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General Surgery

ERAS PROTOCOLS IN ELECTIVE LAPAROTOMIES FOR VARIOUS COLORECTAL SURGERIES – ITS APPLICATION, OUTCOME AND SEQUELAE

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ABSTRACT **Introduction :** Enhanced recovery after Surgery (ERAS) protocol has shown to reduce complications and hospital stay, with improvements in cardiopulmonary function, earlier return of bowel function and earlier resumption of normal activities. **Aims & Objectives :** To study the application and effectiveness of ERAS protocols in patients undergoing elective laparotomies for various colorectal pathologies. **Material & Methods :** This prospective comparative study conducted on 80 patients, admitted in various surgical wards, undergoing elective laparotomies for colorectal surgeries who were randomly allocated into 2 groups by simple randomization as ERAS and NonERAS groups. **Results :** The present study shows that effective application of ERAS protocols can lead to early recovery amongst the surgical patients undergoing elective colorectal surgeries leading to reduced postoperative nausea, vomitings, pain, surgical site infection, Urinary tract infection, increased bowel motility, early recovery, less hospital stay and early discharge. **Conclusion** : ERAS protocols are safe and effective. Its application involves significant change in the practice for the entire care team. There is a need for further evaluation and, if plausible, a more detailed description of the impact of each of the ERAS component on postoperative recovery.

KEYWORDS : ERAS, elective laparotomy

INTRODUCTION

A rapid post-operative recovery is not only beneficial to the individual, but also to the overall health economics of the country [(1)]. Professor Henrik Kehlet initiated Enhanced recovery after Surgery (ERAS) or Enhanced recovery programs (ERPs) or "fast-track" programs in 1990s. ERAS has become an important focus of perioperative management after colorectal, vascular, thoracic, gynecological and various general surgeries.[2] These programs attempt to modify the physiological and psychological responses to major surgery, and have been shown to reduce complications and hospital stay, with improvements in cardiopulmonary function, earlier return of bowel function and earlier resumption of normal activities.

ERAS is a multi-factorial & multi-faceted approach to peri-operative care. There are many different preoperative, intraoperative, and postoperative components in it. The key principles of the ERAS protocols include pre-operative counseling, peri-operative nutrition, avoidance of perioperative fasting and carbohydrate loading up to 2 hours pre-operatively [3], standardized anesthetic and analgesic regimens (epidural and non-opioid analgesia) and early mobilization. Contemporary colorectal surgery is often associated with long length of stay (8 days for open surgery and 5 days for laparoscopic surgery), high cost and high rates of surgical site infections. Within traditional care, the rate of post-operative recovery is slow with long length of hospital stays. Key cornerstones in traditional care such as pre and postoperative fasting, the use of intra-abdominal drains,enforced bed rest and slow mobilization have been shown to be unnecessary or even harmful[4].

In a tertiary care government hospital, because of the high inpatient admissions and extensive operative lists it becomes even more of an importance to have smaller hospital stays for the patients who can be discharged promptly postoperatively. ERAS protocols, thus provide an important measure of care which can be judiciously employed for the different patients to have their course for shortened and also allow a quicker and pain free recovery entailing lower hospital costs both for the authorities and the patients.

Aim & Objectives

The aim of study was to study the application and effectiveness of ERAS protocols in patients undergoing elective laparotomies for various colorectal pathologies in a tertiary care hospital compared to patients receiving routine perioperative care.

Objectives of study were to compare peri-operative nutrition, practices concerning drains and catheters, practices regarding thrombo-prophylaxis, post-operative nausea-vomiting(PONV), need of post-operative analgesia, return of bowel function, post-operative mobilization, post-operative adverse events, duration of hospital stay, readmission rates post-surgery, return to daily activities.

PATIENTS AND METHODS

This comparative study conducted on 80 patients, admitted in various surgical wards, undergoing elective laparotomies for colorectal surgeries in a tertiary care hospital in Mumbai over period of August 2018 to August 2020. 80 patients are randomly allocated (40 in each) into 2 groups by simple randomization, using computerized algorithm. This prospective comparative study compared application of ERAS protocols and their outcomes on patients undergoing elective colorectal surgeries as compared to traditional perioperative care as ERAS and Non-ERAS groups.

Patients undergoing elective laparotomies for colorectal surgeries from age group 18 and 80 years,of both genders and who gave consent were included in study. Patients undergoing emergency surgeries, not complying with the pre and post-operative instructions, patients residing at remote places, unable to present for follow-up after discharge, patients undergoing laparoscopic surgeries, patients not willing to take part in the study, patients with psychiatric conditions were excluded.

The selected procedures included right hemicolectomy, left hemicolectomy, rectopexy, resection anastomosis of various colonic segments, sigmoidectomy, anterior resection, low anterior resection, Hartmann's procedure, abdominal perineal resection, colostomy closure.

Pre-operatively, patients and their relatives were counseled regarding the protocols and also about the procedure being done and the objective of early discharge. The pre-operative preparation procedure did not comprise of mechanic bowel preparation, however for patients undergoing rectal and left colonic surgeries a rectal enema (120ml) was given on the night before and on the morning of the surgery.

Patients were allowed to have solid diet 6 hours before the surgery and clear liquid diet till 2 hours before the surgery. Patients were given a 200 ml of carbohydrate(CHO) rich drink containing (12.5% complex CHO) before the surgery. Injection enoxaparin 40mg given subcutaneously 1 day prior to the surgery and continued post-operatively till the patient is mobilized for prophylaxis against thromboembolism. Screening for PONV was done by using Apfel score. Patients were allowed to continue their regular medications till before the surgery. Prophylactic antibiotic injection ceftriaxone 1gm was given after induction of anesthesia.

Intraoperatively, standard anesthesia protocol was used for all patients. Thoracic epidural catheter was inserted; a local anesthetic lidocaine 2% without adrenaline was given through the epidural. After induction, urinary catheterization and nasogastric tube insertion was done. Ketorolac (1mg/kg) and dipyrone (20mg/kg) were given in a loading dose (unless contraindicated) to offer a multimodal analgesia. Low dose fentanyl (0.5-1ug/kg) was given intraoperatively in the epidural catheter. Intraoperative maintenance of normothermia and normovolemia was done by the anesthetists. Single dose IV dexamethasone 8 mg and ondensetron 8mg was given before reversal of anesthesia (for patients with a Apfel score >2) as antiemetic prophylaxis. To minimize post-operative pain, the suture line was infiltrated with a local anesthetic before closure. Drain insertion and removal of nasogatric tube (NGT) before anesthesia reversal was as per the discretion of the operating surgeon.

Post-operatively, immediate post-operative monitoring was done in intensive care unit, subsequent to recovery; the patients were shifted to wards. Patients received opioid sparing multimodal analgesia-epidural low dose bupivacaine 0.125% along with ketorolac 1mg/kg three times a day till patients were tolerating enteral feeding.

Injection ondensetron 4mg was given if nausea or vomiting was experienced. Patients were encouraged early ambulation and were mobilized out of bed on the day of surgery and then atleast 2 hours per day from 1st post-operative day onwards. Patients were encouraged to have clear liquids after removal of NGT (if not removed before reversal of anesthesia) on post-operative day 1 and were allowed to have semi-solid diet 12 hours post tolerating liquid diet. Urinary catheters were removed on postoperative day 1 (except in patients who underwent low anterior resection or abdomino-perineal resection). Epidural catheter removed on post op day 3. Patient assessment was carried out throughout the post-operative period and passage of flatus and stools were recorded. Patient's tolerance to oral analgesia by Nonsteroidal anti-inflammatory drugs (NSAIDS) / paracetamol was noted.

Patients were discharged once the discharge criteria was fulfilled i.e. patient alert and conscious, tolerating oral feeds and oral analgesics, no fever, mobilized independently and suitable care at home was available.

In non- ERAS group, perioperative management of patients in the other group was done according to the conventional hospital management protocols and findings were observed and recorded as per mentioned in objectives.

Patients of both groups were followed up 15 days post discharge and again after 1 month. Patients' readmission within 30 days of surgery was noted and evaluated.

The study is conducted after obtaining permission from institutional ethical committee. All the data collected from the patients is compiled in a Microsoft office excel sheet and analyzed. Pearson's Chi Square test is used as a test of significance. Where the expected number in a cell <5, Fishers Exact Test (2tailed) is used as a test of significance. In all 2x2 tables, odds ratios and 95% confidence intervals are used. Mean, Median, Standard deviation and 95% confidence intervals calculated. Shapiro Walk procedure used to assess normality. For normally distributed data; unpaired t test was used.

RESULTS

This was a prospective comparative study conducted among patients undergoing elective open colorectal surgeries in a tertiary care hospital in Mumbai. The study duration was of 2 years. The participants were divided into two groups (ERAS and Non-ERAS) of 40 patients each by randomization using a computerized software.

On the ERAS group, the ERAS protocols were applied and on the other group routine perioperative management was carried out. The observations were recorded and compared by using various statistical tests and differences amongst the groups were noted along with calculation of p value to determine significance.

In this study, both the groups were comparable in terms of their demographic profile. The mean age was Mean age 49.3years and 50.2years. There were 19 females, 21 males in ERAS group, equal in non ERAS. BMI was 22.95 and 22.88 amongst the groups. 25 participants in ERAS and 35 in other group belonged to ASA 2.

Most common comorbidity among both groups were cardiovascular (hypertension, ischemic heart disease) and Diabetes. In the ERAS category, 21 had a benign pathology and 19 had a malignant pathology while in the Non ERAS category, 24 had benign pathology and 16 had a malignant pathology.

NGT removal, catheter removal, mobilization, first bowel movement and drain removal was compared in both the groups and it was observed that patients in the ERAS group had earlier removal of drains and catheters, they were mobilised earlier and also passed their bowel movements earlier compared to the other group. Patients who received thoracic epidural analgesia (TEA) (27 patients in ERAS and 10 in Non-ERAS) tolerated oral patient controlled analgesia much earlier in the post-operative course which was statistically significant.

Post Op days (POD)	**NGT removal**		**Catheter removal**		**Mobilization**		**First Bowel Movement**		**Drain removal**		**Oral patient controlled ananlgesia (PCA) required only for**		**SSI**	
	E	**NE**	**E**	**NE**	**E**	**NE**	**E**	**NE**	**E**	**NE**	**E**	**NE**	**E**	**NE**
POD 1-2 days	40	2	32	1	32	1	33	0	1	0	10	0	0	2
POD 3-4 days	0	32	5	8	7	13	7	1	12	0	18	0	2	4
POD 5-6 days	0	6	3	17	1	18	0	20	14	0	12	1	3	5
POD >7days	0	0	0	14	0	5	0	19	0	40	0	39	1	5

Incidence of PONV among the other group was more 81.8% as compared to the ERAS group which was 18.9% which was statistically significant($p<0.001$). This could be attributed to the anti-emetic prophylaxis which was given to the patients in the ERAS group after they were screened on the basis of Apfel score.

In the post-operative period, 6 patients in ERAS, and 17 patients in other group had surgical site infection (SSI) (p value 0.021) which further increased their duration of hospital stay and was found to be significant. Urinary tract infection (UTI) was more seen in patients in the other group as compared to ERAS owing to delayed removal of catheters(>7days).

Mean duration of hospital stay in the ERAS category was 6.83 days while in the Non-ERAS category it was 14.95 days.

Thus patients were discharged earlier in the former group on account of enhanced recovery. 81.8% patients required readmission within 30 days among the other group which was significant (p value 0.015). Participants of the ERAS group returned to their daily activities much earlier (1.95 weeks) compared to other group (4.75weeks) which was found to be statistically significant ($p<0.001$). One mortality occurred in each group and lost to follow up happened with 2 patients of non ERAS group.

	PONV		SSI		UTI		Hospital Stay in days (mean)	Readmission	
	Yes	No	Yes	No	Yes	No		Yes	No
ERAS	7 (17.5%)	33	6 (15%)	34	3 (7.5%)	37	6.83	2 (5%)	37
Non-ERAS	30 (75%)	10	16 (40%)	24	10 (25%)	30	14.95	9 (22.5%)	27

Thus, the present study shows that effective application of ERAS protocols can lead to early recovery amongst the surgical patients undergoing elective colorectal surgeries.

DISCUSSION

Evidence-based medicine has led to an extensive investigation and development of new therapies and programs to improve the care of the surgical patient, both in the post and pre-operative period, known as enhanced recovery after surgery (ERAS) programs, "fast-track" programs or multimodal rehabilitation programs. The primary aims of the incorporation of fast-track programs as customary care are the standardization of patient care, the improvement of the overall outcome as well as the optimization of the use of resources [5,6].

The patients in the two groups (ERAS and Non-ERAS) in present study were similar in sex, age and body mass index. Amongst the surgical approach adopted between the two groups, with all operations being open surgeries in the two groups. There was no difference even in the distribution of colorectal pathology in the groups.

In present study, 16 participants from the Non-ERAS group had undergone mechanical bowel preparation (MBP) while 5 from the ERAS group had undergone MBP. No complications were recorded in present study participants. A meta-analysis done in 2011 could not find statistically significant differences between patients with MBP versus no MBP in terms of anastomotic leakage, mortality rates, need for re-operation and wound infections[7].

PONV affects 25 – 35% of all surgical patients and is a leading cause of patient dis-satisfaction and delayed discharge from hospital. Major abdominal surgery for colorectal disease is associated with a high prevalence of PONV, reaching 70% in some trials.

In present study 37/80 (46.25%) of the participants experienced PONV. Out of these, 30 participants were from the Non-ERAS group compared to 7 participants from ERAS group. The etiology of PONV is multifactorial and can be classified into three factors: patient, anesthetic and surgical. Female gender, those with a past history of PONV or motion sickness and non- smokers, are at particular risk[8].
As per the guidelines for perioperative care in elective colorectal surgery patients with 1–2 risk factors should ideally receive a two-drug combination prophylaxis using first-line anti-emetics. Patients with more than 2 risk factors undergoing colorectal surgery should receive 2–3 anti-emetics [9]. All patients in the ERAS group were screened to identify risk factors if any and were given anti-emetics as per the protocol, which could explain the lower proportion of PONV in the ERAS group.

Urinary drainage during and after colorectal surgery is used traditionally for two main reasons: prevention of urinary retention and monitoring of urine output. The duration of catheterization is directly related to a risk of UTI and may hinder postoperative mobilization and should therefore be limited. As per the guidelines for urinary drainage in ERAS protocols, routine transurethral catheterization is recommended for 1–3 days after colorectal surgery. The duration for removal of catheter is generally categorized based on known risk factors for retention like – male gender, epidural analgesia and pelvic surgery. Accordingly, majority of the participants belonging to ERAS group had their catheter removed on 1st or 2nd day post-surgery while majority of the Non-ERAS participants had their catheters removed after the 3rd or 4th day post-surgery. This could explain that the higher proportion of participants in the Non-ERAS group developing UTI as compared to ERAS group in present study.

In present study, we reinforced the opinion of elimination of the NGT at time of extubation with a compliance rate of 100%. Wisam and colleagues et al showed that most of European and US surgeons do not remove NGT after surgery; however, there is no proof supporting their opinion as this may be linked with patient discomfort as well as more complications [10,11]. In a study done in Egypt, it was pointed that early removal of NGT prompts early enteral feeding in ERAS compared to non-ERAS group [12]. Roulin et al., reported that, early oral feeding keeps the absorptive function of the bowel that leads to more collagen at the anastomotic line, positive nitrogen balance, accelerate wound healing as well as lessen postoperative sepsis [13].

The use of a drain in the pelvic cavity after rectal surgery or the peritoneal cavity after rectal or colonic surgery has historically been advocated to evacuate or prevent blood or serous collections and to prevent or detect anastomotic leakage [9]. However, the latest RCTs now suggest that Pelvic and peritoneal drains show no effect on clinical outcome and should not be used routinely [14,15]

In present study, surgical site infection was more in the non-ERAS group compared to ERAS group which could be attributed to the fact that drain removal in non-ERAS group was done after 7 days in all participants, while in maximum participants of ERAS group drain was done earlier.

In present study mobilization of patients in the ERAS group was done earlier compared to non-ERAS group patients. Quick mobilization is a key for hastening the postoperative recovery period as it stimulates the return of normal gastrointestinal tract function and guards against thromboembolic complications [12]. Gregg et al. also mentioned that, early ambulation is directly linked to a reduction in hazard of chest complications, DVT as well as protection of motor power [16].

Overall, ERAS was associated with a significant decline in mean postoperative hospital stay and ERAS groups participants were discharged earlier compared to non-ERAS group in present study. This was similar to previous studies [12]. Lower PONV rates lower UTI and SSI rates, lower rates of post-operative complications, earlier mobilization and earlier resumption of oral PCA in participants of the ERAS group could cumulatively be considered as factors favoring earlier discharge.

CONCLUSION

ERAS protocols are safe and effective. Its application involves significant change in the practice for the entire care team. There is decreased incidence of post-operative nausea and vomiting, infections and other adverse events which was found to be statistically significant. Improved outcomes with quicker and pain free recovery with earlier return to daily activities was found to be statistically significant in present study. ERAS is beneficial in reducing the length of hospital stay thus providing economic relief. There is a need for further evaluation and, if plausible, a more detailed description of the impact of each of the ERAS component on postoperative recovery.

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