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Original Article

Biliopancreatic diversion for severe obesity: long-term weight maintenance and occurrence of nutritional complications are two facets of the same coin

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Abstract

Background: Despite the widespread clinical use of hypoabsorptive metabolic bariatric surgery, very long-term outcomes are still lacking. The aim of the study was to assess the long-term safety and efficacy of biliopancreatic diversion at 30 years in patients with class 3 obesity (BMI over 40 kg/m^2).

Methods: This retrospective single-centre study used data from a prospectively collected database on a sample of consecutive patients submitted to biliopancreatic diversion with a minimum follow-up of 30 years. Outcomes assessed included overall survival, long-term weight loss and weight maintenance, remission of obesity-related co-morbidities, and short- and long-term surgical and/or nutritional or metabolic complications.

Results: Among 199 consecutive patients (136 female, 63 male) who had surgery between November 1992 and April 1994, the mean age at operation was 38 (range 14–69) years and mean preoperative BMI was 48.7 (32.0–74.3) kg/m^2. At baseline, 91 of 199 patients (45.7%) had type 2 diabetes. At 20 and 30 years, 122 (61%) and 38 (19%) of the 199 patients respectively were available for follow-up. At 30 years, the overall mortality rate was 12% (23 of 199). Surgical complications were concentrated in the short-term follow-up, whereas nutritional or metabolic complications increased progressively over time. A nutritional complication was diagnosed in 73 of 122 patients (60%) at 20 years and 28 of 38 (74%) at 30 years. Weight loss and glycaemic control were maintained throughout the follow-up; mean % total weight loss was 32.8 (range 14.1–50.0) at 1 year and 37.7 (range 16.7–64.8) at 30 years. One patient presented with recurrence of type 2 diabetes at 20 and 30 years; there were no patients with new-onset type 2 diabetes.

Conclusion: Biliopancreatic diversion leads to good and sustained weight maintenance up to 30 years with low perioperative risk, but at the cost of a high long-term prevalence of nutritional complications.

Lay summary

This study analysed the efficacy and safety of biliopancreatic diversion at very long-term follow-up of up to 30 years in patients with severe obesity (BMI over 40 kg/m^2). Long-term weight maintenance was excellent, but the incidence of late complications was high. These long-term results need to be taken into account for all hypoabsorptive metabolic bariatric surgical procedures.

Introduction

In the 1990s, there was a sharp increase in the prevalence of obesity globally and, with the advent of laparoscopy, there were newer, less invasive operations markedly reducing complication risks. Increasing obesity prevalence, together with advanced laparoscopic techniques, created a surge in the number of metabolic bariatric surgery (MBS) operations. Despite this relative increase in MBS procedures, these interventions are still offered only to approximately 1% of eligible patients with severe obesity, underlining the suboptimal access to MBS[1].

Over the years, no single bariatric operation has demonstrated clear superiority over the others. The laparoscopic Roux-en-Y gastric bypass is still considered the gold standard, but since 2014 laparoscopic sleeve gastrectomy has been the most common MBS procedure. Recently, the number of hypoabsorptive procedures has steadily increased[2]. Evidence suggests that hypoabsorptive operations lead to greater weight loss and a higher rate of remission of metabolic co-morbidities, for example type 2 diabetes mellitus (T2DM) or arterial hypertension[3]. Because patients with severe obesity frequently undergo surgery as young adults or at around 40 years of age, very long-term data on safety and efficacy exceeding 10–15 years are extremely important. Very long-term data (20 years or more of follow-up) on the safety and effectiveness of hypoabsorptive MBS is, however, very scant,

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representing a major concern, as hypoabsorptive procedures carry a lifelong risk of nutritional and metabolic complications, and therefore require thorough lifelong follow-up[4].

Biliopancreatic diversion (BPD) was introduced into clinical practice by Nicola Scopinaro in Genoa in 1976 after a preclinical animal model study[5,6]. At that time, a prospective database was started at the authors' institution; clinical data, laboratory values, and complications for all patients undergoing BPD have now been collected for almost 50 years.

Since its introduction into clinical practice, BPD has been modified several times, with the aim of minimizing nutritional complications. The latest and final version of BPD entails adaptation of stomach volume and intestinal limb lengths tailored to individual patient characteristics. It was introduced in 1992 under the name ad hoc stomach, ad hoc alimentary limb BPD[7]. The aim of this study was to assess the long-term safety and efficacy of BPD over up to 30 years follow-up in patients with class 3 obesity (BMI over 40 kg/m^2).

Methods

BPD consists of distal gastrectomy with a long Roux-en-Y reconstruction, with a 50-cm common limb, whereas the alimentary limb (AL) varies between 200 and 300 cm (*Fig. 1*). The stomach volume and AL length were tailored to individual patient's characteristics, with larger stomach volumes and longer AL lengths reserved for patients with an expected lower degree of compliance with follow-up, and to reduce malabsorption minimizing nutritional complications[7]. In this patient population, all procedures were open and performed by laparotomy via a xiphosupraumbilical incision.

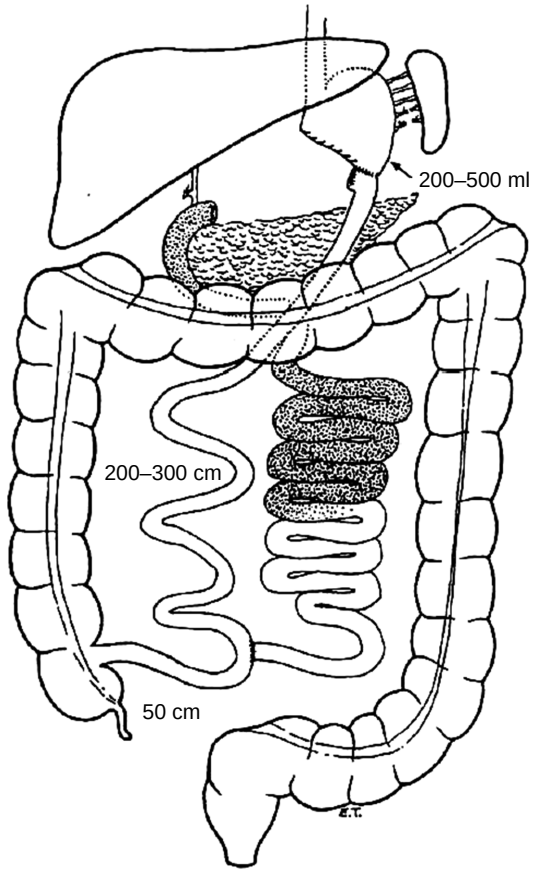

Fig. 1 Schematic representation of ad hoc stomach, ad hoc alimentary limb biliopancreatic diversion

Alimentary limb, from the gastroenterostomy to the enteroenterostomy (EEA); biliopancreatic limb, from the duodenum to the EEA; common limb, from the EEA to the ileocaecal valve).

Patients submitted to BPD at this institution were investigated before surgery and at each follow-up consultation according to a standardized protocol[8]. After surgery, patients were followed up routinely at 1 and 4 months after surgery, and yearly up to the third postoperative year. All patients were then invited for regular follow-up appointments, and most had a yearly outpatient visit thereafter. Operative morbidity and mortality, clinical examination findings, and incidence and details of late complications were recorded in the prospective database.

Preoperative data included patient demographics (age, sex, height, weight), complete blood biochemistry, BP, and prevalence of obesity-related co-morbidities. Weight changes were recorded and expressed as change in BMI, percentage total weight loss (%TWL) and percentage excess BMI loss[9].

Perioperative morbidity and mortality were recorded. At each follow-up consultation, all patients underwent clinical examination and laboratory tests, and potential complications were recorded comprehensively. Patients were considered to have type 2 diabetes when the fasting serum glucose concentration was higher than 7.0 mmol/l, or when on antidiabetic drugs. Dyslipidaemia was defined by a serum concentration of triglyceride higher than 1.7 mmol/l, and of total cholesterol higher than 5.0 mmol/l, or high-density lipoprotein cholesterol value lower than 1.0 mmol/l. BP was measured twice with the patient lying down and the mean value was recorded. Hypertension was diagnosed if BP was over 135 mmHg systolic and/or over 90 mmHg diastolic, or by the use of antihypertensive medication. Remission of T2DM, dyslipidaemia, and hypertension was defined by normal glucose level, haemoglobin A1c concentration, lipid panels, and BP, with no medications for these co-morbidities for at least 3 months.

The development of early (bleeding, leak, anastomotic ulcer or stricture, wound infection or dehiscence, cardiovascular complications, and deep vein thrombosis) or late complications was recorded. Perioperative complications were graded according to the Clavien–Dindo classification[10]. Late complications were divided into surgical or nutritional and metabolic complications. Surgical complications were defined by the need for a surgical procedure (for example, incisional hernia repair, intestinal obstruction, or proctological complications requiring surgical treatment). Nutritional and metabolic complications were defined by prescription of formal nutritional support, or when a nutrient deficiency-related illness was diagnosed (such as anaemia, metabolic bone disease, protein–energy malnutrition, symptomatic vitamin or trace-element deficiencies). Patients

Table 1 Baseline patient demographics and metabolic co-morbidities

	No. of patients (n = 199)*
Sex	
Female	136 (68)
Male	63 (32)
Age at operation (years), mean(s.d.)	38(5)
Bodyweight (kg), mean(s.d.)	131(19)
BMI (kg/m^2), mean(s.d.)	48.7(10)
Diabetes	91 (46%)
Hypertension	123 (62%)
Dyslipidaemia	124 (62%)

*Values are n (%) unless otherwise indicated.

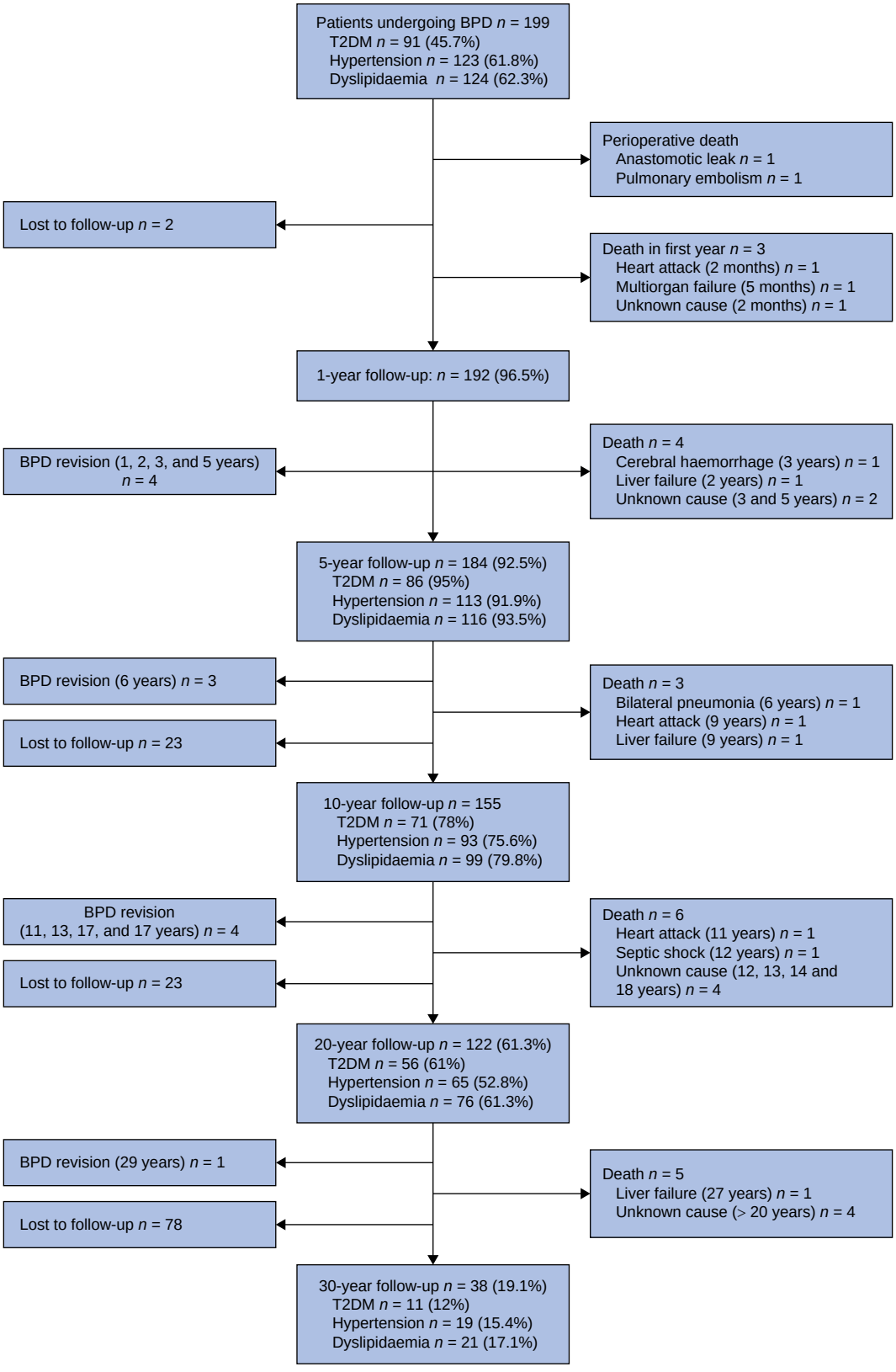

Fig. 2 Study flow chart

A patient could have more than one co-morbidity. T2DM, type 2 diabetes mellitus.

were followed up until death or drop out of follow-up. In the event of patient death, all available information was collected through the referring physician.

The main indication for surgical revision of BPD was recurrent protein malnutrition, or any other medical condition that was aggravated by malabsorption. Each indication for surgical

revision was discussed with the patient on an individual basis, balancing the expected benefits against the surgical risk and the possibility of recurrent weight gain.

Data were extracted from the files by three authors. All patient data were anonymized and deidentified. The study was approved by the institutional review board and is compliant with the Declaration of Helsinki on medical research involving human subjects.

Results

Some 199 consecutive patients (136 female, 63 male), with a mean age of 38 (range 14–69) years and mean preoperative BMI of 48.7 (range 32.0–74.3) kg/m^2, underwent open BPD from November 1992 to April 1994. At baseline, 91 of 199 patients (45.7%) had T2DM, 124 (62.3%) had dyslipidaemia, and 123 (61.8%) were diagnosed with hypertension (*Table 1*). Data on follow-up, including baseline co-morbidity follow-up rates, perioperative and long-term patient mortality, and BPD revisions are presented in detail in *Fig. 2*. Early complications are summarized in *Table 2*. Of the 199 patients, 2 died within 30-day follow-up, 1 patient with an anastomotic leak, and 1 who had a massive pulmonary embolism. During the 30-year follow-up, an additional 21 patients died and the mortality rate in this study population at 30 years was 12% (23 of 199). Five of these deaths were potentially related to the surgery: one case of septic shock in a patient with protein malnutrition, and four of liver failure. For all other deaths, there was no proven direct relationship with the surgery.

Data on weight loss and long-term weight maintenance are shown in *Table 3*. Mean(s.d.) weight loss (%TWL) was 32.8(8.9) at 1 year, and 37.7(13.5) at 30 years. One patient presented with recurrence of T2DM at 20 and 30 years. In the long term, of the 38 patients remaining in follow-up, only 3 presented with arterial hypertension, and 2 with dyslipidaemia.

Table 2 Thirty-day complications after open biliopancreatic diversion

	No. of patients (*n* = 199)	Clavien-Dindo grade
Wound infections	13 (6.5)	I
Delayed gastric emptying	11 (5.5)	I–II
Lung infections	4 (2.0)	II
Anastomotic leak	2 (1.0)	IIIb, V
Haemoperitoneum	2 (1.0)	IIIb
Pancreatitis	1 (0.5)	II
Deep venous thrombosis with pulmonary embolism	1 (0.5)	V
Anastomotic stenosis	1 (0.5)	IIIa
Pneumothorax	1 (0.5)	II
Total number of complications	36 (18.1)	

Values are *n* (%).

During follow-up, the number of patients presenting with a nutritional and/or metabolic complication increased progressively, whereas the incidence of surgical complications decreased over time (*Table 4*). At 20 years, 3 of the 122 patients available for follow-up had a surgical complication; 2 had stomal ulcers (1.6%) and 1 an incisional hernia (0.8%). At 30 years, there was one additional patient requiring incisional hernia repair. At 1 year, 56 of the 192 patients (27%) had developed complications, 45 patients presenting with a surgical complication and 11 with a nutritional or metabolic issue. At 5 years, 69 of 184 patients (38%) had at least 1 complication; there were 28 surgical complications and 41 nutritional or metabolic complications. At 5 years, the most common nutritional or metabolic complications included anaemia (15 patients) and protein malnutrition (19). At 30 years, 29 of the 38 patients available for follow-up had experienced 1 or more complications and 28 (74%) of these were nutritional or metabolic; 7 patients (18%) had anaemia, 6 (16%) had protein malnutrition, 17 (45%) had metabolic bone disease, and 16 (42%) had micronutrient deficiency.

Over the 30-year follow-up, 12 patients (6.0%) (mean age 55 years) underwent surgical revision of BPD, at a mean of 10 (range 1–29) years after the initial operation; there were 4 revisions within 1–5 years, 3 in 6–10 years, 4 in 11–20 years, and 1 in 21–30 years.

Discussion

The results of this study have shown good and sustained weight loss and remission of obesity-related co-morbidities after open BPD at 30 years of follow-up. The study confirmed the excellent long-term weight maintenance and control of metabolic complications obtained after BPD, and, to the authors' knowledge, these results are still unsurpassed by other operations. These outcomes, however, are achieved at the price of a very high prevalence of long-term nutritional and metabolic complications, and a moderate long-term risk of requiring surgical revision. Compared with surgical outcomes in the 1990s, perioperative morbidity and mortality rates in this patient series were much lower for a major operation within a bariatric surgery patient population. In addition, most early surgical complications were mild and directly related to the laparotomy. With the advent of laparoscopy, a sharp decrease in the incidence of early surgical complications was observed[8]. Although surgical complications seemed to plateau during follow-up, this was not the case for nutritional or metabolic complications. On the contrary, the percentage of patients with nutritional issues increased progressively over time, to the point that revisional surgery was still being indicated in the third decade after the original operation. In the authors' experience, the long-term persistence of nutritional complications is an intrinsic trait of hypoabsorptive metabolic bariatric operations,

Table 3 Weight loss and long-term weight maintenance

	Baseline (*n* = 199)	1 year (*n* = 192)	5 years (*n* = 184)	10 years (*n* = 155)	20 years (*n* = 122)	30 years (*n* = 38)
BMI (kg/m^2)	48.7(5)	32.8(10.9)	31.2(5.7)	31.8(7.1)	31.9(7.4)	30.8(7.3)
% excess BMI loss	–	67.1(49.1)	73.8(6.6)	71.5(23.9)	72.3(28.9)	75.6(28.2)
% total weight loss	–	32.8(8.9)	36.1(8.6)	35.0(11.4)	34.3(13.5)	37.7(13.5)
Change in BMI (kg/m^2)	–	15.9(0.5)	17.5(18.9)	17.0(7.2)	17.2(8.7)	18.0(8.1)

Values are mean(s.d.).

Table 4 Postoperative complications at all follow-up times

	1 year (n = 192)	5 years (n = 184)	10 years (n = 155)	20 years (n = 122)	30 years (n = 38)
Anaemia	1 (0.5)	15 (8)	22 (14)	24 (20)	7 (18)
Protein malnutrition	8 (4)	19 (10)	9 (6)	10 (8)	6 (16)
Metabolic bone disease	0 (0)	4 (2)	7 (4.5)	18 (15)	17 (45)
Micronutrient deficiency	2 (1)	3 (1.6)	7 (4.5)	18 (15)	16 (42)
Myocardial infarction	0 (0)	2 (1)	2 (1)	0 (0)	0 (0)
Incisional hernia	20 (10)	11 (6)	5 (3)	1 (1)	1 (3)
Stomal ulcer	6 (3)	9 (5)	6 (4)	2 (2)	0 (0)
Proctological	15 (8)	8 (4)	2 (1)	0 (0)	0 (0)
Nutritional/metabolic	11 (6)	41 (22)	45 (29)	73 (60)	28 (74)
Surgical	45 (21)	28 (15)	13 (8)	3 (3)	1 (3)

Values are n (%).

and it represents the negative counterpart to good long-term outcomes of weight maintenance and the control of metabolic syndrome.

The progressively increasing incidence of nutritional complications may have several explanations. First and foremost, there seemed to be no adaptation of intestinal absorption capacity after BPD during long-term follow-up. Although this may be beneficial for the excellent long-term weight loss maintenance and remission of metabolic co-morbidities, it carries a constant risk of nutritional deficiencies. Despite best efforts, extensive nutritional follow-up and supplementation failed to prevent complications in this study.

Furthermore, ageing is usually associated with increased patient frailty. The authors[11,12] recently described a very high incidence of nutritional complications in an older patient population with more co-morbidities and with shorter follow-up. As intestinal absorption capacity does not seem to adapt over the years, increasingly frail and ageing patients may have more difficulties in coping with the effects of the operation over time. In this instance, advocating long-term and lifelong supplementation after BPD is not sufficient to prevent complications and, in practice, is not sustainable.

Revisional surgery was required up to the 29th year of follow-up, and the indication for reoperation in the very long term is always coupled with the operative risk of more elderly and nutritionally compromised patients. As nutritional complications tend to recur chronically, surgical revision of BPD should be discussed with these patients at an earlier stage. Whether a reversal or conversion to another operation should be advocated for every patient submitted to BPD is debatable. The authors believe that a balanced and honest discussion with the patient about the indications for reoperation should be held as soon as recurrent nutritional issues appear, when the patient still has an acceptable operative risk, balancing reoperative morbidity and mortality with the expected weight regain and severity of nutritional complications.

Although the immediate clinical return of this paper may seem limited, as the original BPD has progressively been abandoned from clinical practice in recent years[13], the authors believe that this study carries broader importance for most hypoabsorptive procedures as surgical complications tend to be concentrated in the short-term follow-up, and are very rare in the long term, whereas nutritional and metabolic complications accumulate over time, and their full magnitude may not be apparent for many years. Most hypoabsorptive procedures lead to nutritional or metabolic complications in the short and medium term at a similar rate to those observed after BPD in the present study[14–17], and it is feared that longer-term results similar to those described here may also be evident after the other hypoabsorptive operations. Drop-out from follow-up in the present study appeared to be particularly steep in the third decade after operation; there is no obvious explanation for this, but it may be that the already significant long-term incidence of complications and death of this series might be underestimated.

In an analysis of the results obtained in 100 patients who underwent BPD or BPD with duodenal switch, with a maximum follow-up of 10 years, Sethi *et al.*[18] reported an overall incidence of hypoalbuminaemia of 18%, with severe malnutrition in 7 patients, 3 of whom needed surgical revision of the operation (reversal or elongation of the common limb). In the present study, there were 7 revisions (4.5%) among 155 patients available for follow-up at 10 years.

In a recent review of their patient population, Sánchez-Pernaute *et al.*[16] reported a revision rate of 7.3% within the first 10 years after single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S). None of the patients with a common limb of 300 cm needed revision of the operation at that point in time, but the cohort with the longer limb also had much shorter follow-up. This overall revision rate is higher than the present 30-year revision rate of 6%, and the long-term revision rate for SADI-S has yet to be demonstrated. The incidence of nutritional and metabolic complications after one-anastomosis gastric bypass is less clear. A particularly large number of revisions was described after only 2 years in the YOMEGA randomized trial[15], whereas other studies[19,20] reported a smaller number of complications.

This study has several limitations. First, despite the prospective data collection, it is retrospective in nature. Second, the major limitation is the high drop-out rate during follow-up over the years, which has created an important source of potential bias and may have resulted in the actual complication rate and long-term mortality in the study population being severely underestimated. Third, the lack of a suitable control group prevented a meaningful comparison with the outcomes of a matched cohort of non-operated patients with obesity.

This study has demonstrated that clinical results after MBS go beyond weight loss and remission of co-morbidities. Most hypoabsorptive procedures appear to be effective if only these endpoints are considered. It needs to be understood that nutritional complications tend to appear and accumulate over time, and these procedures appear to be safe if no long-term follow-up is pursued. The larger picture shows that initial hypoabsorption resulting in actual malabsorption *per se* carries a fundamental and lifelong risk of complications, which is clarified in its entirety only by long-term follow-up. These results should prompt caution in the use of hypoabsorptive

bariatric procedures. Long-term weight maintenance and long-term occurrence of nutritional complications seem to be two facets of the same coin.

In conclusion, BPD yields excellent and sustainable weight loss and metabolic results in the very long term, but at the cost of a very high prevalence of nutritional complications, which tend to accumulate and be evident only over time. Based on these long-term outcomes, the authors believe that BPD should be indicated with extreme caution, if at all. As the nutritional complications and revision rate of most hypoabsorptive procedures seem to concur with those of the present study in the medium term, accurate and committed long-term follow-up after hypoabsorptive metabolic bariatric surgical operations is extremely important to ensure patient safety.

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Author contributions

Francesco Saverio Papadia (Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing—original draft, Writing—review & editing), Gianfranco Adami (Conceptualization, Data curation, Investigation, Writing—review & editing), Alessandra Razzetta (Data curation, Formal analysis, Investigation, Methodology, Writing—original draft), Anna Florenzano (Data curation, Formal analysis, Methodology, Writing—original draft), Gaia Longo (Writing—review & editing), Alice Rubartelli (Writing—review & editing), Flavia Carlini (Writing—review & editing), Ottavio De Cian (Writing—review & editing), and Giovanni Camerini (Writing—review & editing)

Disclosure

The authors declare no conflict of interest.

Data availability

The data that support the findings of this study are available on request from the corresponding author.

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