ORIGINAL ARTICLE

Weight Loss and Improvement of Obesity-related Illness Following Laparoscopic Adjustable Gastric Banding Procedure for Morbidly Obese Patients in Taiwan

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Background/Purpose: Laparoscopic adjustable gastric banding (LAGB) is a newly developed minimally invasive surgical procedure for the treatment of morbid obesity. This study was conducted to evaluate body weight loss, surgical complications, and comorbidities after LAGB surgery.

Methods: Ninety-one morbidly obese patients (mean age, 31.2 years; mean preoperative weight, 120.8 kg) underwent LAGB in a private Taiwan hospital setting within a comprehensive multidisciplinary bariatric program. Patients were followed up to 36 months. Comorbidities were assessed in 55 patients who completed more than 12 months of follow-up by comparing each comorbid condition before surgery and during follow-up.

Results: All procedures were performed laparoscopically with no conversion. Mean operation time was 88.7 ± 32.9 minutes. There were no intraoperative or major postoperative complications. Minor complication of stoma stenosis occurred in three (3.3%) patients. At 36 months after surgery, mean body mass index had decreased from 42.7 to 33.9 kg/m^2, and mean percentage of excess weight loss was 44.8%. Late complications were as follows: intractable vomiting requiring band removal in one (1.1%) patient, tubing problems requiring revision surgery in four (4.3%), and stoma obstruction in two (2.1%). There was no mortality. Resolution or improvement of comorbidities was significant for hyperglycemia and diabetes-related index, dyslipidemia, abnormal liver function, hyperuricemia, sleep apnea, and arthralgia, but not for hypertension.

Conclusion: LAGB provides good weight loss and significant reduction in comorbidities with few minor complications. [*J Formos Med Assoc* 2006;105(11):887–894]

Key Words: gastric banding, morbidly obese, obese-related illness

Obesity is a pan-endemic health problem in both developed and developing countries and is associated with considerable increase in morbidity and mortality.[1–3] For the severely obese patient, nonsurgical methods (including diet, exercise, and behavioral modification) are usually ineffective and rarely result in sustained weight loss.[4,5] Surgery is the only treatment that has been proven to consistently achieve long-term reduction of excess weight in patients with severe clinical obesity.[4–6]

Laparoscopic adjustable gastric banding (LAGB) is a minimally invasive surgical procedure for the treatment of morbid obesity. Kuzmak developed the adjustable silicone gastric band, which was implanted via laparotomy.[7] In 1993, a modified laparoscopic device, the Lap-Band (Bioenterics

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Corp., Carpinteria, CA, USA) was first implanted (Figure 1).[8] Initial trials in Europe and worldwide use were expanded later.[9–13] In June 2001, the US Food and Drug Administration approved the Lap-Band System in the United States. Currently, LAGB is the most commonly performed bariatric surgery worldwide.[6]

This report describes our series of 91 consecutive Taiwanese patients, making this the first clinical trial in Taiwan.

Materials and Methods

A comprehensive, multidiscipliniary, bariatric management program was in place for the preoperative preparation and postoperative management of patients. The program included support groups and ancillary personnel to provide nutritional, exercise and psychologic care. Nurse specialists for medical and psychiatric management were part of the team. Inclusion/exclusion criteria followed the standard National Institutes of Health guidelines: >18 years old, body mass index (BMI) >35 kg/m^2 with important comorbidities, no alcohol abuse and concurrent psychiatric illness. The ethics committee of En-Chu-Kong Hospital and the National Department of Health of Taiwan approved this trial.

Patients were placed supine in the lithotomy position, then to the reverse Trendelenburg position, and an orogastric tube was inserted. A five-trocar technique was used (Figure 2). Pneumoperitoneum was achieved with a Veress-type needle introduced at the supraumbilical area and maintained at 15 mmHg. All bands were placed using the pars flaccid technique.[5] Briefly, the

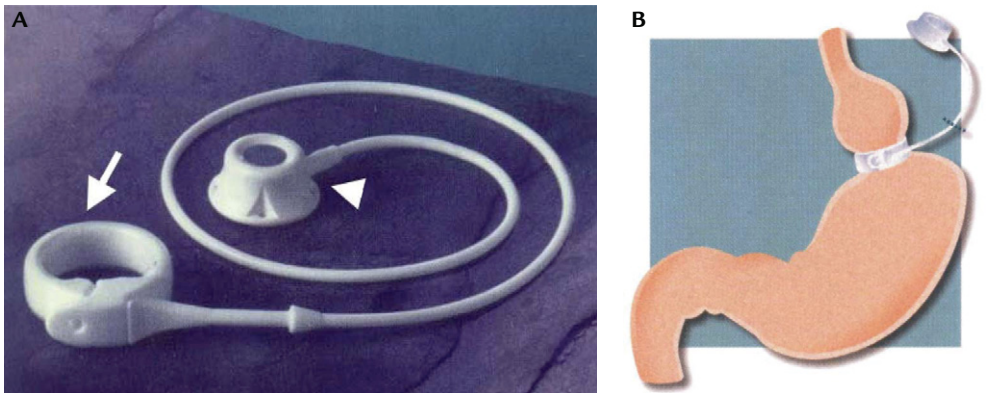

Figure 1. (A) The Lap-Band system with inflatable inner cuff (arrow) that connects by silicon tubing to the implanted subcutaneous injection port (arrowhead). (B) Drawing shows placement of the band around the upper portion of the stomach, creating a small upper pouch with stoma to the remainder of the stomach.

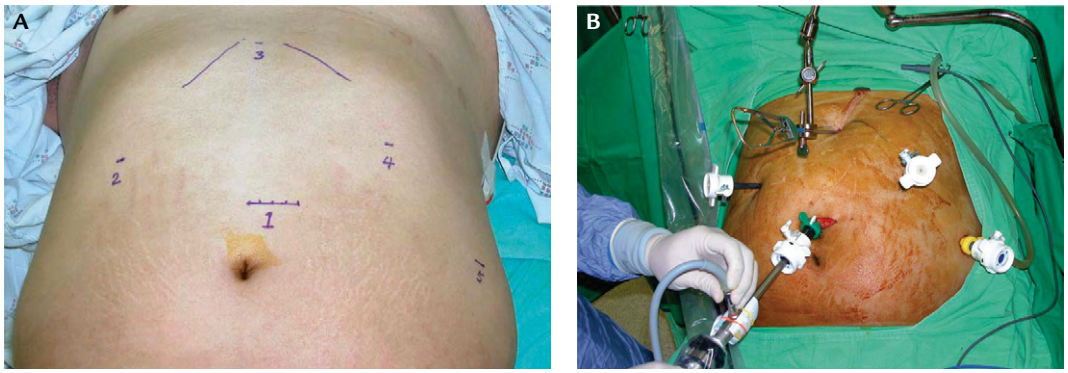

Figure 2. (A) Trocar placement. Trocar 1: a 15-mm port about 4 cm above the umbilicus, from the midline to across the left rectus muscle, viewing telescope and injection port site. Trocars 2 and 4 are placed in the bilateral subcostal areas with 5 mm for bilateral working ports. Trocar 3: a 5-mm port placed subxyphoidal, liver retractor. Trocar 5: a 10-mm port at the left anterior axillary line, gastric grasper. (B) Intraoperative picture.

dissection began at the Angle of His. A very small opening was created in the avascular phrenogastric ligament, close to the gastric wall at the Angle of His. The dissection was then moved to the lesser curvature side. The pars flaccid (gastrohepatic ligaments) was incised and the right crus of the diaphragm was identified. Blunt dissection was performed to create a passage between the diaphragmatic pillars and the posterior aspect of the gastroesophageal junction. The band was then placed around the cardia of the stomach and sutured in place with gastric to gastric sutures. The band tubing was brought outside the abdomen and connected to the access port. The port was fixed to the left rectus fascia.

The surgeon, with the support of the nurse coordinator and nutritionist, provided postoperative follow-up. After discharge, patients were instructed to follow a clear to full liquid diet for the first 48 hours, followed by a soft diet for the first week. Small amounts of solid food were introduced starting in the second week, as tolerated. Patients returned to the office a week after surgery for wound check. They were then scheduled to return between 1 and 2 months later. For adjustment of the LAGB, saline was not added to the band reservoir until at least 4 weeks had elapsed after surgery. We routinely performed adjustments in the clinic. Computed tomography (CT)-guided adjustment was only indicated occasionally. The first adjustment usually involved the addition of 1 mL of sterile saline. The second adjustment involved the addition of 0.5 mL when patients failed to lose weight but had sustained satiety between meals.

Prior to surgery, all patients underwent a thorough laboratory work-up including metabolic profile and complete blood count with indices. For the purpose of comorbidity assessment, patients ($n = 56$) who had completed at least 12 months of follow-up were included. Obesity-related illness status was assessed by comparing each comorbidity before surgery and 1 year later. Criteria used to define metabolic comorbidities are listed in Table 1.

Descriptive data are expressed as mean ± standard deviation. Group characteristics were compared by the paired t test and differences between proportions were tested by the χ^2 test. Statistical analysis was performed using SPSS version 8.0 (SPSS Inc., Chicago, IL, USA) for Windows. Statistical significance was inferred by a two-tailed p value of less than 0.05.

Results

Between May 2002 and May 2005, LAGB was performed on 91 consecutive patients. There were 47 men and 44 women, with a mean age of 31.2 years (range, 18–56 years) and mean BMI of 42.7 kg/m^2 (range, 35.0–62.7 kg/m^2). Of the 91 patients, 80 suffered from obesity-related comorbidities such as hypertension, diabetes, hyperlipidemia, arthritis, asthma, sleep apnea and venous stasis (Table 2). The mean operating time was 88.7 ± 32.9 minutes. The mean operating time for the first 10 cases was 107 minutes, and it was 83 minutes for the last 10 cases. There was neither conversion nor major complication in this series.

Table 1. Definition criteria of obesity-related comorbidities

Comorbidity	Definition
Hypertension	Blood pressure > 140/90 mmHg or previous diagnosis of hypertension on pharmacologic treatment
Hyperglycemia	Fasting glycemia > 109 mg/dL or previous diagnosis of diabetes on pharmacologic treatment
Hyperlipidemia	Fasting triglycerides > 200 mg/dL and/or cholesterol > 200 mg/dL
Hyperuricemia	Fasting uric acid > 8.0 mg/dL in men and > 6.5 mg/dL in women
Abnormal liver function	Aspartate aminotransferase > 40 IU/dL and/or alanine aminotransferase > 40 IU/dL

Table 2. Preoperative and follow-up clinical data of patients who underwent laparoscopic adjustable gastric banding

	Preoperatively	Postoperatively			
		3 mo	6 mo	1 yr	2 yr
Weight (kg)	120.8	110.2	109.9	101.3	97.4
BMI (kg/m^2)	42.7	38.1	37.4	35.3	34.9
Hypertension (%)	47.3	63.8	46.9	48.1	40.1
Hyperglycemia (%)	17.6	9.5	4.6	0	0
Hyperlipidemia (%)	64.8	41.3	34.1	34.2	30.8
Hyperuricemia (%)	60.4	28.6	20.9	8.8	0
Abnormal LF (%)	20.9	8.8	1.1	2.2	0
Arthritis (%)	4.4	12.6	5.6	0	0
Asthma (%)	3.3	1.1	0	0	0
Sleep apnea (%)	8.8	1.6	0	0	0
Venous stasis (%)	3.3	1.6	0	0	0
Satisfaction (%)					
Excellent		63	60	50	43
Good		24	28	35	37
Acceptable		10	8	9	14
Bad		2	4	6	6
Poor		1	0	0	0

BMI = body mass index; LF = liver function test.

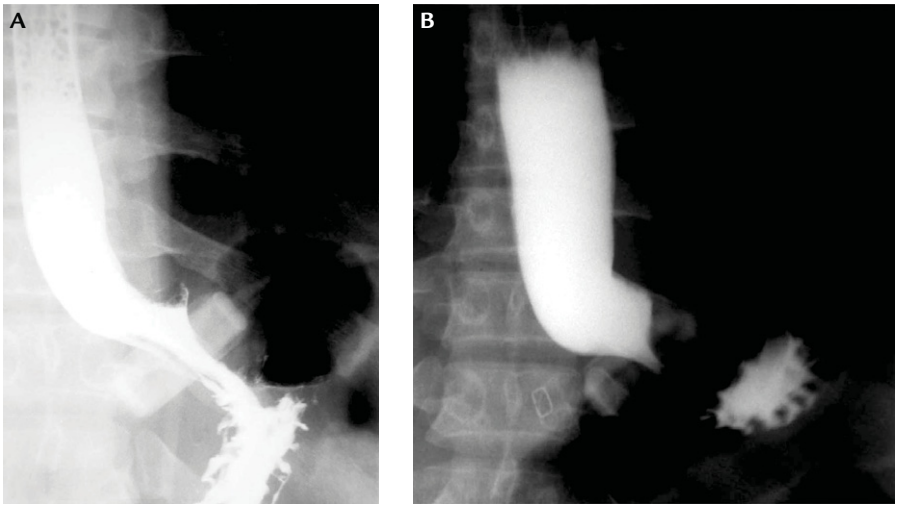

Figure 3. (A) Upper gastrointestinal radiograph after placement of the laparoscopic adjustable gastric band (LAGB) with normal stoma. (B) Upper gastrointestinal radiograph of stoma stenosis after LAGB placement.

Minor complications occurred in three (3.3%) patients, all were transient stoma obstruction and subsided after conservative treatment (Figure 3). Hospital stay averaged 3.2 days (range, 2–10 days).

Patient follow-up

Of the 91 patients, the follow-up rate was 100%. Late complications occurred in seven (7.7%) patients. One (1.1%) had her band removed at 3 months postoperatively due to intractable vomiting. Four (4.4%) received port revision surgery for tubing problems. Another patient had acute food obstruction and required admission for treatment. No band was removed in these patients. The majority of patients received two to five band adjustments during the first year after surgery. Almost

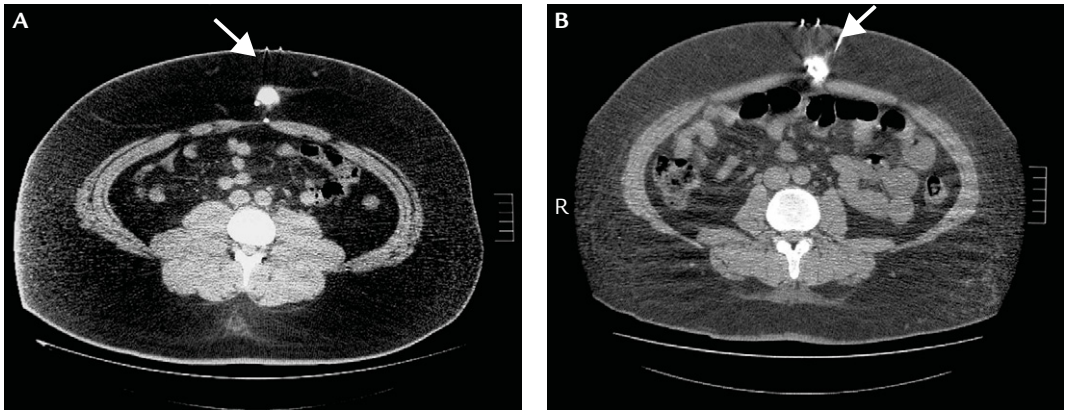

Figure 4. Abdominal computed tomography (CT) shows: (A) subcutaneous injection port floating in the massive subcutaneous fat (arrow); and (B) tilting injection port (arrow). Both cases required CT-guided injection for adjustment.

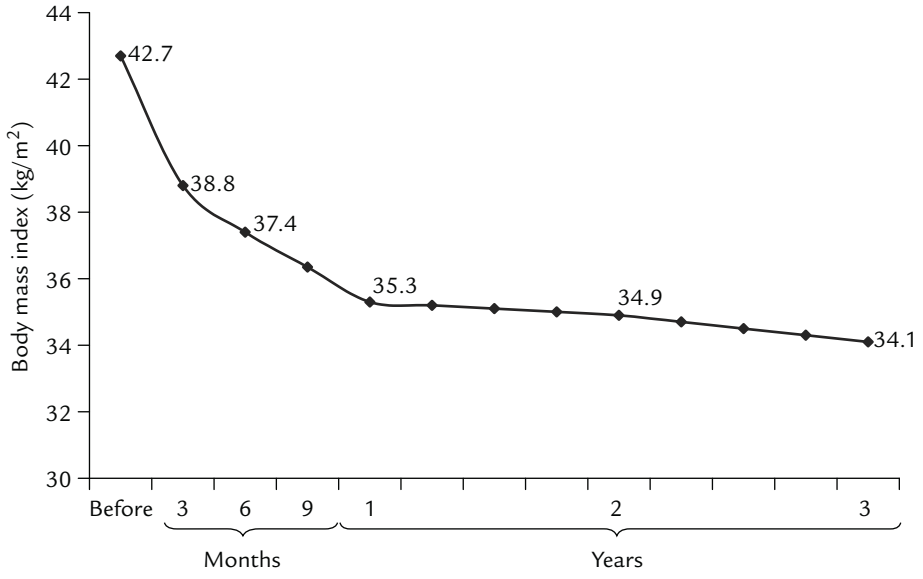

Figure 5. Change in body mass index pre- and post-laparoscopic adjustable gastric banding.

all patients required their first band adjustment within the first 3 months after surgery. Seven patients required CT-guided adjustment due to malposition of the port or massive subcutaneous fat (Figure 4).

Weight loss and comorbidity assessment

After a median follow-up of 30 months, the group had a significant reduction in BMI (Figure 5). Mean preoperative BMI was 42.7 kg/m^2 and had decreased to 33.9 kg/m^2 3 years after LAGB. Mean body weight decreased from 120.8 kg to 94.7 kg. Mean BMI and (reduction of excess BMI as compared to BMI = 25 kg/m^2) were 38.8 (22.1%), 37.4 (29.7%), 35.1 (41.7%), 34.9 (44.0%) and 33.9 (44.8%) at 3, 6, 12, 24 and 36 months, respectively. At 2 years after LAGB, all obesity-related comorbidities had been eliminated significantly except for hypertension (Table 2). Table 3 shows the changes in various clinical variables before and 1 year after LAGB. Recovery from diabetes, hypertriglyceridemia, abnormal liver function and hyperglycemia were more favorable, whereas recovery from hypertension did not differ. The white blood cell count also decreased significantly after surgery. There was no detectable difference in calcium metabolism, hemoglobin, and albumin levels pre- and postoperatively.

Table 3. Laboratory data before and 1 year after laparoscopic adjustable gastric banding

	Preoperatively	1 yr postoperatively	*p*
BMI (kg/m^2)	42.7 ± 6.0	35.3 ± 6.6	< 0.001*
SBP (mmHg)	136.9 ± 22.7	140.8 ± 22.4	0.870
DBP (mmHg)	85.5 ± 13.4	85.7 ± 18.5	0.566
Glucose (mg/dL)	105.2 ± 36.2	84.6 ± 8.1	0.040*
TC (mmol/L)	198.0 ± 35.9	189.8 ± 31.3	0.017*
HDL-C (mmol/dL)	44.02 ± 13.1	50.6 ± 12.7	0.018*
TG (mg/dL)	188.5 ± 148.6	101.4 ± 45.9	0.008*
Uric acid (mg/dL)	7.69 ± 1.69	6.66 ± 1.44	< 0.001*
AST (IU/L)	33.5 ± 23.4	23.4 ± 9.6	0.004*
ALT (IU/L)	51.5 ± 44.7	25.2 ± 16.2	< 0.001*
RGT (IU/L)	46.7 ± 32.9	24.9 ± 11.1	0.017*
Albumin (g/dL)	4.75 ± 0.31	4.36 ± 0.26	0.514
T-protein (g/dL)	7.4 ± 1.3	7.4 ± 0.4	0.219
ALP (IU/L)	75.7 ± 27.5	55.1 ± 47.7	0.393
Ca (mg/dL)	8.9 ± 0.4	9.0 ± 0.4	0.858
WBC (10^3/μL)	8.70 ± 2.30	6.87 ± 1.53	< 0.001*
Hemoglobin (g/dL)	14.1 ± 1.67	14.1 ± 1.8	0.383
MCV	85.6 ± 6.9	86.8 ± 6.8	0.411
Insulin (pmol/L)	22.5 ± 20.5	8.02 ± 4.44	0.007*
C-peptide (mmol/L)	3.91 ± 2.76	2.28 ± 0.82	0.020*
HbA1C (IU/L)	6.2 ± 1.2	5.3 ± 0.4	0.002*

**p < 0.05. BMI = body mass index; SBP = systolic blood pressure; DBP = diastolic blood pressure; TC = total cholesterol; HDL-C; high-density lipoprotein cholesterol; TG = triglycerides; AST = aspartate aminotransferase; ALT = alanine aminotransferase; RGT = gamma-glutamyl transpeptidase; ALP = alkaline phosphatase; WBC = white blood cell; MCV = mean corpuscular volume; HbA1C = glycosylated hemoglobin.*

Discussion

This is the first prospective study of LAGB in Taiwan and Asia. The present study confirmed that LAGB is a safe and effective minimally invasive bariatric surgical procedure suitable for use in Asians. In our experience, LAGB could be performed with a 0% major complication rate and 3.3% minor complication rate, which are compatible with other reports.[9–14] The only early complication in this study was postoperative transient esophageal stenosis due to the band being too small for the super-obese patient. This complication can be avoided either by removal of the thick fat pad over the His angle or by using a larger band. All the three incidences of this complication in our study occurred before the introduction of a larger LAGB (the Vanguard Lap-Band system). This complication was avoided thereafter. Before the maturation of this technique, the late complication rate was reported to be up to 30%, including slippage, band erosion and tube failure.[8] In this study, no slippage, band erosion or port infection was observed up to 2 years postoperatively, and only one band (1.1%) has been removed up till now.

Results of LAGB in the West have shown that good weight loss and significant reduction in obesity-related illness can be achieved. International experience with the LAGB in Europe and Australia shows a reduction in BMI of 9–13 kg/m^2 from baseline within 2 years of placement.[9–14] Weight loss continues even up to 5 years after surgery and stabilizes up to 9 years of follow-up.[9–14] Data from the United States are controversial. An initial trial reported a mean BMI reduction of 8.7 over 3 years and 28% of the LAGB were removed because of complications.[15] However, with improvements in the techniques, some recent studies have reported similar data to the international experience.[16,17] The mean BMI reduction of 8.8

and late complication rate of 7.7% in this series are consistent with other studies.

Vertical banded gastroplasty (VBG) has been a popular bariatric operation in Taiwan for the past two decades, and results have shown the procedure to be effective over a 15-year follow-up.[18] After a report of the feasibility of laparoscopic VBG (LVBG),[19] we conducted a retrospective study comparing conventional VBG and LVBG, and concluded that LVBG was a better procedure because of less pain, shorter hospital stay and less wound complications.[20] However, VBG has some notorious long-term problems, such as regain of weight, vomiting, and impairment of gastrointestinal quality of life. In an analysis by van Germert et al, up to 56% of VBG patients needed revisional surgery over a period of 12 years.[21] In our 5-year follow-up, the revision rate was 9.2%, which is compatible with the reported results for conventional VBG.[22,23] LAGB, as an alternative restrictive procedure, has the benefits of simpler standardized procedure, fewer complications, and sustained weight loss due to its adjustability. Our study confirmed the safety of LAGB and sustained weight loss up to 3 years. The mean operation time is also shorter in LAGB than in LVBG, 88.3 minutes versus 173 minutes.[20] Although the results of weight reduction are similar between LAGB and LVBG, the 0% major complication rate and 3.3% minor complication rate of LAGB are lower than the 1% major complication rate and 5% minor complication rate of LVBG. The revision rate of LAGB is 1.3%, which is also lower than the 9.2% revision rate of LVBG.[22,23] Therefore, we strongly recommend LABG to replace LVBG in Taiwan.

Laparoscopic gastric bypass (LGB) is another common surgical procedure for morbidly obese patients and is the most commonly performed bariatric procedure in the United States.[5] Although LGB is more effective than LVBG, the complication rate is higher than that of LVBG. In our previous study, we found that LGB is much more difficult in terms of technique and carried more than three times the risk of major complications than VBG.[24] The learning curve for LGB is also much steeper than for LAGB. For example, the complication rate for a surgeon performing the first 19 cases was reported to be four times higher than performing the procedure after 20 cases.[25] In our series, the learning curve of LAGB is 10 cases, which is much lower than the 20 cases for LGB.[24] Although LGB results in better weight reduction than LVBG or LAGB, there is no difference in the resolution of obesity-related comorbidities.[26] Because bariatric surgery in Asia is still in its infancy, how laparoscopic bariatric surgery can be performed safely is the most important current issue. Therefore, LAGB is the recommended primary bariatric procedure for Asian people at present.[27]

The well-known inverse relationship between life expectancy and obesity is presumably, in large part, due to multiple cardiovascular and metabolic comorbidities. Our previous study disclosed a higher prevalence of metabolic abnormalities in obese Taiwanese patients referred for weight reduction surgery.[28] However, significant weight reduction 1 year after surgery markedly improved all aspects of the metabolic syndrome and resulted in a cure rate of over 95%.[26] This study confirmed the efficacy of bariatric surgery in the resolution of obesity-related comorbidities except hypertension. The possible explanation for this might be that the case number is small and the procedure is different compared to our previous report.[26] The follow-up is also short when compared to another study.[29] As hypertension has a more complicated mechanism than the other metabolic complications of obesity, ethnic differences may also be a possible explanation.[30,31]

Current indications for surgery in morbidly obese patients include BMI $> 40\ kg/m^2$ or $> 35\ kg/m^2$ if comorbidities are present. However, these criteria are based on data from Caucasians.[4] It has been amply demonstrated that Asians, in general, have a higher percent of body fat at a given BMI than Caucasians.[30,31] Morbidities and mortality among Asians occur at lower BMIs and smaller waist circumferences. The Asia-Pacific Bariatric Surgery Group has recently recommended bariatric surgery in Asian patients with BMI $> 37\ kg/m^2$ or $> 32\ kg/m^2$ when diabetes or two other obesity-related comorbidities are

present.[26] Cost-effectiveness studies of LAGB in the treatment of severely obese patients are needed.

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