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RESEARCH ARTICLE

Impact on Obesity-Related Illnesses and Quality of Life Following Intragastric Balloon

Wilfred Lik-Man Mui · Enders Kwok-Wai Ng · Bonnie Yuk-San Tsung · Chuen Hing Lam · Man Yee Yung

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Abstract
Background The impact of intragastric balloon (IGB) on obesity-related illnesses and quality of life (QOL) has not been previously investigated.
Method One hundred and nineteen consecutive obese patients (86 females; mean age 37.8; mean body weight (BW) 103.7±24.1 kg; mean BMI 38.4±8.0 kg/m^2) who underwent IGB were evaluated for improvement on obesity-related illnesses and QOL after weight reduction in a multidisciplinary university referral center. Bioenterics Intragastric balloon (BIB®) system was employed in the study.
Results Mean treatment period was 169.9±34.8 days. Mean BW, BMI, and excess body weight loss were 12.4±6.9 kg, 4.6±2.7 kg/m^2, and 45.1±35.3%. Mean waist circumference and biceps fold and triceps fold loss were 10.5±8.3, 9.8±8.5, and 8.7±7.4 cm respectively. Metabolic syndrome was decreased from 42.9% to 15.1% after IGB ($p<0.0005$). Improvement of obesity-related illnesses were significant in fasting glucose, cholesterol, triglyceride, C-reactive protein, and blood pressure ($p<0.005$).In 28 diabetes patients, HBA1C level was significantly decreased as compared to baseline (7.4 vs. 5.8%; $p<0.0005$). The QOL of patients was significantly improved after IGB ($p<0.05$). No serious complication related to IGB was observed. Four patients (3.3%) had intolerence and required early removal of balloon. Thirty-one patients (26%) received further bariatric surgery after IGB.
Conclusions IGB produces meaningful weight loss and significantly improves obesity-related illnesses and quality of life.

Keywords Intragastric balloon · Obesity-related illnesses · Quality of life

W. L.-M. Mui (✉) · E. K.-W. Ng · B. Y.-S. Tsung · C. H. Lam · M. Y. Yung
Department of Surgery, Prince of Wales Hospital,
The Chinese University of Hong Kong,
Shatin, Hong Kong SAR, China
e-mail: wilfredmui@hotmail.com

Introduction

Intragastric balloon (IGB) is a kind of behavior therapy and is the only nonsurgical and nonpharmacological method for weight reduction present at the moment. Currently, in Asia, it is applied in patients with body mass index (BMI)>25 associated with obesity-related illnesses who failed conservative management and in those who are not suitable or indicated for bariatric surgery. Data regarding the impact of IGB on quality of life and obesity-related illnesses such as dysglycemia, dyslipidemia, and hypertension are lacking. We are reporting our results of IGB in ethnic obese Chinese in Hong Kong in 119 consecutive patients.

Materials and Methods

This prospective study was conducted in the Prince of Wales Hospital, The Chinese University of Hong Kong between March 2005 and October 2006. The primary objective of the study was to evaluate the outcome of IGB on weight loss and the impact of it on obesity-related illnesses and quality of life in obese Chinese. All patients referred to the center for weight reduction by IGB were asked to participate. Each individual was evaluated and managed by the weight control team of the hospital in a multidisciplinary approach and all were screened for

secondary causes of obesity before participation. The Research Ethics Committee of the Chinese University of Hong Kong approved the study and all patients provided informed consents for chart review before treatment. The indications of intragastric balloon in Asia are listed in Table 1.

Intervention

Bioenterics intragastric balloon system (BIB® system, ALLERGAN-INAMED Corporation, Santa Barbara, CA, USA) was adopted throughout the study and placement and removal of balloon were performed by the surgical team of the hospital. All procedures were performed endoscopically with conscious sedation and admixture of normal saline and methylene blue was used for filling the balloon as a measure to alert patients should unexpected premature rupture of balloon occur.

Patients were put on fluid diet the first week after balloon placement and regular diet was gradually introduced thereafter. A 1,200-kcal/day balanced diet and 150 min/week of moderately intense exercise were prescribed throughout the treatment until balloon removal. Proton pump inhibitor was given for the whole treatment period to prevent gastric erosion and ulceration.

Outcome Measurement and Follow-up

All baseline and outcome measurements were recorded by the designated research assistant during follow-up in a prospective manner. The patients were followed up in outpatient clinic by surgeons and dietitian weekly for the first month and monthly subsequently for progress and diet compliance. Quality of life was assessed by the Chinese version of SF-36 at baseline and after treatment and impact of obesity-related illnesses was evaluated after IGB.

Statistical Analysis

Statistical analysis was performed with statistical software Statistical Package for Social Science (SPSS; version 11.0 for Windows, SPSS, Inc., Chicago, IL, USA.). Comparisons were carried out by Student t test for parametric data and McNemar test where appropriate. A two-sided p value of less than 0.05 was considered significant.

Table 1 Indication of IGB in Asia

Indication of IGB in Asia
1 BMI>50 as a presurgical treatment to minimize surgical and anesthetic risks
2 BMI>30 with repetitive failure of previous weight reduction therapy and are not recommended or suitable for bariatric surgery
3 BMI>25 with obesity-related diseases with repetitive failure of previous weight reduction therapy

Results

One hundred and twenty-seven patients were recruited for the study during the 20-month period. Eight patients who defaulted follow-up were excluded. A total of 119 patients who completed IGB with paired data were subjected to analysis. All patients had history of obesity for more than 5 years and had failed conservative management such as diet, behavioral therapy, and pharmacotherapy in the past. Obesity-related morbidity was present in 89.1% of patients, which included 28 patients from diabetes mellitus (DM), 98 patients from hypertension, 14 patients from dyslipidemia, 28 patients from obstructive sleep apnea, and 39 patients from degenerative joint pain.

The mean age of patient was 37.8±10.0 with 72.3% of them female. The mean treatment period and hospital stay were 169.9±34.8 and 1.4±0.9 days, respectively. The mean filling volume of balloon was 542.7±28.2 ml. The mean baseline body weight (BW) and BMI were 103.7±24.1 (range 63.8–183.6) kg and 38.4±8.0 (range 26.5–69.1) kg/m^2. The mean baseline waist circumference, biceps fold, and triceps fold were 117.7±17.6, 26.6±10.0, and 34.1±9.8 cm, respectively. All patients were available for detailed outcome measurements. The mean overall BW, BMI loss, and excess body weight loss were 12.4±6.9 kg, 4.6±2.7 kg/m^2, and 45.1±35.3% at 6 months. The mean waist circumference, biceps fold, and triceps fold loss were 10.5±8.3, 9.8±8.5, and 8.7±7.4 cm. The excess body weight loss in <30 BMI group, 30–35 BMI group, 35–40 BMI group, and >40 BMI group were 87.0±59.8%, 58.3±31.2%, 35.1±23.1%, and 27.4±17.0%, respectively. The baseline patient's characteristics and results are summarized in Tables 2, 3, and 4.

15 patients defaulted follow-up after IGB. Sixty-eight patients were available for assessment at 1 year and the excess body weight loss was 32.9±48.7%. Thirty-six patients received further therapy after IGB which included five patients who underwent further IGB, three patients who underwent laparoscopic mini gastric bypass, 21 patients who underwent laparoscopic gastric banding, and seven who underwent laparoscopic sleeve gastrectomy. All patients showed further decrease in body weight subsequently.

Metabolic syndrome was present in 42.9% of patients before IGB and decreased to 15.1% after treatment according to the International Diabetes Federation criteria. The mean fasting blood glucose after IGB was significantly decreased as compared to baseline (6.1±2.0 vs. 5.3±1.7 mmol/l; $p<0.0005$). Of the 28 DM patients, the mean

Table 2 Baseline data

Total no. of patients	119
Age[a] (year)	37.8±10.0
Gender (F:M)	86:33
Filling volume[a] (cc)	542.7±28.2
Hospital stay[a] (day)	1.4±0.9
Treatment period[a] (day)	169.9±34.8
Comorbidities (*n*; %)	106; 89.1
Diabetes	28; 23.5
Hypertension	98; 82.4
Dyslipidemia	14; 11.8
OSA	28; 23.5
Joint pain	39; 32.7
Intolerance (*n*; %)	4; 3.3

[a] Mean±SD

HBA1C was significantly improved from baseline after IGB (7.4±1.6 vs. 5.8±0.7%; $p<0.0005$). Total cholesterol level and triglyceride level were significantly decreased after IGB (5.1±0.9 vs. 4.7±0.9 mmol/l; $p<0.0005$ and 1.7±1.0 vs. 1.3±0.7 mmol/l; $p<0.0005$, respectively). The systolic and diastolic blood pressures were significantly improved as compared to baseline (145.4±19.7 vs. 133.2± 20.9 mmHg; $p<0.0005$ and 84.3±12.6 vs. 78.8± 15.4 mmHg; $p<0.005$). C-reactive protein level was significantly decreased as compared to baseline (6.9±6.5 vs. 5.1±6.5 mg/l; $p<0.024$). No significant change was observed in high-density lipoprotein level after IGB. Seven of the eight domains and both physical and mental component summary of Chinese version SF-36 were significantly improved after IGB. The results were tabulated in Table 5.

Complications

No major complication related to IGB such as premature rupture was observed in the study. Four patients (3.3%) developed intolerance and required early removal. One patient developed anemia after IGB and one patient developed hypokalemia which required fluid and potassium replacement therapy.

Discussion

Obesity is becoming a worldwide phenomenon. Although the situation in Asia is less apparent than in Western society, the problem is emerging rapidly. It is estimated that the prevalence of obesity is 3% and over ten million obese patients will require bariatric surgery in Asia. However, the development of bariatric surgery is still at infancy in our locality and the popularity of it remains low at the moment [1]. Less invasive therapies than surgical intervention with meaningful weight loss outcome are warranted in our society to combat the epidemic.

IGB is currently the most effective nonsurgical method for weight reduction and was initially developed from observing the effects naturally caused by bezoars [2]. Earlier balloon designs were plagued by high balloon failure rates and serious complications. The newer designs of balloon (BIB system and Heliosphere® system) were introduced recently and have undergone extensive evaluation worldwide with promising results [3–14]. They are placed inside the stomach endoscopically for a maximum of 180 days to decrease stomach capacity and gastric emptying. IGB facilitates patient's compliance to the restricted diet prescribed and, together with increasing level of physical activities, most reports have shown moderate body weight loss of 15 kg or more. More importantly, the newer design of the balloons is more reliable and predictable. The reported premature balloon rupture and serious complication is rare if it is removed within the recommended period and followed up carefully by a dedicated obesity team in a multidisciplinary approach [3–14].

We have introduced IGB to Hong Kong since 2004 [15, 16]. This is the first report of it on the impact of obesity-related illnesses and quality of life in Asia. Our results

Table 3 Anthropometric data and results

	Before IGB (baseline), *n*=119	After IGB (6 months), *n*=119	Loss at 6 months	*P*
Body weight[a] (kg)	103.7±24.1	91.3±23.4	12.4±6.9	<0.0005[b]
Body mass index[a] (kg/m^2)	38.4±8.0	33.8±7.9	4.6±2.7	<0.0005[b]
Waist circumference[a] (cm)	117.7±17.6	107.0±18.4	10.5±8.3	<0.0005[b]
Bicep[a] (cm)	26.6±10.0	17.5±7.5	9.8±8.5	<0.0005[b]
Triceps[a] (cm)	34.1±9.8	26.4±7.8	8.7±7.4	<0.0005[b]

[a] Mean±SD
[b] Statistically significant

Table 4 Percentage of excess body weight loss at different BMI groups

	<30 BMI (n=12)	30–35 BMI (n=35)	35–40 BMI (n=32)	>40 BMI (n=40)	Overall at 6 months (n=119)	Overall at 1 year (n=68)
Excess body weight loss[a] (%)	87.0±59.8	58.3±31.2	35.1±23.1	27.4±17.0	45.1±35.3	32.9±48.7

[a] Mean±SD

are very promising and encouraging. IGB produces a remarkable excess body weight loss of 45.1% and significantly alleviates metabolic syndrome, blood glucose level, blood pressure, and lipid profile of patients. In addition, it tremendously improves the quality of life of patients with better results than any other nonsurgical therapy available at the moment. It is noted that our data are superior to most others worldwide. It may be due to the strict follow-up protocol as reviewed by the low default rate in our study.

One of the most obvious advantages of IGB and other newly developed endoscopic procedures when compared to surgical therapy for weight reduction is that they are inherently less invasive and more readily acceptable by Asian [17, 18]. In America, approximately only 1% of patient potentially benefited and indicated for surgery would opt of the intervention and the rate is expected to be even much lower in Asia. IGB has been shown to facilitate patient's acceptance for bariatric surgery [19]. It decreases both surgical and anesthetic risks of patients and better prepares patients psychologically for later bariatric intervention if needed. In our study, 26% of patient initially refused surgery but accepted it subsequently. This is of paramount importance especially in the early stage of bariatric surgery development at present in Asia.

The impact of IGB on patient's health is apparent. It significantly alleviates metabolic syndrome and other obesity-related illnesses as shown in our study. Although the effect may be temporary and less than surgery, it exceeds most medical therapy and behavior therapy in combination. IGB remarkably improves glucose control in diabetic patients. In our 28 DM patients, the mean HbA1c level decreased from 7.8% to 5.8% after therapy. Although IGB does not exhibit any metabolic effect on diabetes, it helps patients to comply with the hypocaloric diabetic diet prescribed. The results echo the findings from Ricci et al. [20] that IGB is effective in reversing insulin resistance in obese diabetic. Blood pressure and lipid levels are also tremendously corrected and are directly related to the

Table 5 Metabolic parameters and quality of life outcome

	Before IGB (baseline), n=119	After IGB (6 months), n=119	P
Metabolic syndrome (%)	42.9	15.1	<0.0005[a]
Metabolic parameters[b]			
Fasting blood glucose (mmol/l)	6.1±2.0	5.3±1.7	<0.0005[a]
HBA1C (%;DM patients)	7.4±1.6	5.8±0.7	<0.0005[a]
Total cholesterol (mmol/l)	5.1±0.9	4.7±0.9	<0.0005[a]
Triglyceride (mmol/l)	1.7±1.0	1.3±0.7	<0.0005[a]
HDL (mmol/l)	1.4±0.3	1.4±0.3	0.217
Systolic blood pressure (mmHg)	145.4±19.7	133.2±20.9	<0.0005[a]
Diastolic blood pressure (mmHg)	84.3±12.6	78.8±15.4	0.005[a]
CRP (mg/l)	6.9±6.5	5.1±6.5	
Quality of life[b]			
Physical functioning	28.8±19.0	39.8±15.2	<0.0005[a]
Role, physical	37.5±13.1	46.2±12.7	<0.0005[a]
Bodily pain	36.4±13.1	45.5±10.4	<0.0005[a]
General health	40.3±10.5	49.4±11.3	<0.0005[a]
Vitality	42.1±11.0	49.0±11.4	<0.0005[a]
Social functioning	35.5±16.1	41.4±13.8	0.008[a]
Role, emotional	43.1±11.2	50.5±10.5	<0.0005[a]
Mental health	43.4±11.6	45.1±14.0	0.592
Physical component summary	31.9±14.8	43.6±11.6	<0.0005[a]
Mental component summary	43.8±12.4	47.7±13.3	0.014[a]

[a] Statistically significant
[b] Mean±SD

degree of weight loss it induced. What is more important, meaningful weight loss induced by IGB translates to improvement in quality of life as demonstrated by Chinese version of SF-36 in our study. We are able to show that IGB improves seven out of eight domains and both physical and mental component of quality of life of SF-36. This is one of the most salient outcomes apart from weight loss in assessing any bariatric interventions.

There are some limitations of IGB. First, most consider it a temporary method for weight reduction especially in more heavy patients [21]. We reviewed that IGB has excellent result in lower BMI patients and the percentage of excess body weight loss in BMI<30 group is 87% in contrast to 27.4% in BMI>40 group. This result mirrors other forms of restrictive procedures such as gastric banding and sleeve gastrectomy where they have more superior outcome in lower BMI patients [22] and there is a higher chance for this group of patients to have more sustainable weight loss after IGB. Our data reviewed that there are inevitable rebound of body weight after IGB but the overall excess body weight loss at 1 year is still remarkable (32.9%). Secondly, a portion of patients will develop intolerance and experience gastrointestinal discomfort during therapy and may decrease the overall patient's satisfaction regarding the treatment. Thirdly, IGB is costly. Cost-effective analysis and comparison to other form of medical therapy are required to further delineate the exact role of IGB.

In conclusion, intragastric balloon is effective and safe in treating obesity in Asia. It results in significant improvement in obesity illnesses and quality of life. It is a very valid option for those who do not opt for or not suitable for bariatric surgery in Asia and the role of IGB is expected to be more important than in Western society.

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