ORIGINAL ARTICLES

Prospective Study of Laparoscopic Adjustable Gastric Banding in the West of Scotland

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Abstract

Obesity is an increasing problem in Scotland and Laparoscopic Adjustable Gastric Bands (LAGB) are an effective method of weight reduction. Most outcome data are reported from high volume units with extensive experience or dedicated bariatric practice. We aimed to assess an experienced laparoscopic surgeon's outcome working outwith a dedicated bariatric practice in the west of Scotland.

Methods
All LAGB procedures performed by a single surgeon were prospectively assessed from 1997 to 2004. LAGB were inserted using pars flaccida approach. Patient selection was based on BMI >35 or significant obesity related co-morbidities. Outcomes included percentage excess weight loss (%EWL) and excess BMI loss (EBL). We assessed total operating time to assess the learning curve for LAGB placement.

Results
125 patients were assessed (107 F:18 M). 123 patients were in regular follow-up (98%). Median age was 44 years (range 25-63). Mean follow-up was 34 months (range 11-91). Median initial BMI was 49 (range 37-73). 31% were BMI 35-45, 36% were BMI 45-50 and 33% were BMI>50. %EWL at 1,3 and 5 years was 45, 58 and 74, respectively. EBL at 1, 3 and 5 years was 11.7, 16.1, and 21.7, respectively. Complications included 4 converted procedures, 1 failed band insertion after conversion and re-operation for removal in five. Eight patients had tubing access port problems requiring intervention. The median overall total operation time was 80 minutes (range 50 - 160).

Conclusions
In this cohort LAGB insertion by an experienced laparoscopic surgeon is safe with few re-operations. Satisfactory weight loss is obtained and patient compliance with follow-up is high.

Keywords:obesity surgery, laparoscopic gastric banding, weight loss

Introduction

The worldwide increase in obesity is well recognized[1]. The rise in the prevalence of obesity is associated with increases in the prevalence of obesity related co-morbidities (e.g. type 2 diabetes, hyperlipidaemia, hypertension, obstructive sleep apnoea, heart disease, stroke, asthma, back and lower extremity weight bearing degenerative problems, several forms of cancer, depression, etc) which have been estimated to account for 2.5 million deaths per year worldwide[2].
Almost two thirds of Scottish adults are overweight and more than one in five are classified as obese[3]. By 2010, it is estimated that almost 30% of Scottish adults will be obese. In Scotland, it is a condition with important cost consequences that rank second only to smoking as a cause of burden on the health service[3].

Dietary modification and exercise regimes are ineffective in producing permanent weight reduction in the majority of morbidly obese patients[2]. Effective weight loss can be achieved by bariatric surgery and various surgical techniques have developed over the years[2]. The introduction of adjustable gastric banding has offered a new alternative to accepted techniques which include gastric bypass, gastroplasty and bilio-pancreatic diversion. Modern gastric bands can be sited laparoscopically without permanent anatomical disruption and allow variable restriction to calorie intake. Evidence suggests that gastric banding is safer than other options and is effective in the long term[2]. However, significant differences in complications rates, weight loss and overall outcome have been reported and have stalled widespread acceptance of the technique[4,5].

It seems likely that bariatric surgery in the U.K. (and Scotland) will increase in volume in the future and it is important that the safety and quality of care of bariatric patients is ensured. Many reported results are from high volume surgeons and units with a dedicated bariatric practice from overseas and may not be applicable to smaller units outwith this context[6]. Few reports exist that describe the experience of smaller practices, particularly in the U.K. It is estimated that 50-70 bariatric procedures are performed per annum in Scotland[3]. No formal reports exist in the literature of Scottish practice and in particular, the numbers of LAGB performed each year are not clear. A recent Scottish Executive report aims to place bariatric surgery within its proper context within NHS Scotland, however, the development of services for the surgical management of obesity have been largely unplanned and have arisen through a combination of special interest, service demand and "creeping incrementalism"[3].

This prospective study assesses the outcome of laparoscopic gastric banding by an experienced advanced laparoscopic surgeon working outwith a dedicated bariatric practice. In particular, we determined complications, weight loss achieved and the learning curve for laparoscopic gastric banding.

Methods

All laparoscopic gastric band procedures performed by a single appropriately-trained GI surgeon (DJG) from September 1997 to August 2003 were prospectively audited in a bespoke database and data were revalidated by case note review. The present series reports the experience of over 100 consecutive operations. Patients were considered for LAGB if their BMI was >35, or with major obesity related comorbidity. Referrals were accepted from outwith the West of Scotland providing funding followed the patient. No formal psychological testing was performed. All patients were seen preoperatively by a surgeon to assess overall fitness for surgery having been assessed by an endocrinologist with an interest in obesity to exclude treatable medical causes of obesity. A multidisciplinary approach was adopted including, dietician, physician, anaesthetist, and surgeon. Specialist endoscopy services were available although upper endoscopy was not routinely performed unless dictated by patient symptoms. Patients were provided with extensive information describing the operation, dietary requirements, follow-up protocol and potential complications. During the same study period there were other patients who had a LAGB inserted, at laparotomy, as a planned procedure, because of previous bariatric or other upper abdominal surgery. These patients have been excluded from the present series.

One hundred and sixteen *LAP-Bands* (Bioenterics, Carpenteria, California, USA) and nine *Swedish / SAGB* (Obtech, Johnson & Johnson, New Brunswick, New Jersey, USA) were implanted. In four patients conversion to an open approach was necessary for technical reasons (intra-abdominal adhesions, enlarged left liver lobes, haemorrhage or visceral injury). No post-operative imaging investigations were performed unless suspicion of oesophageal injury existed or in later follow-up unless dictated by the patient's symptoms. Patients were maintained on a liquid diet with vitamin supplements for the first four weeks with deflated bands and reviewed thereafter when attempts to inflate the LAGB were made. One hundred and twenty three patients were in regular follow-up at the time of data analysis.
The first 100 consecutive patients were separated into four categories based upon the order they were operated on (1-25, 26-50, 51-75, 76-100) to determine if a learning curve specific to LAGB insertion existed based upon total operation time.

Surgical technique

The bands were inserted under general anaesthesia using pars flaccida approach. For this approach the pars flaccida of the lesser omentum was opened to allow dissection of a retro-oesophageal tunnel from the medial border of the right crus to the Angle of His. An intragastric calibrating balloon was also employed. Five laparoscopic ports were used and the gastric fundus was sutured across the band anteriorly with three or four sutures. No attempt at posterior fixation was made. Where a LAGB failed and further bariatric surgery was required, a duodenal switch procedure was employed. Data were not assessed for this group of patients. Laparoscopic bypass procedures were not performed during the study period.

Patient demographic data were recorded and admission weight and height were prospectively obtained allowing calculation of BMI at the time of surgery and during follow-up. The patients' ideal BMI and target weight were calculated at the time of admission. Operative duration (minutes), procedure approach (laparoscopic, conversion), band insertion pathway (perigastric, pars flaccida), intra-operative and post-operative complications, reservoir position and length of post-operative stay (days) were prospectively documented. During follow-up, patient weight and BMI were calculated and complications were recorded. Data were continuously updated in a computerised database. Post-operative support was provided with access to the unit in the event of any problems. Support was telephone-based in the event of any problems.

The predominant outcome measures used were excess BMI loss (EBL) and percentage excess body weight loss (% EWL). A BMI of 25 kg/m^2 was deemed the upper limit of normal – any BMI units above 25 kg/m^2 were defined as excess BMI (EBMI). Excess weight was defined as the actual weight of the patient minus the ideal weight of that patient if they were to have a BMI of 25 kg/m^2. The volume of fluid within each LAGB was adjusted by injection of radio-opaque dye (Omnipaque, Nycomed; Amesham Plc, Buckinghamshire, UK) according to the patient's weight loss profile which was calculated at each clinic visit and according to the degree of intake restriction, the patient desired. Measurements such as girth/height ratio (GHR) were not recorded.

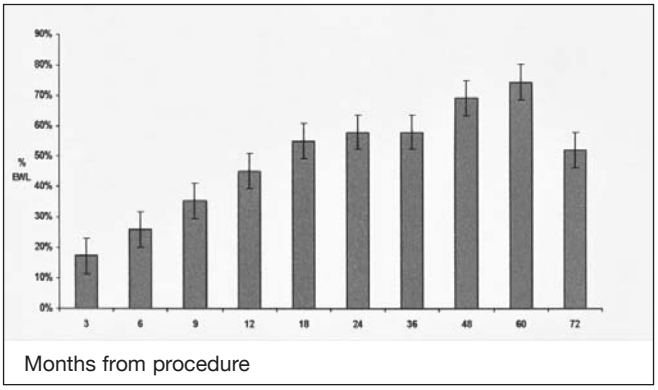
Statistical Analyses

Results are expressed as frequencies, proportions, means +/- S.D. and median values with ranges. Continuous data were compared between groups using Mann-Whitney and Kruskall-Wallis tests. Categorical data were assessed using the Chi-square test (and Fishers' exact test where appropriate). For each analysis, a p-value of 0.05 or less was considered to be statistically significant. Data were analysed using SPSS for Windows Version 11.0 (Chicago, Ill).

Results

Of the 125 patients studied, 107 were women and 18 were men. The overall median age was 44 years (range 25–63 years). The median age in the female group was 41 years (range 33- 58 years) differing significantly from the male group where the median age was 49 years (range 32 – 63 years) ($p=0.014$). The overall median initial BMI was 49 kg/m^2 (range 37 – 73 kg/m^2) and median initial body weight before the procedure was 132.9 kg (range 66- 220 kg). In the female group the median initial BMI was 48 kg/m^2 (range 37 – 73 kg/m^2) and the median initial weight for the group was 124.5 kg (range 66- 190 kg) The median initial BMI in the male group was 50 kg/m^2 (range 40- 69) and median initial weight was 160 kg (range 82- 220 kg). No significant difference in BMI between each gender was identified ($p=0.335$). A significant difference existed between gender and initial weight ($p< 0.005$).

Figure 1

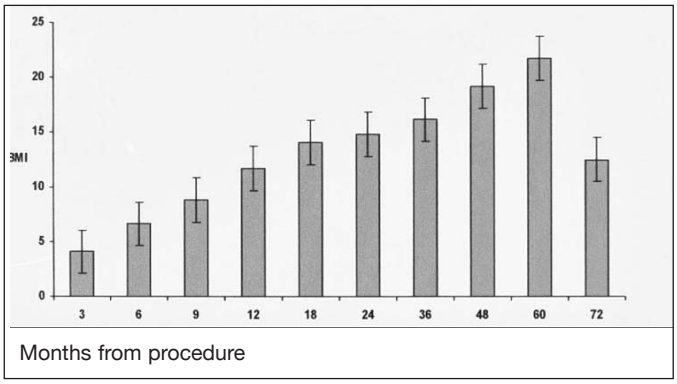


31 percent of patients were within the BMI 35-45 group, 36% were BMI 45-50 and 33% were over BMI 50. No significant association with gender was noted (p= 0.158).

Percentage excess weight loss (%EWL) and excess BMI loss (EBL) over time are annotated in Figure 1. %EWL at 1, 3 and 5 years was 45, 58 and 74, respectively. EBL at 1, 3 and 5 years was 11.7, 16.1, and 21.7, respectively.

No significant complications were noted in the Swedish band subgroup. 4 cases were converted from a laparoscopic to an open procedure. Re-operation was required in 13 patients (12.2%). 5 patients (4.7%) underwent gastric band removal during the follow-up period. In this group, 3 patients had port site infections necessitating removal. 2 patients had tubing/ access port complications necessitating removal. Attempts were made to salvage the LAGB wherever possible, however, it was not possible in this small group. 1 patient was readmitted on 2 occasions with nausea and vomiting although no obstructive cause was identified and her symptoms eventually resolved. 1

Figure 2



patient developed acute renal failure after laparoscopic gastric band removal which was successfully treated. Median time to removal was 18 months (range 3- 30 months). 8 patients (6.4%) required surgical intervention for tubing/ access port problems with a median time to intervention of 12 months (range 1- 28 months). 2 patients in this group required subsequent LAGB removal. No cases of band erosion and no mortality were recorded. 2 patients were lost to follow up but had previously undergone LAGB removal for complications.

Consecutive patients were divided into 4 categories to determine for differences in operative times, complications and length of post-operative hospital stay that may be attributed to a learning curve.

The mean operative time in minutes (+/- S.D) for operative groups 1-25, 26-50, 51-75, and 75 -100 were, 110+/-30.5, 95+/-25, 86+/-31 and 67+/-18, respectively. Significant differences in operative time between groups 1-25 and group 51-75 were noted (p=0.009) and group 1-25 and group 75-100 (p=0.005) although no significant difference between group 1-25 and group 26-50 (p= 0.092) was identified (figure 3.). No significant differences in length of post-operative stay between groups were noted. The median post-operative stay was 2 days (range 1-7 days) Conversion to open procedure occurred in 1 patient in each of the 4 groups. No significant association were recorded between procedure group and early or late complications although complication rates in each group were low.

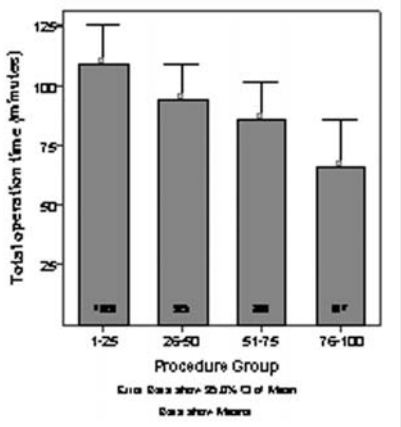
Discussion

Bariatric surgical units in Scotland are low volume compared to North American and European institutes and few data are available regarding performance in such units. In an attempt to improve the quality of surgical care for bariatric patients, the American Society of Bariatric Surgeons (ASBS) recently proposed the categorization of certain bariatric surgical practices into "Centres of Excellence"[6]. These centres would require a threshold of 125 cases per year with acceptable results with 51% of practice dedicated to bariatrics.

The validity of the hypothesis that high surgical volume in bariatric surgery equates to better operative outcomes and improved quality has been questioned. Data are available indicating that for procedures such as Roux-en-Y gastric bypass hospitals with more than 100 cases annually are associated with a shorter length of stay, lower morbidity and decreased costs. A lower rate of overall post-operative and medical complications is also reported[6]. Few data exist for laparoscopic gastric banding. Many researchers do not believe that hospital volume in itself has a direct causal relationship with outcome. It is more likely that volume is a surrogate measure for structural and process components that are followed by necessity at high-volume hospitals and represent a higher quality of care.

Scottish hospital discharge records (SMR1 Forms) show that between 1981 and 1995, a total of 190 operations were performed for morbid obesity, however, more recent data have been difficult to determine owing to a lack of specific discharge codes. Estimates are that approximately 50 to 70 procedures are performed *per annum* in Scotland and the total numbers of LAGB inserted remain unclear[3]. These numbers are dramatically smaller than those reported in the worldwide bariatric literature. The results of LAGB are variable, with some studies reporting poor results and others providing more encouraging evidence for LAGB use[4,5,7]. Reports confirming efficacy and safety have been countered by reports of unacceptable complication rates. Differences in follow-up have been raised as an important source

Figure 3



Total operation times and procedure group

of variation. LAGB requires intensive follow-up and in this study we have identified a very high follow-up rate compared to many other studies[4]. Thorough and close follow-up is required if good results are to be maintained. In this study, we find acceptable results can be achieved with lower volume practice but with appropriate infrastructure in place.

The learning curve for the procedure has been clearly identified in terms of total operation time and satisfactory results are attainable in experienced laparoscopic practice even after small numbers have been performed, however, the total operation time appears to improve over 26-50 procedures. Further categorisation of this group may have indicated a more accurate number to be performed before a significant reduction in operation time is achieved. No significant differences in complications were recorded between each procedure group although the overall numbers of complications were small compared to other studies. Although variable conversion rates are found in the literature and the accrual of experience plays a role, low conversion rates from the laparoscopic approach have been found in this series with no significant association with the procedure group. It has been suggested that figures of about 30 LAGB require to be performed to significantly reduce operation duration[8]. The results, however, indicate that even with advanced laparoscopic skills and experience, a definite learning curve is found which is likely to have implications for the training of future bariatric surgeons.

The incidence of complications is less than that reported in larger series of LAGB procedures[9,10]. Injection port-related complications were observed most commonly and culminated in LAGB removal on 2 occasions. Every effort to salvage the banding device in order to avoid open bariatric procedures was made. Revisions for injection port or tubing problems were technically easy and minimally bothersome for the patients. Previous studies have suggested port site complications occurring in around 8% of patients and we report comparable rates of port-site problems in this study[7]. We have chosen to site our injection port adjacent to a medial laparoscopic port site and this differs to the suggested port implantation site near the manubrium. Our results suggest that such a position is satisfactory. Recent data indicates that a variety of complications arising from LAGB placement can be treated laparoscopically.

In our series, %EWL at 1, 2, 3 and 5 years was 45, 58, 58 and 74, respectively. EBL at 1, 2, 3 and 5 years was 11.7, 14.5, 16.1, and 21.7. The observed weight loss is slightly higher than that reported in other studies though corresponds favourably with data from published systematic reviews. Meta-analysis data from Australia reveals that at 3 year follow-up, a mean %EWL of 58% with a range of 38–64% may be anticipated. At 4 year follow up, a mean %EWL of 56% (range of 44–58%) is identified. With 5 years of follow up with a mean of 56% EWL (range of 53–60%).

Our reoperation rate was 12.2% which favourably compares to the 23% reoperation rate in the results reported from USA. Reoperation on average occurred at 12 months (range 3–30 months) for band removal and 18 months (1-28 months) for tubing/ access port related problems. O' Brien et al. reported an 18.9% reoperation rate with a cohort of patients whose follow up ranged from 2 to 6 years[9], although minor procedures including injection port or cracked tubing replacement were not considered, unlike our data. Re-operations in different series are usually performed for band slippage, however, the usage of the pars flaccida approach has been suggested to account for the difference in this rate and appears to have substantially declined with conversion from perigastric placement of the band[7]. Interestingly, we reported no band slippages and attribute this to our choice of approach. Other studies have noted a marked improvement with this approach and the previously disappointing results from early LAGB studies may be attributed the approach employed[7]. The use of pars flaccida approach is associated with band erosion although in this series we have yet to encounter this complication. The numbers of SAGB were too small in this cohort to determine whether significant differences existed in the performance of each band type.

We have made no attempt to assess quality of life issues with our patients, however, formal assessment will become of greater importance in the future. Moreover, assessment of the impact of LAGB upon obesity related comorbidities will become increasingly important in assessing the quality of patient care. These aspects will be addressed with future LAGB patients in the West of Scotland and for those patients currently in follow-up.

Many studies report poor follow-up after bariatric surgery but with a multi-disciplinary approach, high levels of compliance may be obtained. We have been reassured by the large proportion of patients in follow-up in comparison to other studies where less than 85% of patients may be in follow-up. It is unclear whether such absence from follow-up means absence of weight loss.

In conclusion, LAGB is a safe option when placed by experienced laparoscopic surgeons, although a learning curve exists. It produces significant weight loss in the most patients and we find high rates of follow-up compared to other studies. Our results replicate other data from previously published studies of large series and dedicated bariatric practices.

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