EFFICACY AND SAFETY OF ENHANCED RECOVERY AFTER SURGERY FOR PATIENTS UNDERGOING LAPAROSCOPIC BARIATRIC SURGERY: RANDOMIZED CONTROLLED TRIAL

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Abstract

Background: The efficacy of enhanced recovery after surgery (ERAS) in the bariatric setting is less well defined. Herein, we studied the impact of ERAS implementation protocol on the outcome of laparoscopic bariatric procedures.

Methods: In this prospective randomized trial, sixty patients were enrolled, and they were randomly assigned into two groups: Group A consisted of patients who underwent the ERAS protocol, while Group B consisted of the remaining patients who underwent the traditional pathway of care.

Results: Preoperative characteristics, operative time, and early postoperative complications were comparable between the two groups, apart from vomiting that increased significantly in Group B. All recovery parameters, including time to ambulate, time to enteral fluid intake, time to pass flatus, and total hospitalization time, showed a dramatic improvement in Group A. Group A had a better analgesic profile compared to group B, manifested by lower pain scores, less analgesic consumption, and delayed rescue analgesia. The mean values of %EWL were 54.74% and 55.56% after six months, 69.84 and 71.37% after one year in our two groups, respectively. The performed bariatric operations had a positive impact in 83.33% and 85.72% of diabetic cases, as well as 60% and 75% of hypertensive cases in Groups A and B, respectively, at one-year follow-up.

Conclusion: ERAS implementation led to a significantly better recovery profile compared to the conventional care pathway, without any significant impact on weight loss or comorbidity outcomes.

Keywords: Bariatric surgery; Enhanced recovery; Outcomes.

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Introduction

In Egypt, obesity has become a major health problem as about one-third of adult Egyptians are considered obese, according to the recent "One million health" survey **(1)**. Currently, bariatric procedures are considered the main effective management option for that problem, as it provides durable weight loss and effective resolution or improvement of obesity-related comorbidities **(2, 3)**. These procedures are frequently performed in the Egyptian setting by both general and digestive surgeons **(4, 5)**.

Although most bariatric procedures are performed via laparoscopy, which is associated with faster patient recovery, one must consider the implementation of other protocols to reach optimum patient recovery and satisfaction **(6, 7)**.

"Enhanced recovery after surgery" or ERAS is a broad term used to describe integrated, evidence-based protocols that require cooperation between the patient, surgeon, anesthetist, pain physician, nurse, occupational therapist, and hospital administration, aiming to enhance postoperative outcomes, standardize the surgical care, and decrease financial costs **(8, 9)**.

These ERAS protocols entail preoperative, intraoperative, and postoperative techniques that fasten patient recovery, decrease postoperative pain, help early mobilization and oral intake, and decrease the duration of hospitalization **(10)**. This program was initially described with "day surgery" and then implemented in colorectal surgery. ERAS has proved its safety and effectiveness in improving patient outcomes after different surgical procedures **(11-13)**.

Despite the previous advantages of ERAS, it has its own limitations. Both the patient and the nurse must be aware and compliant with its components. Additionally, there is still a great debate regarding

which of the ERAS components really has a clinical benefit **(14)**.

Recently, ERAS implementation has been described with bariatric procedures. Nonetheless, no single consensus has been defined to achieve the best perioperative care **(15, 16)**.

After intensive research, the current literature is poor with Egyptian studies evaluating the impact of ERAS implementation on post-bariatric outcomes. That is why we conducted this trial to elucidate if ERA implementation improves post-bariatric outcomes.

Patients and methods

This prospective randomized clinical trial was conducted at Mansoura University General Surgery Department over a two-year period, from May 2019 to May 2021, after approval from medical and scientific ethics committee of Mansoura University (MD.19.05.179).

The required sample size was estimated via an online calculator (www.clincalc.com) based on the outcomes published by the previous study conducted by Costa-Ferreira and his colleagues, who reported that the duration of hospitalization had mean values of 5.5 (± 2.2) and 7.5 (± 2.5) days in the ERAS and control groups respectively **(17)**. Thirty patients were required in each group to achieve a 0.05 significance level and 80% study power.

After signing informed written consent, we enrolled adult patients whose body mass index (BMI) was more than 35 kg/m2 with obesity-related comorbidity or more than 40 kg/m2 in the absence of obesity-related comorbidity. Contrarily, we excluded patients with previous bariatric surgery, colorectal or intestinal resections, secondary obesity, pregnancy, and major psychological disorders.

The allocated patients were assigned into two groups using the "sealed envelope approach"; Group A consisted of patients who had the ERAS protocol, and Group B consisted of the remaining patients who followed the traditional course of care. Patients in both groups received the same preoperative assessment, including history taking, clinical examination, laboratory investigations, esophagogastroduodenoscopy, and pelviabdominal ultrasonography.

Regarding preoperative care in Group A, patients were advised to have a high-fiber diet and perform aerobic exercise one month before surgery. Eating solids was maintained till the day before surgery, and the patient was advised to fat six hours before the operation. All patients were asked to have 150 ml water containing 5% dextrose two hours before the surgery. Additionally, a broad-spectrum antibiotic (third-generation cephalosporin) was commenced one hour before surgery. In group B, no dieting or weight loss exercises were advised. Fasting was ordered one day before the surgery, and no antibiotic prophylaxis was given.

The bariatric procedures (sleeve gastrectomy LSG, minigastric bypass MGB, or single anastomosis sleeve ileal bypass SASI) were performed via laparoscopy while the patient was in French position with elastic bandages around both legs. Each of the three procedures was performed according to the published standard guidelines **(18-20)**. In Group A, an epidural catheter was inserted for pain management. Low-volume ventilation (5 – 8 ml/kg) was used during surgery, and the operative theater temperature was kept at 26°C. If abdominal irrigation was needed, it was performed using warm saline, and a surgical drain was selectively placed at the end of the procedure according to the surgeon's preference. In Group B, ventilation volume was kept at 10 – 15 ml/kg, with no special setting for operative room temperature (22 – 24°C). The abdominal cavity was washed with normal saline, and a surgical drain was inserted under the left liver lobe in all cases. At the procedure's end, desufflation of the abdominal cavity was done, and the abdominal ports were closed.

After surgery, early ambulation was encouraged in both groups. Patients in both groups were taught how to express their pain on an eleven-point scale, from 0 to 10, with 0 for no pain and 10 for the worst one **(21)**. These measurements were recorded throughout the first postoperative day for all patients. Patients in both Groups were allowed to take 100 – 200 ml of warm liquids on the first postoperative day, while liquids and semiliquids were allowed on the second and third postoperative days, respectively (total fluid input 2000 – 2500 ml/day). Nausea and vomiting were managed by IV metoclopramide. Pain In group A was managed by infusion of local anesthetic through the epidural catheter while in group B, pain was managed by IV acetaminophen (1 gm/ 8 hours) and IV ketorolac (30 mg/ 12 hours). If the patient reported breakthrough pain, IV pethidine 50 mg was commenced.

After discharge, patients were instructed regarding their diet, mineral, and multivitamin supplementation according to the recent guidelines **(22)**. Once the stitches were removed, regular follow-up appointments were arranged at three, six, nine, and twelve months after the procedure. Weight loss and changes in comorbidities connected to obesity were evaluated during these visits. Weight loss was expressed as the percentage of excess weight loss (%EWL) **(23)**, while changes in comorbidities were defined according to Brethauer and his colleagues **(24)**. Denovo reflux was defined as the experience of reflux symptoms in patients with no such symptoms prior to the surgery **(25)**.

Our primary outcome was the duration of hospitalization, while secondary ones included the incidence of complications, time to ambulation, time to oral feeding, time to pass flatus, pain scores, total

analgesic consumption, weight loss, and comorbidity outcomes.

We used the SPSS software for data tabulation and analysis. Depending on the mode of distribution, quantitative data were expressed as mean (and standard deviation) or median (and range). The former data type was compared between the two groups using the student-t-test, while it was compared within the same group at different time intervals using the paired t-test. The latter data type was compared between the two groups using the Mann-Whitney test. The Chi-Square, Fischer exact, or Monte Carlo tests were used to evaluate categorical variables between the two groups, which were presented as numbers (and percentages). Any p-value less than 0.05 was considered significant.

Results

In Groups A and B, the mean ages of the included cases were 43.47 and 41.07 years, respectively. In the same study groups, women made up 76.67 percent of cases and 83.33 percent of cases, respectively, with men making up the remaining participants. The mean BMI of the cases that were included in the study was 48.76 kg/m2 for Group A and 48.64 kg/m2 for the other.

In the same two groups, diabetes was present in 20% and 23.33 percent of patients, whilst hypertension was prevalent in 16.67 percent and 13.33 percent of cases. 6.67 percent of the cases in the two groups were smokers.

LSG was the commonest performed procedure, as it was performed for 73.33% and 80% of cases in our two groups, respectively. The remaining cases had either MGB or SASI procedures. The duration of the surgical procedure had mean values of 71.07 and 73 minutes in the same groups, respectively, indicating that it was comparable between the two groups.

The mean amount of intraoperative blood loss was 47.9 and 52.13 ml in the same two groups. Regarding the incidence of intraoperative complications, bleeding from the short gastric vessels was encountered in only one case (3.33%) in Group A. All operative data were comparable between our two groups.

Vomiting showed a significant rise in Group B (13.33% vs. 0% in Group A – $p = 0.038$). Leakage occurred in only one case in Group B (3.33%), who underwent LSG, and it was managed by endoscopic stenting. Intraperitoneal bleeding occurred in only one patient (3.33%) in group A, who underwent the SASI procedure, and the case was managed by fluid and blood transfusion (two units) (Table 1).

All recovery parameters showed a dramatic improvement in Group A. This included time to ambulate, time to oral fluid intake, time to pass flatus, and total hospitalization time. All of the previous parameters were significantly decreased in association with ERAS (Table 2).

Group A tended to express significantly lower VAS scores throughout the first post-operative day compared to group B (Table 3).

The number of patients requiring rescue analgesia showed a significant decline in Group A (16.67% vs. 73.33% in the other group). Moreover, the time to the first analgesic request showed a significant prolongation in the same group (96.63 vs. 4.73 in the other group – $p < 0.001$). Moreover, Group A showed a significant decrease in post-operative pethidine consumption (50 vs. 150 mcg in the other group) (Table 4).

Both approaches showed comparable %EWL at follow-up. The mean values of %EWL were 54.74% and 55.56% after six months, 69.84 and 71.37% after one year (Table 5).

At a one-year follow-up, the performed bariatric procedures in Groups A and B, respectively, had a beneficial effect on 83.33 percent and 85.72 percent of diabetic cases (Table 6).

At the final follow-up, the positive impact of bariatric surgery on hypertension was noticed in 60% and 75% of cases in our two groups, respectively (Table 7).

Denovo GERD was experienced in 6.67% and 10% of cases in Groups A and B, respectively ($p = 0.64$) (Table 8).

Table (1): Patient criteria, operative, and early postoperative data.

	Group A (n = 30)	**Group B (n = 30)**	**P value**

Age (years)	43.47 ± 7.63	41.07 ± 7.75	0.232
Gender **-Male** **-Female**	 7 (23.33%) 23 (76.67%)	 5 (16.67%) 25 (83.33%)	 0.519
BMI (kg/m2)	48.76 ± 5.82	48.64 ± 6.45	0.938
Comorbidities **-Diabetes mellitus** **-Hypertension**	 6 (20%) 5 (16.67%)	 7 (23.33%) 4 (13.33%)	 0.754 0.718
Smoking	2 (6.67%)	2 (6.67%)	1
Procedure Type **-LSG** **-MGB** **-SASI**	 22 (73.33%) 5 (16.67%) 3 (10%)	 24 (80%) 3 (10%) 3 (10%)	 0.746
Operative time (minutes)	71.07 ± 17.42	73 ± 15.22	0.649
Blood loss (ml)	47.90 ± 12.35	52.13 ± 10.60	0.160
Operative complications **-Bleeding from short gastric vessels**	1 (3.33%)	0 (0%)	0.313
Postoperative complications **-Leakage** **-Bleeding** **-Vomiting** **-DVT**	0 (0%) 1 (3.33%) 0 (0%) 0 (0%)	1 (3.33%) 0 (0%) 4 (13.33%) 0 (0%)	0.313 0.313 0.038* 1

Table (2): Post-operative recovery data.

	Group A (n = 30)	**Group B (n = 30)**	**P value**
Time to ambulation (hours)	6 (2-9)	8 (5-11)	< 0.001**
Time to oral fluid intake (days)	1 (1 – 2)	3 (3 - 4)	< 0.001**
Time to pass flatus (hours)	9 (7-12)	11 (8-13)	< 0.001**
Hospital stay (hours)	24 (18 – 72)	36 (24 – 72)	< 0.001**

Table (3): Post-operative pain scores.

	Group A (n = 30)	**Group B (n = 30)**	**P value**
PACU	4 (3-5)	6 (5-6)	< 0.001**
2 hours	4 (3-5)	5 (4-6)	< 0.001**
4 hours	3 (2-5)	5 (4-6)	< 0.001**
6 hours	3 (2-4)	5 (3-6)	< 0.001**
8 hours	3 (2-4)	4 (3-5)	< 0.001**
10 hours	2 (2-3)	3 (3-4)	< 0.001**
12 hours	2 (2-3)	2 (1-3)	0.050*
24 hours	2 (1-2)	2 (1-3)	0.131

Table (4): Analgesic profile parameters.

	Group A (n = 30)	**Group B (n = 30)**	**P value**
No patients requiring rescue analgesic	5 (16.67%)	22 (73.33%)	< 0.001**
Time to the first analgesic request (hours)	6.63 ± 1	4.37 ± 0.96	< 0.001**
Total pethidine consumption	50 (50 – 100)	150 (100 – 200)	< 0.001**

Table (5): Weight loss in the two study groups.

	Group A (n = 30)	**Group B (n = 30)**	**P value**

1 month	12.61 ± 5.74	11.77 ± 6.23	0.589
3 months	28.62 ± 6.39	31.72 ± 6.08	0.130
P value	< 0.001**	< 0.001**	
6 months	54.74 ± 4.37	55.56 ± 4.29	0.468
P value	< 0.001**	< 0.001**	
12 months	69.84 ± 7.37	71.37 ± 7.73	0.435
P value	< 0.001**	< 0.001**	

Table (6): Diabetes changes in diabetic cases.

	Group A (n = 6)	Group B (n = 7)	P value
6 months			
-Complete remission	1 (16.67%)	1 (14.28%)	0.968
-Partial remission	2 (33.33%)	2 (28.57%)	
-Improvement	1 (16.67%)	2 (28.57%)	
-Unchanged	2 (33.33%)	2 (28.57%)	
12 months			
-Complete remission	2 (33.33%)	2 (28.57%)	0.940
-Partial remission	2 (33.33%)	2 (28.57%)	
-Improvement	1 (16.67%)	2 (28.57%)	
-Unchanged	1 (16.67%)	1 (14.28%)	

Table (7): Hypertension changes in hypertensive cases.

	Group A (n = 5)	Group B (n = 4)	P value
6 months			
-Complete remission	0 (0%)	1 (25%)	0.665
-Partial remission	1 (20%)	1 (25%)	
-Improvement	2 (40%)	1 (25%)	
-Unchanged	2 (40%)	1 (25%)	
12 months			
-Complete remission	1 (20%)	1 (25%)	0.973
-Partial remission	1 (20%)	1 (25%)	
-Improvement	1 (20%)	1 (25%)	
-Unchanged	2 (40%)	1 (25%)	

Table (8): Incidence of Denovo reflux.

	Group A (n = 30)	Group B (n = 30)	P value
Denovo reflux	2 (6.67%%)	3 (10%)	0.640

Discussion

The current study was conducted aiming to study the impact of the implementation of ERAS protocol on the outcome of laparoscopic bariatric surgery. Looking at our preoperative data, it was impossible to find any preoperative variables where our two groups differed significantly from one another. This demonstrates how we used proper randomization. Additionally, that should eliminate any bias that might have tipped the results in favor of one group over the other.

In the current investigation, there was no discernible difference in operative time between the two study groups. One could expect these results as the type of operation did not differ between the two groups. We did not detect any significant impact of ERAS on operative time. Nonetheless, other previous studies noted a significant decline of the same parameter in association with ERAS **(26, 27)**. They attributed their findings to the fixed multidisciplinary teamwork that has been applied in multiple cases, leading to increased work competence with time, leading to more organized teamwork, and decreased operative time **(28, 29)**.

Our findings showed that the application of ERAS was not associated with an increased incidence of leakage. Another study reported that the application of ERAS was not associated with a significant increase in leakage after different bariatric procedures (either from the staple line or anastomosis). This complication was not encountered in the ERAS group (0%) compared to 1.8% in the conventional group (p = 0.47) **(30)**. Trotta et al. also confirmed the previous findings **(31)**.

In the present investigation, there was no discernible difference in the incidence of postoperative bleeding between the two groups. Likewise, another study also reported that the incidence of post-bariatric hemorrhage was 1.8% and 2.1% in the ERAS and control groups, respectively (p > 0.05) **(32)**.

Our study showed no statistical difference in the incidence of DVT after the operation, and that complication was not encountered in our trial. Another study also reported that implementation of the same program did not have a significant impact on the incidence of postoperative thromboembolic events ($p > 0.05$), which was noticed in 0.3% and 0% of cases in the ERAS and conventional groups, respectively **(26)**.

Our findings showed that the application of ERAS was associated with a significant decline in pain scores. This was mainly due to the epidural analgesia provided for that group. Subsequently, the same group showed a significantly better analgesic profile, which was apparent in rescue analgesia needs and total pethidine consumption. Other multiple previous studies also stated that the application of the same protocol was associated with a significant decline in pain scores **(33, 34)**.

We noted a significant decrease in the time to the first rescue analgesia in the ERAS group compared to the other one. Additionally, total pethidine consumption was significantly decreased with the same protocol. Ma et al. noted a significant decline in analgesic consumption after different bariatric procedures with the implementation of ERAS **(33)**. King and his associates also agreed with the previous results **(35)**.

In our study, ambulation after surgery was earlier with ERAS implementation. This could be explained by a better analgesic profile and better anesthetic management. In agreement with our findings, Ronellenfitsch and his coworkers reported a significant increase in the percentage of cases who ambulated during the first postoperative day in association with ERAS implementation (92.3% vs. 78.1% in the standard care – $p = 0.03$) **(30)**. Moreover, Emile et al. reported that the regional block performed during the bariatric procedure as a part of ERAS was associated with a significantly earlier ambulation time (6.3 vs. 7.3 hours in controls – $p < 0.001$) **(36)**.

We noticed a significant decrease in the time for the first oral intake in association with the ERAS protocol. Another study reported that the application of the ERAS program was associated with a significantly earlier intake of oral fluid supplements (90.8% vs. 20.3% in controls on the 2nd post-operative day – $p < 0.001$) **(30)**. This confirms our findings.

Our results showed that the incidence of vomiting was significantly increased in the conventional group ($p = 0.038$). Similarly, King et al. reported that only 46.2% of ERAS patients required antiemetics, compared to 68.8% of patients in the standard care pathway ($p < 0.001$) **(35)**. Other studies highlighted that ERAS implementation led to a significant decline in the incidence of postoperative nausea and vomiting **(37, 38)**.

In our study, the time to pass flatus showed a significant decline in the ERAS group. This could be secondary to early mobilization as well as early oral fluid intake. In another study, the same parameter showed a significant decline with ERAS implementation (9.5 vs. 10.5 hours in the other group – $p = 0.02$) **(36)**.

In our study, the hospital stay showed a significant decline in the ERAS group. This could be secondary to early mobilization, early oral intake, and better pain control in association with ERAS. Other studies also highlighted the beneficial impact of ERAS on the duration of hospitalization compared to the standard care protocol **(26, 27, 39)**.

We noted no significant impact of the ERAS protocol on weight loss outcomes. One-year %EWL had mean values of 69.84 and 71.37% in our two groups, respectively. Although the literature is poor with studies handling the effect of ERAS on weight loss outcomes, our range of %EWL is near to the literature that reported a mean %EWL of 63.97% and 66.19% for LSG and MGB procedures, respectively **(40)**. Data regarding one-year %EWL after SASI are heterogeneous, ranging from 63.9% up to 90% **(20, 41)**. That could be explained by different surgical techniques, adherence to postoperative exercise, and the recommended dietary plans.

When it comes to diabetes outcomes, the performed bariatric operations had a positive impact on 83.33% and 85.72% of diabetic cases in our two groups, respectively, at one-year follow-up. This is in accordance with previous reports stating that about 78% of diabetic cases achieve normoglycemia without any medications after bariatric surgery, while 87% of them require fewer medications **(42, 43)**.

In the current study, the positive impact of bariatric surgery on hypertension was noted in 60% and 75% of cases in Groups A and B, respectively, at the last follow-up. Our findings are consistent with the literature, which showed remission or improvement of hypertension in about 60% - 70% of patients with preexisting hypertension **(44-46)**.

Denovo reflux was experienced in 6.67% and 10% of cases in our two groups, respectively. One should notice that the majority of our cases had LSG. LSG could increase reflux manifestations by disruption of the angle of His and the creation of a high-pressure tube **(47, 48)**. Emile and his coworkers also reported an incidence of 14.89% for the same complication after LSG.

Our research has some drawbacks. It was a single-center study with a modestly sized sample size. Additionally, it lacks information on the included cases' intermediate- and long-term follow-ups. Therefore, in the next investigations, the prior shortcomings should be thoroughly investigated.

Conclusion

The adoption of the ERAS protocol was linked to a much-improved recovery profile when compared to the traditional care pathway, according to the findings of our study. However, the results of weight loss and comorbidity changes did not significantly change in association with ERAS.

Declarations:

Ethical approval and consent to participate: All methods were performed in accordance with declaration of Helsinki. We obtained Mansoura faculty of medicine Institutional Research Board (MFM-IRB) approval (MD.19.05.179). before patient enrollment. All patients gave their written informed consent during the preoperative visits.

Conflicts of interest: Nil.

Availability of data: the individual participant data will be available on reasonable request with the corresponding auther after the local IRB approval.

Consent for publication: not applicable

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