Original Article

Perioperative, oncological, and survival outcomes of robotic radical cystectomy with urinary diversion in females: A single-center retrospective observational study

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ABSTRACT

Introduction: Robot-assisted radical cystectomy (RARC) is a standrad approach for surgical management of bladder cancer. Currently, most literature on RARC is in men, possibly due to the higher incidence of bladder cancer in males. We reviewed the perioperative, oncological and survival outcomes in 41 women who underwent RARC by a single surgeon at a tertiary health-care center.

Methods: Out of 225 RARC and urinary diversion procedures performed from 2012 to 2020, a retrospective analysis of 41 women was performed. Baseline demographic and perioperative details, oncological data, and survival were recorded and analyzed. Kaplan–Meir analysis was done for survival outcomes and prognostic factors were assessed by log rank test.

Results: Thirty-eight patients underwent intracorporeal urinary diversion, while three underwent extracorporeal diversion. One patient underwent organ preserving cystectomy. Clavien–Dindo 30-day postoperative complications were Grade I in 8 (19.5%), Grade II in 4 (9.8%), and Grade IIIa in 3 (7.3%) patients with no mortality. During the median follow-up of 34 months (range: 6–87 months), 7 patients died of disease recurrence. Five-year survival was 74% (95% confidence interval [CI]: 59–82) and 35% (95% CI: 10–91) in transitional cell carcinoma (TCC) and non-TCC group, respectively, with $P = 0.04$. There was no mortality in Stages 0 and 1 disease. Five-year survival was 78% in Stage 2 and 41% in Stage 3 and 4.

Conclusion: Our study demonstrates acceptable clinical, perioperative, and oncological outcomes of robotic radical cystectomy in females, thus highlighting its safety and feasibility.

INTRODUCTION

Robot-assisted radical cystectomy (RARC) is an alternative approach for surgical management of muscle invasive bladder cancer (MIBC) in view of numerous advantages such as favorable ergonomics, three-dimensional and magnified vision. The benefits for patients by robotic approach include lesser blood loss, less pain, and faster bowel recovery, leading to earlier discharge from the hospital.[1] Ever since Menon *et al.* documented the first ever series of RARC,[2] majority of the subsequent publications have involved men undergoing RARC,[1,3] due

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to male preponderance of bladder cancer (ratio of 3:1).[4] In women with bladder cancer, there are increased chances of the uterus being involved due to lack of anatomical barrier between bladder and uterus and common lymphatic drainage.[5] Hence, females undergo exenteration of anterior pelvic organs; however, genital sparing RARC is possible in select patients.[6] There is a paucity of literature on female RARC. We present the perioperative variables and oncological and survival outcomes in a cohort of 41 women who underwent RARC by a single surgeon at a tertiary health-care center.

MATERIALS AND METHODS

From June 2012 to January 2020, 225 robotic radical cystectomeis and urinary diversion procedures for urinary bladder cancer were performed a the study institute. Out of these, 41 were females who had either anterior exenteration (n = 40) or uterus sparing radical cystectomy (n = 1) with bilateral extended lymph node dissection. The indication for surgery was either MIBC or high-grade recurrent non-MIBC after intravesical therapy.

Factors including age, smoking/tobacco status, American Society of Anesthesiologists (ASA) classification, receipt of neoadjuvant chemotherapy, type of urinary diversion, estimated blood loss, pathologic T (tumor), N (node), and M (metastasis) classification according to the American Joint Commission on Cancer 8th edition, and lymph node status were obtained through patient charts.

Precystectomy staging investigations included computerized tomography (CT), transurethral resection of bladder tumor biopsy, and positron emission tomography (PET) CT. PET-CT was done in 20 patients. Selective components of enhanced recovery after surgery (ERAS) protocol were followed perioperatively such as no bowel preparation, early liquids within 24 h, early nasogastric tube removal, deep vein thrombosis prophylaxis, and early feeding.

The baseline demographic details, perioperative details, postoperative complications, postoperative mortality, pathological information, and oncological data were recorded and analyzed retrospectively. Follow-up was done at regular intervals, which included clinical examination, routine blood tests, urine cytology, kidney function tests, chest X-ray and ultrasonography or CT of the abdomen and pelvis, and PET-CT in some patients. Institutional ethics and review committee-A (IEC-A CODE 032/2020) approval was obtained for retrospective analysis of bladder cancer data from our institute, and standard consent for the surgery was taken during the treatment.

Surgical technique in brief

Surgery was performed using the Da Vinci surgical system (Intuitive Surgical, Sunnyvale, CA). After administering general anesthesia, the patient was catheterized and kept in lithotomy position with arms tucked by the side following which steep Trendelenburg's position was given.

Four robotic and two 12-mm assistant ports and AirSeal (Conmed, USA) were used for abdominal insufflation to avoid decrease in intra-abdominal pressure when vagina was opened. Before the availability of AirSeal, vaginal packs were used. Uterine manipulation was done using vaginal sponge stick. Both 0° and 30° lenses were used for the procedure. Steps of the procedure included pouch of Douglas dissection by incising the peritoneum between bladder and uterus, and identification of posterior vaginal wall. Bilateral ureters were then traced from iliac bifurcation to vesicoureteric junction where they were clipped and cut. This was followed by securing of the bladder pedicle and uterine artery by Enseal (Johnson and Johnson, USA). Next, the posterior fornix was opened and lateral vaginal dissection was performed. The bladder was dropped and endopelvic fascia was incised, thus helping in the identification of the urethrovesical junction. The urethra was then dissected and clipped before its division and the specimen was extracted through the vagina. Finally, bilateral extended lymph node dissection was performed, the boundaries of which were genitofemoral nerve laterally, to bladder, medially, and common iliac artery superiorly to lateral circumflex vein inferiorly. All the nodal tissues from obturator fossa were cleared. Finally, vagina was closed followed by the formation of intracorporeal ileal conduit or neobladder.

Statistical analysis

We used SPSS Statistics v20.0 (IBM Corp, NY, USA) software for the statistical analysis. Descriptive statistics, including mean, median, range, interquartile range (IQR), and statistical significance, were used to report scale and categorical data. Patients were censored at the date of the last follow-up or at the time of death up to April 2020. Kaplan–Meier analysis was done for survival outcomes and prognostic factors were assessed by log rank test.

RESULTS

Median age of the cohort was 62 years (IQR: 53–70) and mean BMI was 25.71 (IQR: 23.64–27.24). All patients were married and three patients had no children. Five patients gave a history of smoking and/or tobacco chewing, and there was no history of chemical exposure. Two patients had bilateral hydronephrosis requiring percutaneous nephrostomy (PCN), and six patients had unilateral hydronephrosis and four required PCN. Patients with MIBC were advised to undergo neoadjuvant chemotherapy, but only eight patients received the same, 15 patients refused chemotherapy, four patients had active hematuria, and 10 patients had decreased glomerular filtration rate (GFR) and hence were not suitable for chemotherapy. Clinical details are given in Table 1. One patient had open partial

Table 1: Baseline demographic and preoperative findings in female patients treated with robot-assisted radical cystectomy and urinary diversion

Variable	Value
Total patients	41
Median age (years) (IQR)	62 (53-70)
Median BMI (kg/m^2) (IQR)	25.71 (23.64-25.71)
Smoking/tobacco chewing, *n* (%)	5 (12.19)
Neoadjuvant chemotherapy, *n* (%)	8 (19.51)
Interval between diagnosis and surgery (weeks)	
<6	21
>6	12
Previous abdominal surgery	13
Clinical stage	
1	4
2	19
3	8
ECOG score	
0	9
1	27
2	5
ASA grade	
1	26
2	13
3	2
Type of urinary diversion	
Intra corporeal	38
Extra corporeal	3
Genital organ preserving cystectomy	1

IQR=Interquartile range, BMI=Body mass index, ECOG=Eastern Cooperative Oncology Group score, ASA=American Society of Anesthesiologists grade, *n*=Number of patients

Table 2: Perioperative findings, postoperative complications, and oncological outcomes in female patients treated with robot-assisted radical cystectomy and urinary diversion

Variable	Value
Median console time, *n* (IQR)	290 (251–324.5)
Average cystectomy time, *n* (IQR)	100 (82–120)
Average lymph node dissection time, min (IQR)	55 (45–75)
Average urinary diversion time, min (IQR)	130 (101–153)
Median blood loss, ml (IQR)	170 (140–200)
Median time to oral feeds, h (IQR)	72 (43–92)
TPN and prolonged ileus	3
Median hospital stay, *n* (IQR)	8 (7–11)
Median lymph node yield, *n* (IQR)	20 (16–29)
Pathological final staging	
pT0	3
pT1	3
pT2	16
pT3	16
pT4a	3
pN1	5
Clavien–Dindo complications, *n* (%)	
Grade I	8 (19.5)
Grade II	4 (9.8)
Grade IIIa	3 (7.3)
Recurrence	7
5-year survival (%)	
Stage 2	78
Stage 3	41
Stage 4	41
7-year survival (%)	70.2
Cancer-specific survival (%)	63.8
5-year survival, % (IQR)	
TCC	74 (59–82)
Non-TCC	35 (10–91)

IQR=Interquartile range, *n*=Number of patients, TCC=Transitional cell carcinoma, TPN=Total parenteral nutrition

cystectomy for localized, MIBC who developed recurrence after 5 years. None of the patients had a previous history of upper tract transitional cell carcinoma (TCC). Four patients had failed bacille Calmette–Guerin therapy and multiple high-grade recurrences. Clinical stage showed Stage I in 4 (multiple, refractory, recurrent high-grade TCC), Stage II in 19, Stage III in 14, and Stage IVa in 4 (uterine involvement) patients.

Among 41 patients who underwent radical cystectomy, majority of the urinary diversions were (38 patients) intracorporeal (intracorporeal urinary diversion [ICUD]). In initial two cases, extracorporeal urinary diversion (ECUD) by ileal conduit was done. One patient was converted to open ileal conduit due to injury to right internal iliac artery. One patient had genital organ preserving radical cystectomy and intracorporeal modified Karolinska Studer ileal neobladder. The other 40 patients underwent ileal conduit urinary diversion. The choice of urinary diversion was based on disease status, previous abdominal surgery, and patient's choice and surgeon's experience.

The mean console time for the surgery was 290 min (IQR: 251–324.5) [Table 2]. There were no intraoperative complications. The average cystectomy time was 100 min (IQR: 82–120), lymph node dissection time was 55 min (IQR: 45–75), and urinary diversion time was 130 min (IQR: 101–153). The median hospital stay was 8 days (IQR: 7–11), estimated blood loss was 170 mL (IQR: 140–200), and resumption of oral feeds with semisolid diet was 72 h (IQR: 43–92). The total parenteral nutrition (TPN) was given to three patients who had prolonged ileus.

The median lymph nodes dissected were 20 (IQR: 16–29) and five patients had lymph node metastasis. Pathological final staging was pT1 in 3 (7.3%), pT2 in 16 (39.1%), pT3 in 16 (39.1), pT4a in 3 (7.3%), and pT0 in 3 (7.3%) patients. All cases were negative for surgical margins on final report. There was no 30-day mortality among these patients. Postoperatively, three patients had prolonged ileus and one patient had urinary leak from ureteroileal anastomosis treated with PCN. None of the patients required resurgery in 30 days.

Clavien–Dindo classification of 30-day postoperative complications included Grade I in 8 (19.5%) patients and Grade II in 4 (9.8%) patients where 3 required TPN and one required blood transfusion. Grade IIIa complications occurred in 3 (7.3%) patients who required pigtail insertion for pelvic lymph fluid collection. Only 14 patients of pT3, pT4, and N1 received adjuvant gemcitabine and cisplatin chemotherapy four cycles. Three patients were not eligible due to decreased GFR; other patients refused chemotherapy.

During follow-up, four patients developed stomal hernia and laparoscopic mesh hernia repair was done. One patient who had uncontrolled diabetes, developed recurrent pyelonephritis and was managed by long-term antibiotics. One patient developed pyloric stenosis for which gastrojejunostomy was done. Two patients developed symptomatic pelvic lymphocele one after 9 months and other 11 months, treated by pigtail insertion.

Recurrences and survival

During median follow-up of 34 months (range: 6–87 months), seven patients died of disease recurrences and one died due to another cause. All seven patients did not receive adjuvant chemotherapy. Site of disease recurrences at the time of presentation was retroperitoneal nodes in four patients and lung and liver in two and one patient, respectively. They were treated with gemcitabine and cisplatin in eligible patients or paclitaxel in ineligible patients. Two patients took second-line chemotherapy with paclitaxel and carboplatin. Seven-year overall survival rate was 70.2% [Figure 1] and cancer-specific survival was 63.8%. We calculated survival differences between TCC (n = 32) and non-TCC (n = 9, squamous cell carcinoma (SCC) 7 and adenocarcinoma 2). The 5-year survival was 74% (95% CI: 59–82) in TCC group and was 35% (95% CI: 10–91) with P value of 0.04, respectively [Figure 2].

Analysis of impact of final pathological stage was done between Stage 0, 1, and 2. Stage 3 and 4 were analyzed together as they have similar survival outcomes. There was no mortality in Stage 0 and 1; 5-year survival was 78% in Stage 2 and 41% in Stage 3 and 4 [Figure 3].

DISCUSSION

Radical cystectomy with pelvic lymphadenectomy has been the mainstay of treatment for MIBC and non-MIBC refractory to treatment.[7] Although initially performed by open techniques, the patient discomfort and morbidity associated with it has led the way to minimally invasive techniques.[8] Cathelineau *et al*. illustrated a substantial number of patients undergoing laparoscopic radical cystectomy and ileal conduit (RCIC).[9] Soon, the paradigm shifted toward robotic approach, when Guru *et al*. and Pruthi and Wallen demonstrated RCIC robotically in a small number of male patients.[1,3] Menon *et al*. documented RARC for the first time in females in a series of three patients, two out of whom underwent uterus and vagina sparing surgeries.[10] Since then, the number of robotic radical cystectomies has only been increasing in view of the benefits provided by a robot, namely improved ergonomics, magnification, and enhanced three-dimensional vision, thus decreasing patient morbidity.[1]

We performed robotic anterior exenteration in 35 out of 41 women. In females, traditionally, anterior exenteration

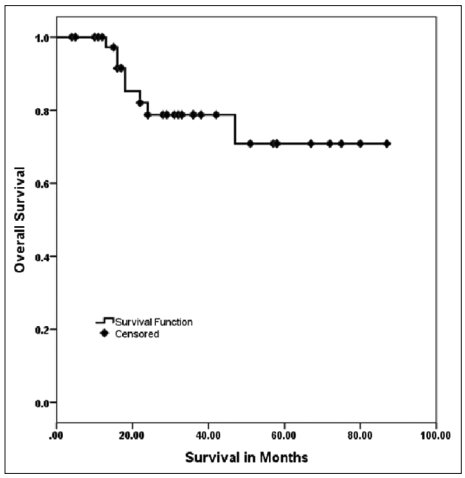

Figure 1: Estimated probability of overall survival with Kaplan–Meier analysis in female patients treated with robot-assisted radical cystectomy and urinary diversion

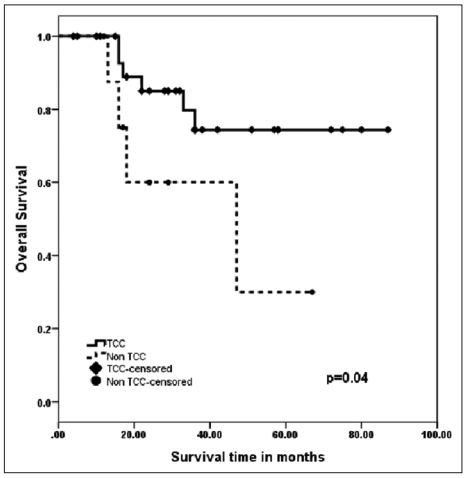

Figure 2: Estimated probability of overall survival with Kaplan–Meier analysis in female patients treated with robot-assisted radical cystectomy and urinary diversion. Stratification based on the histological variant of the disease into TCC and non-TCC. TCC = Transitional cell carcinoma

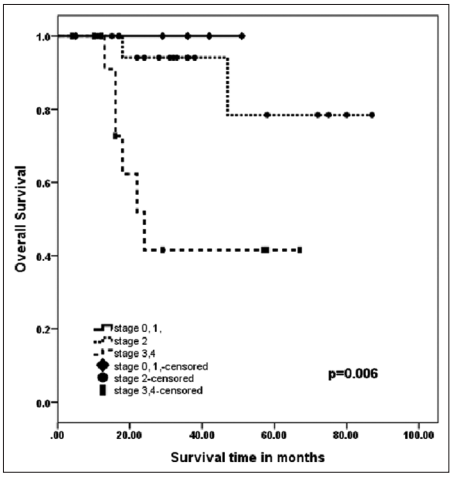

Figure 3: Estimated probability of overall survival with Kaplan–Meier analysis in female patients treated with robot-assisted radical cystectomy and urinary diversion. Stratification based on the stage of the disease

has been the preferred approach. It involves simultaneous removal of the uterus, bilateral ovaries, fallopian tubes, and anterior vaginal wall along with the bladder.[11] It has been postulated to reduce the local recurrence along with adequate oncological control as female genital organs can be involved in up to 7.5% of cases.[12] Gregg *et al*. gave the concept of organ-sparing cystectomy in patients with nontrigonal impalpable tumors without lymphadenopathy.[13] Various reasons described in literature for organ-sparing approach are the support provided by the uterus and vagina to the neobladder, thus preventing kinking of the urethrovesical anastomosis and hypercontinence, preservation of sexual function, and reduction in size of specimen, which can be retrieved by a smaller incision.[10] We used the organ-sparing approach in one such patient. The concept of nerve-sparing cystectomy in females is common. Nerve preservation improves postoperative urinary and sexual outcomes. Avoidance of dissection on the lateral vaginal walls and around the urethra preserves nerves traveling to the external sphincteric muscle fibers, vagina, and clitoris.[10]

There have been mixed opinions about ICUD in the literature. Although the International Robotic Cystectomy Consortium reported favorable outcomes with respect to operative time, blood loss, and the resultant intraoperative transfusion in ICUD, they also observed a higher rate of high-grade complications.[14] However, this theory was later opposed by Bertolo *et al*. from the Cleveland Clinic who found ICUD to have a longer operative time and similar complication rates.[15] The initial two patients in our series underwent ECUD. Intracorporeal approach was used in the next 38 patients as experience was gained The mean operative time and blood loss were 290 min and 170 ml respectively, comparable to Kaufmann *et al*.[16] This was in spite of 13 patients in our study having a past history of abdominal surgery.

The oncological principles followed in male and female cystectomy are quite similar; however, we would like to highlight a few technical differences between the two based on our experience. Women have a rudimentary dorsal venous complex,[17] which does not bleed as much as in males. Second, in our view, the gynecological pelvis is roomier and has much more space to operate. Third, our dissection in the posterior aspect of urethra is much faster as chances of rectal injury are lesser due to presence of vagina. Finally, extraction of entire specimen through the vagina prevents the need for a lengthy scar.

Oncologically, our study drew equivalence with Pruthi *et al*.[18] as the mean lymph nodes harvested were 20 as compared to 19. Both the studies did not have any positive margins. The authors believe that the added advantages of robotic approach helped in adequate oncological control even though 19 (46.34%) patients had pT3 and pT4a on final histopathology report.

The recurrence rate in our series was 17% close to the rates in the study by Gregg *et al*.[13] However, Shim *et al*.[19] had a recurrence rate of 29.9%, which could be due to high margin positivity rate in them as compared to ours. The 5-year survival in the current study was 41% in Stage 3 and 4, similar to Shim *et al*.[19] who had survival rates of 56%, 45%, and 38% in pT3N0, pT4N0, pTanyN1-2, i.e., in stages 3 and 4. A reason could be majority of the patients were operated by us within 6 weeks of diagnosis. Studies have suggested inferior survival rates in cases when time period between diagnosis and definitive surgery is prolonged.[20]

We observed a lower 5-year survival rate in non-TCC bladder cancers, which was statistically significant. Although Rogers *et al*. attributed the poorer prognosis of non-TCC subtypes to the more aggressive forms like adenocarcinoma and carcinosarcoma, they found no differences in the behavior of SCC and TCC.[21] Girgin *et al*. suggested non-TCC subtype to be a predictor of decreased disease-specific survival like in our study.[22]

The limitations of the study are that it is an observational study performed in a single institute. The study is also a retrospective one with lack of assessment of functional or quality of life outcomes and the sample size is small.

CONCLUSION

Although technically challenging, RARC is a safe and feasible option for the treatment of bladder cancer in females. With increasing experience in robotic surgery, the patient morbidity has significantly reduced. Our study highlights acceptable clinical, perioperative, and oncological outcomes of robotic approach for anterior exenteration. Based on findings in this study, it is felt that RARC may be incorporated in treating MIBC in females more frequently. However, series with larger numbers are needed to confirm its validity.

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