Original Article

Randomized controlled trial to compare outcomes with and without the enhanced recovery after surgery protocol in patients undergoing radical cystectomy

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ABSTRACT

Introduction: Very few randomized controlled trials are available globally to support routine use of enhanced recovery after surgery (ERAS) protocol after radical cystectomy (RC), and none so far has been conducted in the Indian subcontinent. The aim of the present study was to evaluate hospital stay and 30-day perioperative outcomes following RC with the implementation of the ERAS protocol.

Materials and Methods: Fifty-four patients undergoing open RC were randomized to ERAS versus conventional surgical care (CSC) at our center from April 2017 to May 2018. Key interventions included avoidance of mechanical bowel preparation, early nasogastric tube removal, early enteral feeding, and early obligatory ambulation. Follow-up was done till 30-day postoperatively or till discharge, whichever longer.

Results: Twenty-seven patients in each group were analyzed. The demographic profile of the groups was similar. Length of stay in each group (8 days [5–57] ERAS vs. 9 days [5–31] CSC group, $P = 0.390$) was similar, with time to recovery of bowel function being significantly less in ERAS group (12 h [12–108] vs. 36 h [12–60] for bowel sounds [$P = 0.001$], 48 h [12–108] vs. 72 h [36–156] for passage of flatus [$P = 0.001$], and 84 h [36–180] vs. 96 [60–156] for passage of stools [$P = 0.013$]). Perioperative complication rate (12 patients (44.4%) vs. 14 (51.9%), $P = 0.786$) was similar.

Conclusions: ERAS protocol leads to faster bowel recovery compared to conventional care in patients undergoing open RC but fails to demonstrate a shorter length of stay and lower complication rate.

INTRODUCTION

Radical cystectomy with urinary diversion (RC-UD) for carcinoma urinary bladder is a morbid procedure with a reported average length of stay of 10.75 days and complication rate of up to 64%.[1-3] Enhanced recovery after surgery (ERAS) protocol aims to reduce surgical stress and expedite postoperative recovery. ERAS items, as detailed by the ERAS Society, are supported by level one evidence in colorectal surgery for the reduction of complications (~50%) and length of hospital stay (LOS) (~2.5 days).[4]

ERAS protocol has been introduced in urology considering the complex nature of RC and the generalizability of majority components of the protocol. However, acceptance of ERAS protocol by urologists has been slow with main barriers cited as a lack of convincing evidence, disbelief in the ERAS concept, and lack of institutional support.[5] Implementation in the Indian population poses further unique challenges

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such as the lack of proper step-down facilities and dedicated nursing staff for patient follow-up after discharge, different dietary patterns, and nonavailibility of some key components of ERAS protocol including carbohydrate-rich drinks and opioid antagonist alvimopan.

To the best of our knowledge, there is no randomized trial published regarding the use of ERAS protocol in Indian patients undergoing RC. Therefore, we conducted this randomized, controlled trial to evaluate the LOS and perioperative complications with the implementation of ERAS protocol in patients undergoing RC compared to conventional surgical care (CSC).

MATERIALS AND METHODS

This study was conducted in a single tertiary care center in India from April 2017 to May 2018. The trial was registered with the Central Trial Registry of India and approved by the institute ethics committee. All patients undergoing open RC-UD for muscle-invasive or high-risk nonmuscle invasive carcinoma urinary bladder at our center were assessed for eligibility. Inclusion criteria included were transitional cell carcinoma of the urinary bladder, surgery with curative intent (cTa-T4a/N0-3/M0), age 18–75 years, and Eastern Cooperative Oncology Group performance score 0–2. Exclusion criteria included were lack of consent, prior abdominopelvic radiotherapy, prior intestinal surgery, and severe cardiac/hepatic/pulmonary/renal dysfunction.

The primary objective was the LOS, defined as the number of nights the patient stayed in the hospital after surgery till discharge.

Secondary objectives included time to bowel movement, time to flatus and stools, time to oral intake, time to ambulation, time to drain removal, postoperative hematological parameters on day 1, perioperative complications graded according to the Clavien–Dindo classification, incidence, and reason for 30-day readmission and perioperative mortality (counted as any death within 30 days of surgery or before discharge, whichever later). Patients were readmitted in case of the development of any complication not manageable on an outpatient basis (e.g., ileus, subacute intestinal obstruction (SAIO), febrile urinary tract infection, etc.).

Randomization was done using a computer-generated block randomization table. Allocation concealment was achieved using opaque envelopes. The patients were blinded. The investigator was not blinded due to feasibility reasons. The statistician was blinded. Patients were randomized after hospital admission.

The details of key perioperative management steps in ERAS and CSC groups are detailed in Table 1. Operating surgeons had more than 10 years of experience in performing open RC-UD. All patients received injectable third-generation cephalosporin (ceftriaxone), aminoglycoside (amikacin) and metronidazole started one night before surgery. Amikacin and metronidazole were stopped after 48 h, and ceftriaxone was continued till postoperative day 5. Patients were considered fit for discharge when they fulfilled the following criteria:

1. Patient taking full oral diet
2. Central venous catheter, arterial catheter, and the epidural catheter removed
3. Nasogastric tube (NG) removed
4. All biochemical investigations within acceptable parameters
5. Adequate pain relief with oral drugs
6. Patient fully mobilizing
7. Stoma functioning well or neobladder washes adequate
8. Abdominal drain removed.

Sample size calculation

We calculated the sample size using the average length of stay for patients undergoing RC at our center, considering the lack of published randomized trials at the time of protocol preparation. Considering the mean length of stay of patients undergoing RC at our center as 8.7 days with the standard deviation (SD) of 2.6 days and the target reduction in the length of stay by 2 days in the intervention group, with the power of the study at 80% and alpha at 0.05, sample size was calculated as 27 patients in each group.

Statistical analysis

Statistical analysis was performed using SPSS v20 software(IBM Corp., Armonk, N.Y., USA). Continuous variables were analyzed using the unpaired Student's *t*-test (parametric variables) and Mann–Whitney test (nonparametric variables). Categorical variables were analyzed using Chi-square and Fisher's exact tests. $P < 0.05$ was considered statistically significant. Both intention of treat and per-protocol analysis were conducted.

RESULTS

From April 2017 to May 2018, 58 patients were admitted at our center for open RC-UD. Four patients were excluded as per exclusion criteria (two patients refused consent for inclusion and two patients had received prior radiotherapy). The included patients were randomized, as shown in the CONSORT diagram [Figure 1]. The baseline demographic profile of both groups was similar [Table 2].

Primary objective

LOS in both ERAS and CSC groups was similar (median 8 days [range: 5–57] vs. 9 days [5–31], $P = 0.390$) [Table 3].

Table 1: Enhanced recovery after surgery procedures

Item	ERAS group	CSC group
Preoperative bowel preparation	Avoidance of any oral or per-rectal mechanical bowel preparation. Allowance of solid food till 8 h before surgery	One packet of PegLac in 2 l of water given over 2 h in the afternoon before surgery. Per rectal PC enema given in the night before and in the morning of surgery. Only clear liquids in the evening before surgery
Intravenous opioid analgesia	Avoidance of long-acting intravenous opioids	Use of long-acting intravenous opioids (morphine)
Resection site drainage	Early removal of resection site drainage (output >100 ml)	Drain kept till drainage <100 ml for at least 1 day
Nasogastric tube	Early removal of the nasogastric tube by the postoperative day 1 morning	Removal of the nasogastric tube after the passage of flatus
Sham feeding	Use of gum chewing postoperatively thrice a day for 1 h each from the postoperative day 1	No sham feeding
Anti-emetic prophylaxis	Multi-modal anti-emetic prophylaxis using metoclopramide 10 mg twice daily and ondansetron 4 mg thrice a day till taking full oral diet	Use of only ondansetron 4 mg thrice a day till taking full oral diet
Multi-modal analgesia	Postoperative analgesia using a combination of epidural opioids and intravenous and oral nonopioid drugs	Postoperative analgesia using a combination of epidural opioids and intravenous and oral opioids
Early enteral feeding	Early initiation of oral liquids (on postoperative day 1) and solids (on postoperative day 2) as tolerated by the patient	Initiation of oral liquids only after passage of flatus
Early obligatory ambulation	Early postoperative obligatory ambulation from the postoperative day 1 (out of bed on the postoperative day 1)	Postoperative ambulation encouraged

ERAS=Enhanced recovery after surgery, CSC=Conventional surgical care, PC=Proctoclysis

Table 2: Demographic profile

Parameter	ERAS* group (*n*=27)	CSC* group (*n*=27)	*P*
Age (years), mean±SD*	57.1±10.1	58.6±10.5	0.590
Sex (male/female)	25/2	25/2	0.99
BMI* (kg/m^2), mean±SD	22.5±2.9	22.7±3.5	0.767
Hb* (g/dl), mean±SD	12.1±1.5	12.5±2.3	0.459
Urea (mg/dl), median (range)	25 (10-81)	29 (11-50)	0.215
Creatinine (mg/dl), median (range)	0.9 (0.5-3.9)	0.9 (0.6-2.1)	0.236
Albumin (g/dl), mean±SD	4.1±0.5	4.1±0.6	0.741
Preoperative T stage, *n* (%)			
T1	3 (11.1)	2 (7.4)	0.99
T2	23 (85.2)	24 (88.9)	
T3	1 (3.7)	1 (3.7)	
T4	0	0	
ASA* score, *n* (%)			
1	18 (66.7)	20 (74.1)	0.76
2	9 (33.3)	7 (25.9)	

*BMI=Body mass index, ERAS=Enhanced recovery after surgery, CSC=Conventional surgical care, SD=Standard deviation, ASA=American society of anesthesiologist, Hb=Hemoglobin

Secondary objectives

Blood loss and operative time

Twenty-five patients in each group underwent open RC with ileal conduit UD. One patient in the ERAS group and two patients in the CSC group underwent neobladder formation. One patient in the ERAS group was found to have cT4b disease at exploration and underwent bilateral ureterostomy formation. He was excluded from per-protocol analysis. Blood loss (median 1200 ml (350–3000) versus 1500 ml (450–4500), P = 0.103) and mean operative time (308.9 min ± 77.7 vs. 358.7 ± 103.1 min, P = 0.051, mean [SD], mean difference –49.8 min, 95% confidence interval [CI] of difference –99.8–0.1 min) in ERAS versus CSC group were similar. The rate of intra-operative (median 1 [0–4] vs. 2 [0–7], P = 0.158) and postoperative (median 0 [0–3] vs. 0 [0–2], P = 0.275) blood tsfusion was similar between the two groups [Table 3].

Time to bowel movements and oral intake

NG tube was removed at a significantly earlier time in the ERAS group (11.0 ± 3.2 h) compared to the CSC group (19.8 ± 10.4 h, P = 0.001, mean difference –8.8 h, 95% CI of difference –13.3 – –4.2 h). Patients in ERAS group had significantly earlier onset of bowel movements (median 12 h [12–108] vs. 36 h [12–60], P = 0.001). Patients in ERAS group also passed flatus (median 48 h [12–108] vs. 72 h [36–156], P = 0.001) and stools (median 84 h [36–180] vs. 96 [60–156], P = 0.013) significantly earlier [Table 3].

Ambulation

Patients were out of bed for significantly longer duration in ERAS group (median 60 min [0–120] vs. 0 min [0–30], P = 0.001 on Day 1; 90 min [30–270] vs. 10 min [0–45], P = 0.001 on Day 2) [Table 3].

Time to drain removal

Time to per-urethral (median 36 h [12–204] vs. 36 h [24–84], P = 0.337) and abdominal drain removal (median 132 h [60–384] vs. 156 h [84–300], P = 0.154) were similar between the two groups [Table 3].

Perioperative complications

One patient in the CSC group had intra-operative injury to the external iliac vessels. He required vascular repair and packing of the surgical site in view of diffuse oozing. The patient was managed in the intensive care unit, and re-exploration with pack removal was done after 1 day. No patient in the ERAS group required re-exploration. Overall, postoperative complication rate between both groups was similar (12 [44.4%] ERAS group vs. 14 [51.9%]

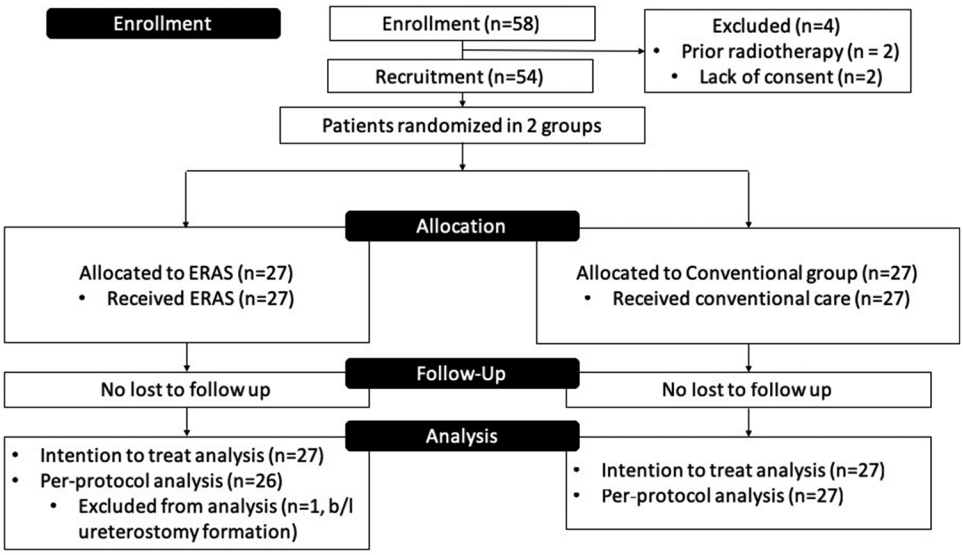

Figure 1: CONSORT diagram

Table 3: Perioperative outcomes

Parameter	ERAS* group (*n*=27)	CSC* group (*n*=27)	*P*
LOS* (days), median (range)	8 (5-57)	9 (5-31)	0.390
Average blood loss (ml), median (range)	1200 (350-3000)	1500 (450-4500)	0.103
Mean operative time (min), mean±SD*	308.9±77.7	358.7±103.1	0.051
Onset of bowel movements (h), median (range)	12 (12-108)	36 (12-60)	0.001
Time to flatus (h), median (range)	48 (12-108)	72 (36-156)	0.001
Time to stool (h), median (range)	84 (36-180)	96 (60-156)	0.013
Time to abdominal drain removal (h), median (range)	132 (60-384)	156 (84-300)	0.154
Postoperative Hb* (g/dl), mean±SD	10.3±1.2	10.5±1.4	0.595
Postoperative urea (mg/dl), median (range)	23 (12-65)	32 (10-58)	0.016
Postoperative creatinine (mg/dl), median (range)	0.8 (0.4-3.2)	0.8 (0.3-1.7)	0.177
T stage, *n* (%)			
T0	4 (14.8)	1 (3.7)	0.334
T1	3 (11.1)	3 (11.1)	
T2	11 (40.7)	12 (44.4)	
T3	7 (25.9)	5 (18.5)	
T4	2 (7.4)	6 (22.2)	
N stage, *n* (%)			
N0	22 (81.5)	19 (70.4)	0.133
N1	0	2 (7.4)	
N2	5 (18.5)	3 (11.1)	
N3	0	3 (11.1)	
Total number of LN* removed, mean±SD	11±4.5	10±4	0.547
Total number of LN positive, median (range)	0 (0-5)	0 (0-11)	0.316

LOS=Length of stay, ERAS=Enhanced recovery after surgery, CSC=Conventional surgical care, SD=Standard deviation, Hb=Hemoglobin, LN=Lymph node

patients in CSC group, $P = 0.786$). Minor peri-operative complications (Clavien–Dindo Class 1–2) were similar between both groups (11 in the ERAS group versus 14 in the CSC group, $P = 0.159$). ERAS group had one Clavien–Dindo Class 3a (major) complication compared to none in the CSC group. The patient developed low-output enterocutaneous fistula and required placement of bilateral percutaneous nephrostomies (PCN), following which, the fistula spontaneously closed. The overall and major (Clavien–Dindo Class 3 or higher) complication rate was not statistically different between the groups ($P = 0.159$) [Table 4].

Re-admission and perioperative mortality

One patient in the ERAS group and two patients in the CSC group were readmitted with SAIO. NG tube placement was required. All patients were managed conservatively and gradually improved. The incidence of within-30-day re-admission in the two groups was not significantly different ($P = 0.99$). There was no within-30-day mortality in either group [Table 4].

Pathology outcomes

The stage-wise distribution of patients according to the postoperative pathological T and N stage was similar between both groups [Table 3].

Table 4: Perioperative complications and re-admission

Parameter	ERAS* group (*n*=27), *n* (%)	CSC* group (*n*=27), *n* (%)	*P*
Overall complication rate	12 (44.4)	14 (51.9)	0.786
Minor complication rate (Clavien Dindo 1-2)	11 (40.7)	14 (51.9)	0.159
Atelectasis	0	4 (14.8)	
LRTI*	1 (3.7)	0	
SSSI*	3 (11.1)	5 (18.5)	
Wound dehiscence	3 (11.1)	0	
Ureteroileal leak	1 (3.7)	0	
Ileus	1 (3.7)	3 (11.1)	
SAIO*	2 (7.4)	2 (7.4)	
Major complication rate (Clavien Dindo 3 or higher)	1 (3.7)	0	0.159
Enterocutaneous fistula	1 (3.7)	0	
Readmission rate	1 (3.7)	2 (7.4)	0.99
SAIO	1 (3.7)	2 (7.4)	

*LRTI=Lower respiratory tract infection, SSSI=Superficial surgical site infection, SAIO=Subacute intestinal obstruction, ERAS=Enhanced recovery after surgery, CSC=Conventional surgical care

DISCUSSION

RC-UD is a complex procedure with significant postoperative morbidity (20%–58%)[1,6] and mortality (0.3%–2.3%).[7,8] Infectious and gastrointestinal complications comprise the most common complications after RC and result in significant prolongation in-hospital stay after surgery. Although originally formulated for colorectal surgery, ERAS protocol may be applicable to any major surgery, including RC. However, ERAS protocol following RC has not been as rapidly accepted by the urologic community as initially expected.

LOS following RC not only depends on the recovery of bowel function but on multiple other factors, including the status of wound, peri-operative complications, and sociocultural factors. Health-care setup in India differs from the Western countries as there are no step-down facilities for patients to stay in after being discharged from the hospital, and there is no dedicated staff for follow-up of such patients. Differences in reimbursement patterns, as even seen among Western literature may also be a contributing factor. In our center, majority of patients come from a poor socioeconomic background, far off places, and do not have a clean place to stay outside the hospital. Therefore, even if the patient is medically fit for discharge, the patients are kept an extra day or two till they are able to find accommodation and are able to do self-care. Studies have found that the length of stay in patients managed with ERAS protocol is either significantly less or similar to conventional care.[9,10] In our study as well, the length of stay for both the groups was similar. Such a difference in outcome might be the result of local reimbursement/cultural factors, as detailed above. However, in the Western setup, due to the availability of step-down facilities and dedicated nursing staff, the LOS might be lower in the ERAS group.

ERAS protocol aims to maintain homeostasis during the period of surgical stress by limiting the time for preoperative fasting for solids and liquids, avoidance or early removal of NG tube, promoting sham feeding in the postoperative period by the use of chewing gum, early allowance of oral liquids, and solid diet and early ambulation. Studies have found that following these principles, the overall morbidity, time to recovery of bowel activity, and the length of stay are either reduced or remain unchanged.[4,11] In our study, we found that patients in the ERAS group had a significantly reduced time to recovery of bowel sounds, the passage of flatus as well as stools. We did not use clear carbohydrate-rich drinks in the preoperative period (due to nonavailability); however, still, the recovery of bowel movements and passage of flatus and stools was significantly earlier in the ERAS group.

Studies have shown that the use of preoperative bowel preparation is not beneficial for the recovery of bowel function and in fact, might be harmful and lead to the higher incidence of postoperative superficial and deep surgical site infections and anastomotic leaks.[12] Dietary patterns and diet composition of the Indian population are different from the West. ERAS protocol proposes the omission of preoperative oral mechanical bowel preparation. We did not find any increase in the intra-operative difficulty during bowel anastomosis due to the lack of bowel preparation. Postoperative recovery of bowel function in the ERAS group was earlier, although it cannot be solely attributed to the omission of bowel preparation. The incidence of wound complications among the two groups was also similar.

Patients in the ERAS group are preferably given nonopioid analgesics for pain relief, and opioid analgesia is only given for breakthrough pain. Studies have shown a significantly lesser incidence of postoperative ileus in patients kept on ERAS protocol.[13] We found a similar incidence of postoperative ileus and SAIO in both groups. One patient in the ERAS group had the suspicion of ischemic bowel anastomosis intra-operatively. The anastomosis was revised, and the final anastomosis was judged to be satisfactory. However, the patient developed anastomotic site leak and urinary leak from the conduit in the postoperative period and required bilateral PCN placement and drain placement for the management of urinary and fecal fistula, following which he improved gradually and was discharged on day 57 on the oral diet. We feel that this patient could have been managed more conservatively; although, he could have developed the leak irrespective of the postoperative protocol. Caution may be advised in restarting enteral feeding in such cases.

The most common complications following RC are infectious and gastrointestinal in nature, and the incidence approximates 64% for minor and 14% for major complications. The 30-day readmission rate, as studied by Djaladat *et al*., averages

at 21%.[14] We found a similar overall complication rate between ERAS (44.4%) and CSC group (51.9%). Majority of the complications were minor (Clavien–Dindo Class 1–2). The 30-day readmission rate for the ERAS group was 3.7% and 7.4% for the CSC group, which was comparably lower as that given in the literature.

To the best of our knowledge, ours is the first randomized controlled trial conducted in India regarding the application of ERAS protocol in patients undergoing RC. Both intention to treat analysis and per-protocol analysis (data not shown) showed similar results. However, there are a few limitations to our study. The investigator was not blinded as it was not practically possible to apply ERAS items without the knowledge of the treating team. We could not include the use of carbohydrate-rich clear drinks and alvimopan in the current study due to nonavailability and further studies may be done to assess their usefulness. Future research may also include analysis of quality-of-life outcomes.

CONCLUSIONS

Open RC-UD is associated with significant morbidity. The study shows that ERAS protocol leads to faster bowel recovery compared to our conventional care in patients younger than 75 years and with good performance status but fails to demonstrate a shorter length of stay and lower complication rate.

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