

# Comparison of the Effects of Special Care Enhanced Recovery and Conventional Recovery Methods after Mini Omega Gastric Bypass

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## Abstract

**Background:** Bariatric surgery is a surgical procedure for patients with extreme obesity. Enhanced Recovery after Surgery (ERAS) is a method that provides special peri- and post-operation care. Here, we aimed to compare the effects of ERAS and standard recovery cares.

**Materials and Methods:** This is a randomized clinical trial that was performed in 2020-2021 in Isfahan on 108 candidates for mini gastric bypass. Patients were then randomly divided into two equal groups receiving ERAS and standard recovery protocols. Patients were examined and visited after one month regarding the average number of hospitalization days, the average days required to return to normal activity or work, occurrence of pulmonary thromboemboli (PTE) and the rate of readmission.

**Results:** Patients that received ERAS had significantly lower frequencies of nausea and vomiting ( $P = 0.032$ ). Patients that received ERAS had significantly lower hospitalization duration ( $P < 0.001$ ) compared to controls. No other significant differences were observed between two groups regarding surgery complication, re-admission rate and occurrence of PTE ( $P > 0.99$  for all).

**Conclusion:** Patients that received ERAS protocol after gastric bypass had significantly lower hospitalization duration and lower incidence of nausea and vomiting. They also had similar post-operative outcomes compared to the standard protocol.

**Keywords:** Bariatric surgery, enhanced recovery after surgery, general surgery

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## INTRODUCTION

Obesity and overweight, are increasingly becoming a significant problem for adults and children around the world, especially in developing countries.<sup>[1,2]</sup> The prevalence of obesity has increased dramatically over the past three decades, one of the most important reasons being lifestyle changes.<sup>[3,4]</sup> Obesity and overweight are significant in populations because most cases of obesity and overweight lead to other diseases such as cardiovascular disease.<sup>[5]</sup> In 2018, the national prevalence rates of normal weight, obesity, and overweight/obesity among Iranian adults

were, 36.7% (95% CI: 36.1–37.3), 22.7% (22.2–23.2), and 59.3% (58.7–59.9), respectively.<sup>[6]</sup>

Bariatric surgery is a surgical procedure in which changes are made in the gastrointestinal tract, resulting in weight loss. Types of bariatric surgeries include Adjustable Gastric Band (AGB), Roux-en-Y Gastric Bypass (RYGB), mini-gastric bypass (MGB), and Vertical Sleeve Gastrectomy (VSG).<sup>[7,8]</sup>

Recovery after bariatric surgery as well as preparations before performing such operations are in the form of written

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instructions and guidelines that are performed by surgeons in different hospitals.<sup>[9]</sup> However, Enhanced Recovery After Surgery (ERAS) is a method that includes various measures before, during and after surgery that aim to reduce physiological stress, reduce pain, return the body to its normal function as soon as possible, improve outcomes and also reduce the cost of the medical system is done by reducing the length of hospital stay.<sup>[10]</sup> These measures generally include cases of early nutrition after surgery, optimal use of opioids, the activity of the patient for a short time after surgery, as well as optimal follow-ups.<sup>[11]</sup> The use of ERAS in various studies has been associated with good results, most of which have been in patients who have had lower bowel surgery. ERAS in bariatric surgery has yielded acceptable results for patients and the surgical team in a limited number of studies.<sup>[12-14]</sup>

However, there are few studies in which this method has been compared with routine methods. Also, a similar study that did not perform this protocol in Iran. The prevalence of obesity is increasing in the communities and there is an increasing trend in performing bariatric procedures. Considering that the use of ERAS method can reduce the complications of these surgeries and improve the condition of patients, in this study, we decided to evaluate and compare the use of part of the ERAS method in bariatric surgeries with the usual protocol of performing these surgeries.

## MATERIALS AND METHODS

This is a randomized clinical trial that was performed in 2020-2021. The current study was conducted on candidates for mini gastric bypass. The Ethics committee has confirmed the study with the code of IR.MUI.MED.REC.1400.530 (Iranian Registry of Clinical Trials (IRCT) code: IRCT20210614051574N6).

The inclusion criteria were age more than 18 years, being a candidate for mini gastric bypass and signing the written informed consent. The exclusion criteria were serious complications during surgery, lack of patient cooperation in postoperative follow-up, exiting from the study at any time during the study and the patient's place of residence far away from the hospital and lack of patient's consent.

The sample size was calculated based on the formula to compare the means in two independent groups with a significant level of 5% ( $z = 96.1$ ) and statistical power of 80% ( $Z = 0.84$ ). To detect the size of a standardized effect with a value of at least  $\Delta = 0.6$  (related to the variables of return time to work and length of hospital stay) and the same number of patients in each group ( $\sigma = 1$ ), 54 patients in each group were calculated.<sup>[15]</sup>

The eligible patients were selected based on the mentioned criteria. At first, the study protocol was fully explained to the patients and the informed consent was completed for each patient. Patients were then randomly divided into two equal groups. In the first group, patients underwent mini gastric

bypass by an expert surgeon but the pre- and post-operative recovery cares for patients were conducted based on ERAS guidelines. The patients in the second group underwent similar surgery procedure by the same surgical team and received conventional pre- and post-operation case.

The ERAS protocol is compared to the standard protocol of our study in Table 1.<sup>[16]</sup>

Patients were examined and visited after one month. In patients in both groups, the presence, nausea, vomiting, its times based on a scale of 0 to 5, and movement were examined. Also, any complications of the operation in patients such as infection and bleeding were reported and compared with each other. Other factors that were examined and compared between the two groups included: the average number of hospitalization

**Table 1: Comparison of ERAS and standard protocols**

	ERAS protocol	Standard method
Perioperative	Clear oral fluids, 6 h preoperatively	Liberal IV. fluid therapy
	PONV prevention:	Overnight fasting
	Ondansetron 30 min before operation	PONV prevention:
	Propofol (induction agent)	Ondansetron 30 min before operation
	Avoiding nitrous oxide as a carrier gas	Propofol (induction agent)
	Anesthetic management:	Anesthetic management:
	Reduced opioid usage	Liberal opioid usage
	IV Fluids (restrictive fluid therapy)	IV Fluids (liberal fluid therapy)
	No urinary catheter needed	Routine insertion of urinary catheter
	No postoperative leak test	Routine postoperative leak test
	Laparoscopy	Laparoscopy
Post-operation	Drain whenever necessary	Routine drains
	Analgesia:	Analgesia:
	Paracetamol (acetaminophen) 15 mg/kg, NSAIDs	Paracetamol (acetaminophen) 15 mg/kg
		Opioids/NSAIDs
	Thromboprophylaxis:	Thromboprophylaxis:
	Compression stockings	Compression stockings
	Chemoprophylaxis, based on weight, heparin	Chemoprophylaxis, based on weight, heparin
	SCD, individualized	SCD individualized
	Ambulation 4 h after surgery	Ambulation individualized
	Orals:	Orals:
	Clear liquids, 2 to 4 h after surgery	Clear liquids, 24 h after surger
	IVF stopped on POD 0	IVF continued until orals
	Oxygen: Routine postop O2 therapy	Oxygen: Routine postop O2 therapy
	CPAP as appropriate	CPAP as appropriate
	Incentive spirometry and deep breathing exercises to be started early	Incentive spirometry and deep breathing exercises to be started early

ERAS: Enhanced Recovery after Surgery

days, the average days required to return to work or normal activity, occurrence of pulmonary thromboemboli (PTE) and the rate of readmission using a checklist.

We used Statistical Package for Social Sciences (SPSS) (version 24, SPSS Inc., Chicago, IL) for data analysis using independent t-test, Chi-square tests. *P* value < 0.05 was considered as significance threshold.

## RESULTS

In the present study, we included 112 patients divided into two groups each containing 56 cases. During the study, 4 patients were excluded due to lack of sufficient cooperation (*N* = 3) and patient’s will (*N* = 1). Data of 108 patients were analyzed. The CONSORT flow chart of patients is shown in Figure 1.

The study population consisted of 37 males (34.3%) and 71 females (65.7%) with the mean age of 33.69 ± 12.09 years. Primary analysis of demographic data showed no significant differences between case and control group regarding age, gender, and body mass index (BMI) [Table 2].

We evaluated the nausea and vomiting and their times in patients. Based on our data, patients that received ERAS had significantly lower frequencies of nausea and vomiting (*P* = 0.032) [Table 3].

Further assessments showed that patients that received ERAS had significantly lower hospitalization duration (*P* < 0.001) compared to controls. No other significant differences were observed between two groups. These data are summarized in Table 4.

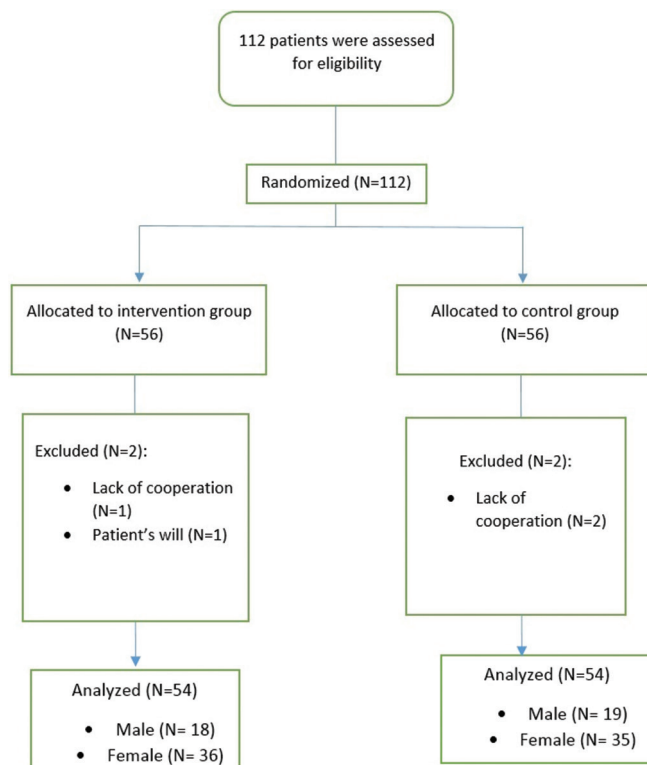


Figure 1: The CONSORT flow chart of patients

## DISCUSSION

In the present study, we assessed 108 candidates of mini gastric bypass and evaluated the efficacy of post-operation recovery care based on ERAS guidelines. Our data showed that patients that received ERAS had significantly lower hospitalization duration and lower frequencies of nausea and vomiting compared to the standard protocols. These data highlight the benefits of ERAS protocol to reduce the hospitalization duration.

We observed no significant differences between two groups regarding post-surgical complications. Patients in the ERAS

Table 2: Comparison of patient’s characteristics

Variable	Case (n=54)	Control (n=54)	P
Age (years) (mean±SD)	32.10±10.71	33.61±10.53	0.63*
Gender (n (%))			
Male	18 (33.3%)	19 (35.2%)	0.72**
Female	36 (66.7%)	35 (64.8%)	
BMI (kg/m <sup>2</sup> )	44.23±2.66	45.81±2.84	0.38*

\* using *t*-test, \*\* using Chi-square test

Table 3: Comparison of nausea and vomiting in patients

	Case (n=54)	Control (n=54)	Total	P
Nausea and vomiting (times)	1.53±1.14	2.19±1.33	1.85±1.27	0.032*
Times of nausea and vomiting (n (%))				
0	9 (16.7%)	8 (14.8%)	17 (15.8%)	0.146**
1	16 (29.6%)	18 (33.3%)	34 (31.4%)	
2	11 (20.4%)	10 (18.5%)	21 (19.5%)	
3	13 (24.1%)	12 (22.2%)	25 (23.1%)	
4	3 (5.5%)	5 (9.3%)	8 (7.4%)	
5	2 (3.7%)	1 (1.9%)	3 (2.8%)	

\* using *t*-test, \*\* using Chi-square test

Table 4: Comparison of patient’s outcomes and surgical complications between two groups

	Case (n=54)	Control (n=54)	Total	P
Work return normal activity (day)	5.56±0.76	6±0.92	5.78±0.86	0.080*
admission time (day)	1.17±0.19	2.09±0.30	1.54±0.58	<0.001*
Surgery complications				
No	54 (100%)	53 (98.1%)	107 (99.1%)	>0.99**
Yes	0	1 (1.9%)	1 (0.9%)	
re-admission				
No	54 (100%)	54 (100%)	108 (100%)	-
Yes	0	0	0	
PTE				
No	54 (100%)	54 (100%)	108 (100%)	-
Yes	0	0	0	

\* using *t*-test, \*\* using Chi-square test

group had also significantly lower nausea and vomiting. Therefore, conducting the ERAS protocol could significantly reduce the hospitalization duration with similar or even better clinical results. Previous studies have also investigated the benefits of ERAS protocol.<sup>[17]</sup> In 2016, a study was performed by Hahl and colleagues on 388 patients that underwent LRYGB with ERAS protocol. By evaluating the outcomes of patients, they indicated that conducting ERAS for LRYGB is possible and associated with acceptable results.<sup>[18]</sup> Our data showed that patients that received ERAS had significantly lower hospitalization duration and lower frequencies of nausea and vomiting compared to the standard protocols. These data highlight the benefits of ERAS protocol to reduce the hospitalization duration.

Another study was conducted by Ruiz-Tovar in 2019 on 180 candidates of gastric bypass surgery. By comparing the results of ERAS protocol with standard protocols, it was demonstrated that patients that received ERAS had significantly lower post-operative pain, lower incidence of post-operative nausea and vomiting and lower hospitalization duration. It was also indicated that both groups had similar complications, mortality and re-admission rates.<sup>[19]</sup> We observed the benefits of ERAS protocol in candidates of gastric bypass surgery in the way that we also observed lower hospitalization duration in our patients.

Another point of this study was that we assessed 108 patients that were candidates of mini gastric bypass. As mentioned, most previous studies have been conducted on candidates of other types of gastric bypass surgeries and we believe that there might be differences in the outcomes of patients based on the types of surgeries. In 2018, Major and colleagues assessed the efficacy of ERAS protocol in candidates of LRYGB and laparoscopic sleeve gastrectomy (LSG). By assessing different clinical data, it was concluded that ERAS is a perfect option for candidates of LRYGB but on the other hand, candidates of LSG require longer hospital care could benefit more from standard protocols.<sup>[20]</sup> Our data were consistent with these findings emphasizing the importance of ERAS protocol in patients.

Blanchet and others had a survey on candidates of MGB and LSG and evaluated the results of ERAS protocol for patients. Based on this study, ERAS was safe and beneficial for patients in both groups that reduced the hospitalization duration.<sup>[14]</sup>

Studies have also suggested that by using ERAS, patients would be less vulnerable to hospital derived infections by reducing the hospitalization duration.<sup>[21,22]</sup> Therefore, ERAS is accounted as a beneficial technique in patients undergoing important surgical procedures.

In another study by Aktimur and others in 2018, 308 candidates of gastric bypass surgery using OAGB were assessed. Based on this study, patients that received ERAS protocol had significantly lower hospitalization duration, lower surgical and recovery costs and lower re-admission rates compared to patients that received standard recovery protocol.<sup>[23]</sup>

Another important point was that we observed significantly lower incidence of nausea and vomiting in patients that received ERAS protocol. This issue has also high clinical importance especially in patients undergoing gastric bypass surgeries because it could potentially reduce the risks of bleeding and therefore, re-admission and mortality.

Furthermore, only few studies have been conducted in this regard in Iran especially on patients undergoing mini gastric bypass. The limitations of our study included restricted study population and conducting a single-centric study. Evaluation of larger study populations in multiple centers might indicate more valuable data. We also recommend that surgeons should pay more attention to the beneficial use of ERAS protocol. As the clinical point of view, patients that underwent post-operation care by ERAS protocol had shorter hospitalization duration and better functions. The shorter hospitalization could significantly lower the risks of infection and further complications.

## CONCLUSION

Patients that received ERAS protocol after mini gastric bypass had significantly lower hospitalization duration and lower incidence of nausea and vomiting. They also had similar post-operative outcomes compared to the standard protocol. These data were consistent with previous studies and could have high clinical importance. Evaluation of larger study populations in multiple centers might indicate more valuable data.

### *Declaration of patient consent*

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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### *Conflicts of interest*

There are no conflicts of interest.

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