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Original Article

Surgery Section

Comparison of Enhanced Recovery After Surgery (ERAS) Protocol versus Conventional Approach for Laparoscopic Cholecystectomy: An Interventional Study

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ABSTRACT

Introduction: Laparoscopic cholecystectomy is considered the gold standard for benign gallbladder disease due to its minimal invasiveness, reduced bleeding, and rapid recovery. Enhanced Recovery After Surgery (ERAS) protocols, recognised for lowering surgical stress and complications, are increasingly adopted for their postoperative benefits.

Aim: To assess and compare postoperative outcomes in laparoscopic cholecystectomy patients undergoing ERAS versus conventional approaches.

Materials and Methods: This prospective interventional study was conducted at the Surgery Department of Mahatama Gandhi Medical College and Research Institute, Puducherry, India from January 2021 to June 2022. All patients above 18 years of age undergoing laparoscopic cholecystectomy with American Soceity of Anaesthesiologists (ASA) I and II were included. A total of 90 subjects, 45 subjects in the Group A (ERAS protocol) and 45 subjects in the Group B (Conventional approach), were included based on computer-generated random numbers with concealment of allocation. Key parameters, including length of hospital stay, morbidity, postoperative pain, and protocol compliance, were evaluated between both groups. Continuous variables were presented as means with standard deviations and analysed using unpaired t-tests. Categorical variables were expressed as percentages and compared using chi-square tests.

Results: The mean age of the study population in ERAS and conventional was 41.3±7.9 years and 41.6±9.6 years, respectively. Similarly, 17 male participants were from the ERAS group and 15 were from the conventional group, whereas among female participants 28 were from the ERAS group and 30 were from the conventional group. The ERAS group demonstrated significant advantages: shorter hospital stays (91.2% vs. 73.4%, p=0.0274), lower Grade 1 morbidity (p=0.0213), and reduced postoperative pain (p=0.0001).

Conclusion: The ERAS group exhibited notable benefits, including a shorter hospital stay, reduced morbidity, and lower postoperative pain. These findings suggest the potential for enhanced recovery outcomes with ERAS protocol implementation in laparoscopic cholecystectomy patients.

Keywords: Length of hospital stay, Morbidity, Postoperative pain

INTRODUCTION

Over the past 50 years, surgical outcomes have significantly evolved. The mortality rate following major surgeries decreased from 10603 per million before 1970 to 1176 per million between 1990 and 2000 [1]. Surgery has advanced by leaps and bounds since 1960 [2]. Most of these reported changes have been linked to improved perioperative care, the use of modern technology, enhanced understanding of physiology, and a decrease in surgical stress. ERAS protocols are a combination of interventions designed to combat stress and understand the neurohormonal mechanisms involved in the body's reaction to the stress caused by surgery itself [3].

Many surgical specialties have successfully utilised ERAS protocols. When technically feasible, combining minimally invasive laparoscopic surgery with ERAS has the potential to significantly enhance patient outcomes and is quickly becoming the preferred course of action [4,5].

Due to its minimal invasiveness, laparoscopic cholecystectomy is considered the gold standard treatment for benign gallbladder disease and offers advantages such as minimal bleeding, reduced discomfort, and rapid recovery [6]. Many of these advancements have been implemented in clinical practice. ERAS protocols have been increasingly adopted in recent years due to their benefits in reducing the incidence of surgical stress and complications, expediting postoperative rehabilitation, and reducing hospital stays [7]. It is essential to evaluate the use of ERAS protocols in laparoscopic cholecystectomy [8]. Therefore, the present study aimed to assess the effectiveness of ERAS protocols on patients undergoing laparoscopic cholecystectomy.

MATERIALS AND METHODS

This prospective interventional study was conducted at the General Surgery Department of Mahatma Gandhi Medical College and Research Institute, Puducherry, India from January 2021 to June 2022. Ethical approval (MGMCRI/Res/01/2020/102/IHEC/362) was obtained from the Institutional Review Board, and informed consent was acquired from all participants.

Inclusion and Exclusion criteria: All patients above 18 years of age undergoing laparoscopic cholecystectomy with ASA I and II were included. Patients with Choledocholithiasis, allergies to Non Steroidal Anti Inflammatory Drugs (NSAIDs), and those requiring transfer to an intensive care unit after surgery were excluded from the study.

Sample size calculation: The total minimum sample size required to produce statistically significant results was determined to be 80 using a formula $n=\left(\frac{r+1}{r}\right)\left(\sigma\left(\frac{z_{1-\alpha/2}+z_{1-\beta}}{d}\right)\right)^2$.

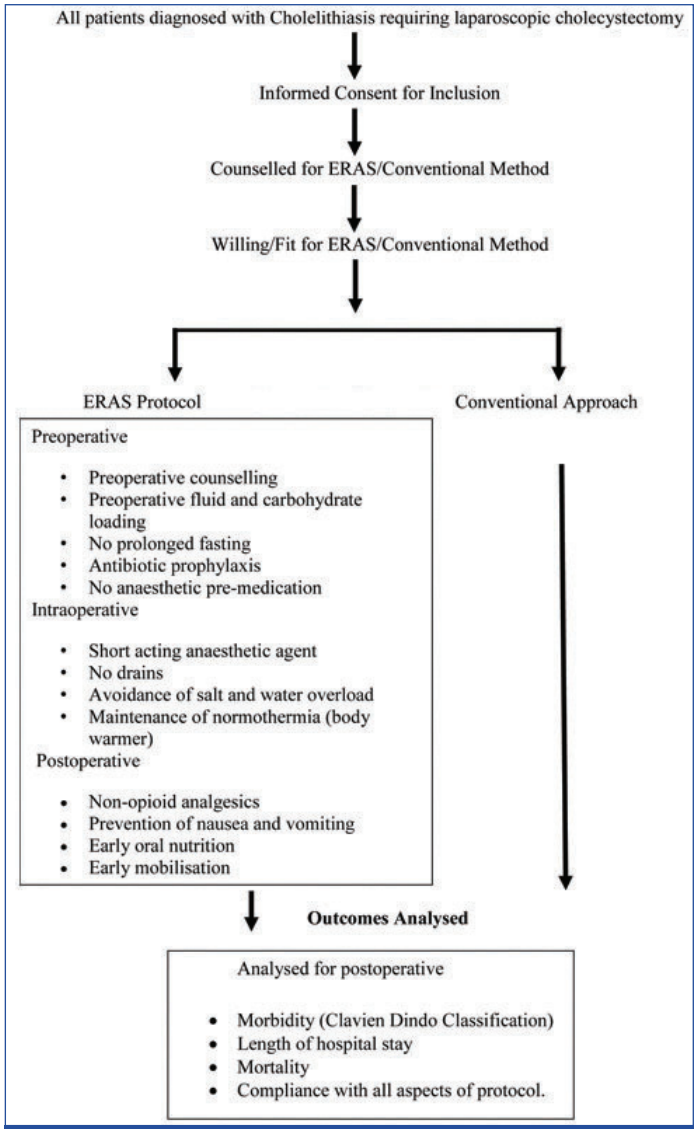
For a two-sample hypothesis test with a 95% confidence level (α=0.05), the critical value $Z_1-\alpha/_2$ is 1.96. Additionally, for an 80% power level (1-β=0.80) with a standard deviation (σ) of 4.7604, the critical value $Z_1-\beta$ is 0.84.

Assuming two groups with sample means M_1=11 and M_2=8, and a difference in means (d) of 3 for the pain variable, a total of 90 subjects, with 45 subjects in the conventional group and 45 subjects in the ERAS group, were included based on computer-generated random numbers with concealment of allocation to account for a 10% dropout rate [8].

Study Procedure

- **Group A (ERAS protocol):** In Group A, following the ERAS protocol, preoperative measures included the administration of 800 mL of water with 100 gm of sugar on the night before surgery, 50 gm of sugar in 400 mL of water two hours before anaesthesia, antibiotics (cefazolin 2 gm i.v.) one hour before surgery, and a proton pump inhibitor (Inj. Pantoprazole 40 mg i.v.) in the morning of the surgery. Additionally, Tab. Paracetamol 1 gm and Inj. Ketorolac 30 mg i.v. were provided in the morning of the surgery. Intraoperatively, i.v. fluid Ringer's lactate at 3 mL/kg/hour (or titrated according to blood loss) was administered, and continuous temperature monitoring and maintenance using a body warmer and warm fluids were implemented. Nasogastric tubes were used if necessary but removed before completing surgery. Long-acting opioids/anaesthetics were avoided, as were drains. Inj. Dexamethasone 8 mg i.v. was given after anaesthesia induction, and Inj. Ondansetron 4 mg i.v. was administered at the end of surgery (or 15 min before extubation). Port site infiltration with 0.5% Bupivacaine was performed. Postoperatively, oral fluids were introduced once the patient was conscious, oriented, and able to respond to oral commands, followed by solids if tolerated. Inj. Paracetamol 1 gm i.v. was given six hours after the last oral dose, Inj. Ketorolac 30 mg i.v. was administered 12 hours after the morning dose, and early mobilisation was encouraged.
- **Discharge:** Patients were discharged once they fulfilled the following criteria: ability to take oral feeding, able to ambulate alone, pain adequately controlled with oral analgesics {Virtual Analogue Scale (VAS)} <4), haemodynamic stability, capable of micturition, and absence of nausea and vomiting. The decision to discharge was made by an attending surgeon; further stay in the hospital was based on the attending surgeon's discretion or failure of patients to fulfil the above criteria.
- **Group B (Conventional approach):** During preoperative care, patients included in this group received standard care with i.v. fluids (liberal protocol), antibiotics (cefazolin 2 gm i.v.), and continued postoperatively, opioid analgesics if, needed (tramadol 50 mg i.v.). Antiemetics were administered preoperatively only if patients presented nausea or vomiting. During Intraoperative care, all patients received general anaesthesia. Standard fluid therapy was followed. During postoperative care, patients were admitted to the postoperative ward. Vitals and pain were recorded. Pain was controlled with opioid analgesia if it was severe (VAS=8-10). Patients were started on oral feeding once bowel function was completely restored, defined by the presence of normal peristalsis, the passage of flatus, or depositions.
- **Discharge:** Patients were discharged once a full normal diet was tolerated, ambulation was achieved, and pain was adequately controlled with oral analgesics (VAS <2).

Both groups underwent assessment for various parameters, including the length of hospital stay, morbidity evaluated through the Clavien-Dindo Classification System [9], mortality, and compliance with all aspects of protocols [Table/Fig-1].



[Table/Fig-1]: Flowchart to summarise the sequence of events.

STATISTICAL ANALYSIS

Statistical analyses were conducted using standard methods to assess the significance of differences between Group A (ERAS protocol) and Group B (Conventional approach). Continuous variables, such as age and Body Mass Index (BMI), were presented as means with standard deviations and analysed using unpaired t-tests. Categorical variables, including gender distribution and the prevalence of co-morbidities, were expressed as percentages and compared using Chi-square/Fisher's-exact tests. The primary endpoints, such as length of hospital stay, morbidity (Clavien-Dindo Classification), and postoperative pain scores Visual Analogue Scale (VAS), were subjected to appropriate statistical tests. The Chi-square test was applied for categorical outcomes, while the unpaired t-test was used for continuous variables. A p-value less than 0.05 was considered statistically significant. All analyses were performed using statistical software Statistical Packages for Social Sciences (SPSS) (version 19.0), ensuring a rigorous examination of the differences in outcomes between the two study, group A.

RESULTS

In the group A 9 (10%) patients were ≤30 years, 15 (16.7%) patients were 31-40 years, 14 (15.6%) patients were 41-50 years, and 7 (7.8%) were 51-60 years. In the group B, the distribution was 10 (11.1%), 12 (13.3%), 15 (16.7%), and 8 (8.9%), respectively. No significant differences were observed in mean age, gender distribution, mean Body Mass Index (BMI), and the prevalence of Diabetes Mellitus (DM), Hypertension (HTN), and dyslipidaemia [Table/Fig-2].

A significant difference was noted, with 91.2% of the group A having a hospital stay of five days or less, compared to 73.4% in the group B (p=0.0274) [Table/Fig-3].

The ERAS group exhibited significantly lower Grade 1 morbidity (Clavien-Dindo Classification) (p=0.0213) and experienced a notably

Parameters	Mean age (years)	Gender		Mean BMI	DM	HTN	Dyslipidaemia
		Male	Female				
Group A (n=45)	41.3±7.9	17	28	26.5±5.6	12	11	9
Group B (n=45)	41.6±9.6	15	30	27.1±4.3	10	10	7
p-value	0.8718$	0.6596*		0.9013$	0.6237*	0.8031*	0.581*

[Table/Fig-2]: Demographic data between groups.
$unpaired t-test was used, *chi-square test was used

Parameters	Group A	Group B	p-value#
≤5 days	41 (91.2%)	33 (73.4%)	0.0274*
>5 days	4 (8.8)	12 (26.6)	

[Table/Fig-3]: Length of hospitalisation in both groups.
#Chi-square test applied

lower mean VAS score 12 hours postoperatively, supported by a Chi-square test (p=0.0001). The length of hospital stay was also significantly shorter in the ERAS group (p=0.0014). Compliance with the protocol did not differ significantly between the groups (p=1.000) [Table/Fig-4].

Parameters	Morbidity (Grade 1)	Mean VAS score (12 h postoperative)	Compliance with protocol	Length of hospital stay
Group A (N=45)	0	4.1±1.6	45	3.5±1.6
Group B (N=45)	5	5.7±2.1	45	4.8±2.1
p-value	0.0213* Fisher's-exact test	0.0001* Chi-square test	1.000 Chi-square test	0.0014* Unpaired t-test

[Table/Fig-4]: Morbidity, pain score, compliance with protocol, and mean duration of hospitalisation in both groups.
*Significant

DISCUSSION

The present study found no significant differences in baseline characteristics such as mean age, gender distribution, and prevalence of co-morbidities between the ERAS and group B, similar to studies conducted by Akhtar MS et al., Kamel RK et al., and Rajareddy GV et al., [6,10,11]. However, it uniquely highlighted a significant difference in hospital stay lengths and postoperative outcomes, including lower Grade 1 morbidity and improved pain management, aligning with the trend of enhanced recovery outcomes reported by Rajareddy GV et al., [11]. Akhtar MS et al., emphasised ERAS's economic benefits, demonstrating reductions in hospital stay lengths and costs, aligning with present findings on efficiency but providing a broader economic perspective [6]. Kamel RK et al., explored the impact of ERAS across different surgical techniques, revealing improved recovery metrics and highlighting the importance of adherence to ERAS protocols [10]. This adherence aspect complements our study's findings on the clinical benefits of ERAS, suggesting that protocol compliance is crucial across diverse surgical settings. Rajareddy GV et al., focused on specific clinical outcomes such as pain management and reduced hospital stay in laparoscopic cholecystectomy patients, which parallels present study's findings on improved postoperative recovery metrics [11].

Matłok M et al., evaluated ERAS's contribution to bariatric surgery. According to their findings, 95.3% of individuals tolerated the oral dose of liquid nutrition within the first 24 postoperative hours, and 95.8% of them were fully mobile [12]. Opioids had to be given to 25.8% of the participants to ease discomfort. In 85.3% of the individuals, intravenous fluid delivery was stopped within 24 hours. The rate of complications was 10.5%. The readmission rate was 1.7%, and the median length of stay in the hospital was 2.9 days. They concluded that the ERAS recommendations were technically feasible, safe for individuals, and permitted shorter hospital stays without an increase in the frequency of problems or readmissions.

El-Shakhs S et al., stated that the ERAS program has been shown to be secure, not only in terms of lowering postoperative hospital stay and morbidity but also in terms of enhancing patient recuperation [13]. Sugisawa N et al., reported that 10.7% of postoperative complications occurred [14]. Pneumonia and anastomotic leakage were noted in one and zero individuals, respectively. The average postoperative hospital stay lasted 8 days, and 85.1% of the ERAS requirements were followed. Both the death rate and the readmission rate were zero. They concluded that people undergoing surgery for stomach cancer can safely use the ERAS recommendations.

Ni X et al., undertook a study to compare regular perioperative care and ERAS guidelines in laparoscopic Gastrointestinal (GI) procedures [15]. According to their findings, the ERAS group's postoperative hospital stay, duration to first flatus, and time to pass stools were all significantly lower than those of the conventional group. Additionally, participants following ERAS guidelines had a much lower rate of total postoperative complications. They concluded that ERAS guidelines are linked to quicker postoperative recovery, a shorter hospital stay, and a lower incidence of postoperative complications. ERAS guidelines should be recommended because they are more efficient and secure than conventional methods when used for laparoscopic GI surgery.

In line with present study, Garmpis N et al., in their review, stated that evidence-based guidelines known as ERAS are intended to standardise postoperative medical care, enhance patient outcomes, encourage quick healing, and lower healthcare costs [16]. ERAS is a multidimensional concept that includes preoperative, perioperative, and postoperative strategies to shorten the hospital stay and lower the rates of morbidity and complications after elective abdominal surgery. Improvements in outcomes are achieved, operational trauma and postoperative stress are reduced, there is less surgical pain, fewer problems, and a shorter period of hospital stay due to the optimisation of postoperative care and the healing process in accordance with these ERAS standards. All healthcare practitioners must collaborate in a multidisciplinary manner in order to implement ERAS, and a strong organisational structure and high protocol compliance rates are other requirements.

Additionally, Udayasankar M et al., evaluated a patient's recovery following an elective laparoscopic cholecystectomy by comparing it with the recommendations of ERAS and the standard perioperative approach [8]. They claimed that the ERAS group experienced less anxiety both before the procedure and six hours thereafter. An overall better perioperative experience also reduced hunger, thirst, and weariness. Blood sugar levels, pain, nausea, and vomiting were comparable between the groups. They concluded that the ERAS technique improves overall perioperative comfort in participants undergoing laparoscopic cholecystectomy by reducing anxiety as well as hunger, thirst, and fatigue.

In addition, Zhang N et al., conducted a study to investigate the application of ERAS in participants undergoing laparoscopic bile duct exploration and laparoscopic cholecystectomy combined [17]. They stated that one day after surgery, the WBC and CRP levels in the ERAS group were considerably lower than those in the laparoscopic cholecystectomy group. Regarding postoperative sequelae, there were appreciable variations between the ERAS group and the conventional group in terms of the frequency of nausea, postoperative pain, and vomiting. The flatus time and length

of hospital stay following surgery in the ERAS group were considerably shorter than those in the conventional group, demonstrating the effectiveness of postoperative rehabilitation. They concluded that the use of ERAS throughout the postoperative period in patients who had laparoscopic cholecystectomy with bile duct exploration decreased the response to stress and postoperative problems and enhanced postoperative recovery.

The present prospective cohort study offers a robust evaluation of ERAS protocols in laparoscopic cholecystectomy. The comparative design, statistical rigor, and multifaceted evaluation of key parameters, including the length of hospital stay and morbidity, contribute to the study's strength.

The study strongly advocates for the widespread implementation of ERAS protocols in laparoscopic cholecystectomy, emphasising the potential for improved patient outcomes. The significantly shorter hospital stays in the ERAS group suggest enhanced healthcare resource utilisation and potential cost savings. The findings also indicate an improved postoperative experience with lower pain scores and reduced morbidity, supporting the prioritisation of ERAS protocols for enhanced patient satisfaction. Comparable compliance rates between ERAS and conventional groups highlight the feasibility of integrating ERAS into routine clinical practice. The study underscores ERAS as a benchmark for standardising perioperative care, encouraging its adoption as a clinical standard. Additionally, the positive outcomes prompt further research exploration in larger populations and diverse surgical procedures, seeking optimisation and customisation of ERAS protocols for broader clinical applicability.

Limitation(s)

However, present study implemented various parameters; not all aspects of ERAS can be implemented in laparoscopic cholecystectomy, such as mechanical bowel preparation and deep venous thrombosis prophylaxis. The present study only involved 90 cases; if the study population were larger, other parameters such as compliance with the protocol could have been significant.

CONCLUSION(S)

The ERAS implementation was associated with a significantly shorter length of stay, reduced visual analogue pain score, and decreased morbidity. ERAS is a better approach after laparoscopic cholecystectomy in terms of outcomes compared to the conventional approach.

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