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Revisional Robotic Bariatric Surgery.
Largest Single Centre Prospective Cohort Study and Review of the Literature.

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Rezumat

Chirurgie robotică bariatrică revizuită.
Cel mai mare studiu de cohortă prospectiv cu un singur centru și revizuire a literaturii.

Introducere: Chirurgia bariatrică robotică (CBR) a cunoscut o creştere a popularității în ultimii ani, dar există dubii asupra utilității acesteia din punct de vedere al complicațiilor post-operatorii, costurilor şi aspectelor tehnice. Date recente sugerează faptul că CBR, reprezintă o provocare tehnică asociată cu mai multe complicații postoperatorii în comparație cu chirurgia bariatrică primară. În prezent, nu există date concrete asupra utilizării CBR în chirurgia revizională. Cu acest context, ne propunem în acest studiu să revizuim literatura de specialitate şi să prezentăm experiența centrului nostru cu privire la valoarea RBS în chirurgia bariatrica revizională.
Material şi Metodă: Am realizat o analiză retrospectivă a pacienților care au fost supuşi la CBR revizională în centrul nostru. Am identificat 42 de pacienți (31 femei, 11 bărbați) în care s-au realizat diverse proceduri, cele mai frecvente fiind conversia gastrectomiei laparoscopice longitudinale (GLL) la bypass gastric-Y-de-Roux (n=30). În niciun caz nu au fost

înregistrate dehiscența suturii sau complicații severe relaționate cu CBR, date comparabile cu cele găsite în urma revizuirii sistematice a literaturii de specialitate, cu rate scăzute de complicații care favorizează chirurgia de revizie robotică.
Rezultate: În comparație directă cu chirurgia bariatrică de reviziune laparoscopică standard, chirurgia robotică a demonstrat rezultate superioare în ceea ce privește eficacitatea, siguranța și durata scăzută a spitalizării. Un fapt încurajator este ca ratele de mortalitate, morbiditate și au fost similare între cele două abordări, în ciuda dificultății tehnice inițiale a CBR.
Concluzii: Având în vedere aceste constatări, considerăm absolut necesar că obținerea competenței în tehnica robotică să facă parte din procesul de formare al chirurgilor, ca parte a procesului mai larg de democratizare și standardizare a chirurgiei bariatrice. Promovarea CBR de reviziune poate duce la rezultate mai bune pentru pacient, justificând implementarea sa pe scară largă care poate duce la o mai bună și eficientă abordare a chirurgiei bariatrice.

Cuvinte cheie: chirurgie bariatrică, chirurgie robotică, Da Vinci, chirurgie revizională, complicații

Abstract
Introduction: Robotic bariatric surgery (RBS) has seen a surge in popularity in recent years, yet questions persist about its utility concerning postoperative complications, costs, and technical aspects. RBS, while increasing in number, presents a greater technical challenge associated with more post-operative complications compared to primary bariatric surgery. In this study, we present our single institution experience and review the literature to assess the value of robotic revisional surgery.
Material and Method: The retrospective review involved 42 patients (31 females, 11 males) who underwent various procedures, with the most frequent being the conversion of sleeve gastrectomy to gastric bypass (n=30). Encouragingly, no leaks or severe complications were identified. Furthermore, a systematic review indicated comparable outcomes, with decreased complication rates favoring robotic revisional surgery.
Results: In direct comparison to standard laparoscopic revisional bariatric surgery, revisional robotic surgery demonstrated superior results in terms of efficacy, safety, and reduced hospital stay. However, rates of mortality, morbidity, and reintervention did not significantly differ between the two approaches.
Conclusions: Considering these findings, we advocate for surgeons to acquire proficiency in the robotic technique, as part of the broader process of democratization and standardization of bariatric surgery. Embracing revisional robotic bariatric surgery can lead to improved patient outcomes, and its wider implementation may lead to enhanced surgical care and patient satisfaction in the field of bariatric procedures.

Key words: baroatric surgery, robotic surgery, Da Vinci, Revisional Surgery, complications

Introduction

Obesity and its associated comorbidities have become a global health concern (1-3). Bariatric surgery, as an effective intervention to treat obesity, has evolved over the years, incorporating advanced technology to enhance patient outcomes and safety (4-5). Revision bariatric surgery, a medical procedure aimed at addressing and rectifying complications or unsatisfactory outcomes from prior bariatric surgeries, has emerged as a crucial option in

managing obesity and its related disorders (6). Revisional Bariatric Surgery (RevBS) encompasses a broad spectrum of surgical interventions conducted subsequent to the ineffectiveness of an initial bariatric operation (7). Fundamentally, the justification for RevBS can be categorized into several scenarios: insufficient weight loss, weight regain, persistence or recurrence of accompanying health conditions, and complications arising after the primary bariatric procedure. The revisional procedures can be classified as follows: a) Revision or correction, entailing abdominal exploration and re-evaluation of the anatomical structure, often undertaken to address unyielding symptoms; b) Conversion, wherein a specific bariatric procedure is transformed into a different type of bariatric technique; and c) Reversal, involving the restoration of the original anatomical configuration (7).

The motivations for undergoing revision bariatric surgery can be diverse, ranging from inadequate weight loss following an initial surgery to the recurrence of obesity-related medical issues. At times, postoperative complications such as pouch dilation, internal hernias, adjustable gastric band slippage, or other specific complications from the original bariatric surgery may necessitate further intervention through revision surgery (8-10). Traditional laparoscopic techniques have demonstrated their effectiveness; however, they may pose certain limitations, especially in complex cases (11). Robotic surgery, with its enhanced dexterity, precision, and three-dimensional visualization, has emerged as an attractive but controversial option to address these challenges in primary and Revisional Bariatric Surgery (12).

Since first robotic bariatric case described, robotic surgery has revolutionized the field of bariatric surgery, particularly in cases involving high complexity (13-14). Among the cutting-edge robotic surgical systems available, the da Vinci Surgical System has emerged as a promising tool, showcasing its efficacy in complex bariatric procedures (15-17). In this article, we will explore the manifold benefits of utilizing the da Vinci robot in cases of high complexity, including revisions and multi-operated patients requiring subsequent bariatric surgeries.

In this article, our objective is to conduct a comprehensive review of the impact of robotic bariatric revisional surgery on postoperative complications. We focus on analyzing the available literature, particularly studies related to both robotic bariatric surgery (RBS) and Robotic Revisional Bariatric surgery (RRevBS).

This review aims to shed light on the specific postoperative complications encountered in patients undergoing robotic revisional procedures, exploring the incidence rates and types of complications observed. By delving into the data from our center and comparing it with the findings from relevant literature, we aim to provide a comprehensive overview of the outcomes associated with robotic revisional surgery.

Material and Methods

In this study, we conducted a retrospective review of cases that underwent robotic revisional bariatric surgery at Vall d'Hebron University Hospital. The main objective was to assess the utility and outcomes of robot-assisted bariatric surgery in the context of revisional procedures. We analyzed the epidemiological data of the patients, including age, sex, and previous obesity-related pathologies.

For the clinical data collection, we focused on the 30-day postoperative period for each patient. Key variables assessed were the type of surgery performed, the total operative time, overall morbidity, hospital stay, and any 30-day post-operative complications. These parameters were essential to evaluating the safety and efficacy of robotic revisional surgery in this patient population.

To gain insights from the existing evidence and compare outcomes, a comprehensive literature review was conducted. We utilized multiple databases, such as PubMed, Embase, MEDLINE, Cochrane Central Register of Controlled Trials, as well as clinical trial data-

bases, including the International Clinical Trials Registry Platform Search Portal and ClinicalTrials.gov. The search encompassed studies published from the inception of these platforms up until June 2023. Keywords used included "robotic-assisted bariatric surgery," "real robotic bariatric surgery," "robotics AND bariatric surgery," "robotic revisional bariatric surgery," "robotic Roux-en-Y gastric bypass," "robotic sleeve gastrectomy," and "laparoscopic bariatric surgery." We also analyzed gray literature and reviewed references cited in the published studies to ensure comprehensive data retrieval.

Language was not a restricting criterion, and data from various sources were included to form a comprehensive analysis. The extracted data from the included articles contained the main features of the studies, such as the author, journal, year of publication, and study type. Demographic characteristics, including the number of patients included, age, gender, and baseline BMI, were also extracted. We focused on the type of procedure performed, focusing on the number and types of complications encountered. Follow-up data and weight loss outcomes were collected to assess the long-term impact of robotic revisional surgery. This meticulous approach to data collection allowed us to evaluate the utility and safety of RBS in revisional procedures. The integration of existing evidence from the literature also provided valuable insights into the advantages and disadvantages of this technique when compared to laparoscopic approaches.

Results

The review of cases at our center included 42 patients who underwent RRevBS, with 31 being female and the rest male (11). The average age of the patients was 50 years and mean body mass index (BMI) before revisional surgery was 35 Kg/m^2.

Previous comorbidities among the patients included type 2 diabetes mellitus (T2DM), hypertension, dyslipidemia, and obstructive sleep apnea syndrome. The most common procedure performed was the conversion of sleeve gastrectomy (SG) to gastric bypass (RYGB), with 9 cases. Additionally, 2 patients required re-Do surgery after GBP. Median operative time was 160 (range 66-240 minutes). Surgeries were all performed robotically, including assistance with a trocar or a laparoscopic endostapler when yet not available in the Da Vinci system. Four cases did not have any external assistance (only a Nathanson retractor) and only one case was real robotic surgery with a three trocar SG to Single Anastomosis Duodeno-Ileal bypass with sleeve gastrectomy (SADI-S) procedure.

The overall postoperative complication rate was 2.4% of the total, with one case of reoperation in the early days after a second stage SADI surgery. The median length of hospital stay was 2.13 days. Fortunately, there were no major intraoperative or post-operative complications, such as gastrointestinal bleeding, anastomotic and/or gastric pouch leak, deep vein thrombosis/pulmonary embolism, or surgical site infection (*Table I*).

The literature review involved the screening of 297 papers by three authors (KD, DH, and RV). After applying the inclusion and exclusion criteria, 12 papers were finally analyzed, providing information about robotic bariatric revisional surgery (RRevBS). The collective data encompassed 17.993 patients, and the overall complication rate ranged from 0% to 9.3%. The most common complications observed were anastomotic leaks in revisional GBP, conversion of SG to GBP or SADI. Other complications included marginal ulcer, ventral hernia, pulmonary embolism, gastrojejunal anastomosis stricture, wound infection, pneumonia, and urinary tract infection. (12, 14-22,24)

When comparing revisional robot-assisted GBP with the laparoscopic approach, no significant differences were found in morbidity, mortality, or reintervention rates. Additionally, RRevBS was associated with a shorter length of hospital stay in complex procedures and demonstrated an equivalent safety profile compared to laparoscopic revisional bariatric surgery.

However, limited data were available on

Table1. Demographic data, outcomes, and 30 days complications of patient with robotic revisional surgery in our Institution.

	Revisional robotic bariatric surgery (n=42)
AGE (years)	
Median	50
Range	29-64
GENDER (n, %)	
Female	31, 73.8 %
Male	11, 26.2 %
PREOPERATIVE BMI (Kg/M^2)	
Median	35
Range	26-47
CO-MORBIDITES (%)	
Diabetes Mellitus	28.5 %
Hypertension	38.0 %
Dyslipidemia	33.3 %
OSA/CPAP	28.5 %
TYPES OF SURGERIES (n)	
Conversion from SG to GBP	30
SG to SADI-S	9
Re-Do GBP (gastro-gastric fistula) to GBP	2
Gastric pouch reduction + hiatoplasty	1
TYPES OF SURGERIES. (n)	
Robotic assisted (including accessory trocar)	37
Totally robotic (including liver retractor)	4
Real Robotic (No accessory trocar)	1
OUTCOMES	
Total operative time (minutes, range)	160 (66-240 minutes)
Overall Morbidity. (n, %)	1 (2.4%)
Intraoperative complications. (n, %)	
Blue test leak	0 (0.0%)
Bleeding	0 (0.0%)
Perforation	0 (0.0%)
Leak	0 (0.0%)
Median Length of hospital stay (days)	2.13 days
30 DAYS COMPLICATIONS. (n, %)	
Deep vein thrombosis	0 (0.0%)
Pulmonary embolism	0 (0.0%)
Pneumonia	0 (0.0%)
Wound infection/seroma	0 (0.0%)
Urinary tract infection	0 (0.0%)
Gastrointestinal bleeding	0 (0.0%)
Re-operations 30 days	1 (2.44%)
Pouch or G-J anastomotic leak	0 (0.0%)
J-J anast leak/intestinal lesions	0 (0.0%)
Intra-abdominal bleeding	0 (0.0%)
Other reasons	0 (0.0%)

Abbreviations: BMI body mass index, OSA/CPAP obstructive sleep apnea and continuous positive airway pressure; SG: Sleeve gastrectomy; GBP: Roux en Y Gastric Bypass; G-J (gastrojejunal); J-J anast: jejunojejunal anastomosis.

costs, with most papers focusing on the feasibility of the technique using robotic platforms. Further research is needed to explore the economic aspects of robotic bariatric revisional surgery (*Table 2*).

Discussion

In cases of high complexity, such as extreme obesity, complicated anatomical alterations due to previous surgeries, or the presence of severe comorbidities, the da Vinci robot offers distinct advantages (23). The articulated robotic arms of the system, operated by skilled surgeons, enable a wider range of motion and finer control than conventional laparoscopy, ensuring delicate maneuvers within confined spaces. Consequently, critical structures can be preserved with greater precision, minimizing the risk of complications and improving patient outcomes (25-27).

One of the key areas where the da Vinci robot demonstrates its utility is in cases of RevBS (11,15,28). Patients who have undergone previous weight loss procedures may experience complications or insufficient weight loss, requiring further surgical intervention (29). In such scenarios, the advanced technology of the robot aids surgeons in navigating scar tissue and anatomical challenges and changes, making the procedure safer and more effective. The enhanced visualization also enables surgeons to identify and address potential surgical complications more efficiently, reducing the risk of further revisions (28).

The primary critique directed at robotic surgery pertains to its elevated expenses, attributed to the procurement and upkeep of the robotic system, along with the costly semi-disposable robotic tools. In a preceding investigation, we illustrated a noteworthy decrease in intraoperative expenditures per surgical operation by curtailing operating room duration, diminishing reliance on laparoscopic staplers for manual anastomoses, and embracing the collaborative utilization of the robotic system (17).

The minimally invasive nature of robotic surgery also contributes to reduced hospital stays, decreased postoperative pain, and faster recovery, compared to traditional open surgeries. This not only improves the patient's quality of life, but also eases the burden on healthcare facilities and resources. The

Table 2.

Study	Journal / year	Type of study	Number of patients included	Gender	Type of procedures	Complication rate	Type of complication	Follow-up	Additional comments
Bauerle et al. [12]	Obesity Surgery/ 2023	Observational Cross sectional	12.855 revisional robotic cases 121.449 revisional laparoscopic cases	RBS 86,1% female 13,9% male	RBS	Not evaluated	Not evaluated	Not evaluated	Nationwide (USA & Canada) increase in the utilization of a robotic approach in bariatric surgery.
Seton et al. [14]	Obesity Surgery/ 2022	Retrospective study Propensity score matching (2:1)	3411 (2274 laparoscopic vs 1137 robotic)	89.9% female 10.1% male	Laparoscopic Revisional bariatric surgery Robotic Revisional	Intraoperative complication : 6.5 vs 5.9% Major complications : 1.9 vs 1.7%	NA	30 days	The robotic approach failed to demonstrate an advantage in perioperative outcomes.
Fantola et al. [15]	Frontiers in Surgery / 2022	Systematic Review	Primary SG 337 RYBP 8914 Revisional SG 1077 RYBP 1230	Not evaluated	Primary and revisional SG, RYSG	Primary SG 2,6% RYBP 12,7% Revisional SG 6,7% RYBP 9,3%	Bleeding Anastomotic leak Strictures Reinterventions	Not evaluated	Robotic surgery not financially sustainable. Revisional and superobese patients could have a potential role in reducing postoperative complications and improving perioperative care and economically sustainable.
Gray et al. [16]	Obesity Surgery/ 2018	Case series	84	84-90% female 16-10% male	Adjustable gastric banding (AGB) to Sleeve gastrectomy AGB to RYGB Stapled procedure RYGB revision SG to RYGB VBG to RYGB	8% (conversion from AGB) 4% in conversion from a stapled procedure	Post-operative morbidity, reflux, intolerance to oral intake, anatomic complications Leak, Stricture, Hemorrhage Surgical site infection	90 days	RRBS is associated with a shorter length of stay than LRBS in complex procedures and has at least an equivalent safety profile.
Ugliono et al. [17]	Updates in Surgery / 2023	Observational Cross sectional	194	L-rRYGB Male 25% Female 75% R-rRYGB Male 8% Female 92%	L-rRYGB vs R-rRYGB	L-rRYGB 22.7% 9.1% minor 13.6% major R-rRYGB 10% 6% minor 4% major:	L-rRYGB: anastomotic leak, intestinal obstruction, anastomotic bleeding. R-rRYGB: pulmonary, anastomotic leak, anastomotic bleeding, bowel perforation.	Not evaluated	R-rRYGB is a safe and feasible and an acceptable alternative from a cost-effectiveness perspective
Vilallonga et al. [18]	Journal of Obesity / 2015	Case series	3	3 males	SG to SADI-S	0%	0%	9 months	Robotic SADI-S was feasible.
Acevedo et al. [19]	Surgical Endoscopy/ 2020	Case–control matched analysis (Revisional robotic surgery versus laparoscopic revisional surgery)	Total number of cases : 26,404 1144 versus 1144 revisional robotic cases	Overall : 85.6% female 14.4% male Matched : Male :1040 and female 1040 in each group.	Conversions from SG and GBP as revisional procedures. 93.3% LBS 6.7% RBS.	Bariatric cases revealed longer operative duration and hospital length of stay, and higher rates of ICU admission, aggregate leak and bleeding complications	RBS was associated with longer operative duration ($p < 0.0001$), LOS ($p = 0.0002$) and a higher rate of ICU admissions (1.3% vs 0.5%, $p = 0.05$). Aggregate bleeding	Not evaluated	In gastric bypass, rates of aggregate leak and bleeding were higher with robotic surgery, while transfusion was higher with laparoscopy. For sleeve gastrectomy cases, reoperation, readmission, intervention, sepsis, organ

						in the robotic-assisted bariatric surgery compared to conventional laparoscopy.	and leak rates were higher in the RBS cohort. In both gastric bypass and sleeve gastrectomy cohorts, the robotic-assisted surgery remain associated with longer operative duration ($p < 0.00019$.		space SSI, and transfusion were higher with robotic surgery. In this matched cohort analysis of revision bariatric surgery, both approaches were overall safe. RBS was associated with longer operative duration and higher rates of some complications.
King et al. [20]	Obesity Surgery/ 2020	non randomized experimental trial	167	RRevBS: 78.8% female 21.2% male Laparoscopic Revisional bariatric surgery 88.7% female 11.3% male	Laparoscopic Revisional bariatric surgery Robotic Revisional Bariatric surgery	LRBS : Major complications: 5.2% minor: 5.8% RRevBS Major complications: 1.95% Minor: 5.2%	Major complications included but not detailed. Marginal ulceration requiring endoscopic intervention, organ space infection requiring intervention, leak from gastrojejunostomy, complications related to feeding jejunostomy placement requiring intervention.	30 days outcomes.	R-RBS has a decreased, albeit non-significant, rate of 30-day major complications with no difference in minor complications, readmission rates, or intraoperative blood loss when compared with L-RBS. R-RBS resulted in a decreased length of stay when compared with L-RBS.
Rebecchi et al. [21]	Obesity Surgery/ 2020	Prospective Cohort Study	68	97.1% female 2.9% male	Revisional RYGB	8.8%	pulmonary embolism, pneumonias, bleeding, small bowel perforation requiring reoperation, leak	1 year	Revisional RYGB is a complex procedure but can be performed with the robotic approach with a low morbidity rate.
Vilallonga et al. [22]	Chirurgia/ 2021	Retrospective Cohort Study	17	29.4% female 70.6% male	SG to RYGB SG to SADI-S Re-Do RYGB (GG fistula)	Intraoperative complication : 0% Major : 5.88%	Re-operation within the first 30 days in a second stage SADI-S	30 days	Once learning curve is established, revisional bariatric surgery can be with robotic approach
Qudah Y et al. [24]	J Laparoendosc Adv Surg Tech A. / 2022	Retrospective Cohort Study	16	69% female 31% male	SG to SADI-S	0%	N=2 (12.5%) emergency department visits for wound checks. No infection.	4.5 months	Robotic revisional SADI-S after previous SG is feasible and safe.
Pennestri F et al. [32]	Langenbecks Arch Surg. 2022	Retrospective Cohort Study	22 • 21 primary SADI-S • 1 SADI	12 female 10 male	SADI-S (Primary) SG to SADI-S	3/19	Bleeding, reoperation, penumonia (1 patient)	6 months	Robotic revisional SADI-S after previous SG is feasible and safe. Operative time longer than Laparoscopic approach.

SADI - Single Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy, RYGB - Roux en Y gastric bypass, DS – duodenal switch, MGB – minigastric bypass; Pts – patients; yrs – years; Mo -months; JLAST - Journal of Laparoendoscopic & Advanced Surgical Techniques ; SOARD – Surgery for Obesity and Related Diseases

SADI-s - Single Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy; RYGB - Roux en Y gastric bypass; DS – duodenal switch; BPD-DS – Biliopancreatic diversion – duodenal switch; MGB – minigastric bypass; Pts – patients; yrs – years; Mo -months; RBS - Revisional bariatric surgery ; L-rRYGB - laparoscopic revisional Roux en Y gastric bypass; R-rRYGB - robotic revisional Roux en Y gastric bypass; JLAST - Journal of Laparoendoscopic & Advanced Surgical Techniques ; SOARD – Surgery for Obesity and Related Diseases; RRevBS - Robotic Revisional Baraitric Surgery.

robotic platform may increase the rate of single step procedure in challenging cases (17, 30-32). However, other studies include controversial results showing no advantages in primary surgery (33,34). The use and adoption of robotic-assisted bariatric surgeries between 2015 and 2020 was seen in RRevBS cases (3.70-fold difference between 2015 and 2020) indicating that the interest in this new technology may be related to some of the advantages of the robotic approach including robotic advantages, all of which may be helpful in overcoming the technical challenges more commonly encountered in RRevBS cases (12).

The retrospective study conducted at Vall d'Hebron Hospital in Barcelona focused on patients who underwent RRevBS. This included details on the frequency and types of procedures performed using the robot, as well as the surgical team's experience and training in utilizing this advanced technology. In fact, it has been proven that the number of cases has increased twofold in a shorter period. Probably, at the expense of SG conversion due to weight regain and gastroesophageal reflux disease (GERD) (35-36).

Despite the remarkable advantages offered by robotic surgery in complex bariatric cases, successful outcomes heavily depend on the surgeon's experience and expertise. Most of the procedures performed in RevBS is conversion of sleeve gastrectomy to gastric bypass. To the same extent, in our series, this procedure is commonly performed, also including the conversion to SADI in case of insufficient weight loss o weight regain (19,22). Adequate training and proficiency in utilizing the da Vinci system are essential to maximize its benefits and ensure patient safety. Conversion to laparoscopic or open surgery may be required when adverse anatomical conditions are present. However, the incidence of complications may not increase when conversion is performed (37).

Another crucial aspect assessed in the study was the occurrence of complications during or after RBS. All complications were meticulously recorded, along with their severity and the approach employed to address them.

By analyzing all the gathered data, the study aimed to evaluate the effectiveness and safety of using the da Vinci robot in RBS at Vall d'Hebron Hospital. The results obtained provided valuable insights into how this robotic technology impacts surgical outcomes and complication rates in such procedures, potentially influencing improvements in surgical care and protocols in the future.

Conclusion

In conclusion, robotic surgery offers substantial advantages in revisional bariatric procedures, promising improved precision, reduced trauma, and potentially better patient outcomes. While cost, specialized training, and technological advancements present challenges, ongoing research and future recommendations aim to address these issues and solidify the role of robotic surgery in the evolving landscape of revisional bariatric procedures. Proper patient selection and continued advancements will shape the future of robotic surgery in this field.

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Authors' Contributions

Ramon Vilallonga; conception and writing;
Clara Pañella: Conception, revision;
Ana Ciscar: Revision;
Kevin Díaz. Conception and data extraction;
Daniel Herms and Javier Solis: data extraction;
Andreea Ciudin and Marta Comas: revisión;
Manuel Armengol Carrasco: revisión and final aproval.

Conflicts of Interest and Source of Funding

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Ethics Statement

The paper has used the Vall Hebron Hospital Database for bariatric surgery which is approved by the Ethical Committee of our institution.

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