

The Bioenteric[®] Intra-gastric Balloon (BIB[®]) as a treatment for obesity: poor results in Asian patients

Ganesh R, Rao A D, Baladas H G, Leese T

ABSTRACT

Introduction: The Bioenteric Intra-gastric Balloon (BIB, Inamed Health, Santa Barbara, CA, USA) is an endoscopic method for achieving restriction of gastric intake in obese patients. It is less invasive and cheaper than bariatric surgery, but can only be left in the stomach for six months. We report our experience with the BIB in Singapore.

Methods: Since its introduction to our hospital in 2004, a prospective database has been kept of all patients undergoing BIB insertion. This database was used to retrieve the information for this study.

Results: 20 patients have undergone BIB insertion. Mean patient age was 40 (range, 28-52) years and 85 percent were female. Mean body weight was 79.6 (range, 67.6-103.7) kg. Mean body mass index (BMI) was 31.5 (range, 27.8-38.8) kilogramme per square metre. Mean excess weight was 21.2 (range, 11.9-37.6) kg. The BIBs were inserted under conscious sedation. BIB intolerance was a major problem and four patients (20 percent) required early BIB removal due to refractive nausea and epigastric discomfort. All remaining BIBs were removed after six months under conscious sedation. The mean maximum weight loss during the six months was 5.9 (range, 1.4-13.4) kg. The mean maximum percentage of excess weight lost was 32.4 (range, 6.7-87). Weight loss was reasonably preserved at the end of the six-month period, but by one year, when all the patients had been without BIBs for at least six months, the mean weight loss for the group compared to pre-BIB weight was only 1.5 kg (range, weight gain 5.3 kg to weight loss 9 kg). The mean percentage excess weight loss at one year was 10.9 (range,

15.1 percent weight gain to 31.3 percent weight loss). Only four patients (20 percent) regarded their experience with the BIB as a success.

Conclusion: The BIB is poorly tolerated by Asian patients, even when lower volumes are inserted into the balloon to compensate for the smaller Asian stature. Although temporary weight loss can be achieved, mandatory removal of the BIB at six months results in regain of the lost weight in the majority of patients. Eligible patients (BMI 32.5 and above) should be encouraged to undergo bariatric surgery rather than BIB to achieve long-term reliable weight loss. Patients who are ineligible for bariatric surgery may benefit from BIB, especially if they have severe comorbidities and have failed to lose weight by any other means in a validated weight management programme, but the chance of long-term success is poor.

Keywords: Bioenteric intra-gastric balloon, intra-gastric balloon, obesity, weight loss

Singapore Med J 2007; 48(3):227-231

INTRODUCTION

Obesity is now a major health issue around the world.^(1,2) Of the multitude of aids on offer to achieve weight loss, many have little or no scientific merit. The plethora of dubious techniques advertised in the papers and magazines is a dramatic example of human ingenuity! Vast sums of money are being spent by a gullible public for little return. Healthy dieting and increased exercise remain the foundation for successful weight loss – possibly supplemented by medication. Unfortunately, although many individuals will temporarily lose weight, only five percent of the severely obese will sustain the weight loss.^(2,3)

Bariatric surgery is currently the only method for achieving long-term reliable weight loss in more than 90% of severely obese patients.⁽⁴⁻⁸⁾ The most popular bariatric

Department of Surgery,
Alexandra Hospital,
378 Alexandra Road,
Singapore 159964

Ganesh R, MBBS,
MMed, MRCSE
Registrar

Rao AD, MBBS,
FRCSE
Registrar

Baladas HG, MBBS,
FRCSE,
Former Chairman,
Bariatric Surgery

Leese T, MBBS,
MD, FRCS
Senior Consultant
and Chairman,
Bariatric Surgery

Correspondence to:
Dr Trevor Leese
Awali Hospital,
Awali,
Kingdom of Bahrain
Email: tbleese54@
hotmail.com

surgical procedure worldwide is now the laparoscopic adjustable gastric band (LAGB).⁽⁸⁾ This is a restrictive procedure which limits the amount of food eaten by creating a low-volume stomach pouch above a constricting band. The operation has the lowest hospital morbidity of all the bariatric surgical procedures,⁽⁸⁾ but it is expensive and invasive, requiring a general anaesthetic to insert the band. It also necessitates a lifelong follow-up for careful control of weight loss by adjustments of band tightness and screening for late complications of the band.

The Bioenteric® Intra-gastric Balloon (BIB®) is an alternative gastric restrictive procedure. It is a smooth, spherical, saline-filled, silicone elastomer with a radiopaque filling valve (Fig. 1). It is inserted endoscopically and left inflated within the stomach. Insertion can be performed under general anaesthetic or conscious sedation. It is intended to reduce weight by limiting food consumption. The BIB is not permanent and should be removed endoscopically after six months to reduce the risk of long-term complications, such as balloon perforation or migration and peptic ulceration. We report the results of our experience with the intra-gastric balloon since it was introduced at our hospital in 2004.

METHODS

The BIB system was introduced in Singapore in 2004 when an international expert ran a symposium at the Alexandra Hospital and directly supervised the insertion of the first five BIBs. We developed a careful protocol for BIB patients based on the patient management guidelines provided by the BIB marketing company⁽⁹⁾ and the international expert's book on the subject.⁽¹⁰⁾

BIB was offered to two groups of patients:

1. Patients with BMI 27.5–32.4 who were severely overweight but not heavy enough to be considered for our well-established LAGB programme and who had at least one obesity-related comorbidity.
2. Patients with BMI 32.5 and above who were eligible for inclusion in our LAGB programme but opted for BIB instead after detailed counselling.

These BMI cutoffs fit with the high and very high obesity risk categories in the guidelines for obesity in Asian patients issued by the Singapore Ministry of Health.⁽³⁾ All patients gave a long history of previous attempts at losing weight in supervised weight management programmes with only temporary success. Contraindications to BIB such as peptic ulcer disease or large hiatus hernia were excluded at initial endoscopy. After BIB insertion into the gastric fundus, the balloon inflation was performed under direct vision with saline. The correct fill volume was determined by the balloon size relative to the individual gastric size.



Fig. 1 Photograph shows a BIB® inflated with saline.

Initially, the endoscopic procedure to insert the BIB was performed under conscious sedation using intravenous Propofol (B. Braum, Melsungen AG, Germany) and Fentanyl (Martindale Pharmaceuticals, UK), but after seven patients, we were happy to insert the BIBs under conscious sedation using Midazolam (Hameln Pharmaceuticals GmbH, Germany). Patients were kept in hospital overnight for intravenous hydration, regular intravenous anti-emetic (Ondansetron 8 mg tds, GlaxoSmithKline, Italy), anti-spasmodic (Hyoscine-N-butylbromide 20 mg tds, Duopharma, Malaysia) and acid suppression (Omeprazole 40 mg daily, Astra Zenca, Sweden).

The next day, they were allowed to go home if they were able to tolerate oral fluids, taking oral anti-emetic (Metoclopramide 10 mg tds, DHA Asia, Singapore), anti-spasmodic (Hyoscine-N-butylbromide 10 mg tds, DHA Asia, Singapore) and acid suppression therapy (Omeprazole 40 mg daily, CCM Pharmaceuticals, Malaysia). The patients were seen by a dietician and a physiotherapist from our well-established weight management team. Only oral fluids were allowed for the first 48 hours followed by soft pureed diet for another 48 hours. After this, a 1,000 cal solid diet was re-introduced, comprising approximately 50% carbohydrates, 26% lipids and 24% proteins. Intensive outpatient follow-up was ensured with patients seen at one week, two weeks and then monthly.

All BIBs still in-situ at six months were removed endoscopically as a day case under intravenous Midazolam sedation. Follow-up with medical, dietary and exercise supervision continued for one year from initial BIB insertion. A computerised, prospective database has been kept of all patients undergoing BIB. Ethical committee approval was obtained for this study. Excess weight was calculated as the number of kilogrammes a patient would need to lose to reduce their BMI to 23 (the upper healthy limit of normal BMI in Asian patients).

Table I. Summary of patients' details.

Patient number	20
Mean patient age (range) (years)	40 (28–52)
Female:male ratio	17:3
Mean patient weight (range) (kg)	79.6 (67.6–103.7)
Mean BMI (range) (kg/m ²)	31.5 (27.8–38.8)
Mean excess weight (using baseline BMI 23) (range) (kg)	21.2 (11.9–37.6)
Obesity-related comorbidity:	n (%)
Orthopaedic problems	13 (65)
Diabetes mellitus	1 (5)
Hypertensive	2 (10)
Hyperlipidaemia	3 (15)
Respiratory problems	4 (20)

Statistical analysis of weight changes with time was analysed using the Wilcoxon signed rank test.

RESULTS

20 patients underwent BIB insertion (Table I). The mean patient age was 40 years and 85% were female. There were 11 Chinese, five Indian, and three Malay Singaporeans and one non-Singaporean. Mean BMI was 31.5 kg/m². Four patients (20%) were eligible for bariatric surgery using the Singaporean Ministry of Health criteria for Asian patients.⁶⁾ These patients opted for BIB instead on the grounds of reduced cost, convenience, and the relatively short-term nature of BIB compared to LAGB. The remaining patients were not eligible for bariatric surgery as their BMI was in the range 27.5–32.4. Obesity-related comorbidity is shown in Table I. There were no complications related to endoscopic balloon placement or removal.

BIB fill volumes were a median of 450 (range, 400–550) ml. All patients were admitted for an overnight stay. 12 patients were allowed to go home the next day on oral medication and a liquid diet. The remaining eight patients required prolonged of hospital stay because of persistent nausea, retching and epigastric pain due to intolerance to the BIB. Four patients had subsequent readmissions to hospital with BIB intolerance. Although most of these patients settled with further intravenous medication and became tolerant of their BIBs, a total of four BIBs (20%) had to be removed early (Days 3, 5, 7 and 18) because of intolerance. 12 of the remaining 16 patients who persisted with their BIBs to six months had significant attacks of recurrent BIB intolerance despite oral medication. All the remaining BIBs were removed at six months other than one patient who had moved abroad and BIB removal

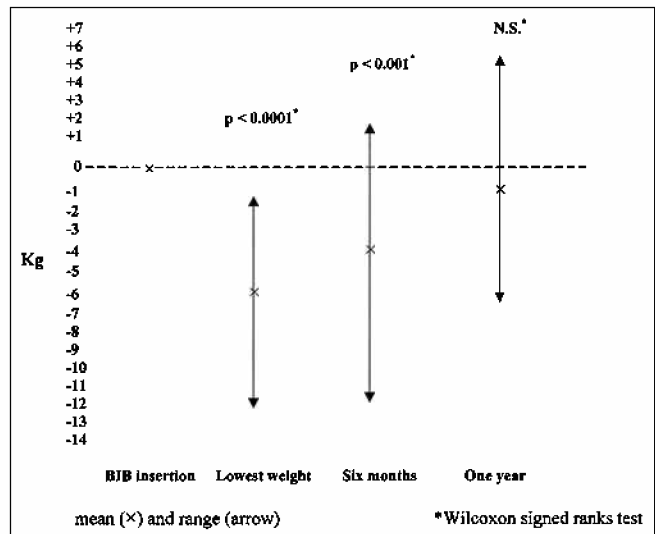


Fig. 2 Graph shows change in weight with time following BIB insertion.

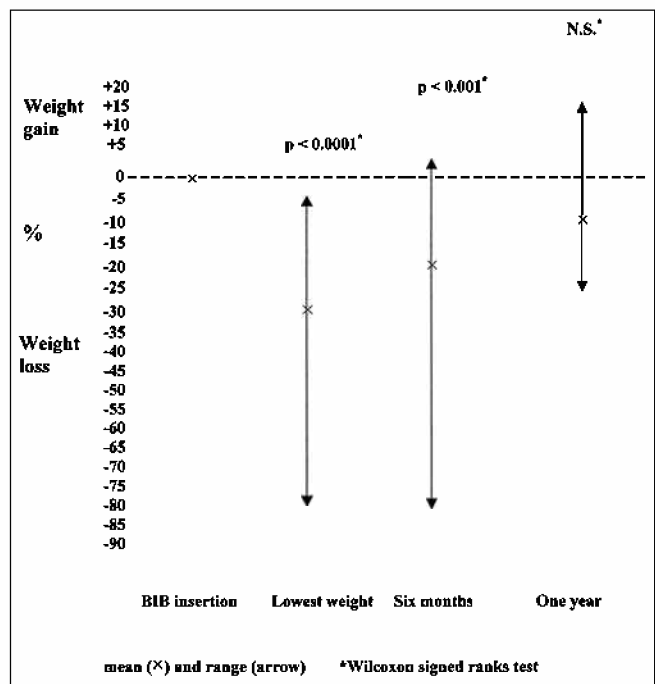


Fig. 3 Graph shows percentage excess weight loss with time following BIB insertion.

was delayed until one year later with no apparent adverse outcome. Another patient developed dyspeptic symptoms two weeks before planned BIB removal and was found to have a small benign gastric ulcer. This healed once the BIB was removed.

Patients' weight loss is shown in Fig. 2. Most of the weight loss occurred in the first two months after BIB insertion and was often associated with BIB intolerance symptoms. The mean maximum weight loss was 5.9 kg. At six months after BIB insertion, mean weight loss had fallen to 4.4 kg. Most patients regained weight after BIB removal so that

by one year, the mean weight loss was only 1.5 kg and four patients were heavier than their pre-BIB weights. Percentage excess weight loss with time is shown in Fig. 3. There was no discernable impact on associated comorbidities with the small weight losses achieved. Only four patients (20%) felt that their experience with the BIB could be judged a success.

DISCUSSION

The use of intragastric balloons to promote weight loss was first reported in the 1980s.^(11–13) Several balloon types were tried but early results were poor and complications were common.^(14–17) The more recently introduced BIB has a spherical shape and higher volume (400–800 ml) and uses saline rather than air filling. Extensive clinical experience has shown a lower complication rate with this balloon,^(17–24) and large numbers of BIBs have been inserted in some countries such as Italy.⁽²⁵⁾ The experience with the BIB in Asia in general and in Singapore in particular is limited.

The BIB does not appear to be a viable option for reducing obesity in Asian patients. Our poor results at one year could indicate poor patient support from our weight management programme, but we adopted closely the protocol advised in the manufacturer's BIB programme⁽⁹⁾ and in the book written by our visiting BIB expert.⁽¹⁰⁾ It is also important to note that we have a well-established weight management programme at our hospital. We have treated more than 5,000 overweight new patients since 2001. Our LAGB surgical programme is the largest in East Asia and has had great success using the same team of doctors/nurses/dieticians and physiotherapists which was used for the BIB programme. Despite this, we have not been able to reproduce the results reported in large European and South American centres which used the BIB.

The problems with the BIB can be summarised as follows:

Patient intolerance. One of the principal problems with the BIB is intolerance of the balloon in the stomach leading to nausea, retching and epigastric pain. This is reported in all of the series, but seems especially severe in Asian patients despite the lower volume of balloon filling used compared to the Caucasian experience with the BIB. Asian patients have smaller anatomy, and fill volumes of only 400–550 ml were used. In Caucasian patients, the average fill volume is 500–700 ml^(25,26) and the balloon can accept 800 ml. In our patients, serious intolerance problems resulted in delayed discharge from hospital or readmissions in 60% and early balloon removal in 20%, despite appropriate medication. This is a higher early removal rate than that experienced in non-Asian centres.^(21,27) It appears that most of the weight loss we achieved while the BIB was in place was due to BIB intolerance rather than gastric restriction. In the last few

months prior to BIB removal, most of our patients lost no further weight and some started regaining weight. They felt very little “restriction” from the balloon once they were able to tolerate it.

Other BIB complications. Balloon rupture, balloon migration, intestinal obstruction, peptic ulceration, stomach rupture and severe oesophagitis have all been reported with the BIB,^(10,25) although we encountered only one small gastric ulcer in our series.

Non-adjustability. The BIB is not adjustable after initial inflation. This is another major weakness compared to LAGB in which repeated adjustments can be made to allow safe and controlled weight loss.

Poor maximum weight loss. The maximum weight loss achieved while the BIB is in place is relatively small.^(25,28–30) The weight loss does not compare to that achievable with bariatric surgery and could probably be matched in some patients by cheaper, non-invasive supervised dieting and exercise programmes alone.

Compulsory removal of the BIB at six months. The main weakness of the BIB is that it has to be removed after six months to reduce the risk of complications. Repeated insertions after periods of stomach “resting” are reported,^(23,29) but cannot be condoned on cost grounds alone. We know from experience that most patients with severe obesity regain weight after any temporary weight loss strategy. Only 5% of severely-obese patients are able to obtain long-term worthwhile weight loss.^(2,4) Our BIB patients were warned about the temporary nature of the physical gastric restriction. They were told that they should regard the BIB as a learning tool. The aim is to adopt new dietary habits, exercise patterns and lifestyle changes while the BIB is in-situ, and then to sustain those changes after BIB removal. It is not surprising that so many BIB patients regain their lost weight after BIB removal despite careful support. Some centres do report significant residual weight loss at one year⁽²⁹⁾ but other centres have abandoned BIB as a tool for long-term weight loss.

We accept that our experience is small, but in view of our poor results, we no longer advocate the use of BIB as a long-term weight loss tool in severely obese Asian patients. If severely obese patients meet the criteria for bariatric surgery, we encourage LAGB rather than BIB. Two of our four BIB patients who were eligible for bariatric surgery has already gone on to LAGB following poor experience with the BIB. Our LAGB programme already has more than 320 patients and is very successful with excess weight loss at one year approaching 50%.⁽³¹⁾ In lighter patients who are not eligible for LAGB, we moderate the patient's expectations and emphasise that use of a BIB will also require a great deal of motivation and lifestyle change to achieve worthwhile weight loss. We will now only insert a BIB if the patient accepts the

mediocre results we have to date.

Another possible indication for BIB is to obtain initial weight reduction in the super-obese just prior to bariatric surgery and several authors have described successfully using the BIB for this purpose.^(18-21,28) We have no experience of BIB for this indication but we are concerned that BIB intolerance and early BIB removal might impact on its usefulness in preparing Asian patients for bariatric surgery. We currently prefer to use a closely supervised two-week very low calorie diet (VLCD) on all patients with BMI above 50 prior to LAGB. We find that we can safely achieve an 8–12 kg weight loss on this diet. This weight loss is adequate to shrink the fatty liver and reduce intraperitoneal fat to facilitate surgery. We would only consider BIB for preoperative weight loss in morbidly obese patients unable to tolerate VLCD.

ACKNOWLEDGEMENTS

We would like to acknowledge the invaluable support of the other members of the weight management and endoscopy teams at the Alexandra Hospital. We would also like to thank Dr Jose Afonso Sallet of Sao Paulo, Brazil for coming to Singapore to help establish our BIB programme.

REFERENCES

1. Obesity: preventing and managing the global epidemic. Report of a WHO consultation. World Health Organ Tech Rep Ser 2000; 894:1-253.
2. Deitel M. Overweight and obesity worldwide now estimated to involve 1.7 billion people. *Obes Surg* 2003; 13:329-30.
3. Ministry of Health Clinical Practice Guidelines on Obesity – revision card. Ministry of Health, Singapore, 2005.
4. O'Brien PE, Brown W, Smith A, McMurrick PJ, Stephens M. Prospective study of a laparoscopically placed, adjustable gastric band in the treatment of morbid obesity. *Br J Surg*; 86:113-8.
5. Buchwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta-analysis. *JAMA* 2004; 292:1724-37. Erratum in: *JAMA* 2005; 293:1728. Comment in: *JAMA* 2005; 293:1726; author reply 1726.
6. Biertho L, Steffen R, Ricklin T, et al. Laparoscopic gastric bypass versus laparoscopic adjustable gastric banding: a comparative study of 1,200 cases. *J Am Coll Surg* 2003; 197:536-46. Comment in: *J Am Coll Surg* 2004; 198:500-2.
7. Clegg AJ, Colquitt J, Sidu MK, et al. The clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity: a systematic review and economic evaluation. *Health Technol Assess* 2002; 6:1-153.
8. Chapman A. Systematic review of laparoscopic gastric banding for the treatment of severe obesity: update and reappraisal. ASERNIP-S report 31. 2nd ed. Adelaide: ASERNIP-S, 2002.
9. Patient Management BIB® Program. Practice Builder Program supplied by Inamed Health, Santa Barbara, California.
10. Sallet JF. The intragastric balloon. *Endoscopic gastroplasty for the treatment of obesity*. Americana, SP; Caminho Editorial, 2002.
11. Nieben OG, Harboe H. Intragastric balloon as an artificial bezoar for treatment of obesity. *Lancet* 1982; 1(8265):198-9.
12. McFarland RJ, Grundy A, Gazet JC, Pilkington TRE. The intragastric balloon: a novel idea proved ineffective. *Br J Surg* 1987; 74:137-9.
13. Schapiro M, Benjamin S, Blackburn G, et al. Obesity and the gastric balloon: a comprehensive workshop. Tarpon Springs, Florida, March 19-21, 1987. *Gastrointest Endosc* 1987; 33:323-7.
14. Benjamin SB, Maher KA, Cattau EL Jr, et al. Double-blind controlled trial of the Garren-Edwards gastric bubble: an adjunctive treatment for exogenous obesity. *Gastroenterology* 1988; 95:581-8.
15. Mathus-Vliegen EMH, Tytgat GNJ. Intragastric balloons for morbid obesity: results, patient tolerance and balloon life span. *Br J Surg* 1990; 77:76-9. Comment in: *Br J Surg* 1990; 77:1313.
16. Hogan RB, Johnston JH, Long BW, et al. A double-blind, randomized, sham-controlled trial of the gastric bubble for obesity. *Gastrointest Endosc* 1989; 35:381-5.
17. Meshkinpour H, Hsu D, Farivar S. Effect of gastric bubble as a weight reduction device: a controlled, crossover study. *Gastroenterology* 1988; 95:589-92.
18. De Waele B, Reynaert H, Urbain D, Willems G. Intragastric balloons for preoperative weight reduction. *Obes Surg* 2000; 10:58-60.
19. Weiner R, Gutberlet H, Bockhorn H. Preparation of extremely obese patients for laparoscopic gastric banding by gastric-balloon therapy. *Obes Surg* 1999; 9:261-4.
20. Busetto L, Segato G, De Luca M, et al. Preoperative weight loss by intragastric balloon in super-obese patients treated with laparoscopic gastric banding: a case-control study. *Obes Surg* 2004; 14:671-6.
21. Doldi SB, Micheletto G, Perrini MN, Librenti MC, Rella S. Treatment of morbid obesity with intragastric balloon in association with diet. *Obes Surg* 2002; 12:583-7.
22. Totte E, Henrickx L, Pauwels M, Van Hee R. Weight reduction by means of intragastric device: experience with the bioenterics intragastric balloon. *Obes Surg* 2001; 11:519-23.
23. Al-Momen A, El-Mogy I. Intragastric balloon for obesity: a retrospective evaluation of tolerance and efficacy. *Obes Surg* 2005; 15:101-5.
24. Sallet JA, Marchesini JB, Paiva DS, et al. Brazilian multicenter study of the intragastric balloon. *Obes Surg* 2004; 14:991-8.
25. Genco A, Bruni T, Doldi SB, et al. BioEnterics intragastric balloon: the Italian experience with 2,515 patients. *Obes Surg* 2005; 15:1161-4.
26. Roman S, Napoleon B, Mion F, et al. Intragastric balloon for "non-morbid" obesity: a retrospective evaluation of tolerance and efficacy. *Obes Surg* 2004; 14:539-44.
27. Milone L, Strong V, Gagner M. Laparoscopic sleeve gastrectomy is superior to endoscopic intragastric balloon as a first stage procedure for super-obese patients (BMI > or = 50). *Obes Surg* 2005; 15:612-7.
28. Genco A, Cipriano M, Bacci V, et al. BioEnterics® Intragastric Balloon (BIB®): a short-term double-blind, randomised, controlled, crossover study on weight reduction in morbidly obese patients. *Int J Obes (Lond)* 2006; 30:129-33.
29. Herve J, Wahlen CH, Schaeken A, et al. What becomes of patients one year after the intragastric balloon has been removed? *Obes Surg* 2005; 15:864-70.
30. Doldi SB, Micheletto G, Perrini MN, Rapetti R. Intragastric balloon: another option for treatment of obesity and morbid obesity. *Hepatogastroenterology* 2004; 51:294-7.
31. Ganesh R, Leese T, Rao AD, Baladas HG. Laparoscopic adjustable gastric banding for severe obesity. *Singapore Med J* 2006; 47:661-9.