

Comparison of perioperative patient comfort with 'enhanced recovery after surgery (ERAS) approach' versus 'traditional approach' for elective laparoscopic cholecystectomy

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ABSTRACT

Background: Perioperative anxiety, hunger, thirst, fatigue, pain along with nausea and vomiting can influence a patient's recovery after surgery. We aimed to compare 'enhanced recovery after surgery' (ERAS) protocol with a traditional perioperative approach to evaluate a patient's recovery after elective laparoscopic cholecystectomy. **Methods:** A prospective randomised controlled study was conducted after institutional ethical clearance on 50 patients undergoing elective laparoscopic cholecystectomy, and divided equally into two groups. In group 1 (traditional); standard fasting guidelines and routine perioperative management was implemented. In group 2 (ERAS); patients received appropriate multimedia information about surgery and anaesthesia beside carbohydrate loading with tender coconut water on the previous night and on the morning of surgery. Standard guidelines of fasting for solids were followed. Intraoperatively, goal-directed fluid therapy and an inspired oxygen concentration of 60% were administered. Postoperatively, early diet and mobilisation were initiated. The primary outcome was the assessment of perioperative anxiety. Hunger, thirst, fatigue, pain, nausea, vomiting and overall perioperative experience were also evaluated. **Results:** ERAS group had reduced anxiety prior to surgery: median (interquartile range) 3 (3–4) vs 2 (2–3) ($P = 0.003$), and at 6 h postoperatively: 4 (3–6) vs 3 (1–4) ($P = 0.001$). Hunger, thirst and fatigue ($P < 0.01$) were also decreased with better overall perioperative experience (5 [4–5] vs 6 [5–7], $P = 0.004$). Pain, nausea, vomiting and blood glucose were similar between the groups. **Conclusion:** 'ERAS approach reduces anxiety in addition to hunger, thirst and fatigue with enhanced overall perioperative comfort in patients undergoing laparoscopic cholecystectomy.

Key words: Cholecystectomy, enhanced recovery after surgery, laparoscopy, perioperative care

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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

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numerous nonsurgical factors. These include anxiety about surgery, PONV, pain, reduced physical activity and unintended prolonged fasting due to improper scheduling. A carefully planned perioperative care can enhance the recovery and thereby improve perioperative comfort. This enables an early return to normal activities contributing to medical and economic benefit in healthcare. Various approaches have been proposed for the same. Enhanced recovery after surgery (ERAS) approach recommended by the Association of Surgeons of Great Britain and Ireland,^[3] and guidelines from ERAS society,^[4] aims to improve perioperative patient comfort. Many components of the ERAS have been studied and proved to enhance recovery.^[1,5-7] Due to limited literature on ERAS in laparoscopic cholecystectomy, we aimed to compare ERAS with the traditional approach in patients undergoing elective laparoscopic cholecystectomy. The hypothesis of the study was that the ERAS protocol would reduce the anxiety and improve the overall perioperative comfort in these patients. The primary objective was to evaluate both protocols with respect to perioperative anxiety. Secondary objectives were to estimate hunger, thirst, fatigue, pain, PONV and to rate the overall perioperative experience.

METHODS

A prospective randomised controlled study was conducted between October 2013 and August 2015 after obtaining approval from the institutional ethical committee (number: IEC 538/2013). Fifty patients of either gender aged between 18 and 65 years, BMI 15–30 kg/m² belonging to the American Society of Anesthesiologists physical status I and II, scheduled for elective laparoscopic cholecystectomy were enrolled, after obtaining written informed consent. Patients with anticipated difficult airway and other comorbidities were excluded from the study. The study was registered with the clinical trial registry of India (number: CTRI/2017/10/010062).

There were three observers in the study. Observer 1: Postgraduate trainee in anaesthesia blinded to assigned groups who performed the preoperative assessment and also evaluated the patients postoperatively. Observer 2: Consultant anaesthesiologist who administered the anaesthetic and managed fluid therapy according to group allocation. Observer 3: Another postgraduate trainee in anaesthesia who executed appropriate preoperative management by providing multimedia information and carbohydrate loading according to

group allocation after observer 1 assessed a patient and enrolled for the study. Observer 3 was neither blinded to the study groups nor recorded any parameters.

Patients were randomised into either of two groups: Group 1 – traditional and group 2 – ERAS approach. All patients were evaluated by observer 1 on the day prior to surgery. Their anxiety levels were scored on a numerical rating scale from 0 to 10 (0 being not anxious and 10 being most anxious).

Group 1 (traditional)

Patients were described about the surgical procedure and the planned anaesthetic as done prior to any other routine surgical procedure. Standard fasting guidelines were implemented with solids and milk intake permitted up to 6 h and clear fluids 2 h prior to surgery. Intraoperatively Ringer's lactate was administered as follows: 2 mL/kg/h of preoperative fasting period (half of this was administered in the 1st h and remaining over the next 2 h), 2 mL/kg for each hour of surgery and 2 mL/kg/h additionally for insensible losses. Postoperatively, fluids were continued at 1.5 mL/kg/h till oral diet was started as instructed by surgeons which were usually about 4–6 h post-surgery. They were further allowed to recover without any active intervention.

Group 2 (ERAS)

Patients were explained about the surgical procedure and the planned anaesthetic via a PowerPoint presentation on a mobile phone or a mobile tablet screen. The information provided was a customised collection of graphical representations of surgical and anaesthetic procedures that was limited but appropriate. Thereafter, their anxiety levels were assessed once again. Further, carbohydrate loading was done twice as follows. Once, on the night prior to surgery after the regular dinner, between 10 and 11 PM where 800 mL of tender coconut water with 100 g added sugar was given orally in 200 mL aliquots. Second, on the morning of surgery, between 6 and 7 AM, 400 mL of tender coconut water with 50 g added sugar was given in 200 mL aliquots. Intraoperatively, Ringer's lactate was administered at a rate of 4 mL/kg/h of surgery. They also received a higher inspired oxygen concentration (FiO₂) of 60%. Postoperatively, intravenous fluids were discontinued after half an hour. Patients were encouraged sips of water within 1 h after surgery and thereafter solids as early as possible. They were also encouraged to actively move their limbs every 5 min and further allowed to recover in the semi-recumbent position.

Procedures common in both groups

Preoperatively patients were premedicated with Tab ranitidine 150 mg and Tab alprazolam 0.25 mg (if bodyweight <60 kg) or 0.5 mg (if weight >60 kg) on the night prior and on the morning of surgery. Intraoperatively, anaesthesia was induced with intravenous (IV) propofol (2 mg/kg) and the trachea was intubated with appropriate-sized endotracheal tube after achieving neuromuscular blockade with IV vecuronium (0.1 mg/kg). Anaesthesia was maintained using isoflurane in a mixture of oxygen and nitrous oxide maintaining a minimum alveolar concentration (MAC) of 1–1.2 with additional boluses of vecuronium as required. Analgesia was achieved with IV paracetamol 1 g and IV fentanyl (2–3 mcg/kg in divided doses). Patients were also given 0.1 mg/kg of ondansetron IV. Further laparoscopic ports were infiltrated subcutaneously with 10 mL of 0.25% bupivacaine. At the end of the surgery, neuromuscular blockade was reversed with IV neostigmine (0.05 mg/kg) and IV glycopyrrolate (0.01 mg/kg) and the patients’ trachea was extubated when they were fully awake and met the clinical criteria of recovery. Postoperatively, in the recovery area, vital parameters were monitored and oxygen at 2 L/min was administered via Hudson mask for half an hour after surgery. All patients were prescribed IV paracetamol 1 g every 8 h for analgesia until the next morning of surgery. No patients received postoperative opioids for analgesia. PONV was treated with IV ondansetron 0.1 mg/kg.

Patient’s postoperative pain, anxiety levels, hunger, thirst and fatigue were noted (based on a numerical rating scale of 0–10 (0 being absent and 10 the worst) after 1 h and 6 h of their arrival to the recovery area and on next morning of surgery. Nausea, vomiting, pain, discomfort, time to oral intake of liquids, solids and normal diet and any other complications were also noted. On the morning after surgery, patients were also asked to rate their overall perioperative experience on a numerical rating scale of 0–10, with 0 being the worst and 10 being the best. This score was called the perioperative comfort score (PCS).

Hence, the outcome measures evaluated were a) preoperative anxiety, hunger, thirst and fatigue, b) postoperative anxiety, hunger, thirst, pain and fatigue at 1 h, 6 h and on next morning, c) PONV and d) overall perioperative experience.

Sample size was calculated using mean and standard deviation with 90% confidence levels and 0.05 of error. We planned to provide novel customised

information to the patients and also implemented certain steps that were minor deviances from the standard ERAS protocol in terms of providing coconut water and intraoperative oxygen of 60%. Since there were no previous studies using these parameters, we anticipated an average mean value of a score of 7 for the perioperative anxiety score (on a scale of 1–10), which was the primary outcome. The standard deviation was estimated to be 1 score value on either side of the mean. Based on these parameters sample size was estimated as 23. Hence, 25 subjects were recruited for the study to compensate for possible dropouts. Data were analysed using Statistical Package for the Social Sciences software version 15 (SPSS South Asia, Bangalore).

RESULTS

A total of 50 patients divided into two groups (traditional and ERAS) of 25 were evaluated. Demographic parameters were comparable between groups [Table 1]. ERAS group showed significant reduction in anxiety levels after the PowerPoint-aided explanation of procedure both on the day prior to surgery: median (interquartile range) 3 (3–4) vs 2 (2–3) (*P* = 0.003), and at 6 h postoperatively: 4 (3–6) vs 3 (1–4) (*P* = 0.001). However, at postoperative 1 h, there was no difference in anxiety levels between the groups (4.24 ± 1.47 vs 3.16 ± 1.46, (mean ± SD), *P* = 0.12), [Table 2]. ERAS group also had reduced hunger (2 [1–5] vs 1 [1–3], *P* = 0.001), thirst (1 [0–3] vs

Table 1: Demographic data between the groups

	Group traditional (n=25)	Group ERAS (n=25)	P
Age in years*	40.72±9.47	39.56±10.95	0.69
BMI in kg/m ² *	22.65±2.18	22.62±2.34	0.95
Gender† (Male/Female)	9/16	13/12	0.25
ASA-PS‡ (1/2)	16/9	18/7	0.54

*Independent Samples *t* test. †Chi-square test. ERAS: Enhanced recovery after surgery; ASA: American Society of Anesthesiologists. All values are expressed as mean±SD. *P*<0.05

Table 2: Anxiety level at various perioperative periods

	Group traditional (n=25)	Group ERAS (n=25)	P
Anxiety on the preoperative day			
Before counselling*	4 (3-5)	4 (2-5)	0.35
After counselling*	3 (3-4)	2 (2-3)	0.003
Anxiety on the day of surgery			
Preoperative waiting period†	4.24±1.47	3.16±1.46	0.01
1 h postoperatively†	4.6±1.91	3.84±1.52	0.12
6 h postoperatively*	4 (3-6)	3 (1-4)	0.001

*Mann-Whitney U test. †Independent Samples *t*-test. The values are represented either as mean±SD or median (interquartile range). *P*<0.05

1 [0–1], $P = 0.001$) and fatigue ($P = 0.008$), with better overall perioperative experience (5 [4–5] vs 6 [5–7], $P = 0.004$). However, there was no difference in blood glucose levels (129.67 ± 18.6 vs 124.34 ± 20.62), pain, nausea and vomiting between the groups [Table 3].

DISCUSSION

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,^[5,8,9] and few did not.^[10,11] In contrast, Kazancioglu *et al.*^[12] found increased anxiety in patients undergoing third molar extraction. This was probably because the entire procedure was shown as a live taping which possibly precipitated anxiety. So, these varied results probably suggest that the preoperative information may be provided in moderation rather than in detail to avoid fear and anxiety. Hence, the reduction of anxiety in our study could possibly be attributed to providing limited, pacifying but sufficient graphical information rather than showing real photographs or videos of procedures (e.g. incisions, laparoscopic port insertions, IV cannulation, intubation etc.) being performed on patients. It is also true that there was no difference in anxiety at 1 h postoperatively between the groups, probably because the patients were sedated and were under the influence of analgesics to report their feeling. However, at 6 h postoperatively, there was a significant reduction in anxiety in the

ERAS group possibly due to early commencement of the oral diet.

Preoperative carbohydrate loading and early commencement of diet significantly reduced the hunger, thirst and fatigue in the ERAS group which was comparable to other studies.^[6,13]

With respect to the incidence of PONV, reports from other studies reported reduced incidence with ERAS approach due to better hydration and avoidance of opioids.^[6,13,14] However, in our study, though fentanyl was used intraoperatively for analgesia, we did not find any difference in the incidence of PONV among the groups. This possibly may be due to the avoidance of opioids postoperatively and the use of prophylactic ondansetron in all patients. Hence, the benefit of preoperative carbohydrate loading on the reduction of PONV could not be demonstrated. Nevertheless, the results suggested that short-acting opioids like fentanyl could be used as analgesia intraoperatively as a part of ERAS protocol without the risk of developing PONV provided they receive antiemetic prophylaxis.

The intraoperative fluid management in the ERAS group was goal-directed with an inclination toward restricted replacement strategy, whereas in the traditional group, it was more of liberal replacement strategy.^[7] However, the implications of this difference in fluid management among both groups could not be elicited, probably because laparoscopic cholecystectomy was a surgical procedure of shorter duration without involving major fluid shifts.

Our study could not establish any relationship of ERAS with pain as it was comparable in both groups, which was in contrast to other reports.^[14] This was probably because, although a painful procedure, laparoscopic cholecystectomy was not painful enough so as to obtain a comparable difference between the groups. Also, judicious use of analgesics in both groups resulted in better pain control.

Studies reported reductions in glucose levels due to preoperative carbohydrate loading in study groups as it reduced insulin resistance maintaining the blood glucose levels.^[6,15] However, in contrast, our study did not find any difference in the blood glucose levels among either group. This was perhaps due to exclusion of patients with diabetes mellitus in either group and, hence, patients had better control toward variations in sugars levels.

Table 3: Pain, nausea, vomiting, blood glucose, hunger, thirst, fatigue and overall perioperative experience in both groups

	Group traditional (n=25)	Group ERAS (n=25)	P
Pain* (Mean±SD)	3.70±1.32	3.57±1.3	0.52
Nausea† Median (IQR)	0 (0-2)	0 (0-1)	0.31
Vomiting‡ (Present/absent)	5/20	3/22	0.46
Blood glucose (mg/dL)§ (mean±SD)	129.67±18.6	124.34±20.62	0.2
Hunger¶	2 (1-5)	1 (1-3)	0.001
Thirst¶	1 (0-3)	1 (0-1)	0.001
Fatigue*	4.08±1.55	2.97±1.37	0.008
Overall perioperative experience¶	5 (4-5)	6 (5-7)	0.004

*Independent Samples *t* test. †Chi-square test. ‡Kruskal-Wallis test. §Freedman test. ¶Mann-Whitney U test. Values are represented either as mean±SD or median (interquartile range), $P < 0.05$

The overall perioperative experience was better among the patients of the ERAS group, which was consistent with the findings of other studies.^[6,16] This was in spite of the minor deviations our study had from the standard ERAS protocol. ERAS comprises numerous elements and all of them cannot be routinely applied to every surgery. Doing so leads to varied compliance with individual elements. Hence, a modification or customisation would be necessary according to the region where practised. Certain studies also supported this view by indicating that, although clear guidelines about ERAS were available, their routine implementation faced certain difficulties.^[17,18]

Our study was unique in certain aspects. The preoperative information to the patients was customised, limited but appropriate which was provided by means of a simple PowerPoint presentation via a commonly used mobile phone/tablet. It is also well known that the inspired gas composition greatly contributes to atelectasis formation during general anaesthesia, which could especially be augmented in patients undergoing laparoscopic cholecystectomy due to the increased abdominal pressure caused by the creation of pneumoperitoneum during laparoscopy.^[19] Hence, the use of 30–40% oxygen during general anaesthesia is recommended for the prevention of atelectasis.^[19,20] It is as well proven that using 80% oxygen as compared to 30% significantly reduces the incidence of PONV.^[21] In addition, ERAS also recommends the use of 80% oxygen in its protocol.^[4] However, a study reported no effect on the incidence or severity of atelectasis using 80% oxygen as compared to 30% during a colon resection.^[22] Hence, we digressed marginally from the standard ERAS protocol and evaluated the use of 60% oxygen on PONV. This was attempted with an intention to achieve the benefits of decreased PONV and in the meantime prevent atelectasis. We also implemented the use of tender coconut water, which was readily available and gladly accepted among the population of the study area (coastal region). Nevertheless, the results of our study are applicable to other invasive surgeries, at least in terms of reducing perioperative anxiety. This is because as invasive surgeries possibly require a longer hospital stay, involve major fluid shifts and are more painful, the results pertaining to other parameters although may be applicable but might need further evaluation.

However, our study had certain limitations. First, since laparoscopic cholecystectomy did

not warrant the use of all parameters of ERAS protocol (e.g., mechanical bowel preparation, deep vein thrombosis prophylaxis using low molecular weight heparin, preferable use of short and transverse incisions for open surgery, short duration of epidural analgesia), certain parameters were omitted which may precipitate argument about possible altered results. Second, the carbohydrate content of the tender coconut water was not measured due to which results based on this parameter could be debated. Third, the effect of preoperative carbohydrate loading on PONV could not be established due to avoidance of postoperative opioids and use of prophylactic ondansetron in either group. Fourth, there is no clear-cut evidence on the use of 60% oxygen intraoperatively. Finally, the scoring system of the parameters was subjective using a numerical rating scale. A future study may be designed keeping all these limitations in mind.

CONCLUSION

It can be concluded that ERAS approach reduces anxiety in patients undergoing laparoscopic cholecystectomy.

Declaration of patient

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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