RESEARCH ARTICLE

Evaluating postoperative complications in radical cystectomy and ileal conduit for bladder cancer using the clavien-dindo grading system

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Abstract

Objective: : To determine the frequency of postoperative complications after radical cystectomy with ileal conduit surgery in patients diagnosed with urinary bladder cancer.

Method: This prospective observational study was conducted at the Department of Urology, Sindh Institute of Urology and Transplantation (SIUT), Karachi, from 30TH December 2019 to 30TH June 2020, following approval from the SIUT Ethics Review Board. The study comprised patients aged 25-70 years diagnosed with urinary bladder cancer who underwent elective radical cystectomy with ileal conduit. Complications were compared with respect to preoperative characteristics, such as disease stage, chemotherapy, radiotherapy, and intraoperative variables, like operation time, predicted blood loss, and the requirement for blood transfusion, as well as postoperative therapies. All postoperative complications occurring within a 60-day period were classified using the Clavien-Dindo grading system. Data was analysed using SPSS 22.

Results: Of the 34 patients, 22(64.7%) were males and 12(35.3%) were females. The overall mean age was 51.00±12.84 years. Grade 0 complications were observed in 14(41.18%) patients, grade 1 13(28.24%), grade 2 3(8.82%), grade 3a 2(5.88%), and grade 4a 2(5.88%). The severity was significantly associated with female gender, preoperative irradiation, larger volume of blood loss, and the requirement of numerous transfusions ($p<0.05$).

Conclusion: The early complications of radical cystectomy and urinary diversion had a substantial impact on the overall success of the procedure.

Keywords: Radical cystectomy, Ileal conduit, Clavien-Dindo classification. (JPMA 75: 1053; 2025)

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Introduction

The standard treatment for patients with non-metastatic muscle-invasive bladder cancer (MIBC) or very-high-risk non-muscle invasive BC (NMIBC) is radical cystectomy (RC), which includes bilateral pelvic lymph node dissection (PLND) and is typically preceded by neoadjuvant chemotherapy (NAC).[1] The majority of individuals exhibit NMIBC, but a subgroup of patients progress to MIBC. RC with urine diversion (UD) and pelvic lymphadenectomy is the primary therapeutic choice for MIBC and it is sometimes used for NMIBC that does not respond to other treatments.[1,2] In males, conventional RC involves the surgical removal of the bladder, prostate, seminal vesicles, distal ureters, and regional lymph nodes (RLNs). In females, standard radical cystectomy includes the removal of the bladder, full urethra, adjacent anterior wall of the vagina, uterus, distal ureters, and RLNs.[3] Although there have been improvements in robot-assisted laparoscopic surgery, there is a lack of substantial evidence proving its superiority over the traditional open approach to RC.[4] RC is associated with a substantial level of morbidity, ranging from 30% to 70%, and a low mortality rate, ranging from 0.3% to 0.5%.[5] There are multiple studies that provide information on the challenges that may crop up after radiation therapy. However, these reports often lack consistency and objectivity in reporting adverse events (AEs).[6] Dindo et al. conducted a survey and evaluated a cohort of 6336 patients. The findings revealed that the participants' Clavien-Dindo (CD) classification was characterised by its straightforwardness (92%), repeatability (91%), logic (92%), practicality (90%) and comprehensiveness (89%).[7] The European Association of Urology (EAU) Ad-hoc Panel sought to validate the CD grading system in the field of urology,[8] with 56.9% of the participants expressing confidence in the reliability of the CD system for categorising postoperative problems. Nevertheless, it was not applicable to issues that arise during surgery, necessitating the utilisation of a different tool. Roghmann et al. discovered that there was a higher occurrence of less severe complications (grades I and II) at 78.2%, and a slightly higher mortality rate (grade V) at 3.9%. On the other hand, Pavone et al. evaluated the 90-day postoperative morbidity in high-risk RC patients using the CD system and found that 46% of complications were classified as low-grade (grades I and II), while the mortality

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rate (grade V) was 3%.[2,6] Johar et al. collected local data in Pakistan to analyse the postoperative problems that occurred within 30 days after RC with ileal conduit (IC). The mortality rate for grade V was 4.5%, with the bulk of complications falling into grade II, accounting for 13.5% cases. Furthermore, 56.2% patients experienced no issues.[9] IC replacement surgery (RC) is associated with increased incidence of complications, especially among the elderly population. The complications might be classified as high-grade (CD III-V) or low-grade (CD I-II). Nevertheless, the lack of standardisation in reporting complications results in inconsistent and subjective statistics, as well as an underestimating of the extent of illness and death due to limited access to data from regional centres.

Given the high volume of cases at the Sindh Institute of Urology and Transplantation (SIUT) in Karachi, assessing the actual morbidity and death rates of the procedure, as well as identifying any additional issues, could be facilitated by employing a well-established and standardised categorization system, such as CD for grading complications following RC with IC. As such, the current study was planned to determine the frequency of postoperative complications after RC with IC surgery in patients diagnosed with BC.

Patients and Methods

This prospective observational study was conducted at the Department of Urology, Sindh Institute of Urology and Transplantation (SIUT), Karachi, from 30th December 2019 to 30th June 2020, following approval from the SIUT Ethics Review Board. The sample size was determined using online OpenEpi calculator,[10] considering a population of 104 cases and a proportion of 17.9% of patients experiencing high-grade complications after RC,[6] with 13% margin of error and 95% confidence interval (CI).

The sample was raised using non-probability consecutive sampling technique. Those included were biopsy-proven urinary BC patients of both genders aged 25-70 years who were categorised as American Society of Anaesthesiologists (ASA) class I or II and were due to underage RC with IC. Patients who were not suitable for general anaesthesia (GA), specifically those classed as ASA III or higher, persons undergoing surgery for tumour recurrence, and patients with metastatic cancer were excluded.

After taking informed written consent prior to surgery, all patients were subjected to thorough investigations to determine the diagnosis and stage of the disease. These investigations included clinical examination, baseline laboratory tests, cystoscopic examination with biopsy and computed tomography (CT) scans of the chest, abdomen and pelvis with intravenous (IV) contrast. Preoperative anaesthesia fitness assessment was conducted and prophylactic antibiotics were administered according to the established protocol. The surgical procedures were performed by a consultant urologist having a minimum of 2 years of experience post-fellowship. The surgeon adhered to strict surgical guidelines for resection and anastomosis, following the established protocol. Every patient received identical postoperative treatment, including standard laboratory tests, such as complete blood count (CBC) and urine analysis (UA). Additional specialised tests, such as cultures, liver function tests (LFTs) and ultrasound, were performed if necessary. In certain cases, chest X-ray (CXR), echocardiogram (Echo), and pulmonary function tests (PFTs) were ordered.

The study's essential parameters were recorded in a proforma at the 60th day after the operation. These factors included the patient's demographics, such as age, gender, and hospital record number. Preoperative factors, such as illness stage, chemotherapy, radiotherapy, and intra-operative factors, such as operation time, predicted blood loss, need for blood transfusion, and postoperative interventions for complications. All complications occurring within 60 days of the surgical procedure were subsequently classified based on the CD grading system.[8]

Data was analysed using SPSS 22. Data was expressed as mean±standard deviation, or as frequencies and percentages, as appropriate. Potential factors that could modify the effect were controlled by stratification, followed by a post-stratification chi-square test. $P<0.05$ was considered significant.

Results

All the 34(100%) patients enrolled completed the study; 22(64.7%) males and 12(35.3%) females. The overall mean age was 51.00±12.84 years. The mean height and weight were 164.84±10.98cm and 62.80±12.31kg, respectively, and the mean body mass index (BMI) was 23.00±3.18kg/m^2 (Table 1).

Table-1: Sociodemographic and clinical characteristics of the participants (n=34).

Parameters	Mean±SD/n (%)
Age (years)	50±12.84
Height (cm)	164.84±10.98
Weight (kg)	62.80±12.31
BMI (kg/m^2)	23.00±3.18
Gender	
Male	22(64.71)
Female	12(35.29)
Comorbidity	
Diabetes Mellitus	2(5.88)
Hypertension	6(17.65)
No known comorbidity	26(76.47)

BMI: Body mass index.

Table-2: Stratification of Age, gender and tumour stage with complications using the Clevian-Dindo grading system.

Complications	Age (year) Groups		*p*-value
	25-50	51-70	
Grade 0	06	08	0.90
Grade 1	07	06	0.37
Grade 2	00	03	0.11
Grade 3a	02	00	0.10
Grade 4a	00	02	0.19
Complications	**Gender**		***p*-value**
	Male	**Female**	
Grade 0	13	01	004
Grade 1	05	08	0.01
Grade 2	02	01	0.94
Grade 3a	00	02	0.05
Grade 4a	02	00	0.28

Complications	Stage of Tumour				*p*-value
	Stage II	Stage IIIa	Stage IIIb	Stage Iva	
Grade 0	04	02	06	02	0.48
Grade 1	00	03	06	04	0.14
Grade 2	01	02	00	00	0.13
Grade 3a	00	00	00	02	0.07
Grade 4a	02	00	00	00	0.04

Grade 0 complications were observed in 14(41.18%) patients, grade 1 13(28.24%), grade 2 3(8.82%), grade 3a 2(5.88%), and grade 4a 2(5.88%). Complications with grades 0, 1 and 3a were significantly associated with female gender, while grade 4a complications were significantly associated with tumour stage (Table 2).

Preoperative radiotherapy correlated with an increased incidence of grade 3a complications ($p<0.0001$). Grade 4a complications were exclusive to patients experiencing 1000-1500ml blood loss ($p=0.007$). Single blood transfusions were associated with a higher incidence of grade 0 problems (Table 3).

Table-3: Stratification of preoperative chemotherapy, radiotherapy, duration of surgery, blood loss and blood transfusion with complications using the Clevian-Dindo grading system.

Complications	Pre-Op Chemotherapy		*p*-value
	Yes	No	
Grade 0	04	10	0.93
Grade 1	06	07	0.09
Grade 2	00	03	0.24
Grade 3a	00	02	0.35
Grade 4a	00	02	0.35
Complications	**Pre-Op Radiotherapy**		***p*-value**
	Yes	**No**	
Grade 0	00	14	0.22
Grade 1	00	13	0.25
Grade 2	00	03	0.65
Grade 3a	02	00	<0.0001
Grade 4a	00	02	0.72

Complications	Duration of Surgery (hours)			*p*-value
	2-4 hours	4-6 hours	6-8 hours	
Grade 0	03	11	00	0.05
Grade 1	00	11	02	0.08
Grade 2	00	03	00	0.75
Grade 3a	00	02	00	0.83
Grade 4a	00	02	00	0.83

Complications	Blood Loss (ml)			*p*-value
	0-500 ml	500-1000 ml	1000-1500 ml	
Grade 0	07	05	02	0.18
Grade 1	02	09	02	0.17
Grade 2	00	03	00	0.19
Grade 3a	02	00	00	0.11
Grade 4a	00	00	02	0.007

Complications	Blood Transfusion		*p*-value
	Single	Multiple	
Grade 0	10	04	0.007
Grade 1	04	09	0.22
Grade 2	01	02	0.70
Grade 3a	00	02	0.19
Grade 4a	00	02	0.19

Discussion

Earlier studies documented overall complication rate 66% and 62% within the initial 90 and 30 days, respectively, after RC. Additionally, significant complications were observed in 24% and 22% patients during the first 90 and 30 days, respectively. Out of the nine patients who had surgery within 90 days, 7(14%) experienced gastrointestinal problems.[11,12] Prior research has demonstrated that the overall incidence of complications following RC differ across medical centres.[13] Yamada et al. gathered data of a large group of patients in Japan related to all postoperative complications following RC, which included open, laparoscopic and robot-assisted procedures.[14] The study found that the overall complication rate was 69%, with high-grade complications occurring in 25% cases within 90 days. This rate was comparable to the rate observed in the current cohort. A recent publication reported an assessment of the Asian Robot-Assisted Radical Cystectomy Consortium database.[15] The overall incidence of complications was 49.2%, with high-grade complications occurring in 16(15.6%) cases.[15]

Only 47% of minimally invasive surgical series met <5 out of the 10 reporting standards. Out of the 36 studies that provided information on the severity of problems, 7(19%) utilised a numerical grading system. The remaining 29(81%) studies used a "major versus minor" categorisation, but they used 26 different criteria to determine what was considered severe.[16] The number of enrolled patients was 467. The median age was 70 years, ranging 35-89 years. Further, 112 cases need the use of an orthotopic neobladder, 217 cases involved an IC and 138 cases involved a cutaneous ureterostomy. The observed abnormalities consisted of Clavien type I (109 patients), type II (220), type IIIa (45), type IIIb (22), type IV (11), and type V (8), totalling 415 cases. Patients who had cutaneous

ureterostomy exhibited a reduced incidence of CD type IIIa (8%) compared to other patients (p=0.03).[17] Applying strict reporting standards revealed that the occurrence of surgical complications after RC was significant and higher than what was previously reported. Accurate reporting of postoperative difficulties following RC is essential for patient counselling, planning combined modality therapy, designing clinical trials, and evaluating surgical performance.[18] Ina study, 79.7% patients experienced surgical issues within 90 days, and, among them, 36.5% were classified as major complications and 43.2% as minor complications.[19] The rate of problems did not diminish with the surgical approach, and RC was found to be a highly burdensome surgery, with perioperative morbidity having a major impact on patient survival.[20]

Malnourished patients may get advantages from minimally invasive robotic surgery, although they nonetheless face an elevated likelihood of extended hospital stay in comparison to well-nourished individuals. Utilising a robotic method in robotic surgery would provide more benefits for patients having preoperative problems, potentially decreasing the extended duration of hospital stay and the heightened need for blood transfusions that are linked to malnourishment.[21] Patients who are on antithrombotic treatment and have underlying comorbidities are at a higher risk of experiencing AEs during RC.[22]

In the current study, there were no deaths related to surgery. A notable correlation was found for severity of complications with female gender, receiving radiation before surgery, experiencing a higher amount of blood loss, and needing repeated transfusions. Essentially, doing a current surgical audit of complications would assist in advising patients and enhancing the outcome by focussing more on surgical approaches to reduce the occurrence of complication of grades III and IV.

The current study has limitation, including 13% margin of error, which indicated difficulties arising from a limited sample size and the infrequency of the condition being examined. The study's statistical power was limited due to just 34 cases from a population of 104, and a low prevalence of high-grade sequelae (17.9%). A further limitation is the brief follow-up period, which did not reveal long-term complications. The sample size was deemed appropriate, taking into account the trial's duration and the difficulties involved with patients presenting at an advanced stage. However, future research is necessary with larger sample size, prolonged follow-up, engage in multicentre collaboration, and utilise stratified sampling to enhance statistical power, improve generalisability, and more effectively evaluate long-term consequences.

Conclusion

Early complications arising from RC and UD, as classified by the CD system, posed a substantial health concern having an impact on the overall success of the surgical treatment. The majority of these complications were classified as low-grade.

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Author Contribution:

SU, LG, SBY, BH, TURG & ASH: Concept, design, data collection, interpretation, drafting, revision and agreed to be accountable for all aspects of the work.