Original Article

Short-term Outcome and Quality of Life of Endoscopically Placed Gastric Balloon and Laparoscopic Adjustable Gastric Band

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ABSTRACT

Background/Aim: A prospective longitudinal study was conducted to describe short-term outcome and quality of life (QOL) of endoscopically placed gastric balloon (EPGB) and laparoscopic adjustable gastric band (LAGB). **Materials and Methods:** Forty seven consecutive patients with body mass index (BMI) of 42 to 72 kg/m^2 were assigned to undergo EPGB (n=17) or LAGB (n=30) between May 2008 and May 2010. The main measured outcomes included weight loss, resolution or improvement of comorbidities, hospital stay, complications and QOL. **Results:** Patients were followed up for a mean of 14 months. Hospital stay was shorter for EPGB patients (one versus two days, P<0.001). Early postoperative complications recorded in EPGB were minor including nausea and vomiting. No late complications were recorded in the EPGB group. One case of band slippage was reported in the LAGB group and fixed laparoscopically. Percent excess weight loss was less in EPGB compared to LAGB (26.2% versus 44.0%, P=0.004). Resolution or improvement of comorbidities was comparable in both groups. The globally impaired preoperative quality of life showed considerable improvement in both groups. **Conclusion:** EPGB is a safe and effective approach in short-term management of morbid obesity. Weight loss, resolution of comorbidities and improvement in QOL were comparable between both groups.

Key Words: Gastric balloon, gastric band, morbid obesity, percent excess weight loss, quality of life

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In recent years, the prevalence of obesity has significantly increased worldwide. One-third of the adult population in the United States are obese and approximately five percent are morbidly obese.[1,2] In the UK the prevalence rates are comparable to the United States with 20% of adults being obese and one percent being morbidly obese.[3] The direct cost of the condition to the UK economy is seven billion pounds per annum and this is expected to rise to £45 billion in 2050.[4] Severe health complications associated with the condition include diabetes mellitus (DM), hyperlipidemia, metabolic syndrome, hypertension (HTN), ischemic heart disease (IHD), and obstructive sleep apnea (OSA).[2,5-7] Morbidly obese patients have reduced life expectancy with a 22% reduction which equates to a loss of approximately 12 years of life.[8] In addition, the disease presents a significant socio-economic burden, which is similar to that caused by poverty, smoking or alcohol abuse.[9]

While non-surgical management of obesity is favorable; several studies have failed to demonstrate maintenance of weight loss in the long term.[10-12] Research has shown that despite conservative modalities resulting in 4–8% weight loss, 90% of patients relapse within five years.[13-15] Indeed the maintenance of weight loss is crucial in attaining the beneficial effects of weight reduction which include: resolution or improvement of comorbidities, improvement in health-related quality of life (QOL) and increased survival.[6] Bariatric surgery is currently the only effective therapeutic alternative that provides enduring weight loss in the severely and morbidly obese.[16-20]

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Due to its efficiency in managing obesity and its related comorbid conditions; bariatric surgery has become widely acceptable. Various malabsorptive and restrictive procedures are available; however, identification of the optimal operation remains elusive.[21] A systematic review determined that the intragastric balloon is safe, and provides additional benefit to weight loss compared with conventional treatment.[22] These results were echoed in a previous meta-analysis that evaluated the efficiency of the endoscopic placed gastric balloon (EPGB) in contrast to conventional modalities.[23] In addition, several studies had compared the laparoscopic adjustable gastric band (LAGB) with either conventional treatment or other bariatric procedures.[24-26] A Cochrane review (2005) compared gastric bands, gastric sleeves, gastric bypass and biliopancreatic diversion. However, it did not include gastric balloons in the review.[21] They highlighted that the LAGB is effective, safe and cost-effective. Few studies have however compared EPGB with LAGB and assessed their impact on QOL.

In this study, the authors postulate that EPGB is a safe and effective approach for short-term treatment of morbid obesity, which could be utilized as a bridge for a more definitive bariatric procedure. The primary aim of this prospective longitudinal study was to describe the short-term outcomes of EPGB and LAGB on obesity and to evaluate their impact on QOL.

MATERIALS AND METHODS

Patient recruitment

Patients recruited into the study were initially referred by general practitioners (GPs), physicians and other surgeons. They were assessed subsequently in a bariatric outpatient clinic in a district general hospital. The surgical procedure was performed by a single experienced bariatric surgeon.

Inclusion criteria

Those included in the study were adults who fulfilled the National Institute for Health and Clinical Excellence (NICE) guidelines for bariatric surgery. These include: BMI ≥ 40 or BMI ≥35, with one or more obesity comorbidities (e.g. DM, OSA), and where appropriate non-surgical measures have been attempted but have failed to achieve or maintain adequate weight loss.[27]

Exclusion criteria

Patients were excluded from the study if they were unfit for anesthesia and surgery, or if they had previously undergone a bariatric procedure or major abdominal surgery. In addition, impaired mental status assessed by a clinical psychologist or those with comorbidities which could interfere with the EPGB procedure (e.g. peptic ulcer disease or large hiatus hernia) were eliminated. Finally, non-compliance during the preoperative assessment period also resulted in disqualification.

Preoperative assessment

Patients were assessed in a bariatric clinic where a detailed account of their medical, surgical, social, psychological, dietary, family and medication history was registered. Blood pressure, height, weight and BMI were recorded. Blood samples were collected and routine tests including lipid profile, fasting plasma glucose (FPG), glycosylated hemoglobin (Hb_{A1c}) and C-reactive protein (CRP) were performed.

Counseling including verbal and written education on obesity, associated comorbidities and bariatric surgery was made available, and a designated helpline provided further support. Patients were discouraged from conception for two years following the procedure. Patients were allowed three visits to demonstrate compliance and commitment to long-term follow-up. During the preoperative assessment period, a specialized dietician provided support and advice in order to assist patients in accomplishing the recommended target weight loss. Pharmacotherapy (Orlistat 120 mg three times a day) was additionally prescribed to aid further weight loss. Patients were encouraged to participate in slimming and gym club activities, which were accessible by referrals from primary care.

Following weight loss in the preoperative assessment period, patients were assigned to undergo either EPGB or LAGB depending on their most recent BMI. Patients with BMI ≥50 were assigned to undergo EPGB which would be followed by a definitive bariatric procedure once their BMI was less than 50. Counseling included verbal and written information. The type of procedure was ultimately left to the patient to decide. A written consent was sought from patients prior to the procedure.

Finally, those who fulfilled the above qualifying criteria were placed on a low calorie diet consisting of 800 calories per day (liver shrinking diet) for a total duration of two weeks preceding the operation. The latter was implemented to allow further weight loss, to shrink the liver preoperatively and improve subsequent recovery.

Surgical technique and postoperative management

Endoscopically placed gastric balloon (EPGB)

The procedure was carried out in theatre under propofol sedation administered by an anesthetist with an interest in bariatric surgery. The BioEnterics Intragastric Balloon (BIB®) System was used. Balloons were inflated using 600 ml of saline dyed with two ml of methylene blue. The procedure was performed under endoscopic direct vision. The balloon was placed in the fundus of the stomach. Regular anti-

emetics and proton pump inhibitor (PPI) were routinely prescribed. The authors recommended against the use of Non-steroidal Anti-Inflammatory Drugs (NSAID). Patients were reviewed in the bariatric outpatient clinic every 3 months to assess their progress including weight loss and any adverse side effects. Balloons were removed after 6 months and replaced if required. The main indication for replacing the balloon was super obese patients who lost weight with the first placement of balloon but required further weight loss to bring their BMI closer to 50.

Laparoscopic adjustable gastric band (LAGB)

The procedure was performed laparoscopically using the Lap-Band® adjustable gastric banding system. The band was placed using the standard technique after dissecting the angle of His. The band was then fixed using non-absorbable monofilament suture. Patients were reviewed in the bariatric outpatient clinic every three months to assess their progress including weight loss and possible adverse side effects. The band volume was adjusted by 1–2 ml of saline at a time according to each patient's clinical condition. The evaluation included an assessment of weight loss, dysphagia, vomiting, and sensation of hunger and satiety.

Primary and secondary endpoints

The primary outcome of this study was to evaluate changes in body weight. This was determined by measuring current weight, weight loss, percent excess weight loss (%EWL), BMI, and BMI loss. Measurement of weight was in kilograms and height in meters. BMI was calculated using the standard formula i.e. BMI = weight kg/height m^2.

Secondary outcomes were to assess the rate of cure or improvement of comorbidities, changes in QOL, hospital stay, and treatment complications. Cure was defined as complete resolution of the comorbidity without the subsequent need for pharmacotherapy to manage the condition. Equally, improvement was defined as reduction in the dose and/or frequency of pharmacotherapy to control the condition. Confirmation of obesity comorbidities necessitated clinical and biochemical evidence. QOL was assessed using the SF-36 health questionnaire.

Minor and major complications were recorded during the peri-operative period and at each visit. Minor complications included nausea, vomiting, minor bleeding, and superficial wound infection. Major complications include mortality, conversion to laparotomy, reoperation, early removal of the balloon, balloon rupture, balloon migration, infection, major bleeding, incisional hernia, band erosion, and band slippage.

Data collection and statistical analysis

Data was collected prospectively and statistical analysis was carried out using SPSS software (version 16, SPSS Inc., Chicago, IL, USA). Continuous variables were expressed as mean (SD). Categorical data were compared using Chi-square, and continuous data were compared using *t*-test with confidence interval (CI) of 95%. *P*-values less than 0.05 were considered statistically significant.

RESULTS

Baseline characteristics of patients

The study was carried out between May 2008 and May 2010. The overall follow-up period was 14 (6) months; 9 months (4) for EPGB and 16 (4) months for LAGB ($P<0.001$). Five patients required replacing the gastric balloon once more.

Table 1 shows that baseline characteristics in EPGB and LAGB were comparable including age (40.9 versus 39.9, $P=0.75$) and females gender (65% versus 80%, $P=0.06$). However, there was statistically significant difference in the initial weight (172.0 kg versus 142.9 kg, $P<0.001$), excess weight (100.2 kg versus 70.9 kg, $P<0.001$), and BMI (61.4 versus 50.9, $P<0.001$).

Table 1: Baseline clinical and biochemical characteristics*

	EPGB (*n*=17)	LAGB (*n*=30)	*P* value
Age years	40.9 (12.1)	39.9 (9.4)	0.75
Number of females (%)	11 (65%)	24 (80%)	0.06
Initial weight (kg)	172.0 (19.5)	142.9 (28.9)	<0.001
Excess weight (kg)	100.2 (17.6)	70.9 (24.2)	<0.001
BMI (kg/m^2)	61.4 (8.3)	50.9 (8.0)	<0.001
Number of patients with DM (%)	3 (18%)	10 (33%)	0.25
Number of patients with HTN (%)	6 (35%)	16 (53%)	0.23
Number of patients with hyperlipidemia (%)	3 (18%)	11 (37%)	0.17
Number of patients with IHD (%)	4 (24%)	9 (30%)	0.63
Number of patients with OSA (%)	2 (12%)	4 (13%)	0.88
Systolic BP (mm Hg)	138.4 (9.3)	133.6 (15)	0.207
Diastolic BP (mm Hg)	88.1 (6.5)	83.7 (7.9)	0.070
Glucose (mmol/L)	6.9 (1.3)	6.3 (1.0)	0.39
Hb_{A1c} (%)	6.2 (0.9)	6.1 (1.0)	0.83
Total cholesterol (mmol/L)	5.1 (0.7)	5.1 (0.8)	0.91
HDL cholesterol (mmol/L)	1.3 (0.3)	1.4 (0.5)	0.76
LDL cholesterol (mmol/L)	2.7 (0.3)	2.8 (0.7)	0.85
Total cholesterol: HDL cholesterol ratio	3.8 (0.8)	4.2 (0.9)	0.32
Triglyceride (mmol/L)	2.3 (1.9)	2.8 (1.7)	0.48
CRP (mg/L)	17.7 (7.7)	13.9 (6.8)	0.22
WBC count	8.4 (2.3)	7.8 (2.0)	0.34
Neutrophil count	5.4 (1.3)	4.5 (1.1)	0.05

*Values are means (SD) unless otherwise indicated

Weight loss

Univariate analysis of variance was applied to explore the difference between EPGB group and LAGB group while statistically controlling covariate factors including age, gender, and baseline weight. Table 2 illustrates that, at mean follow-up of 14 months, the weight loss was in favor of LAGB. The difference between EPGB and LAGB is statistically significant including weight (146.4 kg versus 110.8 kg, $P<0.001$), weight loss (25.6 kg versus 32.0 kg, $P=0.007$), percent excess weight loss (%EWL) (26.2% versus 44.0%, $P=0.004$), BMI (52.1 versus 39.7, $P<0.001$), and BMI loss (9.4 versus 11.2, $P=0.012$).

Looking at EPGB group before and after surgery, paired sample test demonstrates statistically significant difference in weight loss (25.6 kg, $P<0.001$), %EWL (26.2%, $P<0.001$) and BMI loss (9.4, $P<0.001$). A similar result was demonstrated in LAGB group (32.0 kg, $P<0.001$, 44.0%, $P<0.001$, 11.2, $P<0.001$ for weight loss, %EWL and BMI loss, respectively).

Obesity comorbidities

The presence of obesity comorbidities as shown in Table 1 was similar between EPGB and LAGB including DM, HTN, hyperlipidemia, IHD, and OSA without any statistically significant difference ($P=0.25$, $P=0.23$, $P=0.17$, $P=0.63$, $P=0.88$, respectively). In addition, all the baseline biochemical parameters including glucose, Hb_{A1c}, cholesterol, HDL, LDL, triglycerides, CRP and WBC did not show any statistically significant differences ($P=0.39$, $P=0.83$, $P=0.91$, $P=0.76$, $P=0.85$, $P=0.48$, $P=0.22$, $P=0.34$, respectively). The only exception was the neutrophil count ($P=0.05$).

Table 2 demonstrates that the difference in resolution or improvement in obesity-related co-morbidities between EPGB and LAGB at mean follow-up of 14 months was not statistically significant including DM (67% versus 80%, $P=0.66$), HTN (83% versus 81%, $P=0.92$), hyperlipidemia (67% versus 82%, $P=0.61$), IHD (50% versus 64%, $P=0.66$) and OSA (50% versus 100%, $P=0.18$). The difference in systolic BP between EPGB and LAGB was statistically significant (128 mm Hg versus 120 mm Hg, $P=0.003$); however, the difference in diastolic BP was not statistically significant (79 mm Hg versus 78 mm Hg, $P=0.56$).

The change in measured biochemical parameters in Table 2 was comparable at mean follow-up of 14 months in both groups including glucose, Hb_{A1c}, total cholesterol, HDL, LDL, total cholesterol to HDL cholesterol ratio, triglycerides, CRP, WBC, and neutrophil count ($P=0.64$, $P=0.53$, $P=0.48$, $P=0.47$, $P=0.84$, $P=0.57$, $P=0.39$, $P=0.09$, $P=0.46$, $P=0.37$, respectively).

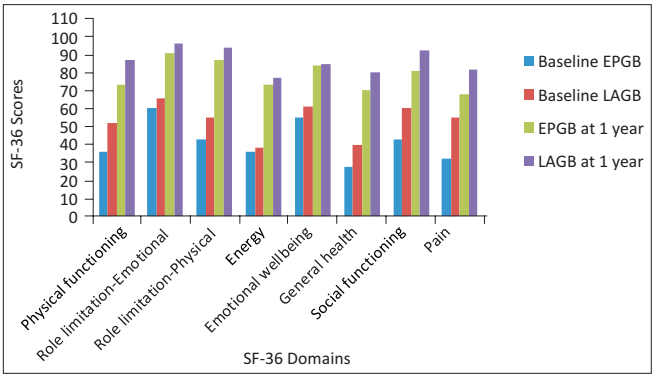

Figure 1: Quality of life in EPGB and LAGB

Table 2: Weight loss, obesity comorbidities and biochemical parameters at follow up*

	EPGB	LAGB	*P* value
Weight	146.4 (24.6)	110.8 (22.0)	<0.001†
Weight loss	25.6 (14.4)	32.0 (17.3)	0.007†
%EWL	26.2 (14.0)	44.0 (21.0)	0.004†
BMI	52.1 (7.9)	39.7 (7.2)	<0.001†
BMI loss	9.4 (5.5)	11.2 (5.3)	0.012†
DM cure or improvement	67%	80%	0.66
HTN cure or improvement	83%	81%	0.92
Hyperlipidemia cure or improvement	67%	82%	0.61
IHD cure or improvement	50%	64%	0.66
OSA cure or improvement	50%	100%	0.18
Systolic BP (mm Hg)	128 (8)	120 (10)	0.003
Diastolic BP (mm Hg)	79 (4)	78 (6)	0.56
Glucose (mmol/l)	5.2 (1.0)	5.1 (0.8)	0.64
Hb_{A1c} (%)	5.3 (0.8)	5.4 (0.4)	0.53
Total cholesterol (mmol/l)	4.2 (0.4)	4.3 (0.8)	0.48
HDL cholesterol (mmol/l)	1.3 (0.7)	1.4 (0.9)	0.47
LDL cholesterol (mmol/l)	2.1 (0.7)	2.2 (0.5)	0.84
Total cholesterol : HDL cholesterol ratio	3.7 (0.5)	3.9 (1.1)	0.57
Triglyceride (mmol/l)	1.6 (0.3)	1.4 (0.9)	0.39
CRP (mg/l)	9.9 (3.4)	7.4 (0.4)	0.09
WBC count	8.4 (2.2)	7.9 (2.5)	0.46
Neutrophil count	5.5 (1.4)	5.1 (1.3)	0.37

*Values are means (SD) unless otherwise indicated. †*P* value corrected after statistically controlling covariate factors of gender, age, and baseline weight

Health-related quality of life

Figure 1 shows that baseline SF-36 scores were worse in the EPGB group in the domains of physical functioning, general health and pain ($P=0.041$, $P=0.021$, $P=0.031$, respectively). After a mean post intervention follow-up of 14 months, both groups enjoyed a similar percentage of improvement in their QOL across all domains. In the LAGB group, however, patients reported significantly greater improvements in the above-mentioned QOL domains compared to the EPGB group ($P=0.025$, $P=0.011$, $P=0.024$, respectively).

Hospital stay

The average hospital stay was shorter for EPGB patients compared to the LAGB group (one versus two days, $P<0.001$).

Complications

No deaths occurred in either of the groups and none of the laparoscopic procedures were converted to laparotomy. Early postoperative complications in EPGB included nausea and vomiting in four patients (25%), which settled with anti-emetic optimization. No late complications were recorded in the EPGB group. In the LAGB group, one band slippage occurred and it was corrected laparoscopically.

DISCUSSION

There are a variety of bariatric procedures including restrictive (e.g. gastric balloon, gastric band, sleeve gastrectomy), malabsorptive (e.g. biliopancreatic diversion - Scopinaro procedure, duodenal switch), and restrictive-malabsorptive (e.g. gastric bypass).[7,28] It is still controversial to name the ideal bariatric procedure. Previous studies compared EPGB with conventional management, and compared LAGB to either conventional treatment or to other bariatric procedures.[21,23-26] However, there is paucity of studies that compared the EPGB versus LAGB, which led the authors to carry out this prospective study.

The total number of patients included was 47; 17 underwent EPGB and 30 underwent LAGB. The baseline demographic characteristics including age and gender were comparable between the two groups with no evidence of a statistically significant difference. Obesity comorbidities were also comparable between the groups. Nevertheless, baseline weight, excess weight and BMI showed a statistically significantly difference highlighting that the EPGB was the heavier group.

At a mean follow-up of 14 months, comparing weight, BMI and excess weight loss between EPGB group and LAGB group shows statistically significant difference in favor of LAGB, which may indicate that LAGB is more effective in terms of weight reduction. Nevertheless, EPGB group experienced considerable and statistically significant weight and BMI loss, which reflects the fact that EPGB is still effective in weight reduction.

Previous studies have shown that modest weight reduction (10 kg) has a beneficial impact on the cardiovascular system, plasma cholesterol levels and blood sugar.[21] The EPGB group lost an average of 24.5 kg compared to 31.2 kg in the LAGB group. This substantial result ensured that both groups enjoyed cure or a noticeable improvement in obesity-related conditions including DM, HTN, IHD, hyperlipidemia, and OSA. A similar result was noted in the SF-36 scores in which both groups reported comparable improvement across all SF-36 domains after one year of study. However, LAGB patients reported significantly greater improvements in the QOL domains of physical functioning, general health and pain compared to the EPGB group, which may reflect the fact that EPGB group was heavier from the onset.

Short falls of the present study include a lack of randomization, and recruitment of a small sample size which may have confounded the findings. In order to get more conclusive results, future research should clarify these points.

In summary, this prospective longitudinal study described the short-term outcomes of EPGB and LAGB. After a mean follow-up of 14 months, resolution of comorbidities and improvement in quality of life were comparable between the two groups. Both groups showed significant weight loss. These results provide evidence to suggest that EPGB is safe and effective in the short-term treatment of morbid obesity.

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