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ORIGINAL ARTICLE

Safety and Feasibility of Enhanced Recovery after Surgery (ERAS) Protocol in Patients Undergoing Stoma Closure

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Abstract

Enhanced Recovery after Surgery (ERAS) protocol is a multimodal approach which includes variety of pre-, intra-, and postoperative components to minimize surgical trauma, reduce complications, and decrease hospital length of stay, while expediting accelerated recovery following elective procedures. This study aimed to compare the postoperative outcome using the conventional management versus ERAS protocol in patients undergoing stoma (ileostomy and colostomy) closure. A prospective, comparative, longitudinal study was conducted using census technique in 30 patients admitted to surgery department, between January 2018 and March 2019 for ileostomy or colostomy closure. The postoperative length of hospital stay, readmission, morbidity, and mortality were compared between two groups of participants undergoing stoma closure either by ERAS (group A, $n = 15$) or by conventional care (group B, $n = 15$) protocol. Chi-square test and Student t test were used for analysis. The mean postoperative length of hospital stay was shorter in ERAS group compared with conventional care group (1.5 vs. 6.5 days, $p < 0.001$). However, no statistically significant differences were reported in terms of readmission and morbidity between the two groups. One major morbidity (anastomotic leak) in conventional group was reported. There was no 30-day mortality in either group. In comparison with the conventional care group, the application of ERAS protocol in the stoma closure resulted in decreased postoperative length of hospital stay. No differences were observed for readmission, re-exploration, and other postoperative morbidities between the two groups.

Keywords ERAS · Stoma closure · Ileostomy · Colostomy

Introduction

Enhanced Recovery after Surgery (ERAS) is an evidence-based protocol designed to standardize medical care, improve outcomes, and lower health care costs. These protocols include techniques to minimize surgical trauma and postoperative pain, reduce complications, and decrease length of hospital stay, while expediting recovery following elective procedures [1, 2].

The formation of intestinal stoma (ileostomy or colostomy) is an integral part of the surgical management of several pathologies of the gastrointestinal tract—in both emergency and elective patients. It has to be taken down surgically after the patient is improved, usually after 6 weeks of surgery [3]. Bowel surgeries, especially anastomoses, are traditionally managed with prolonged nil per oral postoperatively, cumbersome preoperative overnight fasting (> 6 h), enteral feeding only after appearance of bowel sounds and mechanical bowel preparation. This traditional approach results in a longer duration of in-hospital stay. Despite these extensive measures, the complication rates in these procedures remained high at 15–20% [4].

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ERAS includes multiple elements: extensive preoperative education, avoidance of mechanical bowel preparation and excessive fasting, carbohydrate loading, strict fluid balance to avoid fluid over, regional anesthesia block, non-opioid analgesics, early mobilization and enteral feeding (6 h after surgery), avoidance of routine nasogastric tube placement, avoidance of abdominal drains and urinary catheters [2]. Stoma closure involves single incision and single anastomosis, leading to decreased surgical stress and metabolic response to trauma. With implementation of these elements, the postoperative outcome in patients undergoing stoma closure may be improved.

The current study aimed to compare the postoperative outcome using the conventional management versus ERAS protocol in patients undergoing stoma closure.

Material and Methods

This prospective, comparative longitudinal study (January 2018 to March 2019) was carried out in patients undergoing stoma (ileostomy/colostomy) closure in the Department of Surgery, B P Koirala Institute of Health Sciences, Nepal. The study protocol was approved by the Institutional *review board, and informed consent was obtained from each patient for the study. The patients were divided into two groups.* In *group A*, ERAS protocol was followed for *stoma closure by the attending consultant of one surgical unit, while* in *group B*, *conventional method* was used *by the consultant of second surgical unit.* To minimize the selection bias, the members involved in managing these patients were not part of the study, i.e., they were unaware of the outcome studied. *The inclusion criteria for the* study *were as follows: (1)* patients undergoing elective stoma closure from local stoma site; (2) patient aged between 16 and 70 years; (3) ASA grade 1 or 2; (4) body mass index (BMI) < 30 kg/m^2; (5) patient who lived within 2 h from the hospital premises and had access to telephone and suitable means of transport; (6) responsible next of kin staying with the patient for at least 24 h. Those patients undergoing simultaneous other abdominal procedure, uncontrolled co-morbid conditions, stoma closure by the midline abdominal incision, and emergency stoma closure were excluded.

All patients underwent preoperative water soluble contrast enema and/or ileocolonoscopy to demonstrate distal anastomotic integrity. In the ERAS group, the following elements were considered; (1) preadmission counseling by the operating team; (2) saline feed (500 ml DNS over 2 h) from the distal loop of stoma a day prior to stoma closure to confirm the distal patency and also to act as priming agent (feed) to the distal bowel; (3) Fasting for solids for 6 h and for liquids (plain water and carbohydrate rich drinks) for 2 h prior to surgery; (4) preoperative carbohydrate loading with 200 ml apple juice (containing 100 kcal) 6 h and 2 h before surgery; (5) no nasogastric tubes, urinary catheter, or abdominal drain; (6) intraoperative neutral fluid balance; (7) initiation of oral feed as early as possible after 6 h of surgery (irrespective of the bowel sound) and early ambulation (sitting, standing, or out of bed after 6 h of surgery) [5]; (8) discharge on the first or second day of surgery depending on the patient comfort.

In the conventional group, overnight fasting and mechanical bowel preparation as and when required were performed. The nasogastric tube, urinary catheter, and abdominal drains were used when required. Enteral feed was started only after the appearance of the bowel sound. The patient started ambulation after the first postoperative day and discharged only after tolerance of liquid diet and passage of stool and when all the tubes and drain were removed.

In both the groups, surgery was performed under general anesthesia. The induction and maintenance of general anesthesia was uniform in both the groups except for the following measures that were taken in patients belonging to the ERAS group: no premedication; ultrasound-guided unilateral transverse abdominis plane block at the stoma site with ropivacaine 0.25% after patient was anesthetized; intraoperative restrictive fluid therapy (Plasmalyte), i.e., not exceeding > 1000 ml. The details of protocol are available in supplementary file 1. Circumstomal incision was made, stoma mobilized, and margin refreshened. The stoma was closed by intraperitoneal method, end-to-end anastomosis in a double-layer with delayed absorbable suture. If inadvertent perforation occurred, it was either primarily repaired (if away from the stomal opening) or resected and end-to-end anastomosed if nearby, depending on the discretion of the operating surgeon. The sheath was closed with polypropylene no 1 suture. Postoperatively, the visual analog scale (VAS) score for pain was assessed and patients received injectable diclofenac, paracetamol, or fentanyl depending on the score. After discharge, the patients were followed up in surgical outpatient clinic on the seventh day, second week, and fourth week of discharge. The outcome measures analyzed were 7-day readmission rate, morbidity (Clavien-Dindo classification) rate [6], postoperative length of hospital stay, reoperation, and 30-day mortality rate.

Statistical Analysis The statistical analysis was performed using Statistical Package for the Social Sciences (SPSS 11). Data were expressed as the mean (standard deviation), or the number (percentage). Continuous variables were compared for statistical differences using 2-sample Student *t* tests. Categorical variables were tested for significance using Chi-square test or Fisher exact test, as appropriate. A value of $p < 0.05$ was considered significant.

Results

A total of 34 patients were screened for eligibility, out of which 30 were included in the study. There were 15 patients in each

group (group A and group B). The mean age of the patients in group A was 39.42 years (range 17–55 years) and in group B was 41.42 years (range 17–55 years). There were 22 (73.3%) males and 8 (26.7%) females in the study, with 12 and 10 males in group A and group B respectively and 5 and 3 females in group A and B respectively. Both the groups were comparable in terms of age and sex. There were 22 loop/double-barrel ileostomies and 8 loop/double-barrel colostomies. The indications for stoma formations in these patients were ileal perforation (tuberculosis-4; enteric fever-3 and non-specific-7), covering loop ileostomy for chronic ulcerative colitis requiring staged proctocolectomy with ileal pouch anal anastomosis ($n = 1$) and rectal cancer following low anterior resection ($n = 4$), sigmoid volvulus following Hartmann's procedure requiring colostomy ($n = 6$), midgut volvulus requiring ileostomy for gangrenous ileum ($n = 1$), acute necrotizing pancreatitis with colonic fistula requiring loop ileostomy ($n = 1$), traumatic rectal perforation requiring colostomy ($n = 1$), colostomy for sigmoid diverticular perforation ($n = 1$), and extra intestinal GIST (gastrointestinal stromal tumor) with ileal resection and ileostomy ($n = 1$). The mean time to stoma closure in group A and B was 166 (range 90–330 days) and 172 days (range 98–300 days) respectively. The demographics and clinical profile in details are shown in Table 1.

In group A, no patients required urinary catheter in the postoperative period, whereas in group B all patients were catheterized and removed on the first postoperative day. Nasogastric tube was routinely inserted in group B and kept in situ for an average of 2 days, whereas in group A, one (6.6%) patient later required nasogastric placement following readmission for subacute intestinal obstruction. Abdominal drain was placed in 3 (20%) patients in group B, which was removed 2 days later. The mean postoperative VAS scores for pain at 12 and 24 h were comparable in both the groups (Table 2). Intraoperatively, there were two inadvertent perforation of the efferent limb, one in each group, which was primarily repaired without any sequelae. There was no exclusion due to on-table change in the surgical technique.

All patients in group A underwent early enteral feed. Hence, 13 patients were discharged on day 1 as they tolerated feed. Two patients were discharged on day 2 because of non-tolerance of feed and unbearable incision site pain. One patient (6.6%) was readmitted on day 3 because of the sub-acute intestinal obstruction, which resolved on conservative management and discharged on day 6. The readmitted patient was a case of loop ileostomy closure following non-specific ileal perforation in which intraoperative adhesions was present. Two patients (13.2%) developed superficial surgical site infection. There were no reoperations, anastomotic leak, or mortality in this group. The mean postoperative length of hospital stay was 1.58 ± 1.11 days (range = 1–6 days) (Table 2).

In group B, the mean time to start of oral feed was 3.17 ± 1.85 days. Six patients (40%) developed superficial surgical site infection and were managed conservatively. There was one (6.6%) major complication (anastomotic leak with peritonitis following double barrel ileostomy closure) on the fourth postoperative day, requiring re-operation and stoma re-fashioning. This patient had double barrel ileostomy with intraoperative adhesion with antecedent history of non-specific ileal perforation peritonitis. There was no re-admission or mortality in this group. The mean postoperative length of hospital stay was 6.58 ± 0.86 days (range = 6–9 days) (Table 2).

On comparing the outcomes between the two groups, there was an early return of bowel function in the ERAS group (2.75 vs. 5.08 days; $p = 0.008$). Similarly, we observed significant decrease in mean postoperative length of hospital stay in group A (1.58 vs. 6.58 days in group B; $p = 0.001$), with no significant increase in morbidity and re-admissions. The outcome measures in details are shown in Table 2.

Discussion

ERAS protocol is a multimodality protocol comprising of preoperative, intraoperative, and postoperative elements, so as to accelerate the recovery of the patients undergoing surgery. It does

Table 1 Demographic and clinical profile of patients undergoing stoma closure

Parameters	ERAS protocol (group A) ($n = 15$)	Conventional protocol (group B) ($n = 15$)	p value
Age (years)	39.42 ± 11.15	41.42 ± 12.05	0.17
Body mass index (BMI) Kg/m^2	20.39 ± 0.81	19.89 ± 0.25	0.15
Male n (%)	12 (40%)	10 (33.3%)	0.64
Mean Hemoglobin, gm/dl	12.5 ± 1.8	11.6 ± 1.85	0.26
Mean Albumin, gm/dl	4.46 ± 0.73	4.29 ± 0.83	0.62
Ileostomy n (%)	10 (33.3%)	12 (40%)	0.67
Colostomy n (%)	5 (16.6%)	3 (10%)	0.65
Time to stoma closure (mean) (range), days	166 ± 66.52 (90–330)	172.42 ± 69.56 (98–300)	0.82

Values are expressed as mean ± SD, number (%)

Table 2 Outcome measures analyzed in patients with stoma closure

Parameters	ERAS protocol (group A)	Conventional protocol (group B)	*p* value
VAS score			
At 12 h	4 ± 0.60	4.42 ± 0.51	0.08
At 24 h	2.42 ± 0.51	2.83 ± 0.57	0.07
Mean time to oral feed initiation (days)	1.58 ± 0.28	3.17 ± 1.85	0.005
Mean time to passage of flatus (days)	2.75 ± 1.35	5.08 ± 2.13	0.008
Mean postoperative length of hospital stay (days)	1.58 ± 1.11	6.58 ± 0.862	0.001
Readmission, *n* (%)	1 (6.6%)	0	0.99
Morbidity			
Minor (grade I and II)	3 (20%)	6 (40%)	0.40
	SSI-2	SSI-6	
	SAIO-1		
Major (grade III and above)	0	1 (6.6%)	0.99
		Anastomotic leak	
Re-operation	0	1 (6.6%)	0.99

Values are expressed as mean ± SD, number (%)

SSI, surgical site infection; *SAIO*, subacute intestinal obstruction

No 30-day mortality in the either group

set the well-planned steps for initiation of feed, ambulation, drain and tube removal, and discharge criteria. It has extensively been studied for colorectal resections, with early discharge possible as early as at day 3 [2, 7]. Apart from early discharge and decreased length of hospital stay and health-related costs, it has also been found to decrease the rate of morbidity.

In the present study, we found the significantly decreased length of hospital stay (1.5 vs. 6.5 days; $p = 0.001$), without increase in rates of re-admission (6.6% vs. 0%; $p = 0.99$), re-operation, and morbidity. There was no mortality in the either groups. Moreover, there was early initiation of oral feed and ambulation, leading to better sense of well-being in patients undergoing stoma closure by ERAS protocol, compared with the conventional group.

The first study on stoma closure with implementation of ERAS protocol was done by Kalady et al., from Duke University, North Carolina. The study included 28 patients (vs. 30 control group), who were discharged after 23 h of observation following loop ileostomy closure. With this ambulatory surgery, there was 10.7% (vs. 13.3%) readmission, lesser morbidity (3.6%), and significantly decreased length of hospital stay (1 vs. 2.9 days). The author concluded that the ambulatory surgery, with 23 h of observation, can be conducted safely with a reduction on overall costs [8]. Similarly, in a study by Pirzada et al., in 60 patients undergoing stoma closure, the mean duration of hospital stay in patient by ERAS protocol was significantly less as compared with the conventional protocol (7.23 vs. 4.13 days, $p = 0.00$). Moreover, wound infection in ERAS group was also less compared with the conventional care group (26.7% vs. 46.7%, $p = 0.10$). The author concluded that the application of ERAS protocol in the appropriate setting was found to be safe, and it decreased perioperative complications in terms of hospital stay, and wound infections [9]. The present study outcome matches with the published standard with the decreased postoperative length of hospital stay and surgical site infections.

In a study by Berger et al., comparison of loop ileostomy closure was done in 1602 patients (1517 control vs. 85 cases) by ERAS protocol. The median length of stay in ERAS group was less compared with the control (2 vs. 4 days; $p < 0.001$). Thirty-day readmission (15.3% vs. 10.4%; $p = 0.15$) and overall 30-day complications (15.3% vs. 16.7%; $p = 0.73$) were similar between the cohorts. The study concluded that the next-day discharge with protocol diet advancement and telephone follow-up is acceptable after loop ileostomy closure. Patients can benefit from decreased length of stay without an increase in readmission or complications [10].

Our study is one of the very few to discuss the application of ERAS protocol in patients undergoing stoma closure. In the study, we were able to demonstrate the feasibility of ERAS protocol in terms of reducing length of hospital stay and morbidity. Furthermore, there was no significant rise in complications, readmission, or mortality rate, when patients were discharged earlier. Similar results have been demonstrated by almost all studies involving major colorectal surgery [7, 11]. In the preoperative period while applying a fast-track protocol to a patient, special emphasis is laid on diet, nutritional status, and carbohydrate loading. Moreover, the distal bowel patency and anastomotic integrity was assessed by selective use of water soluble contrast study (rather than the barium) and distal loop dextrose-saline feed. The distal enteral feed (with dextrose content in it) acts as a priming agent in de-functionalized bowel loop (thus decreasing postoperative ileus—by coordinating gut-brain axis of neuro-hormonal release), is cost-effective without radiation exposure, and confirms patency

of distal bowel by per anal passage of "gush" of saline on rapid instillation of it from the distal stoma opening [12].

In our study, the time to ambulation and time of passage of flatus were early in group A as compared with the group B, which was also similar to a study done by Prizada et al, in which pain remains the most common reason for delaying discharge after ambulatory surgery [9]. Obtaining a subjective feeling of pain relief has been associated with faster mobilization and early ambulation [13, 14]. It even facilitates early discharge. In our study, ERAS group received unilateral transverse abdominis block for the postoperative analgesia after the induction. The injectable paracetamol was given for postoperative pain control. VAS scores at 12 h and 24 h in both groups were comparable.

The important unusual observation in our cohorts was the considerably longer time (nearly half a year) to stoma closure. The usual time to reverse stoma is after 6–12 weeks [3]. However, it is extremely variable among hospitals and depends on the primary disease pattern (benign vs. malignant and elective vs. emergency). In the present context, the delay can be explained due to prolonged recovery (physical, nutritional, and psychological well-being) time following initial surgery, time for completion of anti-tubercular treatment and adjuvant therapy for malignant diseases. Moreover, due to the logistic reason like financial arrangement by the patient for second surgery and the long waiting list (due to elective and non-priority surgery), the stoma reversal timing was longer.

This study does have its limitations; it has less sample size of 15 in each group and closure was performed by two different surgeons in group A and group B, however, we feel that it is important to highlight that the results of this study demonstrated a shorter hospital stay for patients undergoing stoma closure within an enhanced recovery program with no adverse effect on morbidity, reoperations, or readmission rates. The study is the preliminary reports and forms the foundation of application of ERAS protocol with first day discharge or as a day-care surgery in selected patients undergoing stoma closure.

Conclusion

The application of ERAS protocol in the stoma closure was safe, with no increase in morbidity, re-admission, and mortality rates. It significantly decreased the postoperative length of hospital stay, time to initiation of enteral feed, and time to bowel function. Thus, this point towards the possibility of day-care surgery in patients undergoing stoma closure with ERAS protocol provided the patient meets the inclusion and discharge criteria. However, further large-volume, multi-institutional study is required for its implementation.

Author's Contribution The manuscript has been read and approved by all the authors, that the requirements for authorship as stated earlier in this document have been met, and that each author believes that the manuscript represents honest work.

Compliance with Ethical Standards

The study protocol was approved by the Institutional review board, and informed consent was obtained from each patient for the study.

Conflict of Interest The authors declare that they have no conflict of interest.

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