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RESEARCH ARTICLE

Metabolic Outcomes of Obese Diabetic Patients Following Laparoscopic Adjustable Gastric Banding

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Abstract
Introduction Obesity is an independent risk factor in the development of diabetes. Weight loss surgery is the most effective treatment of morbid obesity. This study examines the effect of gastric banding on metabolic profile in diabetics.
Methods Between April 2003 and November 2007, 1,335 patients underwent laparoscopic adjustable gastric banding. Metabolic profile was examined on a subset of 254 patients. Of these, 122 were diabetic. Data collection included body mass index, weight, blood pressure, HbA1c, fasting glucose, total serum cholesterol, triglyceride, and medications taken for blood pressure and diabetes both preoperatively and 1 year postoperatively.
Results Comorbid conditions in the diabetic patients included hypercholesterolemia (49.3%), hypertriglyceridemia (53.8%) and hypertension (92%). In 1 year, mean BMI reduced from 52.9 kg/m^2 to 41.5 kg/m^2. Of the patients, 93.1% experienced an improvement in fasting glucose levels and 75.4% patients an improvement in HbA1c levels at the end of 1 year. All patients experienced a decrease in insulin requirements, and 36.6% were able to totally discontinue using it. Of the patients, 100% showed improvement in their triglyceride level, and 90.9% showed improvement in their total cholesterol level. The mean arterial pressure improved in 87.5% of the patients.
Conclusion The metabolic syndrome associated with morbid obesity is difficult to adequately control with medication. Laparoscopic gastric banding can be considered a potentially curative treatment option in the management of this syndrome.

Keywords Diabetes · Metabolic profile · Banding · LAGB · Obesity · Bariatric

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Introduction

Obesity is an independent risk factor in the development of diabetes [1], the severity of which rises with increasing excess weight [2]. The risk of atherosclerotic disease in patients with diabetes based on 20 years of surveillance of the Framingham cohort was increased by a factor of three [3]. There is evidence to support the claim that complications of type 2 diabetes mellitus can be reduced with tight control of hyperglycemia [4]. Therapy with drugs alone in diabetes has a failure rate of 50% at the end of 3 years in maintaining target glycemic levels [5]. Current therapies including diet, exercise, behavior modification, oral hypoglycemic agents, and insulin rarely return patients to euglycemia [6]. There remains therefore a great need to find more effective ways of managing diabetes.

The role of weight loss in the control of Type 2 diabetes has been known for some time [7]. The role of surgery in the management of diabetes was first described in 1955 [8]. A systematic review by Buchwald [9] in 2004 demonstrated an improvement in diabetes which was dependent on the type of bariatric surgery performed, but in this review,

studies reporting improvement in diabetes were limited in sample size. Studies in the literature reporting the effect of laparoscopic banding on diabetes are scant and limited to less than 100 diabetic patients [10–12].

Methods

All cases of laparoscopic banding performed between April 2003 and November 2007 in a single consultant unit at Heart of England NHS Foundation trust were included. These cases were either performed or were carried out under the supervision of a single surgeon. All the patients fulfilled the criteria for surgical treatment of obesity (BMI ≥40 without comorbidities or BMI ≥35 with comorbidities) [13].

Data were collected from medical records, operation notes, and computer records. General practitioners for all patients who were identified as diabetic were contacted for further data. Data collection included body mass index, weight, blood pressure, HbA1c, glucose, total serum cholesterol, triglyceride, and medications taken for blood pressure and diabetes preoperatively and at 1 year follow-up. All assays were performed in the laboratories at Heart of England NHS Foundation trust with internal and external quality control. Ideal body weight was determined according to the Metropolitan Life Insurance Company's 1983 height/weight tables [14]. Percent of excess BMI loss was calculated as recommended by Deitel et al. [15]. Metabolic outcomes were calculated for the diabetics at the end of 1 year.

The following criteria were used to define diabetes: (1) fasting plasma glucose of >7.0 mmol/l, (2) random plasma glucose of >11.1 mmol/l, (3) ketonuria and clinically symptomatic. Impaired fasting glucose was defined as fasting plasma glucose 6.1 to 7.0 mmol/l; impaired glucose tolerance as an OGTT 2 hour glucose as ≥7.8 but <11.1; gestational diabetes defined as above, but occurring during pregnancy only [16].

Hypertension was defined by a history of hypertension, taking antihypertensive medication preoperatively, or if the patient had a persistent raised blood above 140/90 mmHg as defined by UK National Institute for Clinical Excellence criteria (NICE) [17].

All the patients were admitted on the morning of the operation. Pars flaccida technique was used for placement of all bands. The band was secured in place by the use of 3 plicating sutures. The first was a gastropexy suture (Birmingham stitch), anchoring the fundus to the left crus. The remaining two were of the gastro–gastro type [18]. Three different bands were used for these procedures (Allergan Vanguard, Allergan AP large and Swedish bands). Use of a calibration tube and balloon was not considered necessary and consequently seldom used for any of the patients.

All the patients received postoperative low-molecular-weight heparins and graduated compression stockings during the surgery. Immediate postoperative mobilization and discharge on the same day or day following surgery was encouraged. Postoperatively, the patients were commenced on oral fluids for 2–4 weeks followed by a soft puree diet for a further 2 weeks. In most cases, normal band diet was achieved at the end of 6 weeks. Fluoroscopy-guided adjustments were performed at 2–3 and 5–6 months, and further fluoroscopic evaluations were performed only if clinically indicated.

For follow up, the patients were seen initially at 6 weeks, then every 3 months for the first 6 months, and every 6 months until 2 years.

Data analysis was performed using Statistical package for social services 13 (SPSS® Chicago, IL, USA). Tests performed included Mann–Whitney U test and Wilcoxon signed ranks test. Spearman's rho was used for nonparametric correlations. Statistical significance was accepted for a p value of ≤0.05. Values have been expressed as mean and range. The data set available at a particular time point has been indicated as number data available on/total patients, or patients who were on a particular drug. One-year data have been expressed as number data available on/patients who had preoperative data.

Results

Overall Results

Between April 2003 and November 2007, 1,335 laparoscopic gastric band insertions were performed by the lead surgeon in two different hospitals. Of these, 254 patients were operated at the Heart of England NHS Foundation trust, and this cohort has been considered for further analysis.

The mean age of these patients was 44.8 years with a range between 18 and 66. Of these patients, 191 (75.2%) were females. The mean preoperative weight and BMI for this subset was 146.3 kg (range 88–268 kg) and 52.5 kg/m^2 (range 35.9–88), respectively. A mean excess weight of 83.2 kg was seen preoperatively in these patients with a range between 36.1 and 200.7.

The mean length of stay was 1.0 day (range 0–2 days) with an overall operative complication rate of 1.2% (three patients). Two of these were in non-diabetic patients, one of whom suffered an early band infection (band removed) and the other was found to have a band malposition (repositioned at 3 months). The single complication in a diabetic patient was a band puncture, which presented at 8 months.

Diabetic Patients Identified

There were 122 diabetics identified from this subset of 254 patients. The mean age of these patients was 46.7 years (range 25–66). 81 (66.4%) were females. The mean preoperative weight and BMI for the diabetic patients was 151.8 kg (range 88–240 kg) and 52.9 kg/m^2 (range 35.9–81), respectively. A mean excess weight of 87.4 kg was seen preoperatively with a range between 36.1 and 169.7. In comparison with the non-diabetics (N=132), statistically higher mean preoperative and excess weights were noticed in the diabetics with no statistical difference in their BMIs (Mann–Whitney U test).

Of these patients, 109 had Type 2 diabetes, 8 had impaired glucose tolerance, with 5 patients being diagnosed with gestational diabetes. Eighty-two patients were on metformin, 42 on insulin, 13 on sulphonylureas, and 25 on thiazolidinediones. Associated conditions included hypercholesterolemia (49.3%), hypertriglyceridemia (53.8%), and hypertension (92%).

Weight loss Excess percent BMI loss in these patients at 3, 6, and 12 months were 21.7 (19.6–23.9), 32.3 (26.5–38), and 37.8 (33–42.5), respectively. Excess percentage weight loss at for the same time period was 19.7% (17.8–21.6), 39.4% (24.1–34.7), and 34.3% (29.8–38.7), respectively. There was no statistically significant difference with regards to the weight loss between the diabetics (N=122) and non-diabetics (N=132; Table 1).

Analysis of Comorbidities

Hyperglycemia Mean preoperative glucose was 9.1 (range 3.9–26.0 mmol/l; N=114/122). Mean preoperative HbA1c was 8.2 (range 4.9–13.3%; N=114/122). Mean glucose and HbA1c at 1 year were 6.9 mmol/l (N=101/114) and 7.4% (N=101/114), respectively. These values were significantly different from the preoperative values (Wilcoxon signed ranks test, $p<0.01$). Of the patients, 93.1% experienced an improvement in fasting glucose levels and 75.4% patients an improvement in HbA1c levels at the end of 1 year. The %EWL did not have a significant effect on the decrease in HbA1c levels ($r=-0.28$; $p=0.149$) and fasting glucose levels ($r=-0.158$; $p=0.625$; Table 2).

Forty-two patients were on insulin with a mean daily preoperative dose of 150.7 U. One-year insulin data were available for 41 patients. Fifteen had discontinued insulin (36.6%), 25 had their dose reduced, and 1 patient was on the same daily dose at the end of 1 year. The mean dose of insulin for patients still on it at the end of 1 year was 37.2 U (Wilcoxon signed ranks test, $p<0.01$). The %EWL did not have a significant effect on the decrease in insulin levels at the end of 1 year ($r=0.299$; $p=0.176$).

Preoperatively, 82 patients were on metformin with a mean dose of 2,026 mg. One-year data were available for 77 patients. Twenty-six were able to discontinue metformin (34.2%). Twenty-six had their dose reduced, 20 experienced no change, and 5 patients had increase in the dose of metformin. One patient was started on metformin during follow-up due to biochemical failure in the improvement of diabetes. The mean dose of metformin for patients still on it at the end of 1 year 1,589 mg (Wilcoxon signed ranks test, $p<0.01$).

Thirteen patients were on sulphonylureas preoperatively with a mean dose of 116.9 mg. Three patients were able to discontinue these. The mean dose at the end of 1 year was 60 mg (Wilcoxon signed ranks test; $p=0.04$). Twenty-five patients were on thiazolidinediones preoperatively. Thirteen were able to discontinue these.

Table 1 Excess weight and BMI loss in diabetics vs. non-diabetics

	Non-diabetics (N=132)	Diabetics (N=122)	p value[a] (diabetics vs non-diabetics)
Preoperative			
Weight (kg)	141±28.6	151.8±30.6	0.001
BMI	52.1±8.5	52.9±8.7	0.349
Excess weight (kg)	79.2±26.4	87.4±27.7	0.004
3 months			
%EWL	18.9±10	19.7±9.2	0.872
%EBL	20.6±10.9	21.7±10.4	0.796
6 months			
%EWL	23.5±10.6	29.4±20.9	0.073
%EBL	25.6±11.7	32.3±23	0.060
12 months			
%EWL	28±15.4	34.3±14.9	0.054
%EBL	30.9±16.9	37.7±16.	0.048

Values have been expressed as means±standard deviation.
[a]Mann–Whitney U test.

Table 2 Metabolic profile of diabetics at the end of 1 year follow-up

	Reference range	Pre LAGB	1 year	*p* value[a]
Glucose metabolism				
		N=(114/122)	*N*=(101/114)	
HbA1c	<5%	8.2±1.9	7.4±1.6	<0.01
Fasting glucose (mmol/l)	<5 mmol/l	9.1±3.6	6.9±2.2	<0.01
Diabetic medications				
Insulin (units)	–	150.7±106.7	37.2±38.4	<0.01
		N=(42/42)	*N*=(41/42)	
Metformin (mg)	–	2026.8±780.8	1052.6±953.6	<0.01
		N=(82/82)	*N*=(77/82)	
Sulfonylureas (mg)	–	116.9±112.9	60±66.6	0.04
		N=(13/13)	*N*=(13/13)	
Dyslipidemia				
		N=(98/122)	*N*=(71/98)	
Total cholesterol	<5.0 mmol/l	5.1±1.2	4.4±0.9	0.05
Serum triglyceride	<2.0 mmol/l	3.9±1.6	2.6±1.7	0.007
Hypertension				
		N=(122/122)	*N*=(115/122)	
Systolic pressure (mmHg)	<140	148±19.9	125±15.5	<0.01
Diastolic pressure (mmHg)	<90	84.1±10.9	76.1±8.1	<0.01
Mean Arterial pressure (mmHg)	–	105.4±12.7	92.7±8.4	<0.01

Values have been expressed as means±standard deviation. Number of patients with diabetes=122. The data set available at a particular time point has been indicated as (number data available on/ total patients, or patients who were on a particular drug). One-year data has been expressed as number data available on/patients who had preoperative data.

[a] Wilcoxon signed ranks test.

Dyslipidemia An elevated level of total serum cholesterol and serum trigylcerides was present in 49.3% and 53.8% of the patients, respectively. There was a reduction in total serum cholesterol levels from a mean of 5.1 (*N*=98/122) to 4.4 (*N*=71/98) at the end of 1 year (Wilcoxon signed ranks test, $p=0.05$). There was a change in serum triglyceride level from a mean of 3.9 (*N*=98/122) to 2.6 (*N*=71/98; Wilcoxon signed ranks test, $p=0.007$). Of the patients, 90.9% showed improvement in their total cholesterol level, and 100% showed improvement in their serum triglyceride levels. The %EWL did not have a significant effect on the decrease in total cholesterol levels ($r=0.347$; $p=0.399$) and serum triglyceride ($r=-0.347$; $p=0.399$).

Hypertension Of the patients, 92.0% had either a history of hypertension, were on anti-hypertensive medication, or were found to be hypertensive at the time of surgery. The mean preoperative systolic and diastolic pressures were 148 and 84 mmHg, respectively (*N*=122/122). At 1 year, they were 126 and 76 mmHg, respectively, (*N*=115/122; Wilcoxon signed ranks test; $p<0.01$, $p<0.01$). The mean preoperative and 1 year Mean Arterial pressure were 105.4 and 92.7, respectively (Wilcoxon signed ranks test, $p<0.01$). The Mean arterial pressure improved in 87.5% of patients.

The %EWL did not have a significant effect on the decrease in systolic ($r=-0.051$; $p=0.812$) and diastolic ($r=-0.282$; $p=0.182$) blood pressure. This was also seen for the fall in mean arterial pressures ($r=-0.171$; $p=0.425$).

Impaired glucose tolerance/gestational diabetes All patients with impaired glucose tolerance (*N*=8) experienced similar improvements in HbA1c, fasting glucose, dyslipidemia, and hypertension. None of the patients had progression to type 2 diabetes. Similar results were also seen in the patients with gestational diabetes (*N*=5).

Discussion

The effect of weight loss in the amelioration of diabetes is well known [7]. The effect of laparoscopic gastric banding on the metabolic profile in patients has been previously discussed in the literature. A recent 4-year study of obese patients carried out by Pontiroli et al. found that no patients

undergoing laparoscopic gastric banding progressed to type II diabetes compared to 17% of those in the diet treatment arm [11]. They concluded that in morbid obesity, sustained and long-lasting weight loss obtained through laparoscopic gastric banding prevents the occurrence of type II diabetes. Similarly, Ferchak et al. have concluded that weight loss prevents progression from IGT to diabetes [19].

One of the most recent articles on this subject by Dixon et al. had similar conclusions. In this unblinded randomized controlled trial, the effect of gastric banding surgery vs medical therapy and weight loss by life style changes in diabetics was studied. The primary outcome measure was remission of type 2 diabetes. Although a 76% remission of diabetes was found with gastric banding surgery, this study only included diabetics with a BMI between 30 and 40 and with a relatively recent onset of diabetes [20].

Studies examining other comorbidities such as gastro-esophageal reflux disease, asthma, dyslipidemia, hypertension, depression, arthritis, joint and back pain, stress incontinence, and sleep apnea have observed similar improvements with gastric banding surgery [12, 21, 22].

Impact on Weight Loss

A mean excess weight loss of 34.3% was noticed in the diabetics undergoing laparoscopic banding at the end of 1 year compared to 38% by O'Brien et al. [12]. However, the mean preoperative weight and BMI of patients was much higher in our series, which could explain the lower excess weight loss [23, 24]. There was no statistical difference in the amount of weight loss between the diabetics and non-diabetics, which is contrary to earlier published evidence [12].

Impact on Diabetes

Improvement in all parameters of diabetes was noticed, and in particular, there was a statistically significant difference between the preoperative and 1 year values of fasting glucose and HbA1c. The fall in these values was not linked to excess weight loss over the same period. The improvements in fasting glucose and Hb1Ac were accompanied by a statistically significant drop in the medications that these patients were taking for diabetes.

Impact on Dyslipidemia

All the patients demonstrated improvement in serum triglyceride levels with over 90% showing improvement in the total serum cholesterol levels at the end of 1 year. There was no significant link between excess weight loss and the fall in these values [12].

Impact on Hypertension

There was a statistically significant reduction in the systolic, diastolic, and mean arterial pressures over the course of 1 year. There was no significant link between excess weight loss and the reduction of these blood pressure parameters.

Conclusion

Laparoscopic gastric banding is obviously effective in producing weight loss over a 1-year period. Although a great deal of research has been performed particularly focussing on resolution of comorbidities with obesity surgery, studies specifically examining comorbidity in diabetics undergoing gastric banding are scant. In this study, a significant improvement in diabetes and associated metabolic syndrome was observed. Improvements in the metabolic profile of these diabetic obese patients appeared to be independent of the degree of weight loss, perhaps highlighting the pivotal role of calorie restriction rather than absolute weight loss in this finding [25].

There were no significant complications in the diabetic subset undergoing laparoscopic gastric banding emphasizing the low-risk nature of this treatment. These data support the view that gastric banding is a safe intervention which significantly impacts on the improvement and resolution of type II diabetes and related metabolic syndrome in the morbidly obese diabetic patient.

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