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Original article

# Effects of gastric banding on glucose tolerance, cardiovascular and renal function, and diabetic complications: a 13-year study of the morbidly obese

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### Abstract

**Background:** Limited information is available on weight loss, metabolic control, cardiovascular disease and diabetic complications in morbidly obese patients undergoing gastric banding (LAGB) compared with morbidly obese patients receiving medical treatment.

**Objective:** To assess the long-term effects of laparoscopic adjustable gastric banding (LAGB) on glucose tolerance, arterial hypertension, and cardiovascular disease and prevention of diabetic complications (retinopathy and renal function) in morbidly obese patients.

Setting: University hospitals, Italy.

**Materials and Methods:** In this retrospective study, 87 morbidly obese patients who underwent LAGB (20 with diabetes) and 87 morbidly obese patients who did not undergo surgery (36 with diabetes) for the treatment of obesity during the period 1995 to 2003 consented for re-examination after a mean ( $\pm$  standard deviation) period of 13.8  $\pm$  2.04 years. At baseline, all mobidly obese patients had a body mass index (BMI)  $\geq$  35 kg/m<sup>2</sup> and were aged 18 to 65 years.

**Results:** At follow-up, LAGB patients maintained a lower weight compared with baseline values and demonstrated significant decreases in both blood pressure and heart rate measurements compared with control patients. LAGB patients also experienced greater improvement of glucose tolerance than did control patients (28% versus 10%, respectively; P < .01) and reduction of insulin and homeostasis model assessment for insulin resistance. Fewer LAGB patients developed carotid plaques than did control patients (10% versus 26%, respectively; P < .01). Intensification of antihypertensive therapy was required in 31% of surgery versus 60% of control patients (P < .05). Among diabetic patients, improved glucose tolerance occurred in 55% of surgery patients versus 0% in the control group (P < .01). In addition, insulin treatment was necessary in 9 control patients versus 0 in the surgery group (P < .05), and carotid plaques occurred in 10% of LAGB patients versus 50% of control patients (P < .01). Creatinine levels and the estimated glomerular filtration rate improved in LAGB diabetic patients but not in control patients (P < .05).

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**Conclusion:** Despite a very small weight loss over the long term (i.e., 2.2 kg/m<sup>2</sup>), improvement of glucose tolerance persisted for long periods after LAGB, with no unfavorable effect on kidney function and retinopathy. In contrast, no effect was observed on prevention of arterial hypertension or cardiovascular disease. (Surg Obes Relat Dis 2016; 1:00–00.) © 2016 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords:

Bariatric surgery; Laparoscopic adjustable gastric banding; Diabetes mellitus; Cardiovascular diseases; Morbid obesity; Renal function; Diabetic retinopathy; Glucose tolerance; Arterial hypertension; Glomerular filtration rate; Insulin resistance; Homeostasis model assessment

Bariatric surgery is a reliable method to achieve significant and sustained weight loss in the morbidly obese population [1,2]. In addition, bariatric surgery (in the forms of laparoscopic adjustable gastric banding [LAGB], Rouxen-Y gastric bypass [RYGB], sleeve gastrectomy [SG], and biliopancreatic diversion [BPD]) significantly outperforms intensive medical therapy for resolution of type 2 diabetes mellitus (T2DM) at 1 to 2 years after treatment [2-4]. Studies also have shown that bariatric surgery prevents new cases of diabetes [5-8] and is probably the most effective preventive approach [9,10]. Finally, bariatric surgery prevents cardiovascular, all causes of noncardiovascular, and overall mortality in obese patients compared with medical treatment [11] in average patients and those with diabetes or with pre-existing cardiovascular disease [12-16]. A few, mostly uncontrolled, studies have shown additional positive including improved endothelial function, outcomes, decreased intima-media-thickness (IMT), reduced insulin resistance, decreased vascular and general inflammation, increased high-density lipoprotein (HDL) cholesterol, decreased sympathetic activity, and decreased left ventricular hypertrophy. These effects were reviewed recently [17] and might explain the positive effects bariatric surgery has on reduced cardiovascular disease. Resolution of diabetes can be temporary; recurrence of diabetes has been described. However, other positive effects, such as those on hyperlipidemia and arterial hypertension, can be of longer duration. This probably is the reason why the overall effect of bariatric surgery on cardiovascular health is maintained and lasting [18].

Compared with RYGB, SG, and BPD, LAGB has demonstrated lower outcomes in terms of diabetes resolution and percentage of excess weight loss (%EWL) [17,18]; therefore, it is not surprising that from 2003 to 2011 a marked rise of SG occurred, together with a decrease in the percentage of LAGB and RYGB performed worldwide, resulting in SG being the most commonly performed procedure (27.8%) after RYGB (46.6%), followed by LAGB (17.8%) [17]. Currently, SG has surpassed RYGB in volume (42.1% versus 34.2%) to become the most common bariatric procedure in the United States [19]. As to microangiopathic complications of diabetes, a few studies have shown limited effects of bariatric surgery on retinopathy [20–26], and a few studies have shown improved kidney function after RYGB and BPD but not in control patients who underwent non-surgical treatment [27,28].

Therefore, the authors explored the long-term effects of LAGB compared with medical treatment on glucose tolerance, diabetes, and manifestations of cardiovascular disease. In addition, for diabetic patients, the authors evaluated resolution or progression of diabetes and the development of associated retinal and kidney complications. For this study, the authors analyzed patients who were part of the LAGB10 study (see the following section) who underwent LAGB surgery or started medical treatment at least 10 years before the study presented here. The LABG10 study evaluated long-term prevention of mortality in obese diabetic and nondiabetic patients.

#### Methods

In 1995, 2 major hospitals started a common program of LAGB procedures. The details of the protocol have been published previously [29]. The aims of this protocol included the study of long-term complications of obesity, such as diabetes, hypertension, and cardiovascular disorders. Recalls were performed in 2004 and in 2008 [7,30]. The specific protocol of the retrospective LAGB10 study was approved by the Ethics Committee after the initial protocol had been approved in 1995, with subsequent modifications in 2002 and in 2006. A total of 520 patients either underwent LAGB (surgery) or received medical treatment (controls) on an outpatient basis during the period 1995 to 2003. Control patients included patients who attended the obesity and diabetes outpatient clinics and refused surgery but agreed to be followed-up. The main criteria for inclusion in this study were body mass index  $(BMI) > 35 \text{ kg/m}^2$  and age 18 to 65 years. Forty patients died during the observational period (6 LAGB and 36 control patients). The authors planned complete clinical and metabolic examinations comprehensive of the parameters of interest (including fundus examination and electrocardiogram [ECG] tracings for detection of ischemic heart disease and left ventricular hypertrophy [LVH]) for 250 patients. Unfortunately, 50 of the patients could not be contacted as a result of change of address or telephone number, 16 refused to be participants in this study, and 10 were unable to attend follow-up. Therefore, 174 patients agreed to be examined

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