

Efficacy of robot-assisted radical cystectomy (RARC) in advanced bladder cancer: results from the International Radical Cystectomy Consortium (IRCC)

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Objective

To characterise the surgical feasibility and outcomes of robot-assisted radical cystectomy (RARC) for pathological T4 bladder cancer.

Patients and Methods

Retrospective evaluation of a prospectively maintained International Radical Cystectomy Consortium database was conducted for 1118 patients who underwent RARC between 2003 and 2012.

We dichotomised patients based on pathological stage (\leq pT3 vs pT4) and evaluated demographic, operative and pathological variables in relation to morbidity and mortality.

Results

In all, 1000 \leq pT3 and 118 pT4 patients were evaluated. The pT4 patients were older than the \leq pT3 patients ($P = 0.001$).

The median operating time and blood loss were 386 min and 350 mL vs 396 min and 350 mL for pT4 and \leq pT3, respectively.

The complication rate was similar (54% vs 58%; $P = 0.64$) among \leq pT3 and pT4 patients, respectively. The overall 30- and 90-day mortality rate was 0.4% and 1.8% vs 4.2% and 8.5% for \leq pT3 vs pT4 patients ($P < 0.001$), respectively.

The body mass index (BMI), American Society of Anesthesiology score, length of hospital stay (LOS) >10 days, and 90-day readmission were significantly associated with complications in pT4 patients.

Meanwhile, BMI, LOS >10 days, grade 3–5 complications, 90-day readmission, smoking, previous abdominal surgery and neoadjuvant chemotherapy were significantly associated with mortality in pT4 patients. On multivariate analysis, BMI was an independent predictor of complications in pT4 patients, but not for mortality.

Conclusions

RARC for pT4 bladder cancer is surgically feasible but entails significant morbidity and mortality.

BMI was independent predictor of complications in pT4 patients.

Keywords

IRCC, robot-assisted, radical cystectomy, bladder cancer, efficacy

Introduction

Although radical cystectomy (RC) and pelvic lymph node (LN) dissection is well established as the 'gold-standard' treatment for muscle-invasive and high-risk non-muscle-invasive bladder cancer [1], the management of locally advanced bladder cancer continues to be controversial. In the absence of local treatment, locally advanced bladder cancer can lead to adverse pelvic and urinary symptomatology, in addition to disease progression, and such local symptoms significantly decreases patient quality of life [2]. Accordingly, it has been suggested that patients with locally advanced bladder cancer may benefit from RC as a palliative procedure or as part of a multimodality attempt towards curative intent [3,4]. However, due to significant reported morbidity and mortality of open RC in the setting of locally advanced bladder cancer, local extirpation has been questioned [5].

Robot-assisted RC (RARC) has emerged as an alternative approach to open RC based on an improved profile in terms of blood loss, transfusion rate, need for postoperative analgesia, recovery of bowel function, and length of hospital stay (LOS) [6–8]. Prior to the present study, the application of a robot-assisted approach to locally advanced bladder cancer has not been appropriately assessed due to previous selection bias for low-volume and LN-negative disease. It has been questioned whether the robot-assisted approach may lead to inferior outcomes in this setting due to a lack of tactile sensation, which may aid in avoiding positive surgical margins and in achieving complete resection. We sought to characterise the feasibility and surgical outcomes of RARC for pathological T4 bladder cancer.

Patients and Methods

A retrospective analysis of the prospectively maintained database of the International Robotic Cystectomy Consortium (IRCC), a collaborative effort of over 20 institutions comprising ≈1300 patients treated with RARC for bladder cancer, was performed. We dichotomised patients based on pathological tumour stage into patients with ≤pT3 and pT4 tumours.

Specific clinical and pathological data was collected and analysed for patients which included: demographic variables (age, gender, body mass index [BMI], American Society of Anesthesiology [ASA] score, and smoking), preoperative disease characteristics (preoperative chemotherapy, abdominal

surgery, and radiation), operative variables (estimated blood loss [EBL], LOS, length of intensive care unit (ICU) stay, type of diversion, and technique of diversion; intracorporeal vs extracorporeal), pathological characteristics (tumour stage, LN yield, and number of positive LNs), and 90-day postoperative outcomes (complications, readmission and mortality).

Patient comorbidity was assessed preoperatively using the ASA score. Complications were identified, defined and classified using the modified Clavien system [9]. The technique of RARC and pelvic LN dissection varied according to the individual surgeon and institution. Urinary diversion was performed both by intracorporeal and extracorporeal techniques.

Descriptive statistics, such as frequencies and relative frequencies, were computed for all categorical outcomes. Numeric outcomes were summarised using summary statistics such as the mean, standard deviation (SD), range, etc. Associations between baseline characteristics and pathological stage were statistically assessed using Fisher's exact test for categorical outcomes, and Wilcoxon rank-sum test for continuous outcomes. Univariate and multivariate logistic regression models were fit to evaluate preoperative, operative and postoperative predictors of readmission, complication and mortality. All statistical analysis was performed using SAS software (version 9.3, SAS Institute Inc., Cary, NC, USA). All tests were two-side, with statistical significance defined as $P < 0.05$.

Results

In all, 1000 ≤pT3 and 118 pT4 patients were analysed. The pT4 patients were older than the ≤pT3 patients, at a mean of 70 and 67 years, respectively ($P = 0.001$). Both groups were comparable for gender, ASA score, rates of prior abdominal surgery or neoadjuvant chemotherapy, LOS, EBL and operating time. The intraoperative blood transfusion rate was significantly higher among pT4 patients compared with ≤pT3 patients, at 12% vs 4%, respectively ($P = 0.049$).

There were statistically significant differences between ≤pT3 and pT4 patients for BMI (27.8 and 26.3 kg/m², respectively; $P = 0.008$), and salvage cystectomy after radiation (1.4% and 5.9%, respectively; $P < 0.001$).

The mean number of LNs removed was not significantly different between ≤pT3 and pT4 patients (19.2 vs 17.3, respectively; $P = 0.145$); however, more pT4 patients had positive LNs (55% vs 23%; $P < 0.001$). The rate of positive surgical margin at cystectomy was 4% and 31.5% ($P = 0.001$) for ≤pT3 and pT4 patient, respectively.

The mean follow-up time for pT4 and ≤pT3 patients was 10.6 and 17 months, respectively ($P < 0.001$). The pT4 patients underwent ileal conduit more often than the ≤pT3 patients (87% vs 66%; $P < 0.001$). The length of ICU stay was 1 day

Table 1 Patient demographics.

	Pathological stage ≤ 3	Pathological stage 4	P
Preoperative characteristics			
Overall number of patients	1000	118	
Age, years			0.001
mean (SD)	67 (0.4)	70 (0.9)	
median (range)	68.0 (26–90)	72.0 (28–90)	
Male gender, %	80	76	0.40
BMI, kg/m ² :			
mean (SD)	27.8 (0.2)	26.3 (0.5)	0.01
Obese (>30 kg/m ²), n (%)	78 (9)	9 (8)	0.90
ASA score ≥ 3 , n (%)	578 (58)	77 (66)	0.12
Neoadjuvant chemotherapy, n (%)	139 (14)	17 (14)	0.90
Clinical stage, n (%)			<0.001
$\leq T2$	673 (93)	63 (76)	
$>T2$	52 (7)	20 (24)	
Preoperative radiation, n (%)	14 (1.4)	7 (5.9)	<0.001
Prior abdominal surgery, n (%)	421 (42)	46 (39)	0.52
Diversion type, n (%):			<0.001
ileal conduit	659 (66)	103 (87)	
continent	341 (34)	15 (13)	
Diversion location, n (%):			0.625
intracorporeal	755 (76)	94 (80)	
extracorporeal	208 (21)	22 (19)	
Pathological outcomes			
Positive surgical margins, n (%)	43 (4.4)	34 (31.5)	<0.001
LN positive, n (%)	228 (23)	65 (55)	<0.001
LN yield:			0.15
mean (SD)	19.2 (0.4)	17.3 (1.1)	
median (range)	18 (0.0–74.0)	17 (0.0–54.0)	
Follow-up, months:			<0.001
mean (SD)	17.0 (0.6)	10.6 (1.2)	
median (range)	11 (0.0–85.0)	6 (0.0–61)	
Perioperative outcomes			
Overall operating time, min			0.47
mean (SD)	406.0 (3.9)	394.6 (9.6)	
median (range)	396 (50.0–862)	386 (0.0–618)	
EBL, mL:			0.47
mean (SD)	450.9 (12.1)	522.8 (51.5)	
median (IQR)	350.0 (0.0–3900)	350.0 (0.0–3700)	
Intraoperative transfusion, n (%)	10 (4.0)	4 (11.8)	0.049
ICU stay, days:			<0.001
mean (SD)	1.0 (0.1)	1.8 (0.4)	
median (IQR)	0.0 (0–36)	1.0 (0–21)	
Hospital stay, days:			0.84
mean (SD)	11.1 (0.3)	11.1 (0.7)	
median (IQR)	9.0 (0–78)	9.0 (1–57)	
Complications, n (%)			0.64
Clavien 1–2	349 (35)	45 (38)	
Clavien 3–5	190 (19)	24 (20)	
Readmission, n (%)			0.32
30 days	114 (11)	9 (8)	
90 days	174 (17.4)	23 (19.5)	
Mortality, n (%)			<0.001
30 days	4 (0.4)	5 (4.2)	
90 days	18 (1.8)	10 (8.5)	

and 1.8 days for $\leq pT3$ and $pT4$ patient, respectively ($P < 0.001$). The complication rate was similar between $\leq pT3$ and $pT4$ patients (54% vs 58%) with 19.0% and 20% of the complications being Clavien grade ≥ 3 , respectively. The 90-day readmission was similar. The overall 30- and 90-day mortality rate was 0.4% and 1.8% vs 4.2% and 8.5% for $\leq pT3$ and $pT4$ patients, respectively ($P < 0.001$; Table 1).

On univariate analysis, BMI, ASA score, LOS >10 days, and 90-day readmission were significantly associated with complications in $pT4$ patients (Table 2). However, on multivariate analysis, only BMI was an independent predictor of complications in $pT4$ patients (Table 2). Meanwhile, on univariate analysis BMI, LOS >10 days, Clavien grade 3–5 complications, 90-day readmission, smoking, previous

Table 2 Univariable and multivariable logistic regression analysis to evaluate variables associated with 90-day complications.

Variable	90-Day complications	
	OR (95% CI)	P
Preoperative variables – univariable analysis		
Gender (female vs male)	1.0 (0.43–2.34)	1.000
Age at surgery (10-year interval)	1.1 (0.72–1.58)	0.744
BMI (kg/m ²)	1.1 (1.04–1.22)	0.005
Obese (BMI >30 kg/m ² , yes/no)	8.0 (0.97–66.34)	0.054
Preoperative chemotherapy (yes/no)	1.2 (0.41–3.22)	0.79
Current smoker (yes/no)	2.42 (0.98–5.98)	0.06
ASA 3–4 vs 1–2	0.50 (0.23–1.09)	0.08
Preoperative variables – multivariable analysis		
Gender (male vs female)	1.30 (0.43–3.92)	0.65
Age at surgery (10-year interval)	1.20 (0.72–1.99)	0.49
BMI (kg/m ²)	1.12 (1.02–1.22)	0.02
Current smoker (yes/no)	2.90 (0.98–8.68)	0.06
ASA (1–2 vs 3–4)	0.34 (0.12–1.02)	0.05
Preoperative chemotherapy (yes/no)	0.90 (0.25–3.10)	0.85
Intraoperative variables – univariable analysis		
Operating room time (≤6 vs >6 h)	0.58 (0.27–1.25)	0.16
EBL (≤800 vs >800 mL)	3.0 (0.90–10.10)	0.08
Type of urinary diversion (continent vs conduit)	0.63 (0.21–1.90)	0.41
Location of diversion (intra vs extracorporeal)	2.50 (0.95–6.80)	0.03
Intraoperative variables – multivariable analysis		
Operating room time (≤6 vs >6 h)	0.58 (0.26–1.30)	0.19
EBL (≤800 vs >800 mL)	3.26 (0.93–11.40)	0.06
Type of urinary diversion (continent vs conduit)	2.69 (0.93–7.77)	0.06
Postoperative variables – univariable analysis		
Hospital stay (<10 vs ≥10 days)	2.14 (1.00–4.56)	0.047
ICU stay	1.15 (0.94–1.42)	0.18
90-day readmission	32.35 (4.17–250.87)	0.0009
Postoperative variables – multivariable analysis		
Hospital stay (<10 vs ≥10 days)	1.49 (0.60–3.80)	0.40
ICU stay	1.13 (0.92–1.40)	0.24

abdominal surgery, ileal conduit diversion and neoadjuvant chemotherapy were significantly associated with overall mortality in pT4 patients. On multivariate analysis, BMI was an independent predictor of complications in pT4 patients, but not an independent predictor for mortality (Tables 2,3).

Discussion

To date, only small case series have been reported regarding RC in pT4 bladder cancer, and data about cancer outcomes are sparse, and no reports specifically address efficiency of RARC in locally advanced bladder cancer [10,11].

Long-term survival is dismal when bladder cancer invades the pelvic sidewall or adjacent structures, yet RC can provide palliation and accurate staging [12]. The rationale behind advocating RC in locally advanced disease could be explained by increasing evidence supporting meticulous surgical clearance with extended lymphadenectomy both of which can significantly impact disease-free survival [13]. Hence, 'debulking' surgery may have oncological benefit in bladder cancer, as is well established in other malignancies, e.g. ovarian cancer. In the randomised Southwest Oncology Group (SWOG) trial in which neoadjuvant chemotherapy followed

Table 3 Univariable and multivariable logistic regression analysis to evaluate variables associated with 90-day mortality.

Variable	90-Day mortality	
	OR (95% CI)	P
Preoperative variables – univariable analysis		
Gender (female vs male)	0.98 (0.41–2.34)	0.96
Age at surgery (10-year interval)	1.04 (0.70–1.55)	0.85
BMI (kg/m ²)	1.10 (1.02–1.20)	0.013
Obese (BMI >30 kg/m ² , yes/no)	3.40 (0.80–14.43)	0.096
Preoperative chemotherapy (yes/no)	3.35 (1.14–9.84)	0.028
Current smoker (yes/no)	3.29 (1.23–8.80)	0.018
ASA 3–4 vs 1–2	1.69 (0.76–3.78)	0.20
Prior abdominal surgery	2.38 (1.10–5.13)	0.027
Preoperative variables – multivariable analysis		
Gender (male vs female)	1.20 (0.42–3.46)	0.76
Age at surgery (10-year interval)	1.09 (0.65–1.82)	0.75
BMI (kg/m ²)	1.07 (0.99–1.16)	0.11
Current smoker (yes/no)	2.69 (0.90–8.10)	0.08
ASA (1–2 vs 3–4)	1.16 (0.44–3.10)	0.77
Preoperative chemotherapy (yes/no)	2.32 (0.69–7.71)	0.17
Intraoperative variables – univariable analysis		
Operating room time (≤6 vs >6 h)	0.70 (0.32–1.54)	0.38
EBL (≤800 vs >800 mL)	1.82 (0.61–5.45)	0.29
Type of urinary diversion (continent vs conduit)	0.20 (0.04–0.93)	0.04
Location of diversion (intra vs extracorporeal)	1.30 (0.53–3.423)	0.54
Intraoperative variables – multivariable analysis		
Operating room time (≤6 vs >6 h)	0.63 (0.28–1.43)	0.27
EBL (≤800 vs >800 mL)	2.19 (0.70–6.77)	0.17
Type of urinary diversion (continent vs conduit)	1.38 (0.52–3.68)	0.52
Postoperative variables – univariable analysis		
Hospital stay (<10 vs ≥10 days)	2.60 (1.20–5.60)	0.015
ICU stay	1.10 (0.95–1.27)	0.19
90-day readmission	3.39 (1.29–8.92)	0.013
Complications		
Clavien 0 vs 3–5	0.15 (0.049–0.45)	0.0007
Clavien 1–2 vs Clavien 3–5	0.67 (0.24–1.87)	0.45
Postoperative variables – multivariable analysis		
Hospital stay (<10 vs ≥10 days)	1.22 (0.47–3.14)	0.66
ICU stay	1.10 (0.92–1.25)	0.40
Complications		
Clavien 0 vs 3–5	0.11 (0.01–1.47)	0.10
Clavien 1–2 vs Clavien 3–5	0.74 (0.23–2.33)	0.25

by RC compared with RC alone showed a survival benefits in patients who received neoadjuvant chemotherapy with T2 disease (105 vs 75 months; $P = 0.05$) and for T3 or T4a disease (65 vs 24 months; $P = 0.05$) [3]. The data for adjuvant chemotherapy are less compelling. However, benefits may be derived for patients who progress to extensive disease [14,15]. Neoadjuvant chemotherapy was administered to 14.4% patients in present cohort, despite proved efficacy.

The present outcomes show that operating time, EBL and LOS were comparable between pT4 and ≤pT3 patients. These findings support similar observations by Hayn et al. [16] who reported an EBL of 400 mL, operating time of 6.3 h and LOS of 8 days. The present overall 90-day complication rate was not higher among pT4 patients; however, 90-day mortality was. The present complication rates were similar to those in previously published RARC series, although the high-grade complications were higher [7,8]. Pruthi et al. [17] reported major surgical complications (Clavien grade ≥3) in 8% of their

patients, with 13% of patients having non-organ-confined disease. Higher mortality and high-grade complications in the present series could be explained by the advanced nature of the disease in our series, which has not been addressed in RARC literature and the multi-institutional nature of our series, which represent variation in operative expertise, patient selection, and quality of perioperative care. In the present study, there was no difference in 90-day readmission between \leq pT3 and pT4 patients. Stimson et al. [18] reported a 90-day readmission rate of 26.6%, which was slightly higher than our present pT4 patients (19.5%) for the same period.

In a study by Nagele et al. [10], 20 patients underwent RC for locally advanced bladder cancer (T4a/b), the LOS was 19 days, 50% of patients received an intraoperative blood transfusion and 50% died within a mean (range) interval of 7 (2–19) months. Furthermore, Hemal et al. [11] evaluated the feasibility of laparoscopic RC for loco-regionally advanced bladder cancer in 13 patients and reported a 57% blood transfusion rate, LOS was 11 days, and there was one mortality at \leq 30 days.

In all, 45% of patients with pT4 disease in the present study underwent a LN dissection with negative LNs and a mean LN yield of 17, similar to Tilki et al. [19] who reported 54% incidence of LN metastasis in pT4 bladder cancer. The impact of LN metastasis on survival after RC was reported by Shariat et al. [20] who found that in patients with non-organ-confined and LN-negative disease the progression-free survival (PFS) and cancer-specific survival (CSS) were 55% and 59%, respectively, compared with patients with LN metastasis, where PFS and CSS were only 29% and 37%, respectively.

Local cancer control in terms of total resection is an important predictor of survival in patients with pT4, as patients with positive margins are significantly more likely to have disease recurrence, as demonstrated by Dotan et al. [21]. In the present study, 31.5% of pT4 patients had positive margins compared with 24% reported in an open RC series by Novara et al. [22] and 25% by Tilki et al. [19]. Due to limitation of data, sites of positive margins could not be defined.

One of the primary aims of the present study was to identify predictors of complications and mortality in pT4 patients after RARC. BMI was the only independent predictor of complications. Reyes et al. [23] reported a higher incidence of infection-related complications in patients with higher BMI. Kouba et al. [24] found more stomal complications after RC and ileal conduit diversion in obese patients. In contrast, Poch et al. [25] found that RARC and intracorporeal ileal conduit was feasible for overweight and obese patients compared with patients with normal BMI, and other investigators have found no association between BMI and complications after RC, including RARC [26].

The present study has its limitations. First, the limitations inherent to retrospective analysis. Given the large number of surgeons and their variability, selection and reporting bias might have influenced the results. Second, most surgeons in the IRCC had previous experience in robot-assisted surgery. Thus, results might not be applicable to all urological surgeons. Third, the number of patients varied widely among the institutions. Thus, the overall outcomes might have been influenced by data from the institutions with greater experience. It is crucial to consider the economic impact of robot use to fully evaluate this approach; however, the present data are lacking regarding the cost. Finally, we did not have prospective data on outcomes for functional status and quality of life outcomes. Additional follow-up is needed to assess any long-term oncological or survival outcomes.

In conclusion, RARC for locally advanced bladder cancer is surgically feasible with significant morbidity and mortality. BMI was found to be an independent predictor of complications in pT4 patients.

Conflict of Interest

K.A.G. reports funding from Simulated Surgical Systems, outside the submitted work; and as a Board Member with Simulated Surgical Systems.

All other authors have nothing to disclose.

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Abbreviations: ASA, American Society of Anesthesiology score; CSS, cancer-specific survival; EBL, estimated blood loss; ICU, intensive care unit; IRCC, International Radical Cystectomy Consortium; LN, lymph node; LOS, length of hospital stay; PFS, progression-free survival; (RA)RC, (robot-assisted) radical cystectomy.