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ORIGINAL ARTICLE

A 9 years comparison of weight loss, disappearance of obesity, and resolution of diabetes mellitus with biliointestinal bypass and with adjustable gastric banding: experience of a collaborative network

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Abstract

Aims Long-term comparisons between bariatric surgical techniques have been performed for gastric bypass (RYGB), sleeve gastrectomy (LSG), and biliopancreatic diversion (BPD) vs gastric banding (LAGB), but short-term studies (6 months–4 years) have only compared biliointestinal bypass (BIBP) and LAGB. The participating institutions regularly perform both BIBP and LAGB with a common protocol, and the aim of this retrospective study was to compare long-term effects of the two procedures on body weight, on clinical and metabolic variables, and on resolution of obesity and of diabetes.

Methods All procedures performed between 01/01/1998 and 31/12/2005 were considered; 73 out of 91 patients undergoing BIBP, and 154 out of 249 patients undergoing LAGB were evaluable up to 9 years.

Results BIBP was significantly more effective than LAGB in terms of weight loss and of resolution of obesity (BMI < 30 kg/m^2), in terms of decrease of systolic blood pressure and of serum cholesterol, and similar in terms of resolution of diabetes. In addition, the effect of BIBP was stable, while the effect of LAGB decreased with time.

Conclusions Both BIBP and LAGB exert long-term effects on body weight, on blood pressure, and on resolution of diabetes mellitus; the effect of BIBP is significantly greater than the effect of LAGB in terms of weight loss, resolution of obesity, of control of systolic blood pressure and of serum cholesterol, but not in terms of resolution of diabetes.

Keywords Biliointestinal bypass · Adjustable gastric banding · Obesity · Bariatric surgery · Diabetes mellitus · Resolution of diabetes mellitus · Resolution of obesity

Introduction

Several bariatric procedures are now available for obesity. After jejunoileal bypass and vertical banded gastroplasty have substantially been dismissed [1, 2], laparoscopic adjustable gastric banding (LAGB) has been for years one of the most popular bariatric procedures, mainly because of low invasiveness, the possibility of laparoscopic removal, and paucity of side effects [3]. The use of LAGB is now declining, due to the rising of other procedures [4], such as laparoscopic sleeve gastrectomy (LSG), and gastric bypass (RYGB) in the US, the former being now more popular than the latter [5].

Malabsorptive procedures are represented by biliopancreatic diversion (BPD, [6]) and by biliointestinal bypass

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(BIBP), a procedure that has been available since a long time ago, but was less popular [7, 8].

All bariatric surgeries are accompanied by the resolution of diabetes mellitus in a high percentage of cases [6, 9]. A series of studies and surveys have indicated short-time and long-term superiority of RYGB, BPD, and LSG over LAGB in terms of weight loss and reduction of co-morbidities [4, 10–17]. In contrast, there are no comparisons available between BIBP and BPD, RYGB, LSG, while only short-term comparisons have been published between BIBP and LAGB [18–21]. We and others have been comparing short-term effects of different bariatric procedures; for instance, we and others compared the 6 or 12 months and 4 years effects of BIBP and LAGB on glucose and lipid metabolism [18–21], and we and others also compared the 1 week effects of BPD and LAGB on insulin and glucose response to oral glucose [22, 23].

Since our Institutions regularly perform a variety of surgical procedures including BIBP, LAGB, BPD, RYGB, and LSG, our aim was to compare long-term effects of different surgical procedures; in this retrospective study we compared the effects of BIBP and LAGB on body weight and diabetes resolution.

Patients and methods

Bariatric surgery (BIBP and LAGB) [8, 24] is routinely performed at the obesity centres of the Institutions participating in this retrospective study (Ospedale San Paolo, Istituto Sant'Ambrogio, Istituto Multimedica, and Ospedale San Raffaele, Milan, Italy). The Institutions belong to the LAGB10 study group [24], a spontaneous network of physicians and surgeons working with bariatric surgey in Lombardy region (Italy). According to the common protocol approved by the local Ethics Committees, patients were eligible for bariatric surgery if they met the following criteria: age 18–65 years inclusive and a BMI > 40.0 kg/m^2 alone, or a BMI > 35.0 kg/m^2 in the presence of co-morbidities plus a history of at least 2 previous dietary attempts followed by a relapse [24]. The clinical protocol included medical history, physical and biochemical evaluation, and a psychological and psychiatric evaluation performed to verify indications, contraindications and the safety of a surgical intervention [25]. All subjects gave their written informed consent. Retrospective studies (this and other protocols) were approved in 2002, 2006, 2012, and 2015 by Ethics Committees of participating Institutions. Surgery was offered to all eligible patients, and the type of surgery (BIBP or LAGB) was discussed with patients in agreement with current guidelines [21, 22]; when patients had a BMI > 50 kg/m^2, or were deemed non-compliant for post-surgery dietary recommendations, BIBP was encouraged instead of LAGB. As a result, 91 patients underwent BIBP and 249 patients underwent LAGB (Table 1). The two techniques are depicted in Fig. 1; all procedures performed between 01/01/1998 and 31/12/2005 were considered; BIBP was performed through laparotomy up to 2002, and through laparoscopy since then. For all subjects undergoing BIBP or LAGB, after surgery the suggested diet after surgery was 970 and 1,090 kcal per day in women and men, respectively; iron was supplemented on the basis of blood examinations performed during the second month. The diet included 48% carbohydrates (starch or bread), 33% proteins (fat-free parts of different animals and fishes), and 19% lipids (olive oil); sweets, cakes, sweetened drinks, alcohol, and animal lipids were forbidden. All foods had to be cooked without oil, butter, or other lipids; in addition, BIBP patients received vitamin D3 at discharge (two administrations per month), calcium, potassium, multivitamins plus vitamin B12 (5000 units once per month), and oral antidiarrheal drugs (diphenoxylate or loperamide) when bowel movements were > 10 per day.

Outcomes

Body weight was measured to the nearest 0.1 kg and height to the nearest 0.1 cm with the subjects wearing swimming costumes. BMI was calculated from weight and height (kg/m^2). Blood glucose, serum cholesterol, triglycerides, and glycated hemoglobin were evaluated through routine laboratory methods. Differences in current (at each year) BMI and in change from baseline (ΔBMI) were considered. In addition, resolution of diabetes was considered. Diagnosis of diabetes mellitus was established as reported previously [13, 24]; resolution of diabetes was defined as fasting blood glucose < 100 mg/dl and HbA1c < 6.0, in the absence of antidiabetic drugs [26].

Statistical analysis

Data are indicated as mean ± SE or as absolute frequencies. All statistical analyses were performed by Stata software for Macintosh (Stata 12, Stata Corporation, 137 College Station, TX, USA). Comparisons between groups were performed on values at baseline, at 1–9 years, and on absolute changes (Delta) by one-way analysis of variance (ANOVA). Frequencies were compared through Chi square test.

Power calculation and sample size

Being a retrospective study, power calculation and sample size were only calculated to understand if the study was meaningful. Due to previous papers dealing with comparison of clinical and metabolic effects of BPD and BIBP with LAGB [13, 21, 22], given a power = 80% and an alfa error 0.05, it was calculated that 60 patients receiving BIBP and

Table 1 Clinical details of patients in the study at baseline and at follow-up

Patients	BIBP	LAGB	Significance (*p*)
Age (years)	41.3 ± 2.14	42.3 ± 2.23	NS
Number (sex M/F) at baseline	91 (20/71)	249 (45/204)	NS*
Number (sex M/F) at FU	73 (15/58)	154 (25/129)	NS*
BMI at baseline (kg/m^2)	43.9 ± 0.59	43.4 ± 0.39	NS
With diabetes mellitus at baseline	19/91	52/249	NS*
With diabetes mellitus at FU	4/73	20/154	NS*
Duration of diabetes (years)	2.0 ± 0.23	1.9 ± 0.22	NS
Pharmacotherapy (oral agents/ insulin)	6/2	16/7	NS*
Pharmacotherapy (oral agents/ insulin) at FU	1/0	6/1	NS*
Fasting blood glucose (mg/dl)	112.0 ± 12.05	106.6 ± 3.72	NS
Fasting blood glucose (mg/dl) at FU	93.7 ± 1.31	98.2 ± 3.33	NS
Hba1c (%) at baseline	8.7 ± 0.55	8.6 ± 0.47	NS
Hba1c (%) at FU	6.0 ± 0.21	6.1 ± 0.15	NS
Systolic blood pressure (mmHg)	137.6 ± 2.22	132.9 ± 1.35	NS
Systolic blood pressure (mmHg) at FU	121.7 ± 1.38	127.9 ± 1.88	< 0.05
Diastolic blood pressure (mmHg)	83.2 ± 1.22	82.4 ± 1.04	NS
Diastolic blood pressure (mmHg) at FU	71.6 ± 1.98	73.5 ± 2.03	NS
Cholesterol (mg/dl)	216.8 ± 7.99	207.1 ± 7.55	NS
Cholesterol (mg/dl) at FU	180.0 ± 3.21	206.8 ± 5.33	< 0.01
Triglycerides (mg/dl)	155.6 ± 8.28	149.6 ± 8.32	NS
Triglycerides (mg/dl) at FU	98.3 ± 7.03	110.3 ± 6.36	NS

Means ± SE or absolute frequencies

BIBP biliointestinal bypass; *LAGB* laparoscopic adjustable gastric banding; *FU* follow-up; *BMI* body mass index; *Hba1c* glycated hemoglobin; *NS* not significant

*χ^2 test

200 patients receiving LAGB were enough to detect significant differences in the outcomes. This manuscript was prepared according to guidelines of the STROBE statement [27].

Results

As reported in bariatric literature [6], men represented a minority of patients undergoing either BIBP or LAGB. The mean age was not different from the majority of previous studies, and the percentage of patients with diabetes mellitus was similar to previous studies [6]. The two groups did not differ in terms of sex distribution, age, BMI, and frequency of diabetes mellitus (Table 1). Patients evaluated for 9 years were not different from patients with a shorter follow-up for BMI, sex ratio, clinical and metabolic variables, and presence of diabetes (not shown).

Surgical outcomes

With BIBP, the main late complications were incisional hernia in open technique and oxalic nephrolithiasis, and the reversal rate was 3.2%. Band adjustment was required in 85 of the 154 patients (1–10 adjustments/patient) remaining in the study up to 9 years; re-intervention was required in 11 patients (laparotomic in 8 patients, because of surgical difficulties with laparoscopy) due to slippage and pouch dilation; removal of LAGB was performed in 12 patients; under no circumstances a different surgical technique was applied.

Clinical outcomes

Figure 2 shows BMI from baseline up to 9 years. A fair number of patients were lost to follow-up 1 and 2 years after surgery, so long-term analysis was only possible for 73 and 154 patients undergoing BIBP and LAGB, respectively. The results were virtually identical when patients with a short follow-up period (i.e., less than 3 years) were included or excluded (data not shown).

After the first 6 months, BMI was always lower with BIBP than with LAGB; in addition, there was a stable or even increasing effect of BIBP, and a progressively lower effect of LAGB. With BIBP, weight loss was satisfactory in 92.3% of operated patients. Weight loss reached a plateau within 18–24 months after surgery with a percentage of excess weight loss (%EWL) of 60–70%. In keeping with these data, decrease of BMI (ΔBMI) was stable or even increasing with BIBP, and progressively lower with LAGB. Since it is known that a fair proportion of patients

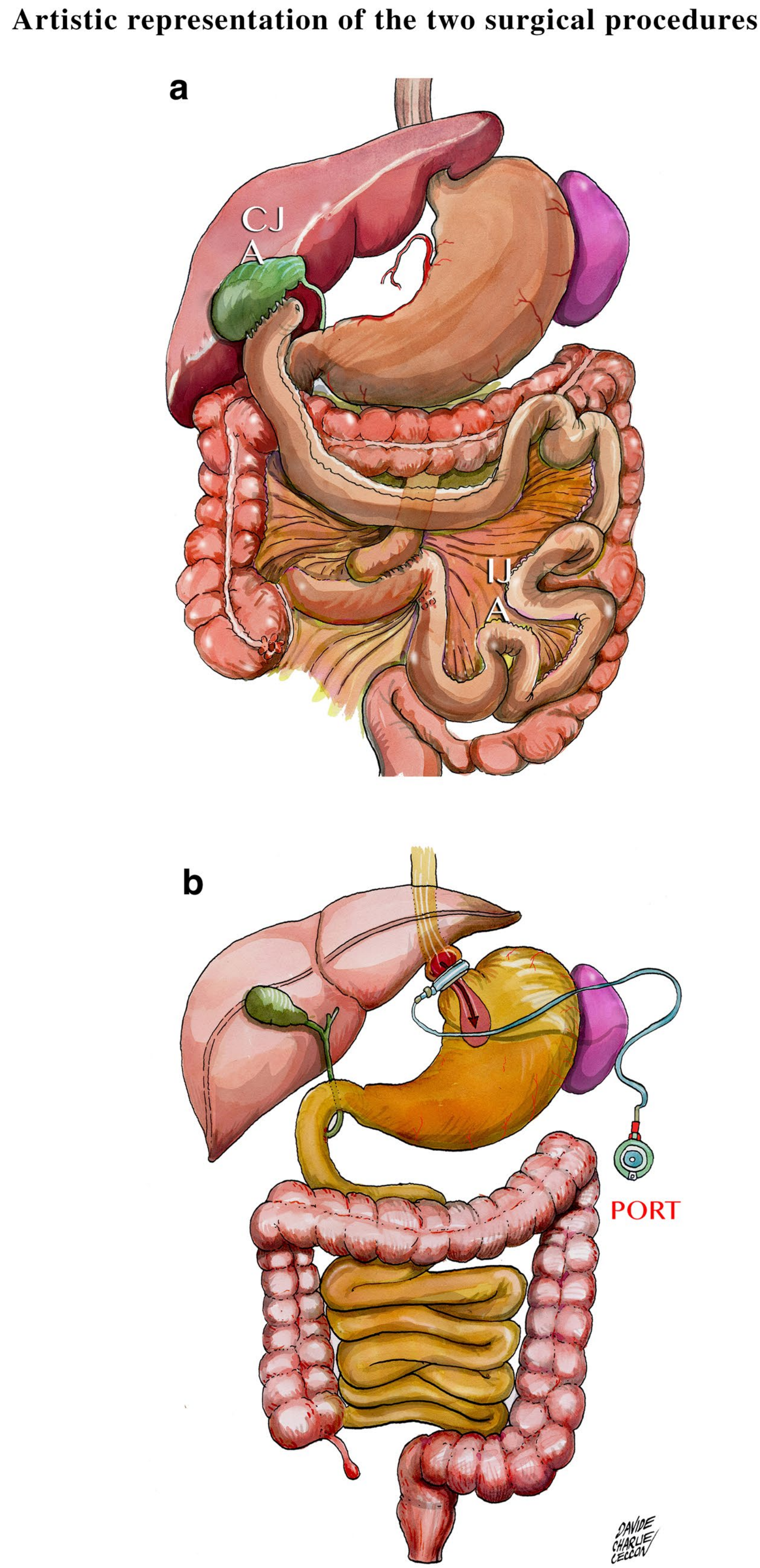

Fig. 1 Artistic representation of the two surgical procedures. **a** BIBP. *CJA* cholecystojejunal anastomosis; *JIA* jejunoileal anastomosis. **b** LAGB. Tubing is connected with subcutaneous tissue in the abdomen (PORT) to allow adjustments of LAGB

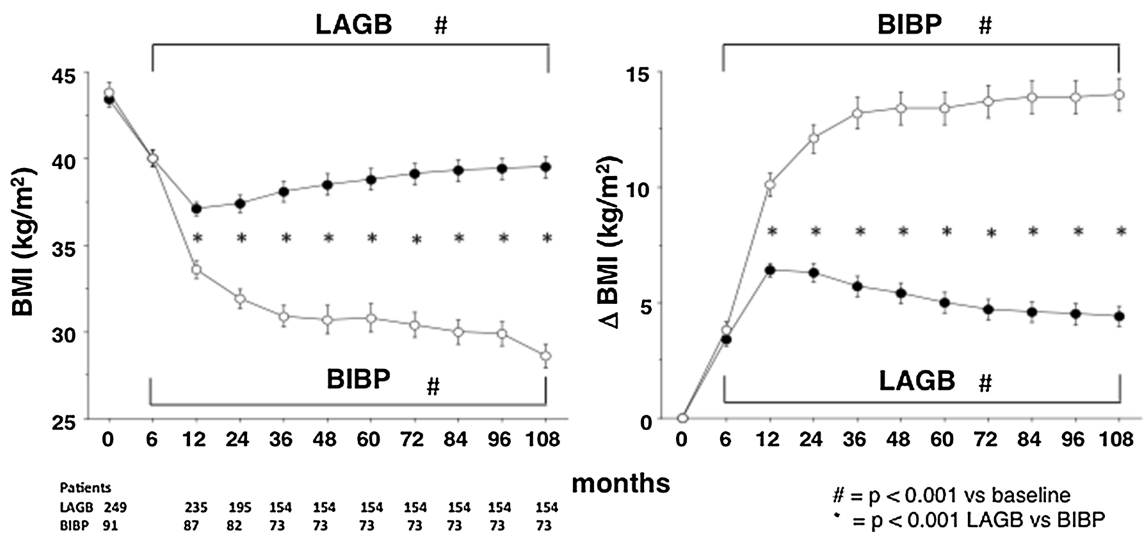

Fig. 2 Body mass index (BMI kg/m^2) and change of BMI (ΔBMI kg/m^2) in obese patients undergoing biliointestinal bypass (BIBP) and gastric banding (LAGB). Means ± SE. Numbers of patients at each time interval are shown

experienced little or no weight loss with LAGB [28–30], we analyzed the mean pattern after establishing different thresholds of weight loss for both groups (i.e., ΔBMI = 0 kg/m^2 at 1 year, 5 kg/m^2 at 1 year, 5 kg/m^2 at 5 years), and the pattern did not change. Resolution of obesity was progressively greater for BIBP, and was present in a minority of LAGB patients at the beginning, and declined thereafter (Table 2). Frequency of diabetes significantly declined with both surgeries. Resolution of diabetes at follow-up was similar in patients undergoing BIBP and LAGB (Table 1, NS). Decrease of systolic blood pressure and of serum cholesterol was greater with BIBP than with LAGB (Table 1). In the 73 patients receiving BIBP with a 9 years follow-up, no differences were observed between those undergoing laparotomy ($n = 27$) and laparoscopy ($n = 46$) (not shown).

Table 2 Resolution of obesity at follow-up (BMI < 30 kg/m^2)

Period	BIBP	LAGB	Significance (p)
Baseline	0/87 (0.0)	0/235 (0.0)	NS
1 year	17/87 (19.5)	23/235 (9.8)	0.0229
2 years	27/82 (32.9)	18/195 (9.2)	0.0001
3 years	37/73 (50.7)	15/154 (9.7)	0.0001
4 years	36/73 (49.3)	9/154 (5.8)	0.0001
5 years	36/73 (49.3)	10/154 (6.4)	0.0001
6 years	38/73 (52.0)	9/154 (5.8)	0.0001
7 years	39/73 (53.4)	8/154 (5.2)	0.0001
8 years	39/73 (53.4)	8/154 (5.2)	0.0001
9 years	40/73 (54.8)	7/154 (4.5)	0.0001

Comparisons are through Chi square test at each time period

Absolute numbers and percentages

BIBP biliointestinal bypass; *LAGB* laparoscopic adjustable gastric banding; *NS* not significant

Discussion

To the best of our knowledge, this is the first long-term comparison of weight loss and resolution of obesity and of diabetes in patients undergoing BIBP and LAGB. As shown in previous studies, LAGB was associated with a significant weight loss, but with a significant decrease in the number of patients affected by diabetes mellitus [6]. The important message is that BIBP has durable effects, in terms of both weight loss and resolution of diabetes, as already reported for short-term studies [9, 20, 21, 23], with no difference between patients operated through laparotomy or laparoscopy. The other message is that these effects, albeit lower than with other techniques, are durable for at least 9 years, in keeping with other studies of similar or longer duration [3].

The main difference between BIBP and LAGB is in the amount of weight lost, and therefore in the resolution of obesity, not in the percentage of diabetes resolution. The effects on weight loss of both BIBP and LAGB are of long duration, but the effects of the two surgeries progressively diverge; this is shown by the mean BMI achieved at various time periods, and by the frequency of disappearance of obesity. In addition, decrease of systolic blood pressure and of serum cholesterol was greater with BIBP than with LAGB. This was already reported in previous short-term studies [18–21] comparing BIBP and LAGB, and is quite similar to what we observed comparing BPD and LAGB [13].

A few studies have indicated a very prolonged weight loss effect for LAGB [3]; others [28–30], and our group [31], have shown that the effect decreases with time, even if after a mean period of 13 years BMI is still lower than at baseline. One might wander whether there is still room for LAGB, given the inferiority of effect in comparison with BIBP; together with low invasiveness, possibility of removal, and paucity of side effects, LAGB has shown to prevent long-term complications of obesity, and to improve survival, similar to RYGB [24, 32]. So far, neither prevention of complications of obesity, nor survival have been studied for BIBP, aside from short-term improvement of risk factors for cardiovascular disease [21]. Obesity, and especially visceral obesity, favor development of cardiovascular disease in type 2 diabetes [33], and predict all-cause mortality [34]; the present results suggest that BIBP, able to induce resolution of obesity in more than 50% for up to 9 years, should be effective in preventing cardiovascular disease and all-cause mortality.

This study has limitations; for instance, there was a great loss to follow-up, especially for LAGB patients, in keeping with available experience and with previous meta-analyses [6]. However, patients with a short follow-up were not different from patients with a 9 years follow-up. In addition, a bias might be represented by the fact that, when patients were super-obese, or deemed non-compliant, BIBP was encouraged instead of LAGB; however, BIBP and LAGB patients completing the 9 years study were not different, nor they had a different diabetes status, at least by duration of diabetes or kind of pharmacotherapy. Finally, we could not report data on quality of life and on eating patterns of patients undergoing either BIBP or LAGB; at that time, greater importance was devoted to psychiatric and psychological aspects, and psychological aspects were mainly evaluated at baseline, while quality of life and eating patterns were not systematically investigated, or were collected in selected studies.

In conclusion, both BIBP and LAGB exert long-term effects on body weight and on resolution of diabetes mellitus; the effect of BIBP is significantly greater than the effect of LAGB in terms of weight loss, of resolution of obesity, of decrease of systolic blood pressure and of serum cholesterol, but not in terms of resolution of diabetes.

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Compliance with ethical standards

Conflict of interest All authors declare that they no conflict of interest.

Statement of human and animal rights All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Informed Consent Informed consent was obtained from all patients for being included in the study.

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