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ERAS IN OPCAB SURGERY, SINGLE CENTRED RANDOMIZED CONTROLLED TRIAL EXPERIENCE IN A TERTIARY CARE HOSPITAL

Anaesthesiology

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ABSTRACT

Objective:- Comparison of Enhanced Recovery after surgery (ERAS) with standard institutional protocols in patients undergoing Off-pump Coronary Artery Bypass Surgery (OPCAB). **Design:-.** Single centered single blinded randomized controlled trial. **Participants:** - Patients (n= 88) posted for elective OPCAB were divided into two groups (Group I and II) by a computer generated randomization chart. Interventions:- In Group I patients, preoperative 2 hours NPO as per ERAS protocol, intraoperative IV fluid administration guided by invasive FloTrac monitor, lung protective ventilation and multimodal analgesic therapy were followed as per ERAS protocol. Group II patients received perioperative care as per standard institutional protocols. **Measurements & Main Results:-** Patient demographics, total ischemia time and surgical parameters were not significantly different between two groups. Extubation time was significantly earlier in Group I patients (Group 1:- 4.89±1.13 hours vs Group II 13.97±1.81 hours with p< 0.01). Secondary outcomes were significantly better in Group I than Group II patients; duration of inotrope requirement (Group I:- 11.14±3.97 hrs, Group II:- 18.90±3.82 hrs ; p<0.001), time to resumption of oral diet [(Group I- 0.84±0.37, Group II 1.05±0.21) post operative day (POD) ; p< 0.001] , chest drains removal [(Group I :- 2.16±0.48, Group II 3.19±0.45) POD ; p value <0.001], and total duration of ICU stay [(Group I :- 4.89±0.65, Group II :- 6.65±0.57) POD; p<0.001]. **Conclusions:-** ERAS protocol improved postoperative outcomes in patients undergoing OPCAB in our Institution.

KEYWORDS

ERAS, OPCAB, Extubation, Cardiac

INTRODUCTION

Off-pump Coronary Artery Bypass surgery, a widely performed surgical procedure for coronary revascularization avoids complications associated with cardiopulmonary bypass.[1,2]. But patients with Coronary Artery Disease associated medical comorbidities including advanced age obesity, diabetes, hypertension, chronic renal disease, low ejection fraction and smoking, they are prone to increased perioperative stress response[3,4]. This often leads to prolonged postoperative ICU stay, prolonged mechanical ventilator support, increased and higher cost of healthcare. So, Enhanced Recovery after Surgery (ERAS) gained popularity in cardiac surgery.

Enhanced recovery after surgery (ERAS) is an evidence-based multimodal perioperative strategy currently used in many surgeries, such as gastrointestinal, orthopaedic, gynaecologic, and thoracic procedures has improved postoperative outcomes, [5,6,7,8,9]. Many changes have been advocated such as a shift from overnight fasting to carbohydrate drinks 2 hours before surgery, minimally invasive approaches instead of large incisions, goal-directed fluid therapy, early removal of drains and tubes, initiation of oral diet from day of surgery and early mobilization [6]. The aim of using ERAS Protocol is to decrease physiological and psychological stress in patients undergoing surgery, to achieve shorter duration of hospital stay, lower rate of perioperative complications, better patient satisfaction as well as to eliminate ineffective practices [10].

Several studies in cardiac surgery including CABG have shown to decrease duration of mechanical ventilation, length of ICU stay and hospital stay . [11,12]. Goal directed fluid therapy (GDFT) which uses targeted fluid therapy also decreased duration of ICU stay [13].

Although the benefits of ERAS are well proven in many surgeries, there is not adequate knowledge in published literature about its effect on patients for OPCABG surgery. This caveat in current knowledge prompted this study to assess the effectiveness of ERAS pathways in off-pump CABG and compare it with conventional Institutional care.

The aim of the study was to compare the duration of mechanical ventilation after OPCAB between two groups of patients – one subjected to the ERAS pathways and the other managed according to conventional Institutional methods in the perioperative period. The secondary outcomes of interest were duration of ICU stay, extent of postoperative vasoactive drug support, time to first resumption of oral diet, time to removal of surgical drains, time to mobilization and overall complication rates.

MATERIALS AND METHODS

After obtaining institutional ethics committee approval, adult patients (n=88) in the age group of 35-65 years, of either sex, with coronary artery disease in NYHA grade II -III were selected for the study and divided into 2 groups –group I and group II, using computer generated randomization process. Informed written consent was obtained from all of them during PAC.

The exclusion criteria included patient refusal to enroll in the study, patients belonging to NYHA class IV preoperatively, emergency and urgent surgeries, BMI > 30 kg/m2, uncontrolled diabetes mellitus, psychiatric disorders, pacemaker/ICD in situ, history of alcohol and drug abuse or in whom the surgical procedure was changed for any reasons.

Patients classified into the group I received relevant health education and psychological counselling by trained personnel. Preoperative bowel preparation and use of preoperative sedatives were withheld in these patients. Patients in this group were allowed to eat normal diet at lunch and dinner on preoperative day 1 within 12 midnight and clear liquids until 2 hours before surgery (upto 7 AM) . Patients in group II were kept nil orally for 6 hours before surgery. Both the groups of patients were wheeled inside the OT at 9 AM .

After arriving in the operation theatre, a peripheral line was established using 18G cannula in all patients. Monitors including ECG, NIBP and pulse oximeter were attached. An arterial line was inserted (left radial preferably) under local anesthetic infiltration. The radial arterial line was transduced using a FloTrac transducer and was connected to an EV1000 platform (Edwards Lifesciences). Prophylactic antibiotic was administered at least 30 minutes prior to surgical incision.

Induction of anaesthesia was done using inj fentanyl (2-5microgram/kg), inj midazolam(0.05-0.1 mg /kg) and sleep dose of thiopentone. Intubation was facilitated with inj rocuronium 0.09 mg/kg. Anesthesia was maintained using inj fentanyl, midazolam,

vecuronium and sevoflurane. A central venous catheter and a Pulmonary Arterial catheter were inserted after induction.

In group II, intraoperative fluid therapy was achieved using PA catheter readings to maintain mean PA pressure 20-25 mm Hg, mean arterial pressure >70 mm Hg and urine output >0.5 ml/kg/hr.

In group I, fluid therapy was guided by FloTrac values and transesophageal echocardiography. In addition to the parameters employed in group II, the hemodynamic target in group I was to maintain Cardiac Index > 2 ml/min/m^2, Stroke Volume Index >30 ml/beat/m^2, Stroke Volume Variation <17%, SVRI 1800-2200 dyne/sec/cm^5/m^2 as measured by the FloTrac device. The left ventricular ejection fraction was assessed using Transesophageal echocardiography, which provided the Left Ventricular End Systolic and End diastolic Volumes (LVEDV and LVESV) and therefore the Left Ventricular Stroke Volume (SV). Intravenous fluid with Ringer's Lactate was given as bolus to maintain the haemodynamics. Lung protective ventilation was provided using low tidal volume (6-7 ml/kg), positive end-expiratory pressure of 5 mm Hg and lung recruitment maneuvers.

Serial arterial blood gas values were obtained, one at baseline and one after completion of each vascular graft or as required by the patient's hemodynamic state. Blood transfusion was done when Hb was less than 8 gm/dl in all patients.

In group I, multimodal analgesia was given with buprenorphine patch, intravenous intravenous paracetamol or fentanyl. Analgesic efficacy was assessed using VAS scale after extubation and rescue analgesia was provided with fentanyl at 0.5-1µg/kg body weight as and when VAS score exceeded 4. PONV prophylaxis was provided using intravenous Ondansetron. Early extubation was attempted within 6 hours of completion of surgery after ensuring adequate reversal from paralysis, and with acceptable ABG values. Oral fluid intake was commenced within 2 hours of extubation. Invasive devices including drainage tubes and urinary catheters were removed early within 2nd postoperative days. Early mobilization was advised.

In group II, analgesia was provided with buprenorphine patch, intravenous paracetamol and inj fentanyl 25-50 microgram on demand.

Both the groups of patients were discharged from the ICU when they met the institutional discharge criteria (fully conscious, breathing spontaneously with pO2 >90% with room air, and not receiving intravenous infusion of vasoactive drugs to maintain haemodynamic stability, with an adequate urine volume and no serious cardiac arrhythmias).

Patients in the control group received standard routine care according to institutional practice.

Statistical Analysis Plan

Sample size for the study was calculated on the basis of duration of intubation as the primary outcome measure. It was estimated that 44 subjects would be required per group in order to detect a difference of 3 hours in this parameter 80% power and 5% probability of Type I error. This calculation assumed a standard deviation of 5 hours for the duration of intubation on the basis of an earlier study[14] and 2-sided testing.

Continuous variables were expressed as Mean, Median and Standard Deviation and compared across the groups using Mann-Whitney U test. Categorical variables were expressed as number of patients and percentage of patients, and compared across the groups using Pearson's Chi Square test for Independence of Attributes/ Fisher's Exact Test as appropriate. Any p value less than 0.05 it has been considered as significant. The statistical software SPSS version 22 has been used for the analysis.

RESULTS

Out of the 88 patients assessed for eligibility, one patient in control group patient was excluded as intraoperatively OPCAB was converted to on pump CABG due to hemodynamic instability.

There was no significant difference in the demographic profiles and patient characteristics between the two groups [group I n=44 and group II n=43]. The preoperative ejection fraction and total number of anastomoses were comparable between the two groups [Table 1]. There was no significant immediate complication associated with any of the cases.

Table 1: Distribution Of Patient Characteristics

PATIENT CHARACTERISTICS	Group I	Group II	p Value
Age (years)	64.89±6.55	64.98±7.49	0.795
Male : Female	40:4	35:8	0.198
Preoperative Ejection Fraction (%)	55.77±5.39	57.26±5.64	0.274
ASA Status(3/4)	42/2	43/0	0.494
NYHA Grade(2/3)	42/2	43/0	0.494
Total Number of grafts	3.80±0.55	3.79±0.47	0.672

Table-1:- ±values depict Mean ± standard deviation; NYHA = New York Heart Association functional status;

ASA = American Society of Anaesthesiology classification; BMI = Body Mass Index;
P< 0.05 is statistically significant

Table 2:- Primary Outcome. Time To Extubation
There was no incidence of reintubation in either groups.

Table-2

Primary Outcome	Group I	Group II	p Value
Time to extubation (hours)	4.89 ±1.13	13.97±1.81	<0.001

Table 3: Secondary Outcome Measures

Secondary Outcome	Group I	Group II	p Value
Duration of inotropic support (hours)	11.14±3.97	18.90±3.82	<0.001
Time to first oral diet (POD)	0.84±0.37	1.05±0.21	<0.001
Time to removal of drainage tubes (POD)	2.16±0.48	3.19±0.45	<0.001
Time to mobilization (POD)	2.75±0.58	4.40±0.58	<0.001
Time to discharge from ICU (POD)	4.89±0.65	6.65±0.57	<0.001

Table -3: - ±values depict Mean ± standard deviation; POD = Post Operative Day;
ICU= Intensive Care Unit

Table 4a: Requirements Of Blood Transfusion And Insulin

Perioperative requirement of administration	Group I	Group II	P Value
Insulin	15.91%	41.86%	0.007
Blood tranfusion	36.36%	46.51%	0.337

Values in % indicates percentage of patients in each group requiring blood transfusion or insulin perioperatively

Table 4a Shows the requirement of Insulin and blood products. In the control group 41.86% patients required Insulin infusion perioperatively as opposed to 15.91% patients in the ERAS group, to maintain blood glucose level <180 mg/dl (p = 0.007). No significant difference was noted regarding requirement of blood transfusion.

Table 4b: Opioid Requirement And Vas Score

Parameters	Group I	Group II	P value
Total opioid requirement (µg)	631.82±100.86	890.70±127.59	<0.001
VAS score at 12 hours	4.32±0.47	4.00±0.00	0.065

Table-4B :- ±values depict Mean ± standard deviation; VAS= Visual Analogue Scale

DISCUSSION

In this study, 88 patients undergoing OPCAB were divided into two groups. Group I received ERAS protocol therapy perioperatively whereas Group II patients received Institutional protocol therapy perioperatively. The demographic parameters and surgical parameters, such as total number of anastomotic grafts and total ischemia time, were similar between the two groups. The time to extubation was significantly shorter in group I than in the group II. Group I patients also manifested earlier resumption of oral diet, earlier

removal of drainage tubes, earlier time to mobilisation and shorter duration of ICU stay than the control group. There was less consumption of inotropes and opioid analgesics in group I than in group II. However the analgesic efficacy assessed by the VAS score was not significantly different at 12 hours postoperatively between the two groups.

Patients with coronary artery disease undergoing OPCAB, usually present with significant comorbidities, resulting in higher rate of complication. So, it is necessary to formulate measures to augment early recovery and reduction in perioperative morbidity and mortality[15].

The primary outcome of the study was extubation time postoperatively. The time to extubation was found to be significantly earlier in the ERAS group. Borys et al [16] studied the effect of ERAS protocol in patients undergoing OPCAB They also found duration of mechanical ventilation was significantly shorter in the ERAS group than in the standard care group. Similarly in our study, the median duration of ventilation was 5 hours in the ERAS group as compared to 14 hours in the control group, with comparable demographic parameters, number of distal grafts and total ischemia time.

Guller et al[17] found early extubation (<6 hours) with significantly shorter postoperative hospital stays than those with later extubation times without any increased risk of re-intubation in 6,446 CABG patients. In the present study, similar results were obtained, with no incidence of re-intubation following early extubation in the randomly selected ERAS group of patients.

It was found in this study that in the patients of ERAS group, where fluid therapy was guided by targeted hemodynamic parameters using TEE and cardiac output monitoring, the mean duration of post-operative ventilation, ICU stay and inotropic requirement was significantly less than the control group where standard fluid therapy was given.

Kapoor et al in 2017[13] performed a study where Goal Directed Fluid therapy was compared to standard intravenous fluid therapy in patients undergoing OPCAB. In their study, by utilisation of the EV 1000 platform, the hemodynamic goals in the GDFT group were set as cardiac index >2.5 ml/min/m^2, stroke volume variation <10%, stroke volume index >30-65 ml/beat/m^2, systemic vascular resistance index >1500-2500 dyne/sec/cm^5/m^2. This study also assessed Global End Diastolic Volume and $ScVO_2$ using Pre-sep catheter and maintained these parameters within physiological limits. The authors showed that the duration of ICU and in-hospital stay was significantly lower in the Goal Directed Fluid Therapy group as compared to control group in whom standard hemodynamic management was instituted by maintaining MAP>70 mm Hg and CVP >6-8 mm Hg. The authors also found that the duration of inotropic support was also less in the GDFT group. This finding is consistent with the result of our study. Mean duration of inotropic support was significantly shorter in the ERAS group where goal directed fluid therapy was instituted.

Insulin requirement in the group II was significantly higher. The excessive Insulin requirement in the control group may be explained as stress related hyperglycaemia due to insulin resistance exacerbated by longer duration of fasting compared to group I (ERAS group).

Here, the mean opioid requirement in group I was significantly lower compared group II. The less opioid consumption in group I may be due to early extubation in group I, and therefore lesser requirement of opioid (Fentanyl) . However, there was no significant difference in VAS score at 12 hours between the two groups.

In this study, significantly early removal of drainage tubes in group I was not associated with any complication. There was no significant difference in blood transfusion requirement between the two groups. This is similar to the result obtained in a study by Zurek et al[18] . They concluded early removal of chest drains after OPCAB neither increased the risk of postoperative complications and nor increased requirement for blood products transfusion.

Oral feeding was resumed earlier in group I as compared to group II to minimise the catabolic effects of the post-operative period.

In the present study, time to mobilisation after surgery was significantly earlier in group I, (2.75±0.58 days), as compared to the group II,(4.4±0.58 days). A meta-analysis carried out by Kanejima[19] et al in 2020, indicated that early mobilisation within the first 5 post-operative days may improve the physical function at the time of discharge in postoperative cardiac surgery patients. In our study also, patients with early mobilization were discharged early from the ICU. The mean duration of ICU stay was significantly shorter in group I. Median time of discharge from ICU was 5 days in group I, compared to 7 days in group II. This is also similar to the results obtained in the studies by Horswell[11] and Saltis[12] et al.

Time to extubation was significantly earlier in group I in this study. So, earlier extubation combined with early institution of oral diet, earlier removal of drainage tubes and earlier mobilisation contributed to the early discharge from ICU seen in group I.

CONCLUSION:-

From the various outcome measures, patients who were included in the group I had a better early post-operative outcome. ERAS protocol significantly improved the probability of early mobilisation and discharge after off-pump CABG without any incidence of major adverse effects. Regional anaesthetic technique was not undertaken for the purpose of providing analgesia. More studies are required on larger patient populations to conclude the feasibility and safety profile of introducing the ERAS pathways in off-pump CABG. A multidisciplinary approach starting from the pre-operative period and extending upto post-operative follow-up in the outpatient department may help to better understand the long-term benefits of the introduction of ERAS protocol in off-pump CABG.

Ethical Approval: Approval was obtained from the institutional ethics committee

Informed Consent: Informed Consent was obtained from all the study participants.

Statement On Human And Animal Rights: The study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments

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Conflict Of Interest: No financial or non-financial conflict of interest pertaining to the manuscript exists.

REFERENCES

1. Mack MJ, Pfister A, Bachand D, Emery R, Magee MJ, Connolly M,Subramanian V. Comparison of Coronary Artery Bypass Surgery with and Without Cardiopulmonary Bypass in Patients with Multivessel Disease. J Thorac Cardiovasc Surg 2004;127:167-73
2. A.F. Elmahrouk, T.E. Hamouda, I. Kasab, M.F. Ismail, A.A. Jamjoom. Short term outcome of conventional versus off-pump coronary artery bypass grafting for high-risk patients. J Egypt Soc Cardio-thorac Surg, 26 (1) (2018), pp. 57-63
3. Edwards ND, Alford AM, Dobson PMS, Peacock JE, Reilly CS: Myocardial ischemia during tracheal intubation and extubation. Br J Anaesth. 1994, 73: 537-539.
4. Choyce A, Avidan MS, Harvey A, Patel C, Timberlake C, Sarang K, Tilbrook L: The cardiovascular response to insertion of the intubating laryngeal mask airway. Anaesthesia. 2002, 57: 330-333
5. Andrew D. Jung, Vikrom K. Dhar, Richard S. Hoehn, Sarah J. Atkinson, Bobby L. Johnson, Teresa Rice, Jonathan R. Snyder, Janice F. Rafferty, Michael J. Edwards, Ian M. Paquette. Enhanced Recovery after Colorectal Surgery: Can We Afford Not to Use It? Journal of the American College of Surgeons, 226 (4), 2018, 586-93
6. Ljungqvist O, Scott M, Fearon KC. Enhanced Recovery After Surgery: A Review. JAMA Surg. 2017;152(3):292–298
7. Pędziwiatr M, Mavrikis J, Witowski J, et al. Current status of enhanced recovery after surgery (ERAS) protocol in gastrointestinal surgery. Med Oncol. 2018;35(6):95
8. Patel HRH, Cerantola Y, Valerio M, Persson B, Jichlinski P, Ljungqvist O, et al. Enhanced recovery after surgery: are we ready, and can we afford not to implement these pathways for patients undergoing radical cystectomy? Eur Urol. 2014;65(2):2636
9. Melnyk M, Casey RG, Black P, Koupparis AJ. Enhanced recovery after surgery (ERAS) protocols: Time to change practice. Can Urol Assoc J. 2011;5:342–348
10. Scott MJ, Baldini G, Fearon KC, Feldheiser A, Feldman LS, Gan TJ et al. Enhanced recovery after surgery (ERAS) for gastrointestinal surgery, part1: pathophysiological considerations. Acta Anaesthesiol Scand 2015;59:1212–31
11. Horswell JL, Herbert MA, Prince SL, Mack MJ. Routine immediate extubation after off-pump coronary artery bypass surgery: 514 consecutive patients. JCardiothorac Vasc Anesth. 2005 Jun;19(3):282-7
12. Soltis, Lisa1; Chapin, Melissa2; Corro, Thomas2; Wheaton, Ellen2; Worden, Wayne2; Keene, Paul3; Thompson-Brazill, Kelly4 319, Critical Care Medicine: December 2013:41(12);pA75
13. Kapoor PM, Magoon R, Rawat RS, et al. Goal-directed therapy improves the outcome of high-risk cardiac patients undergoing off-pump coronary artery bypass. Ann Card Anaesth. 2017;20(1):83-89
14. Anastasiadis K, Asteriou C, Antonitsis P, Argiriadou H, Grosomanidis V, et al. Fast-track Recovery After Elective Coronary Revascularization Surgery With Minimal Versus Conventional Extracorporeal Circulation: A Prospective Randomized Study. J Cardiothorac Vasc Anesth. 2013; 27; 859-864.
15. Coleman, S.R., Chen, M., Patel, S. et al. Enhanced Recovery Pathways for Cardiac Surgery. Curr Pain Headache Rep 23, 28 (2019)

16. Borys M, Żurek S, Kurowicki A, Horeczy B, Bielina B, Sejboth J, Wołoszczuk-Gębicka B, Czuczwar M, Widenka K. Implementation of Enhanced Recovery After Surgery (ERAS) protocol in off-pump coronary artery bypass graft surgery. A prospective cohort feasibility study. Anaesthesiol Intensive Ther. 2020;52(1):10-14
17. Guller U, Anstrom KJ, Holman W, Allman R, Sansom M, Peterson ED. Outcomes of early extubation after bypass surgery in the elderly.The Annals of Thoracic Surgery. 2004; 77(3):781-8.
18. Zurek S, Kurowicki A, Borys M, et al. Early removal of chest drains in patients following off-pump coronary artery bypass graft (OPCAB) is not inferior to standard care - study in the Enhanced Recovery After Surgery (ERAS) group. Kardiochir Torakochirurgia Pol. 2021;18(2):71-74.
19. Kanejima Y, Shimogai T, Kitamura M, Ishihara K, Izawa KP. Effect of Early Mobilization on Physical Function in Patients after Cardiac Surgery: A Systematic Review and Meta-Analysis. Int J Environ Res Public Health. 2020;17(19):7091.