



# Proximal Jejunal Bypass Improves the Outcome of Gastric Clip in Patients with Obesity and Type 2 Diabetes Mellitus

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## Abstract

**Background** Laparoscopic gastric clip (GC), a novel pure restrictive procedure, is a safe and effective treatment for morbid obesity. However, whether adding a proximal jejunal bypass (PJB) to this procedure might increase the efficacy is unknown.

**Methods** Outcomes of 74 (43 women and 31 male) obese patients who had undergone PJB-GC (41) or GC (33) for the treatment of type 2 diabetes mellitus (T2D) with 1 year follow-up were assessed. GC consists of creating a transverse gastric partition with a metallic clip. PJB consists of a jejunio-ileostomy between 20 and 320 cm distal to the ligament of Treitz. Postoperative body mass index (BMI) reduction, total weight loss (TWL), and remission rates of T2D were evaluated.

**Results** The preoperative clinical characters in both groups were similar. The mean operative time was significantly longer in the PJB-GC group than in the GC group. At 24 months after surgery, the BMI was lower ( $32.5 \pm 6.2$  vs.  $37.0 \pm 5.9$  kg/m<sup>2</sup>,  $p = 0.002$ ) and weight loss higher in PJB-GC than GC (TWL  $31.3 \pm 14.8$  vs.  $23.5 \pm 10.4\%$ ,  $p = 0.011$ ). Remission of T2D was greater in the PJB-GC group (90.2 vs. 57.2%;  $p < 0.001$ ).

**Conclusions** In this study, PJB-GC was superior to GC in weight loss and T2D remission at 1 and 2 years after surgery. Adding PJB to GC increased the effect of weight loss and diabetic control.

**Keywords** Gastric clip · Morbid obesity · Bariatric surgery · Metabolic surgery · T2D remission · Jejunal bypass

Obesity and associated type 2 diabetes mellitus (T2D) are serious health issues worldwide now [1, 2]. Bariatric surgery,

a highly effective and long lasting treatment for morbid obesity and T2D, has been widely adopted with a rapid surge in case numbers recently [3]. However, the types of operation are still evolving [4]. Gastric clip was invented and introduced as a novel bariatric procedure for treating obesity and related comorbidity [5]. Similar to gastric banding, GC was a pure restrictive procedure. However, it seems not likely to have an overt effect of gastrointestinal hormone modulation which was found to be important in T2D treatment [6, 7]. Recently, proximal jejunal bypass (PJB) or side-to-side jejunioileal bypass with sleeve gastrectomy (SG) has been introduced as a novel metabolic surgery to treat patients with obesity and T2D, and the results were encouraging [8–11]. The main advantage of PJB was to reduce the technical difficulty of gastric bypass and avoid the risk of malnutrition from duodenal exclusion. Therefore, in order to improve the remission rate of T2D, we advocated adding PJB to the GC (PJB-GC) to treat the patients with T2D. The aim of this study was to investigate the effect of adding PJB to GC through a comparison of 1-year results between PJB-GC and GC patients.

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## Methods

The study was conducted in the Department of Bariatric and Metabolic Surgery of Jen-Ai Hospital, Taichung, Taiwan. Prior approval for the performance of the study was obtained from the ethics committee of the hospital. This was a matched case-control study. A total of 41 T2D patients who received PJB-GC surgery from 2013 to 2015 were retrospectively collected. The inclusion criteria were morbidly obese patients ( $\text{BMI} \geq 32 \text{ kg/m}^2$ ) [12], whom had been well informed about this procedure and agreed to receive it. Patients with previous bariatric operations were excluded. A matched group of 33 GC patients with similar age, sex, and BMI from our historical database was collected as a control group. Patients were followed for 24 months. Operative time, estimated blood loss, length of hospital stay, and postoperative complications were assessed in both groups. Changes in total body weight loss (TWL), body mass index (BMI), and T2D remission ( $\text{HbA1c} < 6.0\%$ ) were compared between the group. Symptoms of gastroesophageal reflux disease (GERD) were specifically evaluated before and after surgery.

## Surgical Technique

GC was performed by creating a transverse gastric partition using a metallic clip (Fig. 1). The clip was made of stainless steel, 9 cm in length, 0.9 cm in width, and 0.8 cm in height. The clip was applied to the upper fundus through retrogastric dissection using the Pars Flaccida method (Fig. 2a). After applied to the upper fundus of the stomach, the open end of clip was fixed with a piece of Marlex mesh, then 4 sero-serous sutures were applied to prevent the sliding or migration (Fig. 2b). After application of the GC, the ligament of Treitz was identified and proximal jejunum was divided at 20 cm distally with an Endo GIA stapler using 45-mm white cartridge (Covidien™). Distally, the jejunum was measured to a distance of 300 cm and was anastomosed to the proximal biliopancreatic jejunal limb with an Endo GIA stapler using 60-mm white cartridge (Covidien™) and the enterotomy wound was closed with intra-corporeal suture technique. The mesentery defect was closed with 3–0 silk sutures (Fig. 3).

**Fig. 1** The clip is made of stainless steel with 9 cm in length, 0.9 cm in width, and 0.8 cm in height. There is an enlarged site, 1.2 cm in diameter in its central part which allows the meal passage



## Results

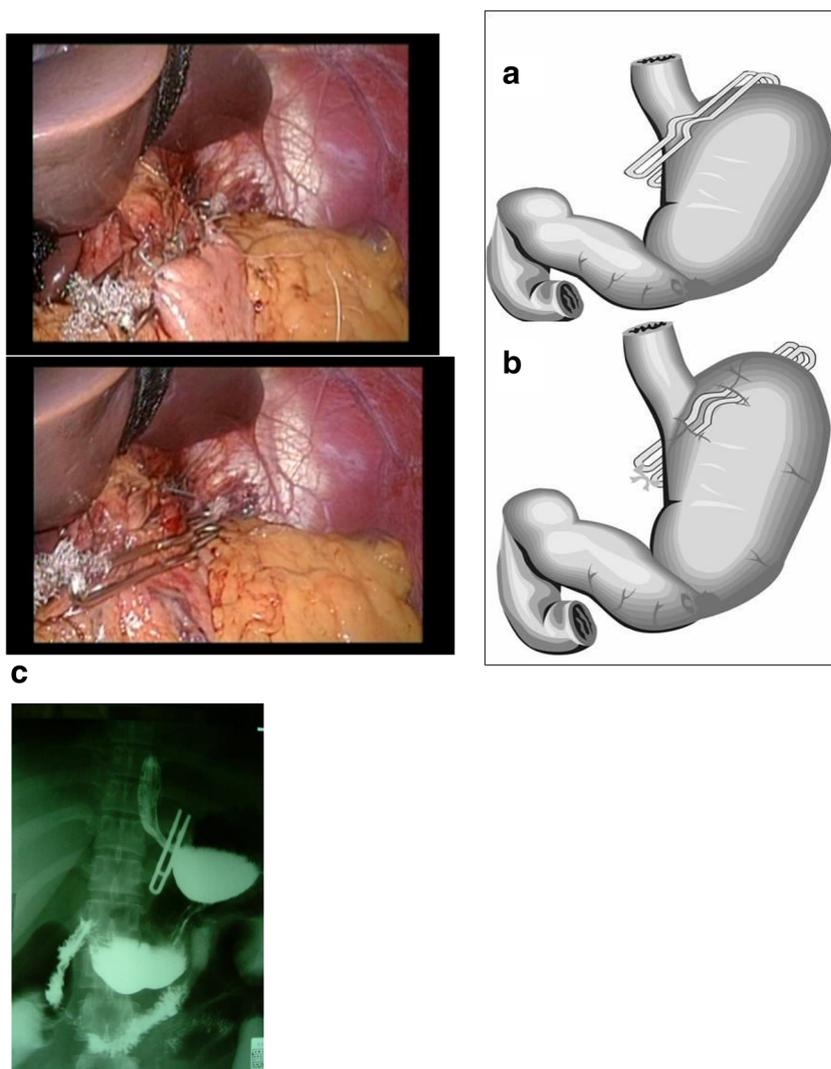
No preoperative deviation was noted in clinical characteristics between two groups (Table 1). The mean preoperative BMI of patients in PJB-GC and GC was similar ( $43.9 \pm 7.4$  and  $44.0 \pm 7.0 \text{ kg/m}^2$  respectively  $p = 0.923$ ).

All the procedures were completed by laparoscopy. The mean operation time and hospital stay were longer in PJB-GC group ( $62.2 \pm 23.3$  vs.  $39.1 \pm 22.7$  min,  $p < 0.001$ ;  $2.2 \pm 1.6$  vs.  $1.4 \pm 1.1$  days,  $p < 0.001$ ) (Table 2). The mean blood loss in PJB-GC and GC was similar ( $23.6 \pm 26.6$  and  $22.1 \pm 16.9$  ml respectively,  $p = 0.145$ ). A total of four patients with minor complications were identified, three (7.3%) in the PJB-GC, and one (3.3%) in the GC group. Three patients in PJB-GC group had tarry-bloody stool in amount that transfusion of packed red blood cells was required. One patient in the GC group developed left-side atelectasis and pleurisy which resolved after conservative management. No patient developed major complications in this study.

At 12 months after surgery, both groups had significant weight loss and resolution of obesity-associated co-morbidities including glycemic control, triglyceride, uric acid, high density lipoprotein (HDL), and low density lipoprotein (LDL) (Table 3). However, PJB-GC had higher %TWL than GC ( $31.3 \pm 14.8$  vs.  $23.5 \pm 10.4\%$ ,  $p = 0.011$ ) and achieved lower BMI ( $32.5 \pm 6.2$  vs.  $37.0 \pm 5.9$ ,  $p = 0.002$ ). Remission of T2D is significantly better in the PJB-GC group where only 4 patients (9.8%) had  $\text{HbA1c} > 6.0\%$  vs. 14 patients (42.4%) in the GC group. PJB-GC group showed a better decline of  $\text{HbA1c}$  (from 7.5 to 5.7% in average vs. 7.4 to 6.2% in GC group,  $p < 0.05$ ). Changes of the mean  $\text{HbA1c}$  of both groups is shown in Fig. 4.

At longer follow-up, median BMI reduction for GC group was 6.2, 9.4, and 9.8  $\text{kg/m}^2$  at 6, 12, and 24 months, and for PJB-GC group was 7.8, 12.4, and 12.9  $\text{kg/m}^2$ , respectively (Fig. 5) No significant nutritional deficiencies were detected in both groups. Hemoglobin levels in both groups showed stationary compared to the preoperative data. Resolution of GERD symptoms was up to 90% in both groups without de novo GERD detection.

**Fig. 2** The clip was applied to the upper fundus and fixed with a piece of Marlex mesh (a) and 4 stitches of sero-serous sutures (b). Postoperative X-ray image (c)



## Discussion

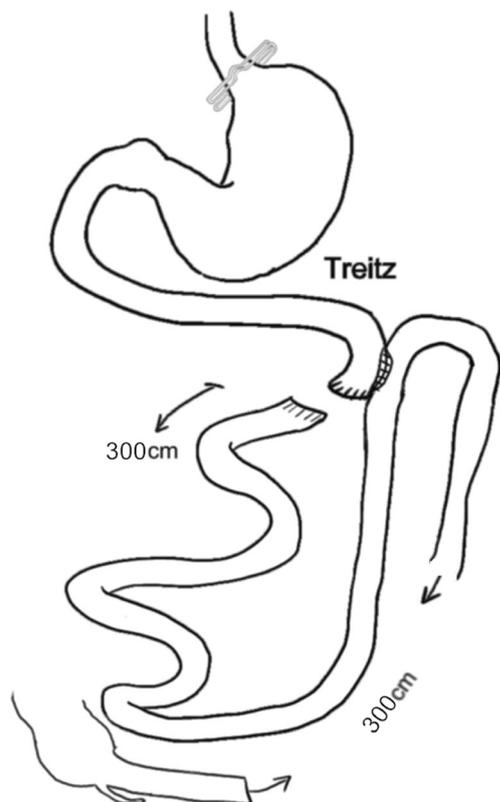
This study confirmed that GC is a low-risk bariatric (<1% major complication rate) and effective bariatric/metabolic procedure with a 23.5% TWL and a decrease of HbA1c up to 1.3% at 1 year. However, by adding a PJB to GC, the PJB-GC can increase 31% of weight loss up to TWL of 31.3%. Furthermore, PJB-GC can improve the glycemic control as well. PJB-GC had a higher complete T2D remission (HbA1C < 6.0%) than GC at 12-month follow-up (90 vs. 53%;  $p < 0.05$ ). Therefore, PJB-GC may increase the metabolic surgery efficacy of GC by adding a PJB to GC.

Comparing to gastric bypass or duodenojejunal bypass, PJB is a technical easier procedure with higher reproducibility and reversibility. In this study, adding PJB to GC increase the operation time around 20 min but without any major complication in both groups. Alamo et al. published the first report of PJB with SG in 2012 of 49 patients with T2D and BMI below 35 kg/m<sup>2</sup>. They reported a EWL of 76.1 and 81.6% of T2D

remission, with no mortality and nutritional deficiencies [8]. In this study, the weight loss and glycemic control of PJB plus GC was compatible to this report and others [8–11]. We also experienced very rare nutritional deficiencies.

The reason for adding a PJB on restrictive gastric procedure is coming from the theory suggested by Rubino that proximal gut exclusion improved the diabetes control [6, 7]. Because gastric bypass or duodenojejunal bypass carried a significant technique difficulty and complication, PJB or side-to-side jejunioleal bypass plus SG was proposed as a technical ease of the procedure [8–11]. This study confirmed that the efficacy of adding PJB to a restrictive gastric procedure improved the weight loss and T2D remission. To the best of our knowledge, this is the first study to demonstrate the efficacy of PJB in a matched case comparison study [8–11].

The mechanism of PJB for the improvement of glycemic control in T2D patients is interesting. Current knowledge of the roles played by intestinal hormones in obesity and T2D explained part of the mechanism. By early exposure of the



**Fig. 3** The proximal jejunal bypass was created by a side-to-side anastomosis between the post-Treitz jejunum, after a division of distal bowel, and the proximal ileum. The Peterson foramen was closed thereafter

**Table 1** Preoperative clinical characteristics of subjects who underwent bariatric surgeries with proximal jejunal bypass with gastric clip (PJB + GC) or only gastric clip (GC) during 2012–2015 (n = 74)

	PJB-GC (n = 41)	GC (n = 33)	p value
Age (mean ± SD)	34.7 ± 9.3	32.1 ± 10.4	0.125
Sex (F/M)	24/17	19/14	0.242
BW (kg)	122.6 ± 27.2	122.1 ± 24.1	0.944
BMI (kg/m <sup>2</sup> )	43.9 ± 7.4	44.0 ± 7.0	0.923
FPG (mg/dl)	127.5 ± 59.3	131.8 ± 53.6	0.456
HbA1c (%)	7.1 ± 1.2	7.5 ± 1.7	0.262
Cholesterol (mg/dl)	187.1 ± 35.6	188.5 ± 37.1	0.872
Triglycerides (mg/dl)	190.0 ± 123.7	187.9 ± 72.3	0.993
HDL (mg/dl)	44.1 ± 9.0	44.1 ± 9.9	0.978
LDL (mg/dl)	118.9 ± 31.2	122.5 ± 31.5	0.646
Uric acid (mg/dL)	6.9 ± 1.8	6.1 ± 1.3	0.267
C-peptide (ng/ml)	5.7 ± 3.6	5.4 ± 3.0	0.686
Duration of T2D (year)	2.5 ± 2.9	2.4 ± 3.0	0.905

Data are presented as mean ± SD

PJB + GC proximal jejunal bypass with gastric clip, GC only gastric clip, BW: body weight, BMI body mass index, FPG fasting plasma glucose, HbA1c hemoglobin A1c, HDL high density lipoprotein, LDL low-density lipoprotein

\*p < 0.05 compared with preoperative data

**Table 2** Operative parameters and complications between PJB-GC and GC

	PJB-GC (n = 41)	GC (n = 33)	p value
Operative time (min.)	62.6 ± 23.3	39.1 ± 22.7	< 0.001*
Intra-Op blood loss (ml)	23.6 ± 26.6	22.1 ± 16.9	0.145
Postop hospital stay (day)	2.2 ± 1.6	1.4 ± 1.1	< 0.001*
Surgical complications % (n)	7.3% (3)	3.3% (1)	0.430
Minor % (n)	7.3% (3) <sup>a</sup>	3.3% (1) <sup>b</sup>	
Major % (n)	0%	0%	

\*p < 0.005

<sup>a</sup> Gastrointestinal bleeding required blood transfusion in 3 patients;

<sup>b</sup> Atelectasis with pleurisy

food to ileum, there is a rapid increase of GLP-1 and Peptide YY, enhancing insulin secretion and improving T2D control [13–15]. However, this study found that patients in the PJB-GC group had a significant lower C-peptide level than patients in the GC group which also implicated a lower insulin resistance state in PJB-GC. Further studies are indicated to elucidate the mechanism of PJB and develop possible new treatments for T2D.

Although RYGB had a durable effect on weight reduction and glycemic control than other restrictive-type procedures, RYGB had a higher incidence of surgical risk and long-term complications including anemia, marginal ulcers, dumping syndrome, and nutritional deficiencies that require lifelong

**Table 3** The results of weight loss and laboratory data 1 year after surgery

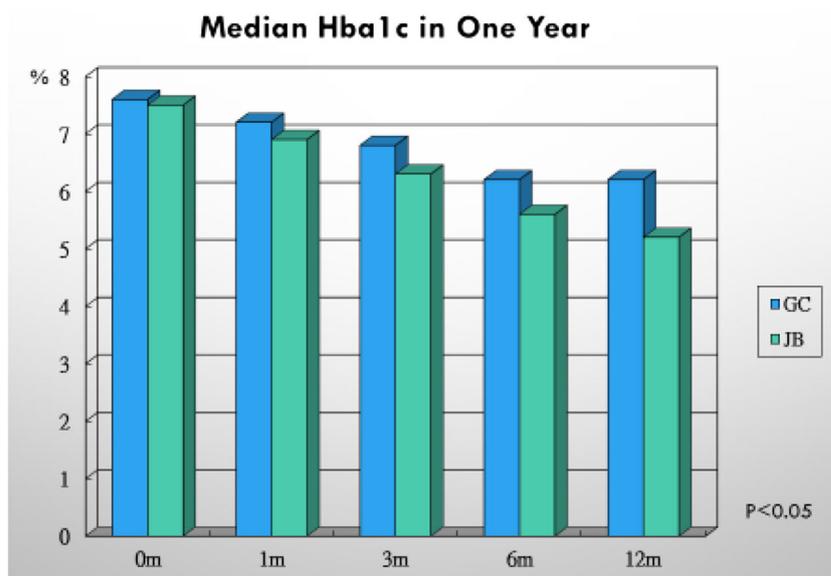
	PJB-GC (n = 41)	GC (n = 33)	p value
BW (kg)	84.1 ± 17.1*	93.4 ± 18.7*	0.029
BMI (kg/m <sup>2</sup> )	32.5 ± 6.2*	37.0 ± 5.9*	0.002
TWL (%)	31.3 ± 14.8*	23.5 ± 10.4*	0.011
HbA1c (%)	5.5 ± 0.3*	6.2 ± 0.8*	< 0.001
HbA1c > 6.0% (n)(%)	37(90.2%)*	19(57.6%)*	< 0.001
FPG (mg/dl)	90.4 ± 11.1*	104.8 ± 29.6*	0.031
C-peptide (ng/ml)	3.5 ± 1.4*	5.8 ± 2.3	0.042
Triglycerides (mg/dl)	108.0 ± 47.0*	133.7 ± 62.9*	0.118
Cholesterol (mg/dl)	174.5 ± 36.5*	180.5 ± 24.1*	0.322
Uric acid (mg/dL)	6.6 ± 1.5*	6.7 ± 1.6*	0.918
HDL	46.1 ± 10.6	39.4 ± 11.9	0.146
LDL (mg/dl)	105.2 ± 27.7	111.2 ± 19.2*	0.587

Data are presented as mean ± SD

PJB-GC proximal jejunal bypass with gastric clip, GC only gastric clip, BW body weight; BMI body mass index, FPG fasting plasma glucose, HbA1c hemoglobin A1c, HDL high density lipoprotein, LDL low-density lipoprotein

\*p < 0.05 compared with preoperative data

**Fig. 4** Proximal jejunal bypass resulted in better HbA1c reduction in 1 year



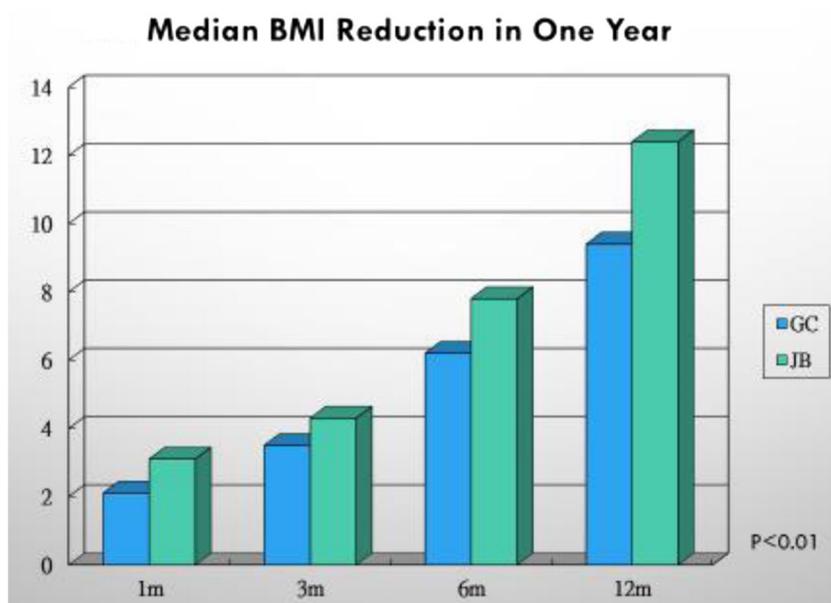
supplements and surveillance. In addition, the risk of remnant gastric cancer from excluded stomach was a great concern in areas with high incidence of gastric cancer [16–19]. With the understanding of the mechanism of bariatric surgery produces weight loss and control of metabolic syndrome, new surgeries and innovations are developed that can achieve similar results but devoid of long-term complications and less difficult to perform. PJB plus SG was one of the new innovations but still required to cut the stomach and had the complication of leakage and de novo GERD [20, 21]. PJB-GC may provide another option of less invasive, less difficult to perform, and reversible bariatric/metabolic procedure.

There are some possible disadvantages of PJB-GC. Firstly, GC is now available and licensed only in Taiwan. This limits

the application of GC in other parts of the world. In a sense, the clip was similar to the bands applied to the proximal fundus and restricting the inlet of meals into stomach. Although this clip is nonadjustable, the smallness of the size of the clip and the lighter tension exerted to the stomach showed some benefits than a larger volume of the band. Secondly, there was no long-term data of PJB-GC available. However, mid-term results in Taiwan with more than 3000 cases showed that it is an acceptable bariatric procedure with very low complication. The occurrence of migration or slippage of the GC was less than 1% after 5 years of follow-up.

Some limitations of the study should be mentioned. First, this is a retrospective study although it is based on a prospective database and all patients were treated by the same surgical

**Fig. 5** Proximal jejunal bypass resulted in more BMI reduction in 1 year



team. Second, the case number is small and follow-up is limited. Without long-term follow-up, we cannot comment on the safety of this procedure based on the presence of gastric foreign body and the isolated jejunal limb. Third, we did not measure the change of gut hormone and glucose metabolism. These limitations require further well-designed randomized trials with elaborated function studies to elucidate the underlying mechanism of PJB-GC.

In conclusion, by adding a jejunoileal bypass on GC, PJB-GC may combine the principles and advantages of gastric restriction with gut hormone manipulation, therefore to increase the weight loss and glycemic control. This procedure may be recommended for the treatment option for patient with obesity and not well-controlled T2D, seeking for a less invasive but effective bariatric/metabolic procedure.

### Compliance with Ethical Standards

**Conflict of Interest** Author 1 is the inventor and owner of gastric clip. The other authors have no conflicts of interest to declare.

**Ethical Approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

**Informed Consent** This article does not contain any studies with human participants or animal performed by any of the authors. For this type of study, formal consent is not required. Informed consent does not apply to the submission.

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