

Gastrointestinal Quality of Life Following Laparoscopic Adjustable Gastric Banding in Asia

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Background: Laparoscopic adjustable gastric banding (LAGB) is a safe and effective treatment for morbid obesity. Previous studies in Western countries disclosed a significant improvement in co-morbidities and health-related quality of life. Data from Asia and regarding the specific GI quality of life following LAGB are lacking.

Methods: From May 2002 to May 2005, 107 consecutive patients – 48 men and 59 women, with mean age 31.4 years (range 17-57 years) with morbid obesity (mean weight 115.8 kg, range 81-174 kg; mean BMI 41.3 kg/m², range 32.0-59.8 kg/m²) underwent LAGB in a prospective trial. All bands were placed via the pars flaccida technique. Quality of life was measured by the Gastrointestinal Quality of Life Index (GIQLI), a 36-item questionnaire before LAGB, and at 3, 6, 12 and 24 months after surgery.

Results: All procedures were performed laparoscopically with no conversions. There was neither intra-operative complications nor major postoperative complications. Minor complications occurred in 3 patients (2.8%); all were transient stoma obstruction. At follow-up, only one band (0.94%) was removed at 3 months postoperatively because of the patient's intolerance. No gastric slippage occurred. 4 patients (3.7%) had tubing problems and required revision surgery for port adjustment. Mean BMI decreased from 41.3 to 33.1 after 2 years. Percent excess BMI loss averaged 48.1% at 2 years (range 6.7-139.2). All co-morbidities were eliminated significantly. 80% of patients were satisfied with the results at 2 years. However, the GIQLI score remained similar before and after surgery. Preoperative score was 110.8±15 points. The score became 116.2±13, 114.7±13, 108.5±14 and 107.2±17 at 3, 6, 12 and 24 months. The patients had improvement in 3 domains of general health (social, physical and emotional functions), but decrease in the domain of symptoms.

Conclusion: Although LAGB was successful in weight loss and resolution of co-morbidities in morbidly obese patients, the GIQLI did not improve. This feature will be the major disadvantage of LAGB.

Key words: Morbid obesity, bariatric surgery, gastrointestinal quality of life, laparoscopy, gastric banding, weight loss

Introduction

Laparoscopic adjustable gastric banding (LAGB) is a minimally invasive procedure for the treatment of morbid obesity.¹ The device first became commercially available in Europe and Australia with good results.² Worldwide usage was expanded and the FDA in USA approved the Lap-Band® System (Inamed, Santa Barbara, CA) in June 2001. Although there was some controversy concerning the effect of weight loss in the USA,³ LAGB has replaced the vertical banded gastroplasty (VBG) as the most commonly performed purely restrictive bariatric operation worldwide.⁴

Because bariatric surgery is still in its infancy in Asia, the data of LAGB in Asia is not clear.⁵ In a previous study, we found that VBG, although effective in reduction of weight and resolution of co-morbidities, had an impaired Gastrointestinal Quality of Life Index (GIQLI).⁶ Data regarding the GIQLI following LAGB is lacking. The current study was undertaken to evaluate the results of LAGB with special emphasis on specific changes in GIQLI in a series of prospectively followed Asian patients.

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Patients and Methods

The study was performed with approval of the ethics committee of the En-Chu-Kong Hospital. All candidates for surgical treatment of morbid obesity were evaluated by a multidisciplinary and integrated medical unit, with the aid of a general physician, endocrinologist, psychiatrist, and dietician, for a thorough assessment of their general condition and mental status, co-morbidities, risk factors, and motivation for surgery. Inclusion/exclusion criteria followed the standard of the Asia-Pacific Bariatric Surgery Consensus.⁶

From May 2002 to May 2005, LAGB was performed on 107 patients. There were 48 men and 59 women, with mean age 31.4 years (range 17-53) and mean body mass index (BMI) 41.3 kg/m² (range 32-62). Of the 107 patients, 80 suffered from obesity-related co-morbidities such as hypertension, diabetes, hyperlipidemia, arthritis, asthma, sleep apnea and venous stasis (Table 1).

Operative Technique

All bands were placed via the pars flaccida technique,^{1,7} and a modified five-port technique for standard laparoscopic gastric surgery was used.⁸ The port was fixed to abdominal wall by the technique of mesh and pro-tec.⁹ The mean operating-time was 88.0±31.2 minutes. The mean operating-time for the first 10 cases was 107 minutes and for the last 10 cases 83 minutes.

There was neither conversion nor major complication in the series. Minor complications occurred in 3 patients (2.8%); all were transient stoma obstruction.

Study Protocol

Follow-up and Outcome Measures

Patients were well educated by our support team. The weight loss, BMI, waist circumference, and obesity-related clinical data were followed and recorded, as well as late complications. Any complication related to the operation that occurred after 30 days and required readmission was defined as a late complication.

For adjustment of the LAGB, saline was not added to the band reservoir until at least 4 weeks had elapsed after surgery. We routinely perform adjustments in the clinic. CT-guided adjustment was only indicated occasionally. The first adjustment usually involved addition of 1 ml of sterile saline. The second adjustment involved addition of 0.5 ml when patients failed to lose weight but had sustained satiety between meals.

Quality of Life Assessment

The 36-item GIQLI questionnaire form was administered to all patients before surgery and at 3, 6, 12 and 24 months after LAGB. The GIQLI is a well-validated tool to assess specific quality of life in patients with various GI diseases.¹⁰⁻¹⁵ The questionnaire measures the following four domains: GI symptoms (19 questions), physical function (7 questions), social function

Table 1. Preoperative and follow-up data of patients undergoing LAGB

	Preop	3 m Postop	6 m Postop	1 Yr Postop	2 Yrs Postop
Weight (kg)	115.8	105.4	102.1	96.4	94.7
BMI (kg/m ²)	41.3	37.5	36.2	34.0	33.1
Hypertension	43.0%	63.6%	43.2%	28.1%	30.1%
Hyperglycemia	16.9%	10.0%	3.8%	0	0
Hyperlipidemia	60.8%	41.4%	30.8%	30.2%	30.8%
Arthritis	28.0%	12.6%	5.6%	0	0
Asthma	4.6%	0	0	0	0
Sleep apnea	7.5%	1.3%	0	0	0
Venous stasis	2.8%	1.3%	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	

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(5 questions), emotional function (5 questions). Each question is quoted from 0 to 4 (0 being the worst and 4 the best option). The maximum score is 144.

Statistical Analysis

Data were recorded in a commercially-available data-base for personal computers and analyzed with the SPSS statistical software. The results of all items were expressed as mean \pm SD or median (range), as appropriate. Analyses of differences between groups for demographic and operative data were performed using two-sample *t*-tests or Fisher exact test for categorical data. Mann-Whitney tests were performed for non-parametric data. The paired Student *t*-test was used to compare each item before LAGB and at follow-up. A two-tailed *t*-test was used for comparison of total scores and scores in each subgroup of items, before operation and follow-up.

Results

Patient follow-up

In the 107 patients, the follow-up rate was 100%. Late complications occurred in 6 patients (5.6%). One patient had her band removed at 3 months post-operatively due to intractable vomiting. Four patients (3.7%) received port revision surgery for tubing problems. The other patient had acute obstruction due to food and required admission for treatment.

Weight Loss and Assessment of Co-morbidities

After a median follow-up of 30 months, the group had a significant reduction of BMI (Figure 1). The preoperative mean BMI was 41.3 and decreased to 33.3 kg/m² at 2 years after LAGB. Mean body weight decreased from 115.8 kg to 94.7 kg. The mean loss of excess BMI (compared to BMI 25)¹⁶ was 27.0%, 31.2%, 44.7% and 44.8% at 3, 6, 12 and 24 months. At 2 years after LAGB, all co-morbidities of obesity were eliminated significantly (Table 1). The patient satisfaction scales are also shown in Table 1: 80% of patients were satisfied with the results at 2 years. However, there was a trend of decreasing percentage of excellent grade with passage of time (Table 2).

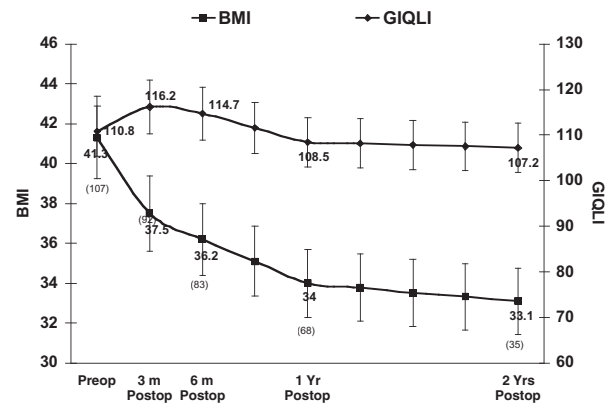


Figure 1. Change in BMI (kg/m²) and GIQLI after LAGB. Lines are means and bars indicate standard deviation.

Quality of Life Assessment

Pre-operative overall score of GIQLI was 110.8 \pm 14.6. The mean score increased significantly 3 months after LAGB to 116.2 \pm 13.2, and remained 114.7 \pm 12.6 at 6 months, but decreased to 108.5 \pm 14.1 at 1 year and 107.2 \pm 17.0 at 2 years after surgery. Figure 1 shows the evolution of GIQLI score associated with the reduction of BMI. The GIQLI had the highest score at the first 6 months and decreased to the preoperative score after 1 year (Figure 2). The patients had improvement in 3 domains of the questionnaire (social, physical and emotional functions) but decreased in domain of GI symptoms. The average scores before and 2 years after LAGB for each item are shown in Table 3. The patients had improvement in 5 items of 3 domains, but also had decrease in 11 items of the domains of specific symptoms, which resulted in no improvement in total score. LAGB patients suffered from symptoms of abdominal floating, flatulence, belching, abdominal noise, regurgitation, dysphagia, slow eating, nausea and constipation. The only item that improved after surgery is incontinence.

Discussion

The present study confirmed that LAGB is a safe and effective mini-invasive bariatric operation in Asian people. In experienced hands, LAGB can be performed with a zero major complication rate and 3% minor complications of transient esophageal

Table 2. Items in questionnaire of gastrointestinal quality-of-life index (GIQLI) and score in each item

Item	Pre-op	Follow-up 2 years	P- value
Symptoms			
Abdominal Pain	3.4	3.4	NS
Abdominal fullness	2.8	2.6	NS
Abdominal bloating	3.1	2.6	.002
Flatulence	3.2	2.3	.001
Belching	3.6	3.0	.003
Abdominal noises	3.6	3.0	0.002
Bowel frequency	3.4	3.3	NS
Enjoyed eating	2.1	1.9	.01
Restricted eating	2.9	2.4	.05
Regurgitation	3.7	2.9	<0.001
Dysphagia	3.8	2.9	<0.001
Eating speed	3.6	2.6	<0.001
Nausea	3.6	3.2	0.02
Diarrhea	3.2	3.5	NS
Bowel urgency	3.5	3.7	NS
Constipation	3.6	2.9	0.001
Blood in stool	3.8	3.7	NS
Heartburn	3.6	3.5	NS
Incontinence	3.9	4.0	0.02
Emotional items			
Coping with stress	2.5	2.6	NS
Sadness	2.6	2.8	NS
Nervousness	2.9	3.1	NS
Frustration	2.5	2.9	NS
Happiness	2.2	2.0	NS
Physical items			
Fatigue	2.9	2.8	NS
Feeling unwell	2.8	2.8	NS
Wake-up at night	3.4	3.1	NS
Appearance	2.3	2.8	0.008
Physical strength	2.3	2.9	0.001
Endurance	2.3	3.1	<0.001
Feeling unfit	2.3	2.9	0.002
Social items			
Daily activities	3.0	3.5	.002
Leisure activities	2.9	3.1	NS
Bothered by treatment	2.8	3.1	NS
Personal relationship	3.4	3.4	NS
Sexual life	3.2	3.5	NS

stenosis. The reason for transient stenosis is too small size of the band for super-obese patients. The avoidance can be either removal of the thick fat pad over angle of His¹⁷ or usage of a larger band. The three cases in our study were before the introduction of the 11-cm VG Vanguard Lap-Band system (Inamed); this complication was avoided thereafter. Late complications up to 2 years occurred in only

5.6%, with a <1% yearly band removal rate. We have not observed any slippage or erosion of the band, nor port infection up to 2 years.

The effects of LAGB on a variety of outcome parameters including BMI and co-morbidities, as well as patient satisfaction before and following surgery up to 2 years, are consistent with other studies.^{1-5,18-20} All patients with hyperglycemia had resolution by 1 year after the operation. However, the major disadvantage of the LAGB was the lack of improvement in the GIQLI despite acceptable weight reduction. Results were somewhat surprising, as most previous reports found improvement in health-related quality of life following weight reduction by LAGB, but the results are similar to our previous study on VBG.^{6,14}

Quality of life is a subjective parameter that ideally should be determined by the patients. Previous studies using the general health-related generic instruments such as the Short Form 36-Item scale (SF-36) found that weight reduction following LAGB leads to significant improvement in the quality of life.^{19,20} However, our study did detect the impairment of GIQLI much like after the VBG. In the present study, short-term GIQLI was better than long-term quality of life. The GIQLI improved significantly at 6 months postoperatively when the patients had a period of rapid weight loss, but GIQLI had returned to the preoperative values at 1 year after surgery, despite an 80% patient satisfaction rate. The explanation emerged of specific GI symptoms following LAGB that caused deterioration in the score in domains of symptoms. These symptoms are mainly related to vomiting, slow food intake, acid regurgitation and constipation, very much like those after VBG. However, the adjustability of the LAGB can avoid the notorious revision operations of the VBG.^{14,21,22}

Although LAGB can avoid the high incidence of staple-line and revisional surgery of the VBG, the LAGB is another form of purely restrictive procedure. The argument that good dietary choices in the LAGB patients will prevent their weight regain may not be a realistic argument, because of a previous lifetime of inability to do so by these patients. A long-term follow-up is definitely indicated in these patients.

Laparoscopic Roux-en-Y gastric bypass (LRYGBP) is another common surgical bariatric operation.⁴ In a previous study, we found that although LRYGBP is much more difficult in tech-

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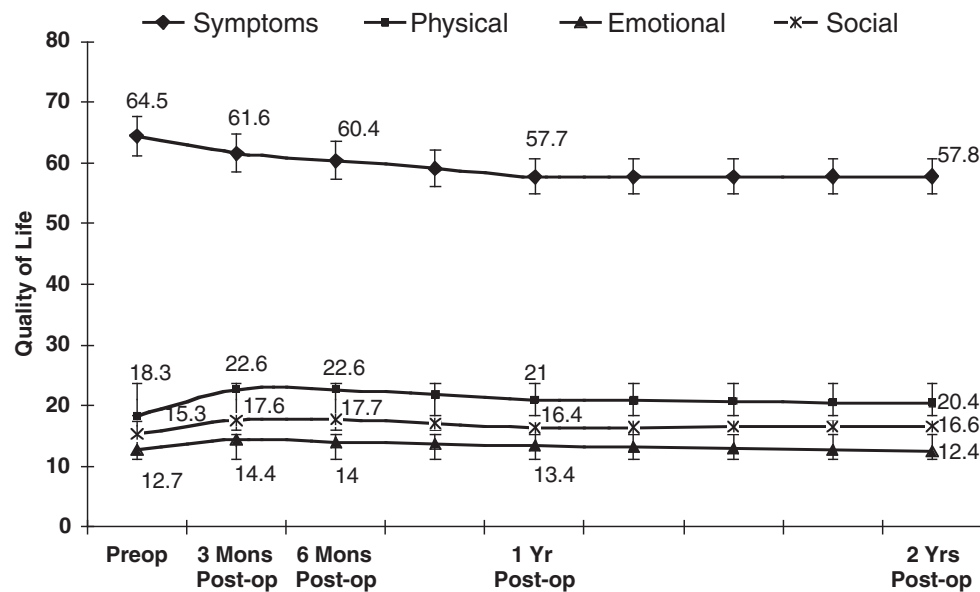


Figure 2. Change in GIQLI scores in the subgroups of GIQLI following LAGB.

Table 3. Overall and individual item scores of the gastrointestinal quality-of-life index (GIQLI) preoperatively and postoperatively for LAGB

GIQLI	Pre-op	3 M Post-op	6 M Post-op	1 Yr Post-op	2 Yrs Post-op
Overall	110.8 ± 14.6	116.2 ± 13.2*	114.7 ± 12.6*	108.5 ± 14.1	107.2 ± 17.0
Symptoms	64.5 ± 6.8	61.6 ± 6.0*	60.4 ± 6.0*	57.7 ± 7.6*	57.8 ± 9.7*
Physical	18.3 ± 5.0	22.6 ± 4.0*	22.6 ± 4.0*	21.0 ± 4.3*	20.4 ± 4.4*
Emotional	12.7 ± 3.6	14.4 ± 3.1*	14.0 ± 3.0*	13.4 ± 3.1	12.4 ± 3.2
Social	15.3 ± 3.3	17.6 ± 2.6*	17.7 ± 2.4*	16.4 ± 3.3	16.6 ± 6.1

* $P < 0.05$ compared with pre-op data.

nique and carried more than three times the risk of major complication than VBG, LRYGBP had a better GIQLI score than VBG at follow-up.¹⁴ LRYGBP patients had a significantly better score because it avoided the annoying GI symptoms of VBG. This difference also very possibly exists between LRYGBP and LAGB. A randomized study to compare the long-term results and quality of life between gastric bypass and LAGB is needed to clarify which operation provides the best results.

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