Original Article

Efficacy of Enhanced Recovery After On-Pump Coronary Artery Bypass Grafting Surgeries, Controlled Randomized Prospective Study

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ABSTRACT

Objective: Prolonged intubation and mechanical ventilation post-cardiac surgery have been demonstrated to be associated with increased hospital and intensive care unit length of stays; higher health care costs; and morbidity resulting from atelectasis, intrapulmonary shunting, and pneumonia. Assessment of the impact of adopting ERAS protocol on extubation time as the primary outcome, the length of ICU stays of patients undergoing elective cardiac surgery, and the incidence of complications during their ICU stay as secondary outcomes.

Design: Prospective, randomized, double-blind clinical trial.

Setting: The study was conducted at Kasr Al-Ainy Hospital, Faculty of Medicine, Cairo University, Cairo, Egypt.

Participants: The study enrolled 58 Patients who were candidates for on-pump coronary artery bypass grafting, after obtaining consent from each of them, they were divided into two equal groups; the ERAS group and the traditional group.

Interventions: We adopted the concept of ERAS on the ERAS group, as the concept of ERAS is a bundle of management in our patient, this bundle included preoperative feeding, intraoperative goal-directed fluid therapy, and postoperative pain management. The traditional group is managed according to the traditional way of management of patients in Kasr Alainy according to the previous clinical trials conducted at Kasr Alainy that do not adopt the concept of ERAS.

Measurements and Main Results: As regards post-induction, post-extubation, on-pump MAP, and off-pump SBP and DBP, there was a statistically significant higher mean value in the ERAS group compared to the traditional group. According to extubation time and ICU stay, was reported that there was a statistically significant higher mean value in the traditional group than in the ERAS group.

Conclusions: In patients undergoing elective cardiac surgery, ERAS protocol improves postoperative outcomes. It shortens extubation time and length of ICU stay. It also decreased the incidence of complications during their ICU stay. Post-induction, post-extubation, on-pump MAP, and off-pump SBP and DBP were statistically significantly higher in the ERAS group compared to the traditional group.

Key Words: Cardiac surgery, ERAS protocol, extubation time.

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INTRODUCTION

Surgical trauma creates a stress response in the body, resulting in an imbalance of homeostasis. The stress response is a natural survival mechanism that generates energy and maintains cardiovascular balance. However, an excessive or persistent stress response, as in the case of surgery, can lead to undesirable outcomes such as protein catabolism[1], hyperglycemia, hypertension, tachycardia, or immunosuppression.

Enhanced recovery after surgery (ERAS) is a multidisciplinary management approach that incorporates several components and therapies and refutes conventional wisdom, such as preoperative fasting.

The International ERAS Society has created evidence-based guidelines for several surgical procedures. These ERAS recommendations have been shown to significantly reduce postoperative complications, length of stay (LOS)[2], and overall costs and improve staff and patient satisfaction. In addition, ERAS could be associated with better long-term survival.

In cardiac surgery, the ERAS guidelines were published in 2019 and showed great promise to decrease post-cardiac surgery complications and help patients return earlier to their normal lives, they were based on three basic items: preoperative, intraoperative, and postoperative interventions[3].

Cardiac ERAS differs from the traditional ERAS protocol in many terms, including prehabilitation, preoperative oral carbohydrate loading, use of non-opioid analgesia, early postoperative enteral feeding, and early patient mobilization in the ICU.

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In this study, we aimed to evaluate the effectiveness of the ERAS in terms of early extubation and reduction in hospital length of stay, incidence of complications, and readmission rate in patients undergoing cardiac surgery.

Methodology:

This controlled, randomized, prospective study was conducted from August 2022 to March 2023 at the Cardiothoracic Theatre of Cairo University's Kasr Al-Ainy Hospital. All patients consented to participate in the study after the nature, scope, and possible consequences were explained in a way they could understand. The study protocol and all the corresponding documents were declared for ethical and research approval by the ethical committee of the Kasr Alinin Faculty of Medicine, Cairo University.

Study population:

The population included in this study consisted of adult patients who had undergone on-pump coronary artery bypass graft surgery with a nutritional risk screening (NRS-2002) score of less than 58.

The exclusion criteria were patient refusal, ischemic patients with valvular disease requiring surgery in addition to CABG, non-insulin-dependent diabetics with HbA1c > 8% and insulin-dependent diabetics, patients with EF below 41%, patients with chronic kidney disease (stages 2-4), patients with more than two-fold increased liver enzymes and albumin levels below 3 g/dl, or patients with hemoglobin levels below 10 g/dl.

Patients were randomly assigned to one of the two study groups using a computer-generated table during preoperative anesthesia assessment (approximately one month before surgery) and assessed by a blinded anesthesiologist who was not involved in the study. Patient compliance was checked weekly using checklists.

We compared the traditional approach of patient management based on prior clinical studies conducted at Kasr-Alainy, which do not adopt the ERAS concept (conventional group). In contrast, the other group applied the ERAS concept, which includes preoperative feeding, intraoperative goal-directed fluid therapy, and postoperative pain management (ERAS group).

As the primary outcome is to measure extubation time, the sample size was calculated according to a previous study that reported that the time required for extubation using conventional protocols was 12.94 ± 5.03 hours[7].

So, the sample size was calculated to find a mean difference of 30% between both groups. A minimum number of 26 patients was required to achieve 80% study performance and an alpha error of 0.05 using the G*Power program version 3.1.9.7. To compensate for potential study dropouts, the number was increased to 58 patients (29 patients per group).

All patients were clinically assessed and evaluated during preoperative visits. Patients were informed of the nature of the procedure and its possible complications, and all candidates explained a visual analog scale (VAS), with zero representing no pain and ten representing the worst intolerable pain.

For the ERAS group:

The ERAS protocol was implemented through the perioperative period. Patient education and counseling before surgery were completed and included an explanation of the procedure and goals that may help to reduce perioperative anxiety, fatigue, and discomfort and improve recovery and early discharge.

Three to four weeks before the operation, a pre-habilitation program was implemented by optimizing nutrition according to the my-plate theory by dividing the plate into 4 quadrants with carbohydrates, proteins, vegetables, and fruits, each representing a quadrant.

Patients were asked to perform regular walking at a low pace according to the cardiological consultation and recommendation, as well as to do respiratory physiotherapy by breathing exercises consisting of 10 deep breathing attempts, pursing of the lips, and diaphragmatic breathing; instruction of a flow-IS-based incentive spirometer (Respiflow™ FS) and effective coughing: guidance on mobilization exercises for the neck and shoulders with an emphasis on chest extension and rotation; guidance on muscle tension exercises; and guidance on exercises to strengthen the muscles responsible for forward and backward movement of the shoulders. In addition, smoking was stopped for a month before the operation.

Random blood glucose was measured at the start of operation and before extubation and managed by insulin according to a sliding scale (random blood sugar / 100) and controlled to be 140-180 mg /dl.

All patients assigned to the ERAS group received preemptive analgesia in the form of pregabalin administered in a dose of 75 mg capsules (LYRICA, Pfizer Inc, Germany) two hours before induction with the apple juice.

For both groups:

All patients (including the ERAS and traditional groups) received a light meal of low-fat cheese, high-protein yogurt, and white bread 6 hours before anesthesia induction and 200 mL of apple juice 2 hours before anesthesia induction, as well as water intake that was allowed overnight to two hours before surgery. They also received 3rd generation cephalosporin 30 minutes before induction.

Standard monitoring using a (GE Solar 8000i) monitor was attached to the patients, including a 5-lead ECG, pulse oximeter, invasive blood pressure monitoring, and temperature; urine output was also monitored.

Anesthesia was induced with IV fentanyl (7-10µg/kg), propofol (1-2 mg/kg), and atracurium 0.5 mg/kg. It was maintained with isoflurane 0.5%–1.5% in oxygen. Mechanical ventilation was provided by DatexOhmeda (GE Medical System, Milwaukee, Wisconsin, 53201 USA) with Volume Controlled Ventilation mode (TV: 6-8 mL/kg, RR: 12-16/min) to maintain PaCO2 between 30 and 35 mmHg.

For the ERAS group:

Intraoperatively, goal-directed fluid therapy was implemented guided by tilting operating table maneuver and shock index (HR/SBP), which is a sum of heart rate divided by systolic blood pressure to be kept between 0.5 and 0.7.

As tilting the operating table in the Trendelburg position raises the lower extremities, which facilitate their venous drainage and transport 150-300 ml of blood to the central circulation, this auto-transfusion increases the cardiac preload and so the cardiac output. This maneuver is rapid and reversible and leads to an increase in the central venous pressure. If this was achieved, fluid resuscitation was provided with the administration of 250 mL of boluses of Lactated Ringer solution. If the increase in the central venous pressure exceeded 4 mmHg, norepinephrine infusion started at a rate of 0.05 µg/kg/min to retain the shock index to the average value.

After the operation, all patients were still intubated and admitted to the intensive care unit.

POSTOPERATIVE MANAGEMENT

For the ERAS group:

VAS guided postoperative pain management; if VAS (< 4), we gave IV Tramadol 50 mg/ 8 hrs; for VAS (> 4), we gave Tramadol /6 hrs; and if VAS > 4 for 1 hr, IV Acetaminophen 1 g every 8 hours may be added (with Ondansetron 8 mg IV every 24 hours to obviate the nauseating effect of tramadol), as well as oral Pregabalin 150 mg once per day.

An early oral feeding strategy will be implemented after extubation through clear warm fluids on day 0 of the ICU stay, then soft food during the first day and regular low-glycaemic index food with a protein intake of 1.3 g/kg/24 hours and low saturated fat intake for the following days of the ICU stay.

For the conventional group:

They received continuous intravenous Morphine infusion [10-20 µg/kg/hr], and if VAS score (> 4), IV Morphine was given in a dose of 0.05 mg/kg with a lockout time of 10 min, in addition to IV Paracetamol [15 mg/kg every 6 hours].The patients will resume oral intake after they pass flatus and auscultating intestinal sounds.

The following table summarizes the applied ERAS protocol in our study (**Table 1**).

Table 1: The applied ERAS protocol:

preoperative	intraoperative	postoperative
Patient education and counselling		
optimizing nutrition status		Multimodal analgesia
regular low pace physical exercise	Goal directed fluid therapy	Early oral feeding strategy
stop smoking		
preemptive analgesia		

Measurements

Primary outcome:

Extubation time (the time between cessation of anesthetic agent and extubation) after ICU admission.

Secondary outcomes:

length of ICU stay, postoperative complications (hypotension, arrhythmia, chest infection, wound infection, and mortality).

STATISTICAL ANALYSIS

Data analysis was performed using Statistical Package for Social Science (SPSS) software, version 15 for Microsoft Windows (SPSS Inc., Chicago, IL, USA). Categorical data was reported as numbers and percentages and analyzed using the chi-squared test. Continuous data was checked for normality using the Kolmogorov-Smirnov test. Normally distributed data was presented as means (standard deviations) and analyzed using an unpaired student t-test. Skewed data was expressed as medians (quartiles) and analyzed using the Mann-Whitney U test. For repeated measures, a two-way repeated-measures ANOVA was used to evaluate the block (between-groups factor) and the time (repeated measures)". Post-hoc pairwise comparison was performed using the Bonferroni test. A *P-value* of 0.05 or less was considered significant.

RESULTS

Our study aimed to assess the effectiveness of ERAS in reducing the extubation time and the length of hospital stay, the incidence of complications, and readmission rates in patients undergoing cardiac surgery. We conducted our study on 56 patients divided into two equal groups: the ERAS group ($n = 28$) and the conventional group ($n = 28$), with the same inclusion and exclusion criteria.

The two groups were comparable in age and sex, and there was no statistically significant difference regarding the baseline heart rate (bpm), baseline SBP (mmHg), and baseline DBP (mmHg) (**Tables 2, 3**).

Table 2: Comparison between groups according to demographic data:

Demographic data	ERAS Group (n = 25)	Traditional Group (n = 25)	p-value
Age (years)			
Range	45-53	40-55	0.790
Mean ± SD	49.46 ± 2.47	49.21 ± 4.28	
Sex			
Male	15 (53.6%)	11 (39.3%)	0.284
Female	13 (46.4%)	17 (60.7%)	

Using: t-Independent Sample t-test for Mean ± SD; x^2: Chi-square test for Number (%); p-value >0.05 is insignificant.

Table 3: Comparison between groups according to the baseline of heart rate, SBP and DBP (mmHg):

	ERAS GROUP	TRADITIONAL GROUP	p-value
Heart rate (bpm)			
Range	71-98	80-99	0.758
Mean ± SD	89.68 ± 6.51	89.18 ± 5.54	
Baseline SBP (mmHg)			
Range	90-118	92-116	0.108
Mean ± SD	105.46 ± 6.09	102.79 ± 6.16	
Baseline DBP (mmHg)			
Range	60-87	56-94	0.064
Mean ± SD	75.14 ± 6.78	70.86 ± 9.92	

Using: t-Independent Sample t-test for Mean ± SD p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant.

These hemodynamic measurements showed a statistically significant difference in the two groups, as the post-induction SBP and DBP, on-pump MAP, off-pump SBP and DBP, and Post extubation SBP and DBP were statistically significantly higher in the ERAS group compared to the conventional group (**Table 4**).

Table (4): Comparison between groups according to post-induction SBP and DBP (mmHg), on pump MAP, off pump SBP and DBP, and post extubation SBP and DBP:

	ERAS Group	Traditional Group	p-value
Post induction SBP (mmHg)			
Range	92-108	78-105	<0.001**
Mean ± SD	100.68 ± 4.47	92.71 ± 7.62	
Post induction DBP (mmHg)			
Range	56-87	53-76	0.002*
Mean ± SD	68.29 ± 8.38	61.39 ± 7.84	
On pump MAP			
Range	52-79	45-79	0.011*
Mean ± SD	66.64 ± 7.63	60.89 ± 8.64	
Off pump SBP			
Range	88-108	82-103	<0.001**
Mean ± SD	99.75 ± 5.30	91.00 ± 6.19	
Off pump DBP			
Range	54-87	43-82	0.007*
Mean ± SD	66.68 ± 9.85	58.71 ± 11.51	
Post extubation SBP (mmHg)			
Range	90-119	82-109	<0.001**
Mean ± SD	103.11 ± 6.03	96.04 ± 8.03	
Post extubation DBP (mmHg)			
Range	53-83	41-79	0.002*
Mean ± SD	65.93 ± 6.81	58.07 ± 10.48	

Using: t-Independent Sample t-test for Mean ± SD. p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant.

Regarding the extubation time (hrs) and the ICU stay (hrs), there was a statistically significant higher mean value in the conventional group than in the ERAS group with a *p*-value ($p<0.001$).

On the other hand, the postoperative complications were fewer in the ERAS group than the conventional group, including the occurrence of arrhythmia that required additional medical treatment, hypotension necessitated management by fluids or inotropes, wound infection, and mortality. Moreover, the incidence of delirium was less in the ERAS group than in the conventional group. However, the two groups had no statistical significance in all these postoperative complications. **(Figure 1**).

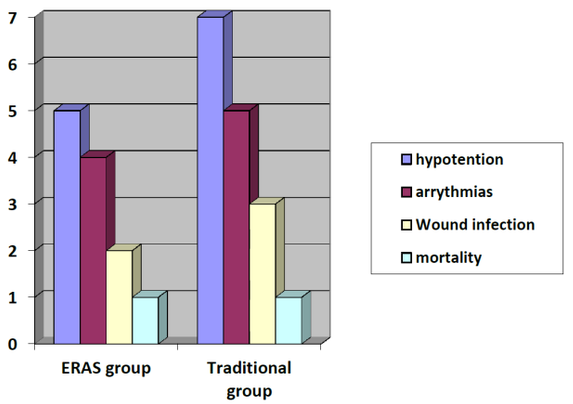

Fig. 1: The number of complications in both groups.

DISCUSSION

It has been shown that longer intubation and mechanical ventilation in cardiac surgery are associated with longer lengths of stay in the hospital and intensive care unit with higher healthcare costs and morbidity like atelectasis, intrapulmonary shunt, and pneumonia. Consequently, this study was conducted and aimed to assess the impact of the implementation of the ERAS protocol on the extubation time as the primary outcome, the length of ICU stay of patients undergoing elective cardiac surgery, and the incidence of complications during their stay in the ICU to be evaluated as secondary outcomes.

Our study found that as regards post-induction, post-extubation, on-pump MAP, and off-pump SBP and DBP, there was a statistically significantly higher mean in the ERAS group compared to the traditional group, and as regarding the extubation time and ICU stay, we reported that there was a statistically significant higher mean value in the conventional group than ERAS group.

In general, we found that implementation of the ERAS protocol was more beneficial than the conventional protocol; these results coincide with the outcomes of a study by Chen *et al.* published in 2020; they wanted to investigate the effect of an ERAS protocol in patients who had undergone off-pump CABG surgery. They agreed with us and reported that the ERAS protocol is safe and effective for OPCABG surgery patients. Patients in the ERAS group had a better understanding of coronary artery disease, a shorter fasting period, a shorter water deprivation time, increased participation in out-of-bed activities, and an improved 6-minute walk test on postoperative day 7[4].

A recent study about enhanced recovery for cardiac surgery conducted by Noss *et al.* agreed with us. It emphasized that the enhanced recovery protocol for cardiac surgery should include optimal analgesia, proper fluid administration, adequate transfusion management, and early mobilization[5].

In our study, we set up a multidisciplinary team, which included surgeons, anesthesiologists, and nurses. It provided more in-depth explanations about the patient's conditions and also enabled patients to understand better the disease's progression and the skills necessary for self-management. As a result, the patient's knowledge of ischemia improved significantly in the ERAS group compared to that of the conventional group, which led to improved outcomes. Was also the finding of a study by McConnell *et al.*, as they stated that perioperative education is an essential component of the ERAS program. Educating patients and their family members on the signs and symptoms of ischemic heart disease, the risk factors associated with this disease, the importance of early ambulation following the surgery, and the precautions that help to prevent infection and secondary disease - all of these can lead to improving the outcome of the patients[6].

As we adopted the use of moderate doses of short - acting narcotics in the ERAS group, we found thit was associated with a shorter stay in the ICU than the conventional group. This finding was also conducted by Hefner *et al.*, as they reported that early weaning of the patients from the ventilator and the use of moderate doses of short-acting narcotics would help to shorten the stay of the patients in the ICU[7].

Also, we encouraged the concept of minimizing preoperative fasting with a carbohydrate loading before anesthesia delivery in our study, as this has been demonstrated to reduce anxiety, hunger, insulin resistance, and postoperative nausea and vomiting that may affect 20-67% of patients undergoing cardiac surgery. In the same line with our study, two publications by Feldheiser *et al.* and Noss *et al.* reported that should be a focus of the ERAS program[8,9].

Our study found a significant difference between the ERAS and conventional groups regarding activity after OPCABG surgery; in the ERAS group, early ambulation helped the patients to recover their physical and cardiac function.

Unlike the usual finding that was shown in an older study by Fiorina *et al.*, which reported that functional capacity, as expressed by the distance walked during the 6-minute walk test (6MWT), is markedly reduced shortly after cardiac surgery and improves rapidly after exercise[10].

The average extubation time of the tracheal tube in this study was less in the ERAS group than in the conventional group; this result was also confirmed in a study by Li *et al.*, which found that the average extubation time of the tracheal tube was 7.2 h in the ERAS group compared to 8.8 h in the compared group[11].

Also other studies by Zaouter *et al.*, Williams *et al.*, investigated the value of the ERAS protocol, and they reported a reduction in the intubation time, shortening in ICU and hospital stays, fewer postoperative morbidities, and the overall cost of the patients undergoing cardiac surgery[12,13].

A study by Cove *et al.* showed that early extubation requires significant workflow changes; for example, anesthesia needs to be adjusted to rely less on high-dose opioid techniques. Unfortunately, the anesthesia technique was not changed in our study. Therefore, the extubation time of the tracheal tube and the pericardial and mediastinal drainage tubes showed no significant improvement, so one of our aims is to investigate this in future research[14].

We found that LOS and HOS-ICU were shorter, and ICU costs and delirium incidence rate in ICU were lower in the ERAS group than in the conventional group, which is consistent with the study by Salhiyyah *et al.*, as they reported similar results and showed that the fast-track group had cost-effectiveness compared to the conventional recovery group[15].

This was in contrast to research by Brown *et al.* that found between 26% and 52% of patients will experience delirium following heart surgery[16].

Furthermore, Li *et al.*, based on their extensive and comprehensive team, concluded that the ERAS protocol can reduce postoperative complications, HOS-ICU and LOS, and costs for cardiac surgery patients. Thus, the implementation of the ERAS protocol requires a multidisciplinary team[11].

Borys *et al.* agreed with us in most of their results and showed that implementing the ERAS protocol could improve patient outcomes after off-pump CABG surgery. Duration of mechanical ventilation, chest tube drainage, and stays in the ICU and hospital were shorter in the ERAS group than in the standard-of-care group. Pain was less intense in ERAS patients, and postoperative opioid requirements were lower. Furthermore, the postoperative troponin *T* concentration increase was minor in the ERAS group[17].

This study was the first at Cairo University Hospitals to evaluate the impact of the adoption of the ERAS protocol on extubation time as the primary outcome, length of stay in the ICU of patients undergoing elective cardiac surgery, and the incidence of complications during their stay as a secondary outcome.

CONCLUSION

Our study shows that the ERAS protocol improves postoperative outcomes in elective cardiac surgery patients.

It shortens extubation time and length of ICU stay. It also decreased the incidence of complications during their ICU stay.

RECOMMENDATIONS

If there are no contraindications, ERAS protocol is advised to be used in patients undergoing elective cardiac surgery.

CONFLICTS OF INTEREST

There are no conflicts of interest.

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