A RANDOMISED CONTROLLED TRIAL TO ASSESS THE IMPACT OF ERAS (ENHANCED RECOVERY AFTER SURGERY) ON LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT Background: Gallstone disease represents a significant burden for healthcare systems making laparoscopic cholecystectomy one of the most common surgical procedures performed in the world. **Aims and Objectives:** To compare the outcome of the Enhanced recovery after surgery (ERAS) program and conventional care in patients undergoing laparoscopic cholecystectomy with respect to their post-operative pain, bowel movements, complications and the post-operative length of stay. **Methods:** A prospective study was conducted on 40 patients undergoing laparoscopic cholecystectomy in Victoria Hospital from the month of November 2019 to May 2021. Laparoscopic cholecystectomy was performed electively on patients diagnosed with symptomatic cholelithiasis. ERAS protocol was implemented for Group A with 20 patients, whereas Conventional care was followed for Group B with 20 patients, all chosen and allocated randomly. **Result:** ERAS protocol resulted in better post-operative analgesia and decreased post-operative length of stay in comparison to Conventional care. **Conclusion:** ERAS protocol in laparoscopic cholecystectomy has a positive impact on the patient and the healthcare system and, therefore, must be followed in all cases.

KEYWORDS ERAS, Laparoscopic cholecystectomy, Post-operative recovery

Introduction

Gallstone disease represents a significant burden for healthcare systems worldwide and is one of the most common disorders among patients presenting to General Surgery OPD and Emergency with abdominal discomfort. In India, the prevalence of gallstones ranges from 6% to 9% in the general adult population. Autopsy reports have shown a prevalence of gallstones from 11% to 36%[1].

Laparoscopic cholecystectomy is one of the most common surgical procedures performed in the world. Elective laparoscopic cholecystectomy is performed as a day-care procedure in a few hospitals, but in most, the hospital stay spans a few days. Causes of prolonged rehabilitation are associated with severe pain, dyspepsia and postoperative complications, including surgical site infections and postoperative ileus. However, this prolonged hospital stay is not always due to postoperative complications, but to the conventional perioperative care protocol followed. Inadequate pain management, intestinal dysfunction, and immobilization have been recognized since 1997 as among the main factors delaying postoperative recovery[2].

In this era of minimal access and fast-track surgery, patients undergoing laparoscopic cholecystectomy prefer to stay at the hospital for a shorter period and resume work as early as possible.

Enhanced recovery after surgery (ERAS) programs may improve rehabilitation quality. This study aims to evaluate the ERAS program's outcome in patients undergoing laparoscopic cholecystectomy.

Review of Literature

M.J. Scott et al. studied the pathophysiological considerations in ERAS for gastrointestinal surgeries in 2015. In the meta-analysis, Scott concluded that ERAS is a synergistic approach which phys-

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iologically makes sense, although it is not always translated into clinical outcome. ERAS is evidence-based. However, translation into clinical care is still lagging. ERAS principles require more research and can lead to major improvements in the quality of patient care, better patient outcomes, and economic benefits for the whole health care system[3].

Prakash Paudel et al. studied the outcomes following the Enhanced recovery after surgery (ERAS) program in Laparoscopic cholecystectomy (1st August 2016 to 31st July 2017) in Nepal Medical College in a prospective randomized controlled study. Among the 204 patients enrolled, mean age, BMI, operative time, pain score, doses of top-up analgesia, hospital stay, time to ambulation and tolerance of oral feeding were comparable between the two groups. In conclusion, implementing the ERAS protocol enhanced postoperative recovery, improved patient satisfaction and reduced postoperative nausea, vomiting and depression in patients undergoing laparoscopic cholecystectomy[4].

Zhengyan Li et al. studied the role of Enhanced recovery after surgery (ERAS) programs for laparoscopic abdominal surgeries in the form of a systematic review and meta-analysis in 2018. It was concluded that the ERAS protocol for laparoscopic abdominal surgery is safe and effective, thereby reducing hospital stay, lower overall postoperative complication rates and decreasing hospital cost. Combined with the laparoscopic technique, ERAS is associated with faster postoperative recovery without increasing readmission rate and perioperative mortality[5].

Methodology

A prospective study was conducted on 40 patients older than 18 undergoing laparoscopic cholecystectomy under general anaesthesia in a tertiary care hospital between November 2019 and December 2020.

Patients with comorbidities (hypertension, diabetes mellitus, ischaemic heart disease, tuberculosis) were excluded from the study.

After taking informed written consent, patients were randomly divided into Group A and Group B based on a randomisation sequence obtained from www.randomisation.org.

Group A

Procedure: Laparoscopic cholecystectomy with the implementation of the ERAS program[4].

Pre-operative: Carbohydrate loading given 12 hours before surgery (800ml over 20 minutes) and 6 hours before surgery (400ml over 10 minutes), using a pre-prepared carbohydrate loading drink.

Intra-operative

1. Low-pressure pneumoperitoneum (8-9 mmHg)
2. Trocar wound and intraabdominal anaesthesia with 0.25% ropivacaine (20ml diluted in 80ml normal saline)

Post-operative care

1. Mobilization did 4 hours after surgery
2. Oral sips were given 4 hours after surgery
3. Liquid food is given 6 hours after surgery
4. The postoperative pain level evaluation at rest by VAS (Visual analogue scale) at 0 hours (immediately after awakening), 6 hours and 24 hours postoperatively. Antiemetics in dyspepsia. Intestinal peristalsis evaluation by auscultation every 2 h after surgery.

Group B

Procedure: Laparoscopic cholecystectomy with conventional perioperative treatment[9].

Pre-operative: No carbohydrate loading.

Intra-operative

1. Standard pneumoperitoneum pressure (12-14 mmHg)
2. No additional anaesthesia

Post-operative care

1. Mobilization 8h after surgery
2. Oral sips gave 8 hours after surgery
3. Liquid food intake started 12 hours after surgery
4. The postoperative pain level evaluation at rest by VAS (Visual analogue scale) at 0 hours (immediately after awakening), 6 hours and 24 hours postoperatively. Antiemetics in dyspepsia. Intestinal peristalsis evaluation by auscultation every 2 h after surgery.

All patients will be analysed for discharge based on the following criteria:

- Tolerating a soft diet with no nausea or abdominal discomfort
- Pain adequately controlled with oral analgesia
- Adequate mobilization.

Patients will be followed up at 1 week, 1 month and SOS. Any complications and readmissions will be recorded.

Assessment tools

Visual analogue scale (For Pain).

Outcome measures

1. Post-operative length of stay

   Time interval measured from the end of surgery till the patient is deemed fit for discharge based on the criteria (1. Tolerating soft diet with no nausea, vomiting or abdominal discomfort 2. Pain adequately controlled with oral analgesia 3. Adequate mobilization, measured in hours.)

2. Complications

   Number of patients who develop postoperative complications (surgical site infections, postoperative ileus, requirement of readmission)

3. Post-operative pain

   Level of postoperative pain measured with a visual analogue scale in centimetres

4. Post-operative bowel movements

   Post-operative bowel movements are measured through auscultation for bowel sounds and mean duration to pass flatus and stools.

Statistical Analysis

SPSS (Statistical Package For Social Sciences) version 20. (IBM SPASS statistics [IBM corp. released 2011] was used to perform the statistical analysis

- Data was entered in the excel spreadsheet.
- The mean, standard deviation for quantitative variables, frequency and proportions for qualitative variables calculated descriptive statistics of the explanatory and outcome variables.
- Inferential statistics like
  - The Chi-square test was applied to qualitative variables
  - An Independent sample t-test was applied to compare the statistical difference of quantitative variables between the groups (Conventional and ERAS).
- The level of significance is set at 5%

Results

The study was conducted in the department of General Surgery, BMCRI, Bangalore, from November 2019 to December 2020. This is a randomized prospective clinical trial.

Age

The majority of the patients in the present series were in the age group of 41-50 years of age, with a mean age of 47.87 years. Our patients ranged from 21-74 years old.

Gender

In our study, there was an equal distribution of males (35%) and females (65%) in both the Conventional and ERAS groups.

Diagnosis

In our study, all the patients had the diagnosis of Symptomatic cholelithiasis except one patient in the ERAS group who presented with a gallbladder polyp.

Mean Duration of Surgery

The mean duration of surgery was slightly higher in the ERAS group, with a mean duration of 67.7 minutes in comparison with the Conventional group, with a mean duration of 62.7 minutes. This could be due to the decreased pneumoperitoneum pressure in the ERAS group. However, the Independent sample t-test showed no statistically significant difference (p=0.46).

Mean Duration to Oral Intake

In our study, the mean duration of oral intake of sips was set at 4 hours and 8 hours post-surgery for the ERAS and Conventional groups, respectively.

Mean Duration to Mobilization

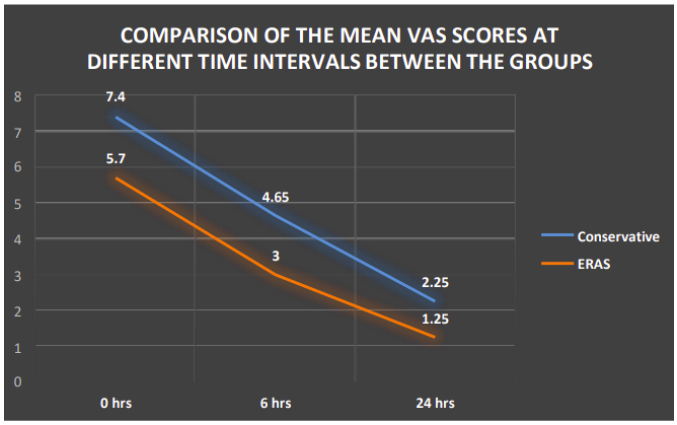
In our study, the mean duration to mobilization post-surgery was decided at the start of the trial to be set at 4 hours for the ERAS group and 8 hours for the Conventional group.

Post-operative Bowel Movements

The mean duration of bowel movements was measured using three parameters, i.e. auscultation of first bowel sounds, the passage of flatus and the passage of stools. In our study, we noted that the ERAS group had an earlier return of bowel movements post-surgery than the Conventional group. However, this result was not statistically significant to clearly state that ERAS protocol alone helps in early bowel movements post-surgery.

Post-operative Pain

Post-operative pain is one of the most important factors determining the timing of patients' discharge from the hospital. In our study, we noted a significant decrease in post-operative pain following surgery in the ERAS group compared with the Conventional group. Independent sample t-test showed a significant statistical difference between the two groups with a p-value of 0.00 at all the time intervals (0 hours, 6 hours and 24 hours)



Graph 1 Comparison of the mean VAS score for post-operative pain

Complications

In our study, there were just 7 patients with minor complications, including excess bleeding, gall bladder perforation during specimen retrieval, and spillage of contents. However, there was no significant statistical difference between the two groups holding one protocol better than the other based on the rate of complications in the ERAS group and the Conventional group.

Post-operative Length of Stay

Strict guidelines were adhered to deem the patient fit for discharge following surgery. These guidelines included adequate mobilization, pain adequately controlled with oral analgesia and the ability to tolerate a soft diet orally with no nausea, vomiting or abdominal discomfort.

In our study, we noted that the patients in the ERAS group were deemed fit for discharge much earlier, with a mean post-operative length of stay of 30.3 hours in comparison with the conventional group had a mean duration of 39.1 hours. The independent sample t-test showed a statistical difference between the two groups with a p-value of 0.004.

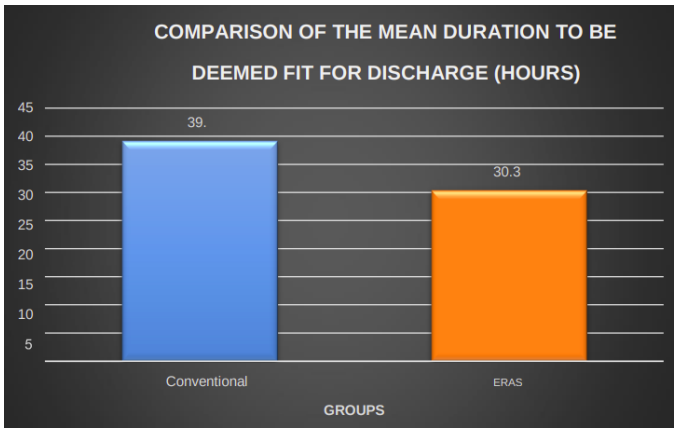
Discussion

Laparoscopic cholecystectomy, one of the most common elective surgeries performed worldwide, need every aspect of the perioperative care addressed to have a positive outcome for the patient, the healthcare system and the economy.

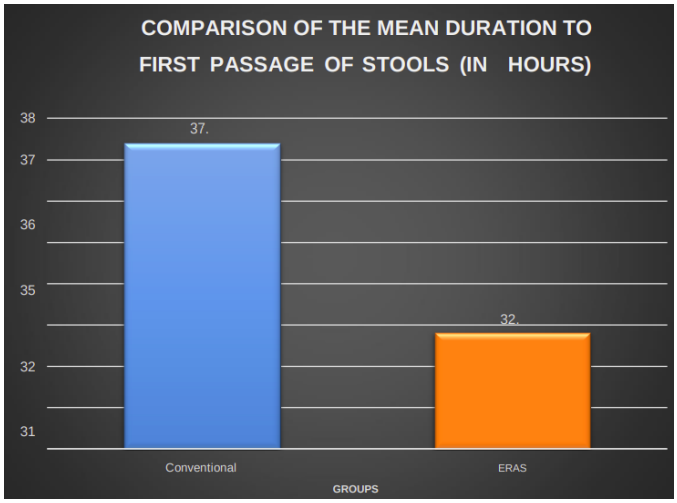
All 40 patients underwent laparoscopic cholecystectomy with no conversion to open cholecystectomy.

Groups	N	Minimum	Maximum	Mean	S.D	Mean diff	p value
Conventional	20	28	62	39.10	10.249	8.75	0.004*
ERAS	20	24	50	30.35	7.365		

*significant



Graph 2 Comparison Of The Mean Duration To Be Deemed Fit For Discharge (In Hours) Between The Groups Using Independent Sample T Test



Graph 3 Comparison Of The Mean Duration To First Passage Of Stools (In Hours) Between The Groups

In this randomized controlled trial, patients were randomly divided into two groups: Group A following the ERAS protocol and Group B following the Conventional care.

The following parameters were used to compare the two protocols.

- Post-operative length of stay
- Post-operative pain
- Post-operative bowel movements
- Complications

Our study had a statistically significant difference with a p-value < 0.05 for the post-operative length of stay and post-operative pain. However, the difference in postoperative bowel movements and complications was not statistically significant, with a p-value>0.05.

Michael Pedziwiatr et al. studied the concept of Enhanced recovery after surgery in gastrointestinal surgery in the form of a systematic review and meta-analysis in 2018. He concluded that ERAS is an evidence-based paradigm shift in perioperative care, proven to lower both recovery time and postoperative complication rates. ERAS thus leads to economic benefits in the majority of surgical disciplines. In addition, ERAS protocol has been well established in colorectal surgery, gastrectomies, liver surgery and pancreatic surgery[6].

We can conclude that ERAS protocols need to be implemented in cases of Laparoscopic cholecystectomy to have better post-operative pain relief.

Patients undergoing ERAS protocols can be discharged earlier than those undergoing conventional care with no additional risk of complications.

Thus, ERAS protocol in laparoscopic cholecystectomy positively impacts the patient and the healthcare system by decreasing the post-operative length of stay burden, hence having a favourable effect on the economy.

Limitations

As the study was conducted on a smaller population, generalizing these results to a bigger population might not be appropriate, and further studies would be needed to have a definitive picture of the effect of ERAS on postoperative recovery in patients undergoing laparoscopic cholecystectomy.

Conclusion

In our randomized controlled study, we found that ERAS protocol in Laparoscopic Cholecystectomy was better than Conventional care when compared in terms of Postoperative length of stay and Post-operative pain relief. In addition, there was no additional risk of complications in adopting the new ERAS protocol.

To conclude, ERAS protocols need to be implemented in all cases of laparoscopic cholecystectomy, as it's proven to have a better post-operative outcome than Conventional care.

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Conflict of interest

There are no conflicts of interest to declare by any of the authors of this study.

References

1. Thai H. Pham, John G. Hunter. Gallbladder and the extrahepatic biliary system. In: F. Charles Brunicardi, Dana K. Andersen, Timothy R. Billiar, David L. Dunn, John G. Hunter, Jeffrey B. Matthews et al. Schwartz's principles of Surgery. Tenth edition. New York: McGraw-Hill; 2015. p. 1309-40

2. Kehlet H. Multimodal approach to control postoperative pathophysiology and rehabilitation. Br J Anaesth. 1997; 78: 606-17
3. Scott M.J, Baldini G, Fearon K.C.H, Feldheiser A,Feldman L.S, Gan T.J, et al. ERAS for gastrointestinal surgery, part 1: pathophysiological considerations. Acta Anaesthesiol Scand. 2015; 59(10): p. 1212-31
4. Paudel P, Ghimire S, Rai S, Shrestha ML. Evaluation of outcomes following ERAS programme in laparoscopic cholecystectomy. Nepal Med Coll J. 2017; 19(4) p. 188-92
5. Li Z, Zhao Q, Bai B, Ji G, Liu Y.ERAS Programs for laparoscopic Abdominal Surgery: A systematic review and meta-analysis. World J Surg. 2018; Volume42, Issue 1; p. 3463-73
6. Pedziwiatr M, Mavirikis J, Witowski, Adamos, Major P, Nowakowski Michael, et al. Current status of ERAS protocol in gastrointestinal surgery. Med Oncol. 2018; 35: 95