

## Efficacy and safety of ERAS protocol in open Cholecystectomy: A case series

Suresh Naik, Bhushan Shah, Khushal Patel\*, Akhil Kandarpa, Firoz Alam, Bahul Vekaria

Department of Surgery, Dr. D Y Patil Hospital and Research Centre, Pune, India.

**Corresponding author:** \*Khushal Patel, Department of Surgery, Dr. D Y Patil Hospital and Research Centre, Pune, India.

### Abstract

**Aim:** Comparison of patients undergoing open cholecystectomy following ERAS protocols and conventional protocols.

**Introduction:** ERAS is a systematic approach to facilitate better state of patient for surgery and early recovery post surgery. ERAS mainly focuses on modification of conventional perioperative modalities followed worldwide to reduce perioperative psychological and physical stress.

**Materials and methods:** 50 cases of open cholecystectomy were considered for study. 25 cases followed ERAS and 25 cases followed conventional protocol.

**Results:** Pre operative fasting for patients following conventional protocols were more. Patients following ERAS have significantly less time required for bowel movements and initiating soft diet. Patients following ERAS have significantly less time required for mobilization and also significantly less length of stay. Rate of complications were not significantly different in both the groups.

**Conclusion:** ERAS is an idea that promotes early recovery after surgery by integrating modalities of therapy in all perioperative phases. Early feeding is possible without any significant nausea and vomiting. Early mobilization helps in faster recovery of patients. Patients following ERAS protocols have less hospitalization with no significant difference in morbidity. ERAS protocol is efficient and safe in emergency situations too.

**Keywords:** Open cholecystectomy, medical centre, ERAS India, Eras in tertiary centre

### Introduction

Enhanced recovery after surgery (ERAS) is a systematic approach to facilitate better state of patient for surgery and early recovery post surgery. It is a multimodal approach involving pre operative, intra operative and post operative protocols. ERAS is also known as fast track or multimodal system. ERAS protocols are made from well evaluated, well proven evidence based individual components of

perioperative surgical care strategies.<sup>1</sup> There are number of studies on ERAS protocols for elective surgeries like colorectal surgery<sup>2</sup>, fundoplication, partial nephrectomy, cardio vascular surgery<sup>3</sup>, hysterectomy, mastectomy, cystectomy<sup>4</sup>. Most of the studies include minimal access surgery as important part of the protocol.

Very few studies available for open procedures. This article mainly focuses on

outcome of ERAS protocols in Open cholecystectomy.

### **Aim**

Clinical study of ERAS protocol in 50 cases of open cholecystectomy at tertiary centre.

### **Objectives**

Application of ERAS protocol in open cholecystectomy. Compare ERAS protocol and conventional protocol with respect to;

1. Efficacy - Time required for bowel movements, time required for complete oral diet, mobilization, length of stay.
2. Safety - postoperative pain, nausea, vomiting, wound infection, pulmonary complications, readmission rates.

### **Materials and methods**

Prospective study in period of July 2015 to July 2016.

**Inclusion criteria:** All patients diagnosed with chronic Cholelithiasis planned for elective open surgery. Age group: 16 yrs onwards

**Exclusion criteria:** Acute cholecystitis, empyema, malignancies, dense adhesions, frozen Calot's triangle.

All patients were operated by same team of surgeons.

Total number of 50 cases were studied, All patients diagnosed with chronic cholelithiasis were included in the study, and alternatively divided into those following conventional protocol (Group A1) and those following ERAS protocol (Group A2). Routine lab and radiological investigations carried out required for anaesthesia fitness and diagnosing chronic cholelithiasis was done with Ultrasonography, and CT or MRCP wherever indicated.

### **ERAS protocol**

Pre Operation assessment: Informed written consent, Counseling of patient verbal and

written, Any co-morbid diseases, than control with appropriate treatment; Day before surgery: Fasting 6hrs for solids, 2 hrs for clear fluids; Intra operative: Inj Cefotaxim 1 g iv stat at time of inducing anaesthesia, Epidural anaesthesia/regional anaesthesia/ total intravenous anaesthesia, Use of blanket, pre warmed iv fluids, Intraoperative core temperature monitoring with oesophageal probe or rectal probe, Local infiltration with 0.5% bupivacaine diluted while suturing, Restricted use of drain, Ryle's tube, Foley's catheter, Intravenous fluids (avoid overloading); Post operative care: Oxygen 4 litres/min for 2 hours, Intravenous fluids: alternate RL and D5 at rate decided by weight of patient and fluid loss estimation, Inj Paracetamol 1g 8hrly, Inj Diclofenac 75mg iv BD, Inj Ondansetron 4mg iv 12hrly, Mobilization within 8-12 hours of surgery for atleast twice in a day, Oral sips of water within 8-12 hours of surgery following anitmetic injection; Post operation day 1: Pain score, Inj paracetamol 1g iv 8hrly, Inj Dynapar 75 mg iv HS, Mobilization atleast 2 hours walking a day, soft diet, Stop iv fluids; Post operation day 2: Inj paracetamol 1 g iv HS, Tab Paracetamol 500mg bd orally, Pain score, Mobilization atleast 2 hours a day, Soft diet, Stop iv fluids; Post operation day 3: Check dressing, Tab. Paracetamol 500 mg 12hrly orally, Full diet, Mobilization for atleast 4 hours.

### **Conventional protocol**

Pre operation assessment : Informed written consent; Day before surgery : Overnight fasting; Intra operation : Inj Cefotaxim 1 g iv at the time of inducing anaesthesia, Use of conventional anaesthesia techniques, Loading with two pints intravenous fluids prior to inducing spinal anaesthesia plus intravenous fluids according to urine output, No restriction for use of drains, Ryles tube, Foley's catheter; Post operation care : Intravenous fluids 5 pints within 24 hrs, Inj

Tramadol one ampoule in 100cc NS iv 8 hrly, Inj Ondansetron 4 mg iv 12hrly, Mobilization after 24 hrs, Nill by mouth minimum for 24 hrs; Post operation day 1 : Start oral sips after bowel sounds appears, Intravenous fluids till starting liquids orally, Inj Tramadol one ampoule in 100 cc NS iv 8

hrly; Post operation day 2 : Inj Tramadol one ampoule in 100 cc NS iv hrly, Soft diet, Stop iv fluids, Check dressing; Post operation day 3 : T. Ultracet 75 mg bd orally, Full diet; Post operation day 5 : T. Ultracet 75 mg bd orally, Full diet, Patient fit for discharge.

**Observation**

**Table 1: Patient Demography: AGE wise distribution of patients in each group.**

Age (in yrs)	A1	A2
17-35 yrs	6	7
36-60 yrs	19	18
Mean yrs	41.25	41.64
P value	0.33	

**Table 2: Pre Operative fasting period: Comparison between conventional and ERAS protocol Efficacy.**

Group	Mean of fasting For solids (in hrs)	Mean of fasting For liquids (in hrs)
A1	8 hrs	8 hrs
A2	6 hrs	2 hrs

**Table 3: Time required for bowel movements.**

Group	Mean of time required for bowel movements (hrs)	P value
A1	30.24	
A2	21.4	< 0.0005

**Table 4: Time required for initiating soft diet.**

Group	Mean of time required for initiating soft diet (hrs)	P value
A1	35.6	
A2	23.5	<0.0005

**Table 5: Time required for mobilization – 2 hrs walking and sitting on bed.**

Group	Mean of time required for mobilization (hrs)	P value
A1	61.38	
A2	58.5	> 0.0005

Above table is showing mean of time required for able to mobilise patient at least 2hrs walking or sitting without support.

**Table 6: length of stay: Complications.**

Group	Mean of time required for patient to be fit for discharge (days)	P value
A1	6.25	
A2	4	<0.0005

**Table 7: Post op day 0.**

<b>Complications</b>	<b>Group A1 n = 25</b>	<b>Group A2 n = 25</b>
<b>Pain score</b>		
1-3	10	22
4-7	09	03
8-10	01	00
<b>Nausea</b>	19	17
<b>Vomitting</b>	2	1
<b>Urinary retention</b>	0	1
<b>Pulmonary infection</b>	0	0

**Table 8: Post op day 1.**

<b>Complications</b>	<b>Group A1 n = 25</b>	<b>Group A2 n = 25</b>
<b>Pain score</b>		
1-3	14	25
4-7	11	0
8-10	0	0
<b>Nausea</b>	10	6
<b>Vomitting</b>	0	0
<b>Urinary retention</b>	0	0
<b>Pulmonary infection</b>	0	0

**Table 9: Post op day 2.**

<b>Complications</b>	<b>Group A1 n = 25</b>	<b>Group A2 n = 25</b>
<b>Pain score</b>		
1-3	21	25
4-7	4	0
8-10	0	0
<b>Nausea</b>	0	0
<b>Vomitting</b>	0	0
<b>Pulmonary infection</b>	0	0
<b>Wound complications</b>		
Seroma	6	5
Haematoma	0	0
Superficial infection	1	1
Deep infection	0	0

**Table 10: Post op Day 3.**

<b>Complications</b>	<b>Group A1 n = 25</b>	<b>Group A2 n = 25</b>
<b>Pain score</b>		
1-3	25	25
4-7	0	0
8-10	0	0
<b>Nausea</b>	0	0
<b>Vomitting</b>	0	0
<b>Pulmonary infection</b>	0	0
<b>Wound complications</b>		
Seroma	3	3
Haematoma	0	0
Superficial infection	1	1
Deep infection	0	0

**Table 11: Post op day 7.**

<b>Complications</b>	<b>Group A1 n = 25</b>	<b>Group A2 n = 25</b>
<b>Pain score</b>		
1-3	25	25
4-7	0	0
8-10	0	0
<b>Wound complications</b>		
Seroma	0	0
Haematoma	0	0
Superficial infection	0	0
Deep infection	0	0

**Table 12: Post op day 30.**

<b>Complications</b>	<b>Group A1 n = 25</b>	<b>Group A2 n = 25</b>
<b>Wound complications</b>		
Seroma	0	0
Haematoma	0	0
Superficial infection	0	0
Deep infection	0	0
<b>Readmission</b>	0	0

**Discussion**

Enhanced recovery after surgery (ERAS) programme is a modern pathway for perioperative care. It is a multidisciplinary and multimodal approach which is designed to reduce surgical stress responses and to support function of vital organs aiming to achieve early recovery of patients undergoing surgery<sup>5</sup>. To involve ERAS protocol in any surgery requires intervention at multiple perioperative phases. Since the patient is admitted to immediate preoperative period, intraoperative period and post operative period

till patient is discharged. In our study, time required for appearance of bowel sounds in Group A2 was significantly less than Group A1 with mean being 21.4 hrs and 30.24 hrs respectively.

In our study, time required for initiating soft diet in Group A2 was significantly less than Group A1 with mean being 23.5 hrs and 35.6 hrs respectively. Soft diet was initiated in both groups only after patients tolerated liquids completely. Patients in Group A2 were started on liquids after 12hrs as per protocol and in Group A1 after appearance of bowel sounds.

In immediate post op period, 19 patients of Group A1 had nausea whereas 17 patients of Group A2 had nausea ( p value > 0.05 ) and 2 patients of Group A1 and 1 patient of Group A2 had vomiting. This was managed by administering inj ondansetron 4 mg half hour prior to initiating diet. 24 hrs after operation, 10 patients of Group A1 and 6 patients of Group A2 had nausea. None patients in both groups had nausea post op day 2 onwards. In a study by de Aguilár-Nascimento et al, he studied 74 patients who underwent open cholecystectomy, of which average of time required for initiating soft diet was 22hrs in patients following ERAS protocol and 28.5 hrs in patients following conventional protocol. He had less number of patients having nausea / vomiting in both the groups.

In our study, average time required for patient to mobilization for atleast 2 hrs walking and sitting in Group A2 is 58.5 hrs which is not significantly different than Group A1 61.38 hrs. In a study by Majeed et al, patients undergoing open cholecystectomy by conventional method had average time required for complete mobilization as 62 hrs. He did not study for patients following ERAS protocol. In a study by Tania Castelino et al, mean of time required for mobilisation in abdominal and thoracic surgery were directly proportional to rate of complications like DVT and pulmonary infections<sup>7</sup>.

In our study, average length of stay for patients of Group A2 was significantly lower than Group A1 - 4 days and 6.25 days respectively. In a study by Berggren U et al, mean length of stay for open cholecystectomy group is 5 days with those following ERAS protocol is 2.5 days. It includes laparoscopic surgery in ERAS group.

#### **Complications in both groups were as follows:**

9 patients of Group A1 had pain score post op day 0 as 4-7 and 1 patient had pain score of 8-10. In Group A2 3 patients had pain score between 4-7 in post op day 0. Next post op day, 11 patients of group A1 still had score 4-7 whereas all patients of group A2 had scores

1-3. Group A2 have lower pain score than Group A1 statistically. This was mainly due to epidural anaesthesia in Group A2.

There was no statistical difference in patients having post op nausea and vomiting in both the groups on day 0. In day 1, 10 patients in Group A1 had nausea and 6 patients of Group A2 had nausea. this was statistically significant. 6 patients of Group A1 had seroma in the wound , whereas 5 patients of Group A2 had seroma with 1 patient having purulent discharge from wound in each group. (p value >0.05). One male patient had urinary retention which was resolved by Foleys catheterization for one day. No patients had complications of DVT, pulmonary infections. No patients required readmission.

#### **Limitations of study**

In this study efforts were taken to involve maximum points of ERAS protocol in patients of Group A2. However in post op analgesic requirements, patients having pain score more than 4 consistently were treated with opioid derivative analgesics Inj Tramadol.

#### **Conclusion**

ERAS or Fast track surgery is an idea that promotes early recovery after surgery by integrating modalities of therapy from the fields of surgery, anaesthesiology, nutrition, nursing and physical rehabilitation. ERAS protocol is efficient and safe in both emergency and elective surgeries. ERAS protocols can be successfully applied even in open laparotomy surgeries.

**Conflicts of interest:** None

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