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Impact of clinical stage on the outcome of laparoscopic radical cystectomy: a prospective cohort study

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Abstract

Background: Some authors recommend not to perform laparoscopic radical cystectomy (LRC) for large bulky bladder cancer (BC) as the laparoscopic manipulation will be difficult. As there were no prospective studies focusing on the effect of the tumor stage of BC on the outcome of LRC, the aim of this prospective cohort study was to evaluate the effect of tumor stage on the outcome of LRC.

Results: LRC was completed for 47 patients. All patients were followed for at least 1 year, and there was no recurrence. COPD, DM, hypertension and renal impairment were detected, respectively, in 57.4%, 36.2%, 44.7% and 10.6% of patients. Transitional cell carcinoma and squamous cell carcinoma were found, respectively, in 91.5% and 8.5% of patients. Complications were reported in 29.78% including 29.78% Clavien grade 1, 17.02% grade 2 and 6.38% grade 3. There was no significant difference between cT2 and cT3 in perioperative criteria including demographic features, operative time, estimated blood loss, blood transfusion, pain score, hospital stay and complications. Upon final pathological assessment, 44.68% of patients were upgraded to higher pathological stages. Additional comparison was performed according to pathological stage and revealed no significant difference in the outcome of LRC between pT2 and higher stages except the pain score at first postoperative day which was higher in patients with pT3 stage.

Conclusion: LRC is a feasible and safe technique for both T2 and T3 clinical and pathological stages.

Keywords: Laparoscopic radical cystectomy, Clinical stage, Pathological stage, Complications

1 Background

Open radical cystectomy (ORC) is the standard of care for treatment of muscle-invasive bladder cancer (BC) [1–7]. However, ORC is associated with a significant complication rate [1, 3, 8–11].

Therefore, there has been a widespread shift toward minimally invasive surgery including robotic and laparoscopic RC (LRC) to reduce these complications and to improve the recovery time with comparable oncological outcome to ORC [1, 2, 8]. However, most LRC series had a selection bias as they favored patients with more localized disease and less comorbid conditions leaving more complicated cases to the open surgery [1, 2]. Therefore, the rate of patients with localized disease; pT2 or less, undergoing LRC was reported to be 70% in some studies [8]. Some authors recommend not to perform laparoscopy for large bulky tumors as the laparoscopic manipulation will be difficult due to reduced working space together with the increased incidence for associated nearby organ involvement which may necessitate their resection. They prefer ORC which is more suitable for these complicated circumstances [2]. As there were no prospective studies focusing on the effect of the tumor stage of BC on the outcome of LRC, the aim of this study

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was to compare the outcome of LRC for patients with cT2 versus cT3.

2 Method

2.1 Study design and inclusion criteria

This is a prospective cohort study that recruited patients with cT2–3 BC amenable for LRC from January 2015 to March 2017. Patients with American Society of Anesthesiologists (ASA) score of > 3, clinically positive lymph nodes (L.N.s), BMI ≥ 35, multiple prior abdominal and pelvic open surgical procedures and/or severe pulmonary restrictive conditions precluding safe pneumoperitoneum were excluded.

2.2 Clinical assessment

History taking, clinical examination and basic laboratory tests were performed for all patients to assess their performance status. Additionally, age-adjusted Charlson comorbidity index in addition to ASA score was assessed in each patient. Preoperative staging was performed using CT abdomen and pelvis with IV contrast. CT was replaced by MRI for patients with renal impairment or contrast allergy. CT chest without contrast was also performed. Cystoscopic biopsy/TURBT was performed for all patients. All patients were clinically staged using the 2010 tumor–node–metastases (TNM) staging system from the American Joint Committee on Cancer (AJCC).

The study was approved by the local ethical committee, and an informed written consent was taken from all patients.

2.3 Surgical management and postoperative care

Neoadjuvant chemotherapy was used for fit patients whenever possible. All patients underwent preoperative bowel preparation. DVT prophylaxis was performed using prophylactic dose of low molecular weight heparin the night before the procedure and continued for 5 days in addition to wearing above-knee elastic stockings. Prophylactic third-generation cephalosporin and metronidazole were administered 2 h before induction of anesthesia. Patients were placed in the low lithotomy position to facilitate access to the rectum and perineum. Patient's arms were secured to their sides in an adducted position. Pneumoperitoneum was obtained using a veress needle placed at the umbilicus. LRC was performed using 4–5 ports which were placed in a fan-shaped manner across the lower abdomen in addition to 10-mm camera port one finger breadth above the umbilicus (Fig. 1). Patients were then placed in a steep Trendelenburg position. After complete radical dissection of the bladder, the specimen was placed immediately in an impermeable retrieval bag. Obturator, external, internal, common iliac lymph nodes were dissected.

Pfannenstiel or midline incision (7–10 cm) was performed for both retrieval of the specimen and extracorporeal urinary reconstruction. A Studer orthotopic neobladder was reconstructed. Alternatively, ileal conduit was performed if the tumor was involving the prostatic urethra, the patient had renal impairment or poor performance status. The urethro-ileal anastomosis was performed intracorporeally after closure of the Pfannenstiel or midline incision and re-establishing pneumoperitoneum. All ureterointestinal anastomoses were stented with an 8 Fr external feeding tube which was removed 5–9 days postoperatively before discharge. Tube drains were removed after stent removal. Neobladder patients were discharged with a urethral catheter which was removed 2 weeks postoperatively following a pouchogram to rule out leakage. All our patients were ambulant on first day following the surgery.

2.4 Data collection and follow-up

Perioperative data were collected. Patients were classified according to tumor stage into T2 or T3 groups. The perioperative data including operative time, estimated blood loss (EBL), blood transfusion, complications, return of bowel activity and hospital stay of these groups were compared.

Complications were reported according to the Clavien–Dindo classification [12]. Additionally, postoperative pain score was calculated according to the numeric rating scale (NRS-11) which is an 11-point scale for patient self-reporting of pain [13].

Follow-up ultrasonography of abdomen and pelvis was performed at the first month then every 3 months during the first year and then biannually together with CT/MRI of abdomen and pelvis every 6 months.

2.5 Statistical analysis

Data were coded and entered using the statistical package SPSS (Statistical Package for the Social Sciences) version 24. Comparisons between quantitative variables were done using the parametric Student *t* test or the non-parametric Mann–Whitney test according to normality of data. For comparing categorical data, Chi-square (χ^2) test was performed. Fisher's exact test was used instead when the expected frequency was less than 5. *p* values less than 0.05 were considered as statistically significant. We calculated the sample size based on assuming that a mean difference of 10 min in cystectomy time between cT2 group and cT3 group will be significant. The minimum sample size was found to be 17 participants in each group to be able to reject the null hypothesis in the presence of an 80% power and a 5% α error level. Calculations were done using PS Power and Sample Size Calculations

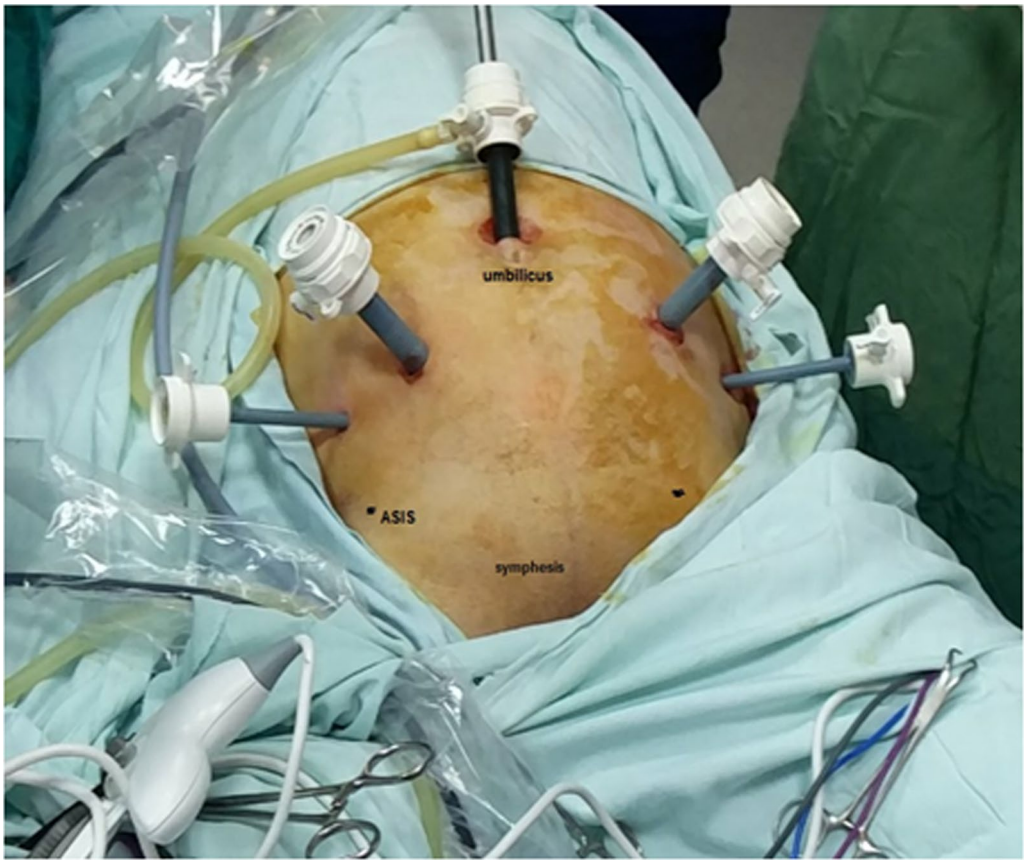

Fig. 1 Port placement distribution

Software, version 3.0.11 for MS Windows (William D, Dupont and Walton D. Vanderbilt, USA).

3 Results

LRC was performed in 47 patients. An additional 2 (4.7%) cases were converted to a palliative chemo-radiotherapy due to fixation to the lateral pelvic wall and non-resectability even upon open exploration. They were excluded from the study as they were pT4 masses. All patients were followed for at least 1 year, and there was no recurrence.

3.1 Demographic, perioperative and pathological data

Demographic, perioperative and pathological data are presented in Table 1. Twenty seven (57.4%), 17 (36.2%), 21 (44.7%), 5 (10.6%) and 7 (14.9%) patients presented, respectively, with COPD, DM, hypertension, renal impairment and hepatitis C virus. However, renal impairment in these five patients was mild (serum creatinine: 1.5–2.1 mg/dL). Additionally, 31 (66%) patients were smoker. Transitional cell carcinoma was the main pathological finding [43 patients (91.5%)]. The remaining four (8.5%) patients had squamous cell carcinoma. No positive margin was found in the 47 patients.

3.2 Complications

Complications were reported in 14/47 (29.78%) patients. Most complications were minor complications including Clavien grade 1 (29.78%) and Clavien grade 2 (17.02%). Only 3 (6.38%) patients suffered from major complications (Clavien grade 3). The most common complication was fever [11 (23.4%) patients]. The remaining complications included wound infection [5 (10.6%) patients], ileus (>5 days) [5 (10.6%)], urine leakage [6 (12.76%)], blood transfusion [8 (17%)] and wound dehiscence [1 (2.1%) patient]. No major vascular or bowel injury was reported. None of our patients had bowel leakage. Wound dehiscence required operative closure under general anesthesia. Additionally, 2 patients with urinary leakage were diagnosed with neobladder–vaginal fistula and required surgical repair after 3 months. The remaining 4 patients with leakage were treated conservatively with prolonged drainage (Table 2).

Table 1 Perioperative criteria and pathological findings

	47 patients
Age (years)	57.65 ± 10.42 (35–78)
Gender	
Male	35 (74.5%)
Female	12 (25.5%)
BMI (kg/m^2)	28.19 ± 3.79 (19.1–34.77)
Preoperative creatinine (mg/dL)	1.27 ± 0.32 (0.6–2)
Preoperative hemoglobin (g/dL)	11.88 ± 1.36 (10–16)
Postoperative creatinine (mg/dL)	1.3 ± 0.33 (0.5–2.1)
Postoperative hemoglobin (g/dL)	10.11 ± 1.15 (8.9–13)
ASA score	3 (1–3)
CCI score	5 (3–9)
Operative time (min)	316.91 ± 35.13 (240–380)
Cystectomy time (min)	146.06 ± 26.92 (105–200)
Diversion time (min)	172.87 ± 28.22 (110–230)
Incision for extracorporeal urinary diversion	
Pfannenstiel	33 (70.2%)
Midline	14 (29.8%)
Extracorporeal urinary diversion type	
Orthotopic neobladder	35 (74.5%)
Ileal conduit	12 (25.5%)
Estimated blood loss (mL)	458.9 ± 359.2 (150–1350)
Pain [numerical rating scale (NRS-11)]	
Day 1	3 (1–6)
Day 5	1 (0–2)
ICU stay (days)	1 (0–3)
Time to bowel activity (days)	2 (1–6)
Hospital stay (day)	10 (5–25)
cTNM staging	
cT2	27 (57.4%)
cT3b	20 (42.6%)
cN0	0
cM0	0
Pathological stage	
pT2b	13 (27.7%)
pT3b	34 (72.3%)
pN0	34 (72.3%)
pN1	10 (21.3%)
pN2	3 (6.4%)
Reoperation	3 (6.38%)
Conversion to open surgery	2/49 (4%)

Values are presented as mean SD (range), median (range) or number (%) as appropriate

CCI age-adjusted Charlson comorbidity index score

3.3 Effect of clinical stage on LRC outcome

We compared the effect of clinical stage on LRC outcome and found no significant difference between cT2 and cT3 in perioperative criteria including operative time, estimated blood loss, pain score, hospital stay and complications (Table 2). Upon final pathological assessment, 21/47 (44.68%) patients were upgraded to higher pathological stages (Table 1). Additional comparison was performed but according to pathological stage. Again, we found no significant difference in the outcome of LRC according to the pathological stage between pT2 and higher stages except the pain score at the first postoperative day which was higher in patients with > pT2 stage (Table 3).

4 Discussion

The current study may be the first prospective study that focused on the comparison of the effect of clinical stage of BC on the outcome of LRC.

The outcome of LRC in the current study was similar to what previously was reported in a systematic review on LRC [1]. In that meta-analysis, Tang et al. compared LRC versus ORC and analyzed sixteen studies (seven prospective and nine retrospective studies) with 1165 cases (545 LRC and 620 ORC). The LRC group had a lower ASA score and a significantly higher proportion of organ confined ≤ pT2 disease and fewer nodal disease (11%) which lead to lower distant metastasis rate (8.6%) and fewer death (8.4%). However, there was no significant difference in other criteria including age, gender, BMI, history of previous surgery, pathological grade and type of diversion [1]. We had a higher incidence of nodal disease (27.7%), but we had no mortalities which may be due to exclusion of T4 cases and short follow-up in the current study. In their meta-analysis, Tang et al. reported that there were no differences between the LRC and ORC in wound dehiscence, neurologic, renal fistula/leak, ureteric obstruction, GI fistula/leak or thromboembolic events. However, LRC had a longer operative time (371.5 min) but significantly fewer overall complications (33.5%) including less blood loss (469.15 mL), less infections especially wound infections, shorter time to ambulation and shorter length of hospital stay (15.3 days), less need of blood transfusion (25.7%), less narcotic analgesic requirement, less ileus (11%) and fewer positive surgical margins (3%) [1]. We had a comparable complications rates (29.78%), ileus (10.6%), blood loss (458.9 mL) and blood transfusion (17%). Furthermore, we had a comparable operative time (316.9 min).

In a more recent study, Khan et al. [8] compared the outcomes of ORC, RARC, and LRC in 60 patients. Similar to our study, the urinary diversion was performed extracorporeally. ORC complication rate (70%) was significantly higher than LRC (26%) but no significant difference in major complications [8]. In the LRC arm (19 patients), the mean operative time (301 min), mean EBL (460 mL) and mean hospital stay (9.7 days) were similar to our results.

Table 2 Comparison of the two groups according to clinical stage

	cT2 27 patients	cT3 20 patients	*p*
Age (years)	58.11 ± 11.48 (35–77)	57.05 ± 9.05 (42–78)	0.743
BMI (kg/m^2)	28.2 ± 4.16 (20.76–34.77)	28.17 ± 3.34 (19.1–32.28)	0.98
Gender			0.943
Male	20 (74.1%)	15 (75%)	
Female	7 (25.9%)	5 (25%)	
Smoking	19 (70.4%)	12 (60%)	0.458
COPD	15 (55.6%)	12 (60%)	0.761
DM	9 (33.3%)	8 (40%)	0.638
Hypertension	11 (40.7%)	10 (50%)	0.528
Renal impairment[a]	1 (3.7%)	4 (20%)	0.148
HCV +ve	3 (11.1%)	4 (20%)	0.438
Preoperative creatinine (mg/dL)	1.24 ± 0.33 (0.6–2)	1.30 ± 0.32 (0.83–2)	0.528
Preoperative hemoglobin (g/dL)	11.9 ± 1.37 (10–16)	11.86 ± 1.38 (10.5–14.5)	0.762
Postoperative creatinine (mg/dL)	1.27 ± 0.34 (0.5–2)	1.33 ± 0.33 (0.9–2.1)	0.983
Postoperative hemoglobin (g/dL)	10 ± 1 (8.9–13)	10.27 ± 1.34 (9–13)	0.663
ASA score	3 (1–3)	3 (1–3)	0.565
CCI score	4 (3–6)	5 (3–9)	0.072
Incision for extracorporeal urinary diversion			0.537
Pfannenstiel	18 (66.7%)	15 (75%)	
Midline	9 (33.3%)	5 (25%)	
Extracorporeal urinary diversion type			0.2
Orthotopic neobladder	22 (81.5%)	13 (65%)	
Ileal conduit	5 (18.5%)	7 (35%)	
Operative time (min)	314.2 ± 35.21 (240–380)	320.5 ± 35.61 (260–380)	0.553
Cystectomy time (min)	142.77 ± 25.73 (110–200)	150.5 ± 28.51 (105–200)	0.322
Diversion time (min)	171.48 ± 24.6 (120–220)	174.75 ± 33.06 (110–230)	0.699
Estimated blood loss (mL)	300 (150–1250)	400 (200–1350)	0.158
Complications (Clavien–Dindo classification)	8 (29.6%)	6 (30%)	0.978
Grade 1	8 (29.6%)	6 (30%)	0.978
Fever	5 (18.5%)	6 (30%)	0.358
Wound infection	2 (7.4%)	3 (15%)	0.638
Ileus (5 days)	2 (7.4%)	3 (15%)	0.638
Urine leakage (conservative)	2 (7.4%)	2 (10%)	1
Grade 2	4 (14.8%)	4 (20%)	0.707
Blood transfusion	4 (14.8%)	4 (20%)	0.707
Grade 3	2 (7.4%)	1 (5%)	1
Wound dehiscence[b]	0	1 (5%)	0.426
Urine leakage (repair of fistula)[c]	2 (7.4%)	0	0.5
Pain [numerical rating scale (NRS-11)]			
Day 1	3 (1–6)	5 (1–6)	0.447
Day 5	1 (0–2)	1 (0–2)	0.779
ICU stay (days)	1 (0–3)	1 (0–1)	0.425
Time to bowel activity (days)	2 (1–5)	2 (1–6)	0.763
Hospital stay (day)	11 (5–17)	10 (5–25)	0.146

Values are presented as mean SD (range), median (range) or number (%) as appropriate

CCI age-adjusted Charlson comorbidity index score

[a] Renal impairment was mild (serum creatinine: 1.5–2.1 mg/dL)

[b] Required surgical closure under general anesthesia

[c] Required surgical repair for a neobladder–vaginal fistula after 3 months

Table 3 Comparison of the two groups according to pathological stage

	pT2 13 patients	pT3 34 patients	*p*
Age (years)	60.9 ± 12.87 (35–77)	56.41 ± 9.24 (42–78)	0.187
BMI (kg/m^2)	27.9 ± 4.21 (20.76–33.9)	28.2 ± 3.68 (19.1–34.77)	0.766
Gender			0.269
Male	8 (61.5%)	27 (79.4%)	
Female	5 (38.5%)	7 (20.6%)	
Smoking	9 (69.2%)	22 (64.7%)	1
COPD	7 (53.8%)	20 (58.8%)	0.758
DM	4 (30.8%)	13 (38.2%)	0.743
Hypertension	4 (30.8%)	17 (50%)	0.263
Renal impairment	1 (7.7%)	4 (11.8%)	1
HCV +ve	1 (7.7%)	6 (17.6%)	0.655
Preoperative creatinine (mg/dL)	1.2 ± 0.36 (0.6–2)	1.29 ± 0.314 (0.80–2)	0.421
Preoperative hemoglobin (g/dL)	12.4 ± 1.31 (11–16)	11.68 ± 1.34 (10–14.5)	0.054
Postoperative creatinine (mg/dL)	1.23 ± 0.43 (0.5–2)	1.32 ± 0.29 (0.9–2.1)	0.729
Postoperative hemoglobin (g/dL)	10.4 ± 1.08 (9–13)	10 ± 1.17 (8.9–13)	0.126
ASA score	2 (1–3)	3 (1–3)	0.409
CCI score	4 (3–5)	5 (3–9)	0.029
Incision for extracorporeal urinary diversion			0.163
Pfannenstiel	7 (53.8%)	26 (76.5%)	
Midline	6 (46.2%)	8 (23.5%)	
Extracorporeal urinary diversion type			0.136
Orthotopic neobladder	12 (92.3%)	23 (67.6%)	
Ileal conduit	1 (7.7%)	11 (32.4%)	
Operative time (min)	321.15 ± 35.12 (250–380)	315.29 ± 35.52 (240–380)	0.614
Cystectomy time (min)	141.92 ± 23.58 (120–180)	147.64 ± 28.26 (105–200)	0.572
Diversion time (min)	179.23 ± 22.53 (130–220)	170.44 ± 30.05 (110–230)	0.345
Estimated blood loss (mL)	300 (200–1200)	350 (150–1350)	0.606
Complications	5 (38.5%)	9 (26.5%)	0.486
Grade 1	5 (38.5%)	9 (26.5%)	0.486
Fever	4 (30.8%)	7 (20.6%)	0.467
Wound infection	1 (7.7%)	4 (11.8%)	1
Ileus (5 days)	1 (7.7%)	4 (11.8%)	1
Urine leakage (conservative)	1 (3.7%)	3 (15%)	1
Grade 2	2 (15.4%)	6 (17.6%)	1
Blood transfusion	2 (15.4%)	6 (17.6%)	1
Grade 3	2 (15.4%)	1 (2.9%)	1
Wound dehiscence[a]	0	1 (2.9%)	1
Urine leakage (repair of fistula)[b]	2 (15.4%)	0	0.5
Pain [numerical rating scale (NRS-11)]			
Day 1	2 (1–5)	5 (1–6)	0.021*
Day 5	1 (0–1)	1 (0–2)	0.642
ICU stay (days)	1 (0–3)	1 (0–2)	0.956
Time to bowel activity (days)	2 (2–5)	2 (1–6)	0.513
Hospital stay (day)	10 (6–14)	10 (5–25)	0.598

Values are presented as mean SD (range), median (range) or number (%) as appropriate

CCI age-adjusted Charlson comorbidity index score

*Significant

[a] Required surgical repair

[b] Required surgery for repair of a neobladder–vaginal fistula after 3 months

In the current study, the clinical stage did not affect the operative and postoperative outcome including operative time, EBL and blood transfusion, complications, return to bowel activity, ICU stay and hospital stay. Moreover, we repeated the analysis according to pathological stage without detecting any significant difference in these parameters between pT2 group and pT3 group. Only postoperative pain on day 1 was less in pT2 group. We found only one study that commented on the tumor stage as a predictor of postoperative complications after LRC [14]. It was a retrospective multicenter study that assessed risk factors for postoperative complications in 548 patients. In that study, urinary diversion was performed mainly via an extracorporeal approach (95%). As regards the pathological stage, 56% of patients had organ-confined disease ($pT \leq 2$) and 44% had locally advanced disease (pT3–4), while 24% had positive nodes. In that study, Albisinni et al. reported a median hospital stay of 14 days and a positive surgical margin rate of 5.8%. Conversion to an open approach occurred in 12 patients (2%), mainly as a consequence of extensive intraabdominal adherences (0.91%) or due to massive bleeding (1.09%). Albisinni et al. reported also a 29% minor complications (Clavien 1–2), while 18% experienced major complications (Clavien ≥ 3). A total of 12% of patients underwent surgical reoperation. Most reoperations were due to bowel leaks, urinary leaks or wound dehiscence [14]. In the current study, we had a similar rate of minor complications but less major complications and also less rate of reoperation (6.38%) which may be due to exclusion of T4 cases. In their retrospective multicenter study, Albisinni et al. [14] reported that increased BMI, blood loss and neoadjuvant treatment were significantly associated with a greater risk of complications. They reported also that a pT status was not a significant predictor of overall complication risk similar to our results.

Although this study will add data to the literature data regarding effect of the clinical and pathological stages on the outcome of LRC, it has its limitations. The number of patients was adequate according to the sample size but more studies with larger number of patients are important for a better analysis of complications and subgroups. Additionally, the study has short-term follow-up. However, it was reasonable for the primary outcome intended in this study.

5 Conclusion

Laparoscopic radical cystectomy is a feasible and safe technique for both T2 and T3 clinical and pathological stages. After establishment of an adequate learning curve, clinical stage of the tumor may not represent a major obstacle in front of LRC.

Abbreviations

AJCC: American Joint Committee on Cancer; ASA: American Society of Anesthesiologists; BC: bladder cancer; EBL: estimated blood loss; LRC: laparoscopic RC; NRS: numeric rating scale; ORC: open radical cystectomy; TNM: tumor–node–metastases staging system.

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Authors' contributions

AAA, MSE, AA and IRS were involved in protocol development and research design, data collection and management, data analysis and manuscript writing/editing. MAEH, AS, AK, MAAH helped in protocol development and data collection. ME contributed to protocol development and research design, and supervision. All authors read and approved the final manuscript.

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Availability of data and material

The datasets generated and/or analyzed during the current study are not publicly available but are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

All procedures performed were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study was approved by the local ethical committee (committee's reference number 15092014). Written informed consent was obtained from all patients included in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no conflict of interest.

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