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Laparoscopic adjustable gastric banding in adolescents: Results at two years including psychosocial aspects

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ABSTRACT

Background/purpose: Obesity now affects 3%–4% of the pediatric population and contributes to the increase in cardiac mortality in adulthood. Bariatric surgery is the best treatment for weight loss and the obesity-associated comorbidities in adults. We report here our experience of laparoscopic adjustable gastric banding (LAGB) in adolescents.

Methods: The medical charts of the first 16 patients operated on in our center were reviewed. Data were compiled concerning weight loss, physical and biological comorbidities, health-related quality of life (QOL) and surgical complications before surgery and during 24 months of follow-up.

Results: The maximal pre-operative median body mass index was 43.0 $kg \cdot m^{-2}$, decreasing to 33.0 $kg \cdot m^{-2}$ at 2 years post-LAGB, which corresponded to a 49.2% excess body weight loss ($p < 0.001$). Most comorbidities (glucose intolerance, hypertension and sleep apnea) resolved within the first year post-LAGB and QOL was improved on the PedsQL™ scales. No severe surgical complications were noted, with only three re-interventions for device failure (2) or band removal (1).

Conclusion: LAGB is well tolerated in adolescents and shows a beneficial impact on weight loss and obesity-related comorbidities. Associated with global management, it may have a positive impact on patients' QOL and social and psychological status.

Obesity affects about 6.7% of the pediatric population worldwide [1]. In France, 15.8% of the pediatric population is overweight and 2.8% is obese [2]. Chronic excessive caloric intake and a sedentary lifestyle are the major culprits explaining this prevalence [2,3].

Obesity has been associated with cardiovascular, respiratory, orthopedic, endocrine and digestive complications [3,4]. It also has a significant negative psychosocial impact, especially in adolescence [5]. A severely obese teenager has more than a 70% risk of remaining so in adulthood [6], and the body mass index (BMI) in adolescence has been independently associated with the risk of coronary heart disease in the future [7,8], as well as with other associated adverse events such as diabetes, colorectal cancer and arthritis [9]. The efficacy of lifestyle interventions on weight loss has been shown to be poor [10,11]. In the last 20 years, bariatric surgery has become the treatment of choice in adult obesity and has therefore also come under consideration for adolescents. Within this context, the Teen Obesity Network-Angers was created in 2008, although obesity surgery has not yet been validated in France for teenagers with severe obesity. The purpose of the network is to propose laparoscopic adjustable gastric banding (LAGB) as a treatment for morbid obesity in adolescents 14 years old or more; all must be volunteers for the procedure, meet specific criteria, and agree to comply with the associated medical monitoring, strict nutritional management, physical reconditioning and psychological follow-up. All the adolescents undergo metabolic, digestive, cardiac, respiratory, and psychological evaluation. This study reports the results at 1 and 2 years in the first 16 patients included in the network regarding weight loss, changes in comorbidities, and improvement in quality of life. Tolerance and complications related to the placement of LAGB are also reported.

1. Material and methods

1.1. Selection of the patients and clinical survey

The data from all consecutive patients having a LAGB placed between 2008 and 2012 were prospectively collected within the

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framework of our specialized care center for severe obesity. Surgery and further clinical, metabolic, cardiorespiratory and psychological investigations were all performed in the Pediatric Department of the University Hospital of Angers. This adolescent LAGB program was approved by the local ethics committee in 2007. Patients suffering from severe obesity with failure (persistent increase in BMI) of at least one year of conventional lifestyle intervention (nutritional and physical care) were recruited in the cohort of obese adolescents followed in the Pediatric Department. Secondary obesity (of endocrine or syndromic origin) was excluded by appropriate genetic and hormonal testing. Inclusion criteria were in agreement with the current recommendations for bariatric surgery for adolescents [12] and adults; all patients had a BMI ≥ 40 $kg \cdot m^{-2}$ or ≥ 35 $kg \cdot m^{-2}$ with associated comorbid conditions, showed no physical or psychological contraindication to bariatric surgery, and were 14 years old or more (because growth and puberty are nearly achieved at this age). The patients and their parents gave their written informed consents. They did not receive any financial compensation. Prior to surgery, the patients were closely followed by regular encounters with a dietician, a pediatric psychiatrist and a pediatric endocrinologist for at least 6 months, and all showed good compliance. Agreement for bariatric surgery was then given during a multidisciplinary meeting. The Midband® LAGB (M.I.D., Dardilly, France) was placed using the "pars flaccida" method, and was initially kept deflated.

After the usual post-operative care, the first inflation of the LAGB occurred at 6 weeks and was controlled by upper gastrointestinal studies. Further adjustments were made thereafter if needed, based on the symptoms described by the patients: It was a subjective but joint (surgeon and patient) assessment of the patient's weight loss, the tolerance of a solid meal and the sensation of hunger. Weight regain or plateauing of the weight loss along with the loss of a light and transient dysphagia was the indication for band filling in the clinical cohort.

1.2. Clinical, psychological, and metabolic assessment. Evaluation of comorbidities

Patient follow-up consisted of regular 3-month evaluations starting from the surgical procedure in the first year, 6-month appointments over the next 2 years, and a yearly consultation thereafter, in the Pediatric Department of the University Hospital of Angers. Additional nutritional and psychological consultations could be made if necessary.

The efficacy of LAGB for weight loss was assessed by weight and height measurements, and body mass index (BMI = weight (kg)/height $(m)^2$) and excess body weight loss calculations (EBWL, %, calculated with an ideal body weight set at BMI = 24.9 $kg \cdot m^{-2}$).

1.3. Cardiorespiratory and metabolic assessment

All the subjects had an oral glucose tolerance test (OGTT) every 6 months (75 g glucose intake, and blood glucose and insulin measurements at 0, 30, 60, 90 and 120 min). Homeostatic model assessment for insulin resistance (HOMA-IR) was calculated as follows: fasting insulinemia (μUI/ml) × fasting glycemia (mmol/l)/22.5) [13]. Standards for defining insulin resistance have not been established in children or adolescents, as there is no consensual threshold value for HOMA [14]. In 2012, reference values for insulinemia were published for a representative sample of healthy French children and adolescents from 7 to 20 years old [15]. We therefore defined insulin resistance as fasting insulinemia over 2 standard deviations (DS) for age and sex. Glucose intolerance was defined as fasting plasma glucose ≥ 110 and < 126 mg/dL, or 2-h plasma glucose ≥ 140 and < 200 mg/dL. Diabetes was defined as fasting plasma glucose ≥ 126 mg/dL, or 2-h plasma glucose ≥ 200 mg/dL [16].

Fasting triglycerides, total cholesterol and high density lipoprotein (HDL) cholesterol, liver enzymes, vitamins and mineral trace elements were also measured every 6 months, with commercially available kits. Hypercholesterolemia was defined by a total cholesterol value over the 95th percentile for age and sex, i.e. >5.5 mmol/L, as well as a low HDL level, set at <1 mmol/L [14].

Hypertension and sleep apnea were assessed through blood pressure measurement and polysomnography, respectively, before the surgical procedure and were repeated one year later if necessary. Hypertension was defined by a systolic and/or diastolic blood pressure over the 95th percentile for age and sex at two successive and distinct consultations [14]. Sleep apnea was diagnosed when the obstructive apnea–hypopnea index was > 1/h [17].

The diagnosis of non-alcoholic fatty liver disease (NAFLD) was estimated on abdominal ultrasonography when hepatomegaly occurred with increased liver echogenicity.

1.4. Quality of life and psychological assessment

Health-related quality of life was evaluated before and at one and two years post-surgery with the PedsQL™4.0 self-questionnaire [18] and the PedsQL™ Multidimensional Fatigue Scale [19] adapted for adolescents. Both self-questionnaires have been validated in pediatric chronic diseases and in the pediatric obese population [18]. These self-questionnaires were answered during regular metabolic and psychological evaluations, which took place in the Pediatric Department at University Hospital of Angers. Qualitative assessment was also performed through regular encounters with a pediatric psychiatrist, at least every 3 months and more often if needed.

1.5. Statistical analysis

Statistical analysis was performed using R® 2.13.1 and GraphPad Prim® 5.04 for Windows (GraphPad Software, San Diego, CA), with a significance level at $p < 0.05$. All data are given as median and extremes. At the time of analysis, sixteen patients had completed one year of follow-up, and only ten patients had completed two years of follow-up. There was no loss of follow-up.

Wilcoxon's paired test or the Mann–Whitney test was used as comparison test for quantitative data and Fisher's exact test for qualitative data. The Kruskal–Wallis test was used for multiple comparisons.

2. Results

2.1. Patient characteristics at inclusion

The main clinical characteristics of the 16 patients are summarized in Table 1. All had suffered from severe obesity since early childhood. Eleven of them had previously undergone one or more 3-month hospital stays in specialized pediatric obesity care centers, with a median weight loss of 13.5 kg [5–32 kg], all with relapse after discharge.

The maximal pre-operative BMI was 43.0 $kg \cdot m^{-2}$ [36.8–48.5 $kg \cdot m^{-2}$], and the BMI at LAGB was 40.6 $kg \cdot m^{-2}$ [31.9–47.5 $kg \cdot m^{-2}$]. Two thirds of the patients had morbid obesity (BMI ≥ 40 $kg \cdot m^{-2}$). All patients suffered from one or more associated comorbidities (Table 1). Five patients were insulin resistant and three patients were glucose intolerant, but none had diabetes mellitus.

2.2. Effectiveness for weight loss

The median follow-up was 25.5 months [10–41] after LAGB. Median EBWL with our care program was 13.8% ([6.1–58.5], n = 16) at one month after LAGB and stabilized around 40% between 6 months and one year (39.8% [14.2–95.6], n = 16), before reaching 49.2% ([17.1–98.1], n = 10) at 2 years. The BMI decreased from 40.6 $kg \cdot m^{-2}$ at day 0 to 36.2 $kg \cdot m^{-2}$ ([23.5–42.4], n = 16) at one year and 33.0 $kg \cdot m^{-2}$ ([23.1–42.7], n = 10) at 2 years after the procedure (Table 1). At that time, 16.3% patients were no longer obese, 50%