

Intensified recovery clinic in bariatric surgery: results after 10 years of implementation.

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Received (first version): July 15, 2020

Accepted: July 19, 2020

Published online: October 2020

Summary:

Objective: ERAS programs are multidisciplinary perioperative care guides that lead to early recovery. There are numerous clinical pathways for the treatment of the obese patient. The Obesity Unit of the Getafe University Hospital developed its own clinical pathway according to its resources. The objective of this study is to analyze the results after its implementation in 2010.

Material and methods: A retrospective observational study was conducted from January-2010 to December-2019 of patients consecutively treated with a vertical gastrectomy or a derivative technique, as primary or revision surgery, in the Obesity Unit of the Hospital.

Results: 675 patients were included, 573 bypass techniques (85%), 63 vertical gastrectomies (9%) and 39 revision surgeries (6%). The reoperation rate was 0.8% with zero overall mortality. Overall morbidity was 5.5%, with bleeding being the most frequent complication (4.7%). The mean stay was 2.8 days without readmissions. Outpatient follow-up was 95% at 12 months.

Conclusion: Teamwork implementing an intensified recovery program improves quality standards, increases bariatric patient safety, reduces complications, and favors a faster postoperative recovery with a shorter hospital stay.

Keywords:

- Laparoscopic bariatric surgery
- Enhanced recovery after surgery
- Fast track
- ERAS
- Length of stay

Introduction

The Intensified Postoperative Recovery programs, also called ERAS (Enhanced Recovery After Surgery) Protocols, are multi-modal and multidisciplinary perioperative care guidelines based on scientific evidence, which lead to an early recovery (1, 2). These programs systematize all perioperative care, reduce difficulty, especially thromboembolic and respiratory complications, improve patient well-being, reduce hospital stay and, finally, optimize the cost of the process. There are numerous clinical pathways developed by national and international societies such as the approach of the European Society for the Perioperative Care of the Obese Patient (3, 4) and in Spain, the clinical approach of the Spanish Society for the Surgery of Obesity (SECO), which, with a multidisciplinary focus, include all phases of the process (5). The Obesity Unit of the Getafe University Hospital developed its own clinical approach (6) in 2010, taking into account its resources, professionals and the recommendations with scientific evidence published in the literature (7-9). The objective of this study is to analyze the results after its implementation in 2010.

Methods

Data design and collection

From January-2010 to December-2019, a retrospective observational study of the patients operated on in the

Morbid Obesity Unit of the Getafe University Hospital was performed. All patients were treated according to the multi-modal rehabilitation protocol of the Obesity Unit of the hospital (6). The data were collected prospectively including those patients treated by sleeve gastrectomy (VG), gastric bypass (BPG) or another derivative technique (SADI, Duodenal switch or BAGUA), both as primary or revision surgeries. Patients treated with an adjustable gastric band were excluded from the study because it was a specific and structured surgical process in major outpatient surgery or early discharge programs.

Study variables

Age, sex, BMI, surgical technique, index of primary or revision surgery, surgical time, medical comorbidities such as arterial hypertension (HT), type 2 diabetes mellitus (DM2), were recorded as control variables. dyslipidemia (DL), sleep apnea-hypopnea syndrome (SAHS), preoperative weight loss, associated surgery, hospital stay (number of nights with admission), readmission rate, thromboembolic events, morbidity postoperative and hemorrhagic complications defined as those with a drop in hemoglobin (Hb) greater than 3g / dL or that required transfusion or re-operation.

Surgical process

The clinical approach establishes the care split according to the different settings (outpatient consultation, hospitalization and operating room) and also, according to the participation of the different professionals of the



multidisciplinary team (nursing, surgery, endocrinology, anesthesiology and psychology). Likewise, it standardizes the sections of information, complementary tests, medication and diet.

Outpatient consultations

The unit's outpatient clinic is an independent building structurally adapted to the characteristics of obese patients (tables, stretchers, chairs, etc.) and represents the place where the patient meets with the professionals of the multidisciplinary team. All patients receive personalized and complete information about the care process. The bariatric surgeon coordinates the entire process and supervises the recommendations of each professional on the team. The anesthesiologist especially assesses the airway and the risk of SAHS during the pre-anesthetic consultation to diagnose these patients and treat them with CPAP before and immediately after surgery. Patients must quit smoking eight weeks before surgery.

After the being on the bariatric surgery waiting list, all patients are incorporated into a weight loss and comorbidities optimization program that follows the nutritional recommendations established in the SECO App (10) In general, patients follow a hypo-caloric-hyper-protein diet with nutritional supplements such as Optisource[®] and Optisource plus[®]. The unit nurse, in agreement with the endocrinologist and the surgeon, establishes the objectives required from the patient in order to continue the process. In high-risk patients, an intragastric balloon is placed for 6-12 months. Likewise, a program of continuous physical activity and respiratory physiotherapy is established with the daily use of the incentivized spirometry device.

The outpatient follow-up after hospital discharge is performed in the same consultation at 15 days, a month, and quarterly during the first year and every six months in the 2nd. and 3rd. years. Patients can contact the unit nurse by phone or email aside from these established appointments throughout the follow-up.

Operating room

The operating room is structured for laparoscopic bariatric surgery with an operating table that supports 450 Kg with extreme movements of Trend and Antitrendelenburg, supports and special padding for the back and backing points, laparoscopy with HD and 3D vision, basic and advanced monitoring and devices for difficult airway management.

Intermittent pneumatic compression systems are systematically used in the operating room with a circumferential, sequential, progressive and simultaneous design (model DVT-2600, Sorevan[®]) and in cases of high risk of thrombosis (history of previous venous thrombosis, super-obesity, etc.), the compression is kept during the patient's stay, in resuscitation and / or hospitalization until ambulation.

Before trocar placement, the wall is infiltrated with 0.25% bupivacaine and the peritoneum with 0.2% ropivacaine (with 1 / 200,000 adrenaline).

Alternatively, during the last two years, an infiltration of the transverse abdominal plane (TAP) has been performed by the surgical team itself before completing the pneumo-peritoneum. The anesthesiologist applies a deep muscle block and, since 2016, a multi-modal opioid-free anesthesia (3).

The surgical technique has not changed during the study period. All interventions were approached via laparoscopy. The VG and derivative techniques were performed with laparoscopic mechanical suture (Echelon Flex 60 manual and Powered Echelon Flex 60 electrical, Ethicon endo-surgery[®]) with reinforcement of the stapling line of the gastric reservoir with bovine pericardium (PeriStrip Dry with Veritas, Baxter[®]).

The gastrojejunal anastomosis was performed manually with continuous double-plane suture with reabsorbable mono-filament material (monocryl 3/0 with antiseptic, Ethicon endo-surgery[®]) and that of the loop foot with mechanical or electrical endostaplers of 60mm or 45mm in length with a height of 2.5mm vascular type open load (ETS Flex 45 manual or Powered Echelon Flex 45-60 electric, Ethicon endo-surgery[®]); before closing the enterostomy with a continuous suture of reabsorbable material, the hemostasis of the staple line was checked. Finally, a revision of hemostasis of the rest of the staple lines was performed; no nasogastric tube was left in any patient and a closed suction drain was only used in selected cases of revision surgery. The surgeries were performed by 2 specialist physicians with more than 500 cases of experience in laparoscopic derivative surgeries before starting the study.

Resuscitation and hospitalization

The operated patients were transferred -without tubes- from the operating room to the resuscitation room where they remained for 4-6 hours for hemodynamic and analgesic control, continuous mobilization of the IMM, and respiratory physiotherapy; After the discharge to the hospitalization floor, they got up from the couch to start early oral tolerance (infusions and water) and take short walks. The next day, the liquid diet was progressed with broths, liquid yogurts and strained juices, they continued respiratory physiotherapy and walked freely until they were discharged. Regarding the anti-thrombotic prophylaxis, they were initially treated with Fondaparinux (Arixtra[®]) at a dose of 2.5mg / 24h subcutaneously for 10 days. In 2016, the pharmacological diets recommended in the Guide of the Spanish Society of Obesity Surgery (11) were established with Enoxaparin (Clexane[®]) at doses adjusted to BMI: 40 mg / day with a BMI of 35-40; 60 mg / day between 40 and 60; and 40mg / 12h in patients with a BMI > 60.

The pharmacological prophylaxis always began 6-12h after the end of the intervention according to the surgical session was kept for 10 days, including the hospital stay. The preoperative dose was never administered or was anti-Xa activity quantified.

Before administering the first dose of LMWH, the nursing staff, trained to rule out the bleeding (melena, hematochezia, or tachycardia), assessed the patient to proceed with the administration of LMWH or to suspend it in the event of suspected bleeding.

The ambulation was encouraged, the pneumatic compression systems were kept in IBD, and the pertinent analytical or imaging controls were performed if necessary.

Statistical study

The qualitative variables are expressed as a percentage and the quantitative ones are expressed as averages \pm standard deviation with the interval between the

minimum and maximum value. A study investigator recorded (MG) all the data in an Excel database.

Results

Between 2010 and 2019, 675 patients were operated on, in the Morbid Obesity Unit. All surgeries and reinterventions were performed via laparoscopy, without any conversion to open surgery.

Table 1 shows the clinical and surgical characteristics of the total sample and Table 2, the postoperative morbidity and hospital stay. All patients attended the presurgical process (dietary education, respiratory physiotherapy, etc.) and were not scheduled for surgery until the estimated weight loss (10% of excess weight) was achieved, but none were rejected. The most frequent abdominal complication was postoperative bleeding (32 cases; 4.7%), with half of these patients requiring a transfusion or urgent re-operation.

Three patients had non-hemorrhagic abdominal complications: two leaks (one leak after GS and others after conversion from a Nissen-type fundoplication to an LGA) treated with percutaneous drainage and parenteral nutrition, and one intestinal obstruction after revision surgery for a Scopinaro-type biliopancreatic diversion. Two cases had respiratory complications, of atelectasis with clinical repercussions (fever) registered during the first two years of application of the route.

No thromboembolic event was recorded.

The overall re-operation rate was 0.8% (6 cases), mainly due to the described bleeding (5 cases). Overall mortality was zero. The overall average stay was 2.8 ± 2 days. There were no readmissions. Outpatient follow-up was 100% during the first 6 months after surgery and 95% after 12 months, decreasing to 75% in the second year of follow-up. During the consultation, numerous doubts related to diet and / or medication were answered by telephone and cures for wall hematomas or superficial infections of the access ports.

n	675
Women, n (%)	454 (67,3)
Average age \pm DE	43,3 \pm 10,4
Average BMI \pm DE	45,7 \pm 6,1
HTA, n (%)	310 (45,9)
DM2, n (%)	190 (28,1)
DL, n (%)	215 (31,9)
SAOS, n (%)	144 (21,3)
GV, n (%)	63 (9,3)
BPG and other derivatives*, n (%)	573 (84,8)
Preparatory weight loss, average \pm DE)	7 \pm 5 (0-34)
Revision surgery	39 (5,8)
Associated surgery, n (%)	50 (7,4)
Average surgical time \pm DE	175,2 \pm 46

* DBP (2), SADI (1), CD (1), BAGUA (1), REVERSION (3)

Table 1. Series clinical and surgical features

	Total sample
n	675
Hemorrhage, n (%)	32 (4,7)
Severe	16 (2,3)
hemorrhage *, n (%)	
Non-bleeding abdominal complications, n (%)	3 (0,6)
Leak	2
Intestinal obstruction	1
Pulmonary complications, n (%)	2 (0,3)
Atelectasis, n	2
Pneumonia, n	0
TVP o TEP, n	0
Global morbidity, n (%)	37 (5,5)
Reinterventions, n (%)	6 (0,8)
Mortality, n (%)	0
Hospital stay, average \pm DE	2,8 \pm 2 días
Readmissions, n	0

* Re-operated or with transfusion

Table 2. Postoperative morbidity and hospital stay

Discussion

This observational study responds to the objective of evaluating the implementation of the clinical approach for intensified recovery in patients operated on, in the Obesity Unit over a period of 10 years, with very satisfactory results in terms of morbidity, safety and postoperative recovery.

Their creation has meant a substantial change in the philosophy of perioperative care when compared to traditional care, avoiding clinical variability and developing standardized processes based on scientific evidence (7-9, 11)

In our center, global morbidity was less than 6%, with an average hospital stay of 2.8 days without readmissions and a re-operation rate of 0.8%. These results are within the currently accepted quality standards (12, 13), taking into account the degree of complexity of the series with 85% of derivative surgeries and 5.8% of revision surgeries. With respect to other controlled studies published applying ERAS programs, the incidence of major complications and re-operations in our series was lower, although the hospital stay was longer (8, 14, 15).

During the studied period, the application of the multi-modal rehabilitation programs was very strict, and the recommendations made in the RICA Guide of the Ministry of Health (9), the Spanish Multi-modal Rehabilitation Group (7) and the Clinical Approach of the Spanish Society were followed. of Obesity Surgery (5), with special attention to preoperative optimization, multidisciplinary assessment coordinated with the Anesthesiology, Endocrinology and Nutrition Services, the protocolization of the techniques by the surgical team and early oral mobilization, ambulation and tolerance.

The availability of a specific building adapted for obese patients, where the patient could meet with all the specialists of the multidisciplinary team, allows integrating all the topics included in the intensified recovery program. In the selection of the technique, the opinion of the team

and multidisciplinary work were essential to obtain healthy habits before and after surgery, as a means of controlling obesity. The gastric bypass is the technique of choice for the Unit as long as there is no contraindication (super-obesity, inflammatory bowel disease, need for oral medication, etc.) that advises non-derivative surgery such as a sleeve gastrectomy; malabsorptive surgeries are usually discouraged due to long-term side effects and has been exceptionally indicated in cases of super-obesity or failure of primary surgeries.

The preoperative habilitation is another key element to prevent postoperative complications (16); It includes psychological support, modification of eating habits, preoperative weight loss and respiratory physiotherapy. Although it included the practice of physical activity (especially walking), it was not quantified or objectified in time or length. In the next update of the approach, physical pre-habilitation programs will be included and developed. In our Unit, it is essential that each patient achieve preoperative weight loss based on the degree of obesity and its comorbidities in order to continue the surgical process. All patients achieved preoperative weight loss goals in a 4-6-week period, although in some cases, surgery was delayed until the established goal was achieved.

The role of the nutritionist is very important in the obesity teams, however, in our unit, as in most public hospitals, we don't have this type of professionals.

His work is performed by a nursing professional who, with adequate training and motivation, is involved in all phases of the process and coordinates all the care that the patient receives from the multidisciplinary team.

The low incidence of pulmonary complications is explained by quitting smoking before surgery, pre- and postoperative respiratory physiotherapy from the same resuscitation room, early mobilization and, finally, the diagnosis and treatment of SAHS with CPAP before and immediately after surgery.

The pre-anesthetic evaluation, the preparation of the operating room, the systematic infiltration of the access ports and the peritoneal cavity with local anesthetics, multi-modal opioid-free analgesia and muscle block, make the role of the anesthesiologist decisive in terms of patient safety, resuscitation and early postoperative recovery. No doubt, the integration of all these measures in the last years of the study has shortened the stay in the Resuscitation Unit and facilitated mobilization and oral tolerance after 6-8 of surgery, reduction of the hospital stays and the cost of the process.

The protocolization and systematization of the surgical technique on the part of the entire surgical team and the gastrojejunal anastomosis with manual suture, have contributed significantly to the low incidence of leaks and septic complications.

Bleeding was excessively high in our series (4.7%), so we have analyzed both the surgical technique and the experience of the team, as well as the chemo-prophylaxis diet to explain these results. In the first case, the two main surgeons had accumulated more than 600 laparoscopic procedures at the beginning of the study and the anastomoses were performed manually or mechanically linearly with vascular load, always reviewing the suture line with pressure washing before closing the anastomosis. In the case of the pharmacological thromboprophylaxis as

a source of bleeding, the doses of LMWH prescribed in the study may be adequate for "high-risk" patients but they are probably excessive when multi-modal rehabilitation programs are systematically applied that reduce the risk factors for thrombosis at level of "low risk patients" which could originate a supra-therapeutic level that causes bleeding.

In the study, the use of elastic stockings and mechanical pneumatic compression systems to favor propulsion and venous circulation while the patient was immobilized in the operating room was very strict.

It is surprising that its use is not more extended to all abdominal surgery interventions (17) when it is a safe, effective method with very few side effects).

The zero incidence of thrombosis is due to a combination of several factors: on the one hand, the prioritization of ambulation, with the patient being admitted on the same day of surgery and mobility immediately after surgery until discharge from hospital; on the other, the low incidence of major non-hemorrhagic postoperative complications; and finally, to a short average stay. No doubt, complications that entail an increase in hospital stay and / or longer immobilization, increase the risk of thrombosis and require a more aggressive attitude with an increase in the dose and duration of pharmacological and mechanical prophylaxis (18).

According to the national venous thromboembolism survey recently published by Arcelus (17), it is essential to analyze the data from each hospital in the multidisciplinary thrombosis commissions to adapt the prophylaxis guidelines in surgical patients, taking into account that the risk of postoperative surgery bleeding can be so severe that its prevention is as important as the prevention of a thrombosis.

The postoperative recovery is another essential part of this process of continuous improvement and excellence that bariatric surgery involves. The nursing staff in the recovery and hospitalization areas are trained to identify the problem of morbidly obese patients and the symptoms and signs associated with immediate serious postoperative complications; They promote early stimulated respiratory physiotherapy, continuous limb movements, control and pain-manage postoperative pain and monitor alarm signs such as desaturation, tachycardia or fever. In the analyzed series, compliance with the criteria for hospital discharge and in-person or telematic outpatient follow-up prevented readmissions or visits to the Emergency Service.

Teamwork and the adherence of professionals are essential for the development and implementation of a clinical approach in the healthcare practice. It provides a nursing care plan to standardize problems and solutions. It is very important that it be a flexible tool that integrates the suggestions and updates proposed by the members of the multidisciplinary team.

The study has the limitations of an observational work without a control group. However, the size of the sample is representative of the bariatric surgery in Spain both in degree of obesity and in frequency of comorbidities, in order to evaluate and validate the results obtained with the application of the intensified clinical approach of recovery. However, it is necessary to launch prospective and metacentric studies to analyze the effect of these

intensified recovery programs in bariatric surgery with a higher degree of scientific evidence.

In conclusion, we consider that teamwork, by implementing an intensified recovery or multi-modal rehabilitation program, improves the quality standards accepted in the literature, which means greater safety for the bariatric patient with a reduction in global complications, and a postoperative recovery faster with the consequent reducing of the hospital stay.

Conflicts of interest

None.

Acknowledgments

To Rosa M^a Avila Ortiz for registering and processing the database.

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