

Original article

Implementation of enhanced recovery programs for bariatric surgery. Results from the Francophone large-scale database

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Abstract

Background: The feasibility, safety, and efficacy of programs for enhanced recovery after bariatric surgery (ERABS) are now well established. However, data concerning their large-scale implementation remain insufficient.

Objectives: The objective of the present study was to review the multicenter implementation of ERABS

Setting: This retrospective analysis of a prospective database was conducted in 15 Groupe francophone de Rehabilitation Améliorée après ChirurgiE centers from data from March 2014 to January 2017.

Methods: The Francophone working Group for Enhanced Recovery After Surgery (Groupe francophone de Rehabilitation Améliorée après ChirurgiE) edited and released protocols of ERABS for its members. Compliance with ERABS, lengths of hospital stay, and postoperative morbidity were obtained from the Groupe francophone de Rehabilitation Améliorée après ChirurgiE–audit database.

Results: In this study, 1667 patients were included. Procedures were sleeve gastrectomy (n = 1011), gastric bypass (n = 300), or mini-bypass (n = 356). Mean body mass index was 41.8 ± 8.3 kg/m². Global morbidity was 2.57%, and surgery-related morbidity was 1.67% (mostly anastomotic leakages and hemorrhage). Mean length of hospital stay was 2.4 ± 3.6 days. Overall compliance was 79.6%. Among the 23 elements of the ERABS program, 14 were applied in >70% of instances, 6 in between 50% and 70%, and 3 in <50%. The elements least often applied were limb intermittent pneumatic compression during surgery (23.3%), multimodal analgesia (49.5%), and optimal perioperative fluid management (43.8%).

Conclusion: This study shows that even if the overall compliance was good, the large-scale implementation of ERABS can still be improved, as several elements remain insufficiently applied. This finding highlights the importance of thorough, continuous training in addition to the need for repeated audits by centers involved in ERABS programs. (Surg Obes Relat Dis 2018;14:99–105.) © 2018 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords:

Obesity; Sleeve gastrectomy; Gastric bypass; Enhanced recovery after surgery

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Far-reaching changes occurred in the late 1990s with the emergence of a new perioperative approach that incorporated evidence-based perioperative interventions for the optimization of patient care. What had initially been “fast

track surgery” became “enhanced recovery after surgery” (ERAS) [1,2]. Enhanced recovery (ER) programs set standardized perioperative pathways to improve convalescence and reduce postoperative morbidity and length of hospital stay.

An abundant literature supports ER in various types of surgery [2,3]. ER programs were first developed in colorectal surgery, where they are now widely implemented [4]. The extension of ERAS programs to bariatric surgery came later, but studies have now confirmed their feasibility, safety, and efficacy [5–8]. However, data on the implementation of enhanced recovery after bariatric surgery (ERABS) are still scant.

The aim of this study was to review the implementation of ERABS programs through a large prospective database.

Methods

Type of study

This was a retrospective analysis of a prospective database from the Francophone Group for Enhanced Recovery After Surgery (Groupe francophone de Réhabilitation Améliorée après Chirurgie [GRACE]). Fifteen centers registered in the GRACE-Audit database participated in this study. GRACE-Audit has a dual function: it serves as database and audit tool software. It is freely accessible online (www.grace-audit.fr) and was provided to all participating GRACE centers. Data were collected in a web-based host, requiring manual submission of each patient’s data that had been accredited for healthcare data handling (according to the French ministerial decree of January 4, 2006). Data collection was declared to the French data protection authority (CNIL) according to the terms of the modified law of January 6, 1978 and CNIL authorization 2014 (#1817711). For the purpose of the present study, the participants were asked to provide the overall number of bariatric procedures performed during the same period.

Inclusion and exclusion criteria

The inclusion criteria were patients with age >18 years, American Society of Anesthesiologists class ≤ 3 , and a body mass index between 30 and 50 kg/m² needing bariatric surgery according to the French Public Health Authority (Haute Autorité de Santé) either by sleeve gastrectomy or bypass (Roux-en-Y gastric bypass or mini-bypass, i.e., one anastomosis bypass), who agreed to participate to the study. The decision to carry out the surgery was validated by a multidisciplinary team: patients had no contraindication for general anesthesia, none were living alone, all were able to go home or be transferred to a convalescent home after being discharged from the hospital, and all could be contacted by telephone. All patients gave their written informed consent to take part.

The exclusion criteria were patients who were unwilling to participate, those who presented severe associated

diseases (heart or lung diseases, diabetes, immunosuppression, platelet disorders, or receiving curative anticoagulant treatment), and pregnant women.

Assessment criteria

Implementation of ERABS elements. The primary assessment of this study was to determine the extent of compliance with ERABS in France.

The ERABS consists of a list of guidelines for the multimodal perioperative management of patients. Twenty-four elements are divided into pre-, intra- and postoperative recommendations. ERABS is a bariatric protocol that was established by the GRACE group according to international guidelines.

Regarding preoperative management, precise preoperative information for the patient (counseling and education) was recommended. More than 3 weeks of tobacco smoking cessation was also recommended. Routine premedication was not recommended, but tranquilizers could be prescribed on a case-by-case basis for preoperative anxiety. Preoperative fasting was to be maintained for <6 hours for solids and 2 hours for clear fluids such as water, coffee, or clear juice. Preoperative carbohydrate loading was also recommended, except for diabetic patients.

For intraoperative management and surgery, the laparoscopic approach was preferred to open surgery. Dexamethasone administration was recommended on induction of anesthesia, and prophylactic antibiotic treatment was planned before incision. Hypothermia prevention was recommended. Limb intermittent pneumatic compressions, adequate fluid management during surgery, and immediate gastric tube removal at the end of the surgery were also recommended. Abdominal drainage and epidural analgesia during surgery were not recommended.

Postoperatively, multimodal analgesia, nonsteroidal anti-inflammatory drugs at weight-adapted doses and limited to 48 hours, adequate prevention of nausea and vomiting, and venous thromboembolism (VTE) prophylaxis were recommended. The importance of early mobilization and refeeding (starting with liquid meals) was also clearly emphasized. Routine bladder catheterization and gastric tubes were not recommended. Routine prophylactic oxygen supplementation or noninvasive positive pressure ventilation was recommended only in the case of diagnosed obstructive sleep apnea.

Other endpoints. Overall morbidity and surgery-related morbidity were analyzed. All complications were collected and sorted by type. We considered “surgery-related morbidity” to be any complication resulting from the surgical procedure, such as anastomotic leakage, peritonitis, intraperitoneal bleeding, anastomotic bleeding, or any other event directly caused by the surgical act. The Clavien-Dindo [9] classification was used to categorize complications.

We analyzed decompensation of latent preexisting conditions or acute medical conditions, such as cardiac arrhythmia, stroke, pulmonary embolism, or pulmonary atelectasis as “medical morbidity.”

Readmissions and unplanned medical or surgical procedures were also analyzed.

Length of hospital stay was another secondary assessment in our study. Delays, and their causes, between the theoretical and actual discharge date were also evaluated.

Statistical analyses

Every patient included in GRACE-Audit was taken into consideration in the final analysis, including those whose registration was incomplete. Missing data were handled through a worst case scenario approach: when data were missing, the ER element was considered to be nonapplied. Regarding our primary assessment (implementation of ER elements) we calculated the mean compliance rate for each element of the ER program and the compliance rate of all the elements in our entire sample.

Results

A total of 1667 patients from 15 centers were included between March 2014 and January 2017: 80.92% were women (n = 1349). Mean body mass index was 41.84 ±

8.32 kg/m²; 1662 patients were operated laparoscopically (99.7%). More than half of the procedures were sleeve gastrectomies (n = 1011; 60.6%). The others were either gastric bypasses (n = 300; 17.9%) or mini-bypasses (n = 356; 21.3%). During the same period, the 15 centers treated another 1297 obese patients. These patients were not included in the database mainly because of time constraints that did not allow the participants to complete the electronic form for each patient (although all patients did undergo surgery in the setting of ERABS in that period). Hence, the rate of inclusion in the GRACE-Audit database was 56.2%.

Compliance with ERABS elements

The mean compliance rate of ER elements was 79.6% ± 22.3%. The compliance rates are summarized in Table 1. Among the 23 elements in the program, 14 were applied in over 70% of instances and 3 in less than 50% of the patients. Compliance rates for the remaining 6 elements ranged between 50% and 70%.

The least applied element was intraoperative limb intermittent pneumatic compression, having been applied in only 23.3% (n = 389) of patients, followed by goal-directed fluid management, the compliance rate for which did not reach 44% (n = 730). The third least applied element was the use of multimodal analgesia at 49.5% (n = 825). The ER elements

Table 1
Implementation of enhanced recovery after bariatric surgery items in 1667 patients of the study

	n	Rate of applications, %	MD
Preoperative items			
Information and counseling of the patient	1613	96.7	6
>3 wk tobacco smoking cessation	1006	60.3	5
No premedication	1655	99.2	5
Fasting <6 hr for solids and <2 hr for clear fluids	1431	85.8	5
Carbohydrate loading (taking into account its contraindications)	948	56.8	5
Intraoperative items			
Prophylactic antibiotics before incision	1639	98.3	4
Limb intermittent pneumatic compression	389	23.3	3
Hypothermia prevention	1512	90.7	3
No epidural analgesia	1662	99.7	3
Goal directed fluid management	730	43.8	3
Nausea and vomiting prevention	1583	94.9	3
Laparoscopic approach	1662	99.7	3
Nasogastric tube removal at theater exit	1080	64.7	3
No abdominal drainage	1088	65.3	3
Dexamethasone (single injection)	1106	66.3	3
Postoperative items			
Multimodal analgesia	825	49.5	7
Noninvasive ventilation only in case of OSA	1591	95.4	3
No epidural analgesia	1658	99.4	5
Use of NSAID	1662	99.7	5
No bladder catheterization	1649	98.9	5
VTE prophylaxis	1280	76.8	5
Mobilisation on D0	1632	97.9	5
Refeeding on D0	1134	68	5

MD = missing data; OSA = obstructive sleep apnea; NSAID = nonsteroidal anti-inflammatory drugs; VTE = venous thromboembolism; D0 = day 0. There were 97 missing data in 69 patients.

applied in 56% to 68% of instances were sufficient preoperative duration of tobacco smoking cessation, carbohydrate loading, intraoperative dexamethasone, gastric tube removal at the end of the procedure, and refeeding on the day of surgery. Abdominal drainage, although not recommended, remained a routine practice in one third of patients. This element was a routine procedure in 2 of the participating centers, which accounted for 34.55% (n = 575) of all patients included in this study. The same centers also applied a routine postoperative gastric tube. Because all participants had the policy to use drains or gastric tubes in case of intraoperative events, no center reached a 100% compliance rate for these elements.

Other endpoints. The overall postoperative morbidity rate was 2.57%. The rates of grade 3 and grade 2 morbidity (Clavien-Dindo classification [9]) were 1.67% and .36%, respectively—see Table 2 for details. The postoperative mortality rate was nil.

Mean length of hospital stay (postoperative stay) was 2.4 ± 3.6 days. In 95.7% of cases (n = 1595), patients were discharged as soon as all discharge criteria were met, but 70 (4.2%) outstayed their theoretical discharge date and 2 (.1%) left prematurely.

Detailed analyses showed that 61 (3.65%) were discharged 1 day after fulfilling all discharge criteria, 5 (.3%) 2 days after, and 2 (01%) 3 days after. Two patients remained hospitalized longer than their theoretical discharge date (an extra 10 and 69 d, respectively), and in both cases the delays were due to no places being available in rehabilitation and convalescence centers.

On the other hand, 2 patients left the hospital before meeting all discharge criteria. One premature defecation was secondary to the patient's refusal to remain hospitalized,

while the other was due to organizational problems. These patients were not readmitted after discharge.

The main cause of discrepancy between theoretical and actual discharge date was patient refusal to either leave or remain hospitalized (n = 42, 58.3%). Other causes were organizational and material problems such as missed transmission of discharge prescription, poor communication between the caregivers, or lack of vacant places available in postdischarge centers (n = 30, 41.6%).

Discussion

The main finding of this study was that the overall compliance with the ER program was almost 80%. This high rate of compliance is encouraging because previous studies in colorectal surgery have shown that a compliance rate of over 70% is important to improve outcomes [10]. However, among the 24 elements, only 15 were implemented in more than 70% of instances (11 >90%; see Table 1). These results are in line with what is known in the literature [4–8]. Moreover, a previous GRACE study reviewing the implementation of ER programs in colorectal, bariatric, and orthopedic surgery [4] found a mean compliance rate of ER elements in bariatric surgery of 75%, with 11 of 21 elements applied in over 80% of instances. That study [4] also suggested that a minimum of 15 elements must be implemented to obtain a significant reduction of length of hospital stay. However, in the present study, some elements could have been applied more often. We must strive to increase compliance with ER guidelines to achieve a significant reduction in postoperative morbidity and hospital stay.

As previously noted, the 24 elements of the ERABS program reflect national and international recommendations and conduct [11,12] and, apart from minor divergences, are overall very similar to the ERAS Society 2016 guidelines. We will not discuss the elements that were optimally applied (>70%) because demonstrating their utility [5–8,11–14] is not the purpose of the present study. We will focus on the less often applied elements.

We were surprised by the very poor compliance with limb intermittent pneumatic compression (23.3%, n = 383). Obesity is an independent risk factor for thromboembolic complications [15]. In addition, thromboembolic complications are the main cause of morbidity and mortality after bariatric surgery [16]. In high-risk bariatric surgery patients, VTE prophylaxis requires the combination of mechanical methods, pharmacologic prophylaxis, and early mobilization [17]. However, although the 2 latter were applied in >75% of patients, limb intermittent compression remained insufficiently applied (Table 1). This reflects the lack of consensus concerning VTE prophylaxis: this situation has already been criticized in a 2017 French survey showing that thromboprophylaxis practices in obese patients remain unstandardized and vary greatly between

Table 2
Postoperative morbidity and adverse events.

Morbidity	Number of patients with morbidity	Rate, %
Overall morbidity	43	2.57
Surgical morbidity (Grade 3 – Clavien-Dindo [9])	28	1.67
Anastomotic leak	3	
Intraperitoneal bleeding	14	
Anastomotic bleeding	6	
Abdominal wall complications	4	
Unknown event	1	
Medical morbidity (Grade 2 – Clavien-Dindo [9])	6	.36
Cardiac arrhythmia	3	
Stroke	1	
Pulmonary embolism	1	
Pulmonary atelectasis	1	
Unknown event	9	.54
Readmission	26	1.26
Unplanned medical or surgical procedures	13	.78

centers and surgeons [16]. Pneumatic compression also requires additional specific materials, leading to higher costs, which could also explain its low compliance rate.

On the one hand, optimal pain management enables early mobilization and prevents bedsores complications, thus making multimodal analgesia essential in ER programs [18,19]. Using different methods of pain control also reduces the consumption of opioids. On the other hand, epidural anesthesia was not recommended [12], as it can be technically difficult in obese patients and is not free of specific risks. In this study, compliance with multimodal analgesia was applied for only half of the patients, which means that pain control guidelines must be reactivated and improved.

The third element applied in <50% of patients was optimal perioperative fluid management. It should be noted, though, that accurate assessment of volume status in bariatric surgery is a challenge. In addition to physiologic differences, such as increased risk of postoperative rhabdomyolysis [20] or reduced blood volume/weight ratio, morbidly obese patients often present multiple co-morbidities, such as respiratory, heart, or kidney failure. ERAS society 2016 guidelines [12] stress that excessive intraoperative fluids do not prevent rhabdomyolysis or maintain urine output. Yet, intraoperative hypotension must be avoided and postoperative fluid infusion should be discontinued as soon as reasonable. This study found that optimal perioperative fluid management had a low compliance rate, thus reflecting the need to further improve our understanding of the effect of this therapy on obese patients.

We were also concerned by the incidence of abdominal drainage in one third of the patients. Initially, the rationale behind abdominal drainage was the early detection of postoperative leakage and the nonoperative treatment of such leakages. However, except in pancreatic surgery, studies have always failed to prove its efficacy [21]. Few studies have evaluated the role of prophylactic abdominal drainage in bariatric surgery, but those suggest that drainage does not offer any additional benefit to patients [22]. There is no scientific explanation for why drainage is still anchored in surgeons' habits, given that imposing unnecessary and invasive abdominal drains goes against the principles of ER and patients benefits.

Duration of smoking cessation also remains a major concern [23]. In the ERAS 2010 guidelines [12], the duration of smoking cessation recommended before surgery was 4 weeks—a conclusion also supported by a 2011 meta-analysis [24]. However, optimal smoking cessation duration before bariatric surgery has yet to be defined. Although we settled for a less challenging smoking cessation period of 3 weeks, its implementation remained insufficient. Dealing with tobacco addiction still requires more aggressive, efficient measures. While the safety of preoperative carbohydrate loading in obese patients was suggested in a randomized trial [25], further large studies are required in

this field. Indeed, the effect of a short preoperative administration of carbohydrate on associated liver disease (such as the non-alcoholic steatohepatitis) has yet to be proven. Moreover carbohydrate loading (taking into account its contraindications of diabetes and gastroesophageal reflux) [25], gastric tube removal at the end of surgery [26], and early refeeding starting with liquid meals [27] could be better applied and would also benefit from continuous training as well as repeated audits by centers involved in the development of ER.

Understanding barriers to and facilitators of ER implementation in conventionally run wards is a prerequisite for achieving optimal compliance [28–30]. It has been clearly shown that a protocol (even adopted and shared by the whole team) is not enough to allow optimal compliance over time [31]. Several barriers, such as resistance to change, lack of coordination, limited resources combined with the special needs of a highly co-morbid patient population, and rotating staff, can hamper the implementation of ER. To overcome these barriers, specific measures facilitating the implementation of every innovation should be applied. These facilitators are teamwork, communication (among nurses, surgeons, and anesthesiologists), education, training, and repeated audits. Having case managers or team leaders responsible for coordination, training, regular auditing, and dissemination of results could improve implementation [28–30].

In our study, length of hospital stay was 2.4 ± 3.6 days, which was congruent with results found by other ER teams, but our morbidity was lower than reported in the literature [13,14]. Our research found that the overall morbidity rate was 2.4%, while surgical morbidity was 1.44%. These values are lower than those of Mannaerts et al. [13], whose postoperative morbidity rate was 16.1%, or of Awad et al. [14], for whom it was 4.4%. However, our results must be interpreted with caution and are very unlikely to reflect the general morbidity of bariatric surgery, considering that all the participating centers were expert centers.

Our study has some limitations. The data come from expert centers highly trained in both bariatric surgery and ER, thus making generalization impossible. In addition, the survey conducted in parallel with the study showed that 56% of patients treated during the study period were actually included in the GRACE-Audit database. The participants found completing the form to be too time consuming. Consequently, at the late stage of the study, we shortened and simplified the form to improve the inclusion rate of the GRACE-Audit database. We must also be aware of the possibility of selection bias when interpreting these results. If selection bias were tilted to preferentially include uncomplicated patients, the results would be unfairly skewed to incorrectly support the use of ERAS. A previous study from our group has already shown that the inclusion rate in GRACE-Audit with regard to all procedures performed in the same period did not exceed 20% [4].

Two years later, the inclusion rate of 56% in this study suggests a clear improvement in inclusion of bariatric cases, although this situation could be improved further.

This prospective study remains an informative one, involving a substantial number of patients and using a multicenter design, which confers good external validity. This study is one of the first prospective trials analyzing a nationwide implementation of ERABS in a large population of bariatric patients.

Despite a good mean overall compliance, the compliance with some elements can be improved. This underlines the importance of thorough, continuous training in addition to repeated audits by centers involved in the development of ER.

Conclusions

This study shows that nationwide, the implementation of ER can be improved, as the compliance with several elements is still suboptimal. Progress must be made to implement the program better, as it is now recognized that efficacy is linked to the number of elements applied. This underlines the importance of thorough, continuous training, besides repeated audits by centers committed to developing ER.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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