



ENHANCED RECOVERY AFTER SURGERY-WAY FORWARD IN LAPAROSCOPIC CHOLECYSTECTOMY?

General Surgery

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ABSTRACT

Background: With the paradigm shift happening in perioperative care which is progressively towards better patient recovery in terms of speed & quality of patient comfort, ERAS has emerged as a method to achieve it. With LC being one of the most common surgical procedures with most surgeons adopting "FastTrack" approach in respect to it, it makes a strong case for developing a standard ERAS protocol for the same.

Aims & Objectives: The purpose of this study was to implement a tailored ERAS program for elective LC in patients to promote early recovery while maintaining standard of care.

Methods: A prospective randomized controlled study was conducted on 156 patients undergoing laparoscopic cholecystectomy procedure from August 2018 to December 2019- Data regarding length of hospital stay, patient satisfaction, pain score, PONV, SSI, readmissions, morbidity & mortality were collected.

Results: Patients in mERAS group showed early recovery, shortened LOHS (mERAS=1.54 +/-0.14 Vs conventional=2.3+/-0.23) & better postoperative pain tolerance.

Conclusion: Patients in enhanced recovery group showed better overall recovery and satisfaction in peri operative period.

KEYWORDS

ERAS, Laparoscopic cholecystectomy, LOHS

INTRODUCTION

Laparoscopic cholecystectomy (LC) is considered as the "Gold" standard procedure for treatment of benign gallbladder diseases^[1] and, rightly so. In experienced hands it causes minimum trauma, decreased bleeding, low pain, & quick recovery. With this advantage the practice of same day discharge (SSD) & overnight hospital stay (OHS) are applied in many centers for LC without significant difference in outcomes. All of these are using certain measures to facilitate early patient recovery at the discretion of treating surgeon. No standardized evidence-based protocol is available to implement across all patients.

Henrik Kehlet in 1997 conceptualized fast-track surgery, better described as early recovery after surgery (ERAS)^[2]. It was a multimodal approach aimed at reducing the incidence of perioperative stress, accelerating postoperative rehabilitation, and shortening hospital stay^[3-4]. ERAS has shown to decrease overall complication rates & decreased in-hospital costs^[5-6]. ERAS society^[7] has published these protocols primarily for colorectal surgery patients, but have since extended recommendations to hepatobiliary, gastric, and urologic surgeries.

In LC, ERAS implementation has certainly been scattered, with some groups publishing data on their early experience. With an opportunity to evolve and adopt ERAS protocol into LC we have conducted this study.

MATERIALS AND METHODS

Study design. Our study was a prospective, randomized, non-blinded clinical trial. Patients diagnosed with calculous cholecystitis/polyps between august 2018 and December 2019 at BGS Global institution of medical sciences, Bengaluru were consecutively recruited for the study. The patients were educated with details of research study, the surgical procedure, postoperative rehabilitation plan, expected complications, & contact details of the medical and research staff. Institutional Ethics committee approval obtained.

The following inclusion criteria were applied:

- American society of anesthesiologists (ASA) classes I & II
- aged between 18 years-60 years.
- Gall bladder stones, polyps

Exclusion criteria were as follows:

- refusal to participate in the study or to sign the informed consent form; choledocholithiasis, pulmonary illness, intraoperative complications like biliary tract injury, requirement of intensive care unit (ICU) after surgery; conversion to open procedure; uncontrolled diabetes with neuropathy; ASA grade III and above; Acute cholecystitis, Gangrenous cholecystitis, empyema.

Randomization. On admission to hospital, the patients were randomly assigned (1:1) to ERAS & conventional group by a random number generator. The diagnosis was supported by clinical signs, laboratory tests, and ultrasound or computed tomography/MRI scans. Treatment allocation wasn't blinded to patients, operating surgeons, and researchers.

Modified ERAS protocol group.

As there's no ERAS protocol for LC, a modified ERAS protocol based on the well-known ERAS program for elective (colorectal) surgery^[7] was developed. The choice of components was determined by how well they may be adapted to our setting. We chose not only from ERAS protocol but also from practices proven to decrease surgery related stress and improve rehabilitation.

Preadmission. All patients were optimized for elective LC like, strict diabetic control, normalizing blood pressure levels etc.

Preoperative care. The patients received an information booklet containing an in-depth description of their pathology, planned surgical procedure, the rehabilitation process, possible complications, etc.

Normal meal at night + carbohydrate rich drinks 6 hours before surgery.

Surgery

- Low-pressure (10-12 mmHg) pneumoperitoneum was maintained throughout procedure. Low-pressure pneumoperitoneum has proven advantageous in reducing the incidence of shoulder and neck pain^[8].
- Prophylaxis like Inj dexamethasone 8 mg to prevent postoperative nausea and vomiting (PONV).

3. Additional local anesthesia.

Intraoperative preemptive intraperitoneal & preperitoneal local anesthesia was used to decrease postoperative pain. Subdiaphragmatic space was irrigated, and every trocar wound was infiltrated with 5 ml of Ropivacaine at the end of the procedure.

4.No nasogastric tube placement routinely. If placed removal before reversal.

5.No routine drain placement.

Postoperative care.

Goal directed fluid management avoiding Normal saline. Early mobilization out of bed and liquid intake (2 h after surgery); 4-6 h after surgery the patients were encouraged to regular diet.

Multimodal analgesia avoiding opioids.

Standard care group.

Preadmission: Routine optimization for surgery.

Preoperative care. The patients were educated about their pathology, the planned surgical procedure, & possible complications. No brochure was given.

Surgery. Pneumoperitoneum was maintained at 12-14 mm Hg. Patients received a drain/NG tube as per surgeons' preference.

Postoperative care. As per conventional care.

Both groups.

Preoperative care. Surgery was performed within 6-8 hours of admission. Antibiotic prophylaxis was administered to all patients at the time of induction.

Surgery. Well trained surgeons past their learning curve, operated all the cases. Both groups received general anesthesia; hemodynamics were well monitored during procedure. LC was performed using monopolar/bipolar coagulation. After achieving critical view of safety, the Cystic duct & artery were clipped & divided. Thorough wash given in subhepatic fossa. Drains placed only if there was significant bile spillage or ooze from liver bed.

Postoperative care. Postoperatively, all patients got antibiotics for 1 day, depending on their response to therapy. Postoperatively pain intensity was measured by visual analog scale (VAS) immediately after the patients became responsive & then after 2, 6, 12 & 24 h following the surgery. Those who developed PONV were given antiemetics.

Complications were classified according to the Clavien-Dindo classification^[9]. In patients with an intra-abdominal drain, it was removed 12–24 h after surgery. Intestinal peristalsis was assessed by auscultation every 4 h after surgery.

The patients were discharged home if they had no complications, tolerating oral diet, adequate pain relief on oral analgesia, they had restored active bowel movement regardless of having passed flatus or stools, & they gave their consent.

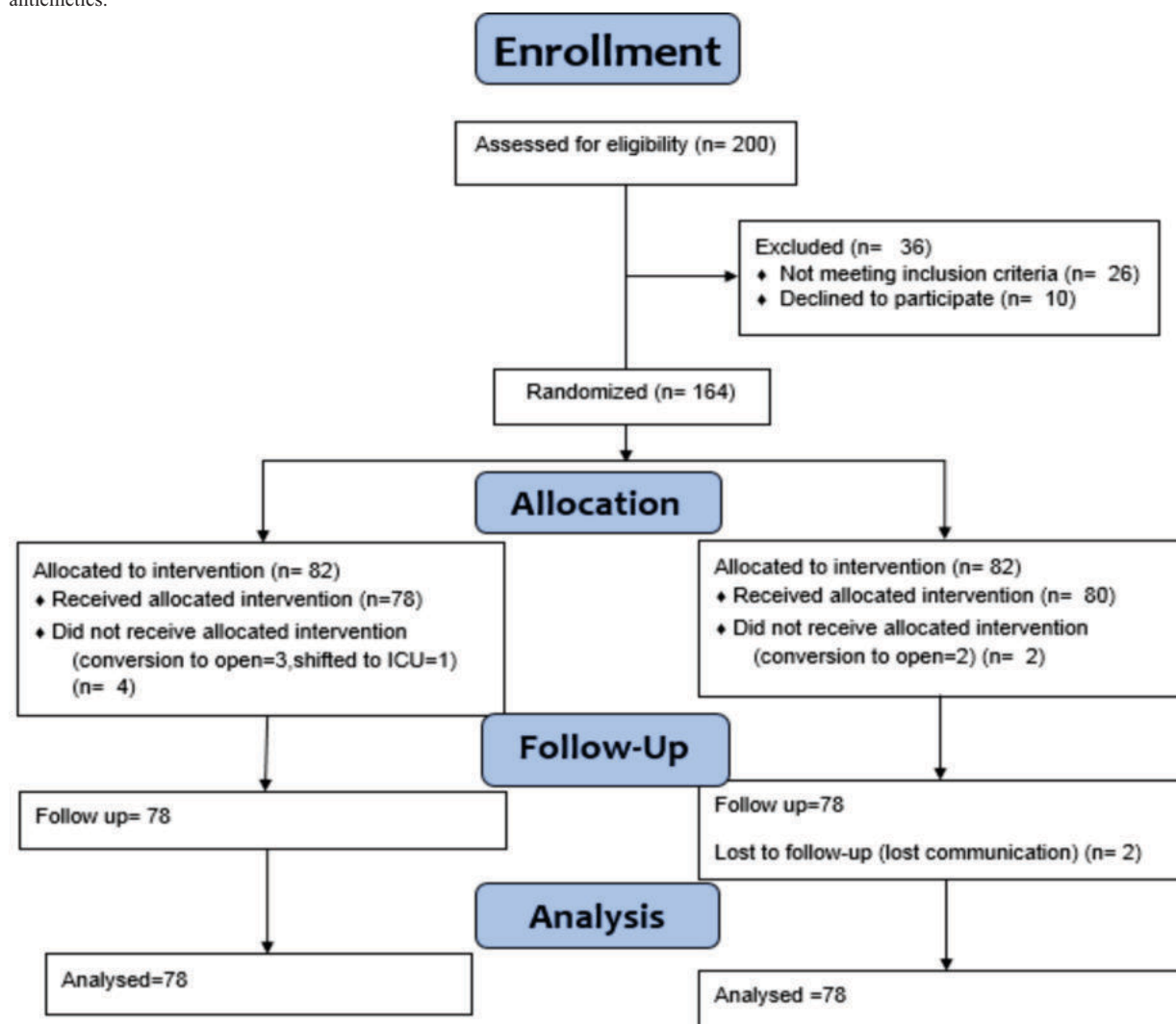
Patients were followed up on day 3, day 10(follow up) & day 30(telephonic) after discharge from hospital. The patients were asked about the presence of pain, the episodes of fever and indigestion, any complications, & readmissions/emergency visits.

Outcomes. The primary outcome of the study was length of hospital stay (LOHS). The secondary outcomes included the frequency of postoperative complications, the readmission rate, postoperative pain intensity, & patient satisfaction.

Statistics. The obtained data were processed using a commercial SPSS 22.0, MS Excel and word. The results were analyzed as mean values & standard deviations (SD) for continuous normally distributed variables and as counts and percentages for other variables. Chi square test was used wherever required. Differences were considered statistically significant at $p < 0.05$.

RESULTS

One hundred fifty-six patients were randomized between September 2018 & December 2019. Eighteen patients were excluded from the study. Details of the enrollment process are shown on the CONSORT 2010 flow diagram (Fig. 1.)



Thus, 78 patients each in the mERAS group and in the control group, were selected for statistical analysis.

Baseline characteristics did not differ significantly between the groups. (Table 1).

	mERAS group (n=78)	Conventional group (n=78)	P value
Sex (M/F%)	36/42(85.7)	33/45(73.3)	.628
Age (Years)	45.2±3.8	44.3±3.6	.521
BMI	26.08±5.2	27.5±5.3	.076
Comorbidities	14(17.9%)	13(16.7%)	.556

(Table 2).

	mERAS	Conventional	P value
LOHS(Days)	1.54±0.14	2.3±0.23	<0.05
Mean Pain score (VAS)	2.56±1.98	4.10±1.56	<0.05
PONV	7(9%)	38(48.7%)	<0.05
Time to mobilization(hrs.)	3.61±2.34	5.82±3.89	<0.05
Time to beginning of oral diet	2.65±0.51	4.82±0.24	<0.05
Flatus time	18.36±0.5	26.8±0.1	<0.05
Ileus	2	2	1
Patient satisfaction	60(76.9%)	40(51.2%)	<0.05
Readmission/Emergency visit	3	6	0.31

P<0.05 was considered statistically significant.

In the mERAS group, the median LOHS was shorter than in the conventional group (1.54 days vs. 2.3 days, $p < 0.05$). Postoperative pain & PONV was lower in mERAS group than in the conventional group & the differences were statistically significant ($p < 0.05$). In both groups, no patients required opioid analgesics. Patients in mERAS group could mobilize early, acceptance of oral diet better & passed flatus earlier than patients under conventional postoperative care ($p < 0.05$).

Two patients each in the mERAS group & in the conventional group developed postoperative ileus & it was not statistically significant. All of them responded to conservative management & recovered well. Readmissions were seen in both groups, mERAS -3(3.8%) (dyspepsia & pain) & conventional-6(7.7%) but not statistically significant.

Patients' satisfaction was highest among mERAS group (76.9%) with significant p value (< 0.05). No mortality was reported in either group in 30 day follow up period.

DISCUSSION.

Patient comfort in surgical practice has been evolving rapidly in past few decades. Gone are the days of bigger incisions & radical surgeries. Now the emphasis is on minimal invasiveness, better pain management & rehabilitation, early discharge. In LC studies have shown that early discharges don't compromise patient care & outcomes [10]

In our study, hospital stay was shortened in ERAS group, 1.54+/-0.14 (mean+/-SD) in comparison to conventional group (2.3+/-0.23). Many studies which have implemented few or more components of ERAS show similar trends of decreased LOHS [10,11].

Administering preemptive antiemetics like Inj Dexamethasone 8 mg decreased postoperative nausea, fatigue & pain. Glenn s Murphy *et al* has further added that it has also shown to improve quality of recovery [12].

Preemptive local anesthesia usage, carbohydrate loading, & low-pressure pneumoperitoneum are well established methods to improve patient recovery by reducing overall surgical stress [8,13]. Our study findings agree with these recommendations.

Early mobilization & early diet have shown better GI functional recovery in our study. All ERAS protocols have these as essential components [7]. Many factors contribute to prevention of complications, enhanced recovery and early discharge. Ryan JM *et al* in his metanalysis suggests implementation of a dedicated care pathway, preoperative antibiotics, preoperative NSAIDs, and the antiemetic dexamethasone as factors influencing LOHS but surprisingly states that preoperative patient education an important aspect of all ERAS pathway couldn't be established as an important contributing factor [14].

Our study had its share of limitations. Its objective was to evaluate the

overall efficacy of mERAS protocol adopted & not individual components. This made it difficult to identify how much each component contributed for better outcomes. Secondly, we couldn't establish the overall cost reduction effect due to adoption of mERAS pathway, as both direct and indirect costs couldn't be calculated.

Adopting ERAS protocols are tedious since it requires multidisciplinary contributions (surgeon, anesthetist, Nursing staff, support system, Patient & relatives), with each arm needed to maintain standard of care.

CONCLUSION

mERAS components have proven to be efficacious in speeding up patient recovery with excellent outcomes. Our study showed reduced LOHS, better patient satisfaction without significant complications

Conflict Of Interest: None

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