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Original Research Article

Evaluation of Enhanced Recovery after Surgery (ERAS) Protocols in Laparoscopic Cholecystectomy: Outcomes at Tertiary Care Centre in Rural North India

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Conflict of interest: Nil

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. Enhanced Recovery after Surgery (ERAS) protocols, recognized for lowering surgical stress and complications including length of hospital stay, are increasingly adopted for their postoperative benefits.

Aims and Objectives: To compare the outcome of the Enhanced Recovery After Surgery (ERAS) program and conventional care in patients undergoing laparoscopic cholecystectomy, in hospital setting in rural North India, with respect to their post-operative pain, bowel movements, complications, total opioid used, readmissions, surgical site infection (SSI) and the post-operative length of stay.

Materials and Methods: This prospective study was conducted at the Surgery Department of Hind Institute of Medical Sciences, Mau, Ataria, Sitapur, U.P., India. from May 2022 to April 2024. All patients above 18 years of age undergoing laparoscopic cholecystectomy with American Society of Anaesthesiologists (ASA) I and II were included. A total of 100 subjects, 50 subjects in the Group A (ERAS protocol) and 50 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 analyzed 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 38.6±6.8 years and 37.3±8.7 years, respectively. Similarly, 19 male participants were from the ERAS group and 17 were from the conventional group, whereas among female participants 31 were from the ERAS group and 33 were from the conventional group. The ERAS group demonstrated significant advantages: shorter hospital stays (92% vs. 68%, p=0.01), and reduced postoperative pain (p=0.01), Surgical Site Infection (SSI), no increase in readmissions.

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

Keywords: Enhanced Recovery after Surgery (ERAS), Cholecystectomy, Laparoscopy, Length of hospital stay, Postoperative pain. Surgical Site Infection (SSI).

Introduction

Several surgeries in the future are expected to be performed on an ambulatory basis due to economic advantages and reduced hospital stay for the patient. This approach warrants a better recovery of

the patient after surgery [1]. Laparoscopic cholecystectomy done under general anaesthesia is one such widely performed day care surgery. It also has various complications due to pneumoperitoneum and positioning including changes in cardiac output and blood pressure, decreased lung volumes, basal atelectasis, increased intrapulmonary shunting, raised airway pressures and pain apart from postoperative nausea and vomiting (PONV) [2]. Recovery of a patient after any surgery and anaesthesia is influenced by numerous nonsurgical factors. A carefully planned perioperative care can enhance the recovery and thereby improve perioperative comfort [3]. This enables an early return to normal activities contributing to medical and economic benefit in healthcare. Various approaches have been proposed for the same [4,5]. Enhanced recovery after surgery (ERAS) approach recommended by the Association of Surgeons of Great Britain and Ireland,[6]and guidelines from ERAS society,[7] aims to improve perioperative patient comfort. 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 [8]. With the development of ERAS in recent years, many of these measures have been applied in clinical practice, because of their advantages in reducing the incidence of surgical stress and complications, accelerating postoperative rehabilitation, and shortening hospital stay [8,9]. There have been many reports on the use of ERAS in surgery. Many components of the ERAS have been studied and proved to enhance recovery.[2,9-11] Due to limited literature on ERAS in laparoscopic cholecystectomy, we aimed to compare ERAS with the traditional approach in patients undergoing elective laparoscopic cholecystectomy. This study aims to evaluate the ERAS program's outcome in patients undergoing laparoscopic cholecystectomy.

Materials and Methods

This prospective study was conducted at the Surgery Department of Hind Institute of Medical Sciences, Mau, Ataria, Sitapur, U.P., India. From May 2022 to April 2024. Ethical approval 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 (18-70 Years) 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.

A total of 100 patients were selected by consecutive sampling after meeting inclusion and exclusion criteria. Patients were randomly allocated into two groups after taking informed consent. Randomisation was done by computer-generated random method into two groups designating one group as ERAS group and another group as Conventional Group. 50 patients in each group. Patient age, sex and ASA Score were recorded. Appropriate perioperative parameters were applied in perioperative period to each group. Outcomes like length of hospital stay, readmissions, frequency of SSI were recorded for each patient. Total opioid dose was recorded in form of morphine equivalent units. Difference of score from base line for all patients was calculated and their mean compared in each group. Kolmogorov Smirnov Test was used to assess the distribution of data. Data were reported as Mean ±SD or frequencies (%) where applicable. Mean difference within the groups were compared by student t test. P value less than 0.05 was considered statistically significant. Categorical variables were analysed by chi-squared test.

Study Procedure:

Group A:

Procedure: Laparoscopic cholecystectomy with the implementation of the ERAS program.

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

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:

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 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 were considered statistically significant.

All analyses were performed using statistical software Statistical Packages for Social Sciences (SPSS) (version 26.1), ensuring a rigorous examination of the differences in outcomes between the two study group, A and B.

Results

In the group A- 10 (20%) patients were ≤30 years, 19 (38%) patients were 31-40 years, 15 (30%) patients were 41-50 years, 5 (10%) were 51-60 years and 1 (2%) were 61-70 years. In the group B, the distribution was 9 (18%), 17 (34%), 14 (28%), 7 (14%) and 3 (6%) 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-1/Fig-1].

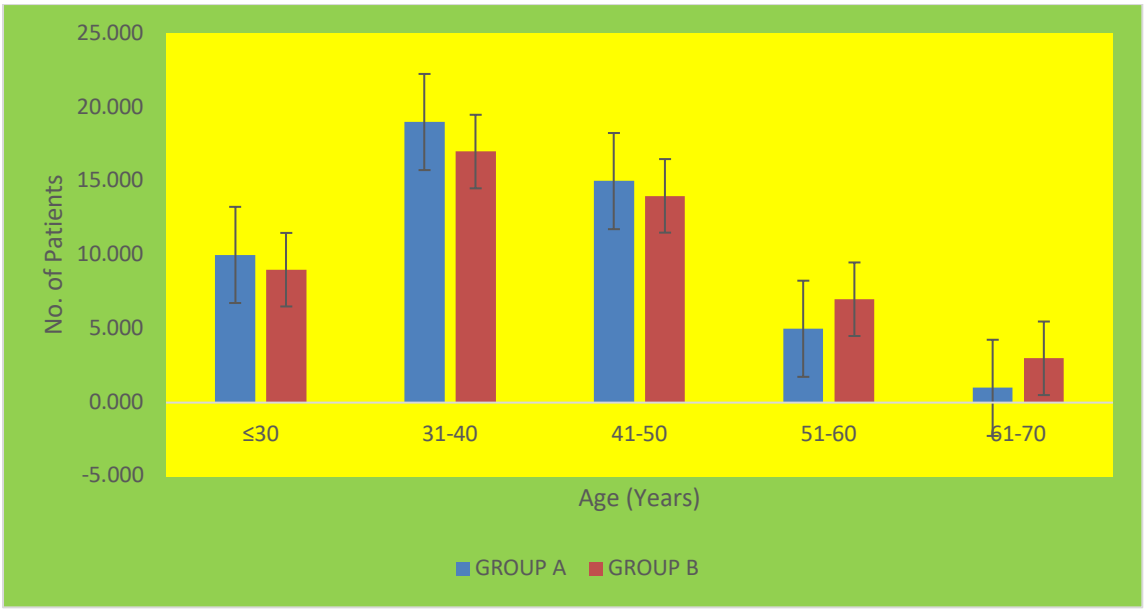

Figure 1: Age (years) distribution of patients in two groups (A & B)

Table 1: Demographic data between two groups:

Parameters	Mean Age (Years)	Gender		Mean BMI	DM	HTN	Dyslipidaemia
		Male	Female				
Group A (ERAS) N=50	38.6±6.8	19	31	26.81±3.66	11	12	6
Group B (Conventional) N=50	37.3±8.7	17	33	27.21±3.12	12	13	5
P value	0.873 (NS)	0.05		0.884 (NS)	0.675 (NS)	0.983 (NS)	0.545 (NS)

Unpaired t-test was used, *chi-square test was used

A significant difference was noted, with 92% of the group A having a hospital stay of five days or less, compared to 68% in the group B (p=0.01) [Table-2].

Table 2: Length of hospitalisation in both groups

Parameters	≤5 days	≥5 days	P Value
Group A,N=50	46 (92%)	4 (8%)	0.01
Group B, N=50	34 (68%)	16 (32%)	

Chi-square test applied

The ERAS group exhibited significantly lower Grade 1 morbidity (Clavien-Dindo Classification) (p=0.0211) and experienced a notably lower mean VAS score, 12 hours postoperatively, supported by a Chi-square test (p=0.01). The length of hospital stay was also significantly shorter in the ERAS group (p=0.01). Compliance with the protocol did not differ significantly between the groups (p=1.000) [Table-3/Fig-3].

Table 3: Morbidity, pain score, compliance with protocol, and mean duration of hospitalisation in both groups

Parameters	Morbidity Grade-1	Mean VAS score (12 h postoperative)	Compliance with protocol	Length of hospital stay	Total Opioid Use (morphine equivalent units)	Readmissions	Surgical Site Infection
Group A, N=50	0	3.9±1.2	50	3.8±1.7	12.64±4.31	6	3
Group B, N=50	4	5.1±1.3	50	5.3± 1.9	17.22±5.48	12	7
P value	0.0211 Fisher's-exact	0.01 Chi-square test	1.000 Chi-square test	0.01 Unpaired t-test	0.05	0.05	0.05

	test						

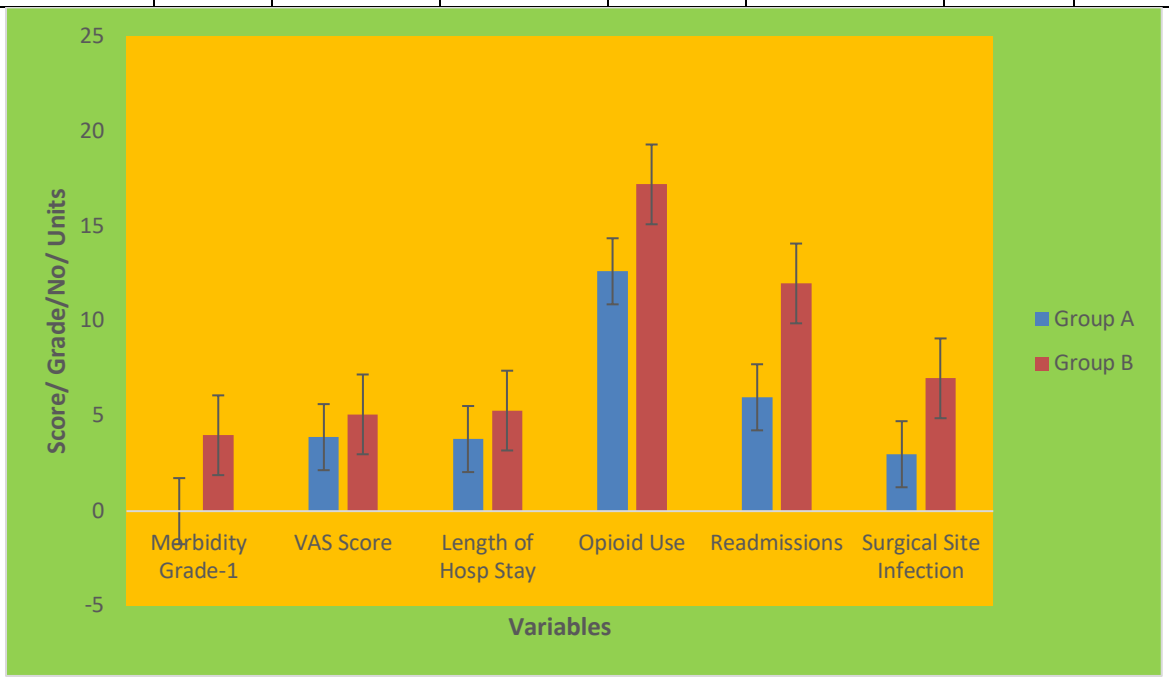

Figure 2: Morbidity, pain score, Opioid used, Readmissions, Surgical Site Infection and mean duration of hospitalisation in both groups

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 previous researchers [11-16]. 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 in a previous study [17]. A study also 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 [19]. A study also explored the impact of ERAS across different surgical techniques, revealing improved recovery metrics and highlighting the importance of adherence to ERAS protocols [20]. This adherence aspect complements our study's findings on the clinical benefits of ERAS, suggesting that protocol compliance is crucial across diverse surgical settings. A previous study also 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 [21].

A study 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 [31]. 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 [28,29]. The present study was accordance with the above findings.

A similar study also advocated 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 [30]. A study reported that 10.7% of postoperative complications occurred [16]. 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 [23,24].

A previous study also undertook a study to compare regular perioperative care and ERAS guidelines in laparoscopic Gastrointestinal (GI) procedures [25]. 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, a 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 [26]. 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, a study also evaluated a patient's recovery following an elective laparoscopic cholecystectomy by comparing it with the recommendations of ERAS and the standard perioperative approach [27]. 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.

The present study was also accordance with the above findings. In addition, a previous study was conducted to investigate the application of ERAS in participants undergoing laparoscopic bile duct exploration and laparoscopic cholecystectomy combined [32]. 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. It was also accordance with our study.

The present prospective 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, emphasizing the potential for improved patient outcomes. The significantly shorter hospital stays in the ERAS group suggest enhanced healthcare resource utilization and potential cost savings. The findings also indicate an improved postoperative experience with lower pain scores and reduced morbidity, supporting the prioritization 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, subsequently our findings were concordant with many previous researches [11,18,22, 24].

Moreover, Anxiety about surgery and anaesthesia influences the recovery of a patient. Providing information about these procedures have been found to reduce anxiety among patients and influence recovery.[5,8] In our study, the ERAS group which received appropriate information about surgical and anaesthetic procedures using multimedia showed a marked reduction in anxiety. However, earlier studies obtained conflicting results, where some observed a reduction in anxiety levels[3,5,10].

The study underscores ERAS as a benchmark for standardizing 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 optimization and customization of ERAS protocols for broader clinical applicability.

Limitations

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 100 cases; if the study population were larger, other parameters such as, cost, other

benefits, compliance with the protocol could have been significant.

Conclusion:

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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