 days, with patients starting liquid diet on day 4 and semisolid on day 5. The mean hospital stay was 10.4 ± 5.4 days. A wide

range of post-operative hospital stay has been described in previous studies. Eight days by Bochner *et al.*,^[25] 5.1 days by Nix *et al.*,^[19] and 18.8 days by Treiye *et al.*^[26] The length of hospital stay depends upon the policy of the hospital, particularly for a radical procedure such as cystectomy and urinary diversion where many factors are considered for the well-being of the patient. The population we serve is often economically challenged, and comes from remote areas with no local step down or rehabilitation facility. Hence, our policy is to discharge the patient after removal of drains and full oral intake tolerance.

The rates of overall complications vary in the studies done previously. In a randomized study, Bochner *et al.* reported an overall complication rate of 62% after 90 days of RARC,^[25] while Yuh *et al.*^[27] reported a rate of 80%. Results from the IRCC show that a total of 48% patients had a complication within 90 days of RARC.^[28] 29% had low grade (Clavien 1–2) and 19% had high grade (Clavien 3–5) complications. The overall complication rate in our study was 38.09%. Low grade (Clavien 1–2) complications were 31.74% while high grade (Clavien 3–5) complications were 6.34%. The complications included in this study were during hospital stay.

There are certain limitations in our study that are inherent to a retrospective study. The number of patients in our

Table 4: Complications

Clavien-Dindo class	n (percentage of total patients)	BMI			ACCI	
		<25	25-29	30-39.9	<3	≥3
1	14 (22.22)	5	6	3	4	10
2	6 (9.5)	2	3	1	2	4
3	1 (1.58)	0	1	0	0	1
4	2 (3.17)	0	2	0	0	2
5	1 (1.58)	1	0	0	0	1
Total	24 (38.09)					
System wise	n (percentage of total complications)	<25	25-29	30-39.9	<3	≥3
Cardiac	1 (4.16)	1	0	0	0	0
Pulmonary	2 (8.33)	0	2	0	0	0
Gastrointestinal	1 (4.16)	0	1	0	0	0
Wound/skin	6 (25)	2	3	1	0	0
Infections/metabolic	14 (58.33)	5	6	3	0	0
Thromboembolic	0	0	0	0	0	0

BMI=Body mass index, ACCI=Age Adjusted Charlson Comorbidity Index

Table 5: Comparison with other series

Series	Study design	Diversion	n	Mean/median operative time (min)	Mean/median blood loss (ml)	Mean in hospital stay (days)
Guru <i>et al.</i> , 2007 ^[23]	Prospective	Extracorporeal, conduit	7	-	335	-
Murphy <i>et al.</i> , 2008 ^[11]	Retrospective	Extracorporeal, conduit	23	397	278	11.6
Pruthi <i>et al.</i> , 2010 ^[20]	Retrospective	Extracorporeal, conduit	100	276	250	4.9
Abbas <i>et al.</i> , 2013 ^[21]	Retrospective	Extracorporeal, conduit	25	618	700	-
Saar <i>et al.</i> , 2013 ^[22]	Retrospective	Extracorporeal, conduit	62	410	404	17
Parekh <i>et al.</i> , 2013 ^[18]	Prospective	-	20	300	400	6
Nix <i>et al.</i> , 2010 ^[19]	Prospective	Extracorporeal, conduit - 14, neobladder - 7	21	252	258	5.1
Our series	Retrospective	Extracorporeal, conduit - 56, neobladder - 3, ureterostomy - 4	63	348	868	10.4

study was small, but it is in line with other studies published that have been compared in this study. There has been no comparison with an ORC series.

CONCLUSION

Our experience with RARC in this study shows acceptable surgical and pathological outcomes with low complication rates. The operative time, blood loss, return of bowel activity and in-hospital stay were marginally higher than reported in recent series, but these parameters were acceptable and may reflect the learning curve. Our study shows the feasibility and safety of RARC in selected patients. There still remains space for larger and prospective studies to evaluate RARC against the gold standard of ORC.

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