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# National survey for bariatric procedures in adolescents: Long time follow-up<sup>☆</sup>



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## ABSTRACT

*Introduction:* The role of bariatric surgery and its role in adolescent is still under discussion worldwide. The aim of this study is to report an Italian survey for bariatric procedures in adolescents and the outcome with a medium and long-term follow-up.

Materials and methods: We retrospectively analyzed consecutive data added into the Italian register of the society for bariatric surgery(period 2000–2010). We evaluated all patients treated in a 10-year period with a mean follow-up of 3 years. Inclusion and exclusion criteria were created. All patients were aged between 13 and 18 years. We evaluated and compared clinical data.

Results: After reviewing medical charts, 173 patients were considered for the study; 85 patients were treated with adjustable gastric band (AGB), 47 with intragastric balloon (IB), 26 with sleeve gastrectomy (SG) and other 15 patients with malabsorptive techniques (MT). Among clinical data, there was a statistical difference in terms of %excess weight loss (%EWL) between techniques only after 1 year post-procedure; at 5 years, considering the percentage of patients studied, sleeve gastrectomy had the best %EWL respect to other non malabsorptive techniques (p<0.05); at 5 year more than 90% resolved their comorbidities especially hypertension, dyspnea, orthopedic problems and dyspnea.

Conclusions: This study is the first reporting a national survey in adolescent; more than 80% of patients are followed until 5 years post-op but only few patients (less than 5%) until 10 years. Our results demonstrated that sleeve gastrectomy in adolescent is safe and had a better %EWL respect to other non-malabsorptive bariatric procedures. Level of evidence: level III.

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Obesity, as well as its complications, is a chronic disease. In 1998 the World Health Organization warned that obesity had reached the rank of a pandemic and that its prevalence was increasing alarmingly, especially in the child population [1–2].

Outcomes for obesity treatment are expressed as excess of weight loss (EWL) during continuous follow-up. The approach could be either surgical or nonsurgical, but it was reported that the most aggressive nonsurgical weight loss approach had provided at best 10–15% of excess weight loss in less than 30% of the patients, with a high rate of associated recidivism [3].

Until effective nonsurgical treatment becomes available, including pharmacological therapy, bariatric surgery and its procedures are the only viable options for providing durable and significant weight loss as well as improvement of heath conditions for morbidly obese patients [3–4].

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This proved to be true in adults, but at present there are only a few studies regarding pediatric patients with short follow-ups. Even though there are clear surgical indications for adolescents, specific indications about the techniques to be used in this population are not available yet. Many authors showed promising results with different surgical techniques and bariatric procedures in adolescents, although none compared such techniques and procedures with the outcomes of long-term follow-up [5].

Through the systemic analysis of a national register, the aim of this study was to compare the results obtained from different procedures used to treat obesity in adolescent patients.

# 1. Materials and methods

The clinical and surgical data of adolescents treated for obesity were analyzed using the Italian register of the Italian Society of Obesity Surgery and metabolic disorders (S.I.C.O.B.) to select the study population.

This retrospective cohort study included all consecutive patients (aged 13–18 years) who had received bariatric procedures between

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2000 and 2010. A minimum follow-up of 3 years (for 80% of patients) was considered the first criterion for inclusion. In general, inclusion criteria for bariatric procedures included body mass index (BMI)  $\geq$  40 kg/m<sup>2</sup> or BMI  $\geq$  35 kg/m<sup>2</sup> with obesity-associated comorbidities according to the international guidelines [1–6].

Exclusion criteria were as follows: patients lost to follow-up and patients who had received other bariatric procedures, dependency on alcohol or drugs, subjects with severe learning or cognitive disabilities or emotionally unstable. At present, based on the current international guidelines, there is not a gold standard procedure for adolescents. In general, the choice for each procedure was based on the surgeon's experience. Only malabsorptive procedures were performed for severe obesity (BMI > 45 kg/m²) associated with more than 3 comorbidities. Following the S.I.C.O.B. and I.F.S.O. (International Federation for the Surgery of Obesity & Metabolic Disorders) guidelines, all procedures were performed in bariatric centers of excellence by highly skilled surgeons [6].

Demographic and weight data were collected at 3, 6 and 12 months and then annually. Operative data, hospital stay, morbidity, mortality and procedure-related complications were also recorded and compared. *Morbidity* was defined as 'early', when the onset was within 30 days from surgery, or 'late', when the onset was after the first 30 post-operative days. Procedure-related complications included bleeding, slippage, leakage, stricture formation and ulceration. The other complications considered were the following: gastritis (irritated stomach tissue), gastroesophageal reflux (regurgitation), heartburn, gas bloat, dysphagia (difficulty in swallowing) and dehydration.

Statistical analysis was performed using the student t-test, chi-square and Fischer exact tests. Significance value was set at p < 0.05. The analysis was conducted with the Statistical Package for Social Sciences (SPSS) software version 15 for Windows SPSS Inc., Chicago, USA.

#### 2. Results

After reviewing the registry, 173 patients were considered for the study.

# 2.1. Demographic data

The study population included 55 males and 118 females. Median age at operation was 15.9  $\pm$  1.4 years (range: 13–18 years) (females 16  $\pm$  2 years and males 15  $\pm$  2 years) (p > 0.05). Mean BMI before surgery was 44  $\pm$  8 kg/m² (females 44  $\pm$  9 kg/m² and males 45  $\pm$  4 kg/m²) (p > 0.05). Mean excess weight was 63  $\pm$  24 kg in females and 71  $\pm$  9 kg in males (p > 0.05). 65% of patients were from the south of Italy, 30% from the north and 5% from central Italy (p < 0.05). 43% of patients had comorbidities, such as hypertension (4 patients), arthropathy (4 patients), obstructive sleep apnea (4 patients), dyspnea (5 patients), dyslipidemia (15 patients), depression with psychiatric disorders (binge eating, sweet eating, nibbling) (12 patients), cholelithiasis (4 patients), steatosis (28 patients) and diabetes mellitus (6 patients). There were no significant differences between the distribution of comorbidities and the type of procedure used to treat obesity.

# 2.2. Techniques

Eighty-five patients were treated with laparoscopic adjustable gastric band (AGB), 47 patients with endoscopic intragastric balloon (IB), 26 patients with sleeve gastrectomy (SG) and other 15 patients with malabsorptive techniques. All surgical procedures were performed laparoscopically. Pneumoperitoneum was obtained with blind access to the abdominal cavity by inserting a Veress needle through Palmer's point in 60% of patients and with an open trans-umbilical technique in the remaining 40%. No complications were reported during induction of the pneumoperitoneum. All bands were positioned using the pars flaccida technique without complications. Endoscopic removal of the intragastric balloon was performed under mild anesthesiological sedation within 12 months after its positioning. In 75 patients, when the BMI was stable within 1 year after surgery, the band was subsequently removed 3 years later. The other patients are still banded. 10 patients preferred to remain banded (with a full deflated band) in order to prevent any further procedures. All IBs were removed within 12 months.

Regarding the different procedures, there was no statistical difference between mean BMI at surgery, age at surgery and male/female ratio, whereas it was possible to observe a statistical difference in the length of hospital stay compared to the different surgical techniques. Mean hospital stay was 3 days (range: 1-14 days) with 1-3 days for AGB, 1-2 days for IB, 3-6 days for SG and 6-14 days for MT (p < 0.05).

The two most frequently used surgical procedures (AGB and SG) showed a statistical difference in the duration of the procedure with  $67 \pm 17$  min for SG and  $39 \pm 12$  min for AGB (p < 0.05).

# 2.3. Complications

None of the patients needed conversion to open surgery and there were no cases of major complications during surgery; none had intraoperative bleeding. There were no cases of umbilical hernia. No other major or minor complications were reported in the register.

# 2.4. Clinical data and comorbidities (Tables 1 and 2)

The mean follow-up time was 62.6 months. The number of patients with post-operative follow-up at 3 months, 6 months, 1 year and 2 years was 173/173 (100%), 173/173 (100%), 162/173(93.6%) and 158/173 (91.3%) respectively. There were 142 patients (82%) who completed a 3-year follow-up, 65 patients (35%) who completed a 5-year follow-up and 2 patients who completed a 10 year follow-up. The number of patients with multiple comorbid conditions after 2 years was small, with the mean number of comorbidities per patient falling from 2.1 before surgery to 0.7 at 2-year follow-up.

Compared to mean pre-operative BMI, there was a significant decrease in mean BMI for each procedure; BMI at 5 years for the AGB group was 33  $\pm$  3 kg/m² (pre-op 44  $\pm$  6 kg/m²), 32  $\pm$  4 kg/m² for the SG group (pre-op 46  $\pm$  8 kg/m²) and 33  $\pm$  6 kg/m² for the IB group (43  $\pm$  6 kg/m²). The %EWL at 3 years (82% of patients as required by the main point) was 43  $\pm$  10% for AGB, 56  $\pm$  14% for SG, 68  $\pm$  18% for IB and 77  $\pm$  20% for malabsorptive techniques respectively (p < 0.05).

There were no cases of non-responders (%EWL < 30%) at 3 years.

One of the most interesting findings was that 6 months after the procedures there were no statistical differences in BMI reduction and %EWL between the study groups. However, this changed after 1 year: a comparison between the procedures (excluding the malabsorptive techniques) showed that SG and %EWL achieved significantly higher BMI reduction than AGB and IB (p < 0.05). After 5 years, %EWL was more

Table 1
Excess weight loss data.

EW	EW pre-op	%EWL 6 m	%EWL 3 years	%EWL 5 years
AGB (n = 85) SG (n = 26) IB (n = 47) MT (n = 15)	$68 \pm 9 \text{ kg}$ $63 \pm 12 \text{ kg}$ $59 \pm 22 \text{ kg}$ $63 \pm 20 \text{ kg}$	$26 \pm 14\% (n = 85)$ $24 \pm 9\% (n = 26)$ $19 \pm 9\% (n = 47)$ $18 \pm 8\% (n = 15)$	$43.1 \pm 10.3\%$ (n = 70) $56.2 \pm 13.6\%$ (n = 21) $68.2 \pm 14.7\%$ (n = 39) $78.6 \pm 19.8\%$ (n = 12)	$47 \pm 3\%$ (n = 24) $58 \pm 9\%$ (n = 14) $49 \pm 9\%$ (n = 18) $71 \pm 11\%$ (n = 9)

**Table 2** BMI value between groups.

BMI	BMI pre-op	BMI 6 m	BMI 3 years	BMI 5 years
AGB $(n = 85)$	$44 \pm 6 \text{ kg/m}^2$	$41 \pm 4 \text{ kg/m}^2 \text{ (n} = 85)$	$35 \pm 1 \text{ kg/m}^2 \text{ (n} = 70)$	$33 \pm 3 \text{ kg/m}^{2 \text{ (n=24)}}$
SG (n = 26) IB (n = 47)	$46 \pm 8 \text{ kg/m}^2$ $43 \pm 6 \text{ kg/m}^2$	$43 \pm 2 \text{ kg/m}^2 \text{ (n} = 26)$ $41 \pm 5 \text{ kg/m}^2 \text{ (n} = 47)$	$31 \pm 2 \text{ kg/m}^2 (n = 21)$ $34 \pm 5 \text{ kg/m}^2 (n = 39)$	$32 \pm 4 \text{ kg/m}^2 ^{(n=14)}$ $33 \pm 6 \text{ kg/m}^2 ^{(n=18)}$
MT(n = 15)	$45 \pm 9 \text{ kg/m}^2$	$39 \pm 3 \text{ kg/m}^2 (n = 15)$	$36 \pm 7 \text{ kg/m}^2 (n = 12)$	$30 \pm 2 \text{ kg/m}^{2 (n=9)}$

significant than %EWL after 1 and 3 years compared to SG and other procedures (excluding MT procedures) (p < 0.05).

It is interesting to highlight that the percentage of EWL in the IB group was satisfactory up to 3 years after the procedure.

With regard to comorbidities, there was a statically significant improvement in 35% of patients within the first year after procedures, rising to 78% of patients within 5 years (p < 0.05).

SG showed the best improvement rate compared to AGB and IB; for malabsorptive techniques the results were not comparable because of the reduced number of cases included.

There were no cases of gastroesophageal reflux disease, gastritis, hiatal hernia or dyspepsia after surgery. Median hospital stay was 3 days (range: 1-14 days) (p > 0.05).

#### 3. Discussion

The vast range of bariatric surgical literature relates mainly to adults, where surgery is associated with the most considerable weight loss and the lengthiest maintenance over time when compared to nonsurgical treatments. Surgery is also associated with satisfactory remission of comorbidities and decreased mortality rate related to obesity [6–8].

Patients who undergo such procedures, and mainly those receiving different types of bypass, may suffer malnutrition and various metabolic consequences; as a result, they need to comply with lifelong use of vitamin and mineral supplements.

Morbidly obese patients have an increased risk for metabolic complications; it has been proven that many of obesity-related comorbidities recognized in adulthood begin to develop in childhood, and have two or more cardiovascular risk factors. The health consequences of childhood obesity include increased risk for metabolic abnormalities such as type-2 diabetes mellitus, cardiovascular diseases, hypertension, non-alcoholic fatty liver disease, obstructive sleep apnea syndrome and orthopedic complications.

Recently, bariatric surgery and procedures are also suggested in adolescents, although to date most of the published studies include case series with a small cohort of patients. One of the most important studies in adolescents, a randomized trial by O'Brien et al. comparing lifestyle intervention and bariatric surgery (laparoscopic gastric banding), demonstrated favorable weight loss and improvements in cardiovascular factors, as well as improved quality of life in the surgically treated group [9–11].

Among nonsurgical procedures, the intragastric balloon represents a temporary nonsurgical and non-pharmacological treatment for obesity which is considered restrictive, totally reversible and repeatable. The temporary aspect of IB is attractive but the duration of implantation, during which the patient is closely followed, is short. Many authors speculate whether such short time is sufficient to change the patients' lifestyle and eating habits so that they can maintain their weight reduction after IB removal. Also, this procedure presents complications, such as intolerances, esophagitis, peptic ulcers and others. It is for this reason that patients should be well informed before balloon implantation.

The most recent available meta-analysis provides good initial evidence in support of surgical intervention also in adolescents. This meta-analysis reported a complication rate comparable to that of adults, indicating that these procedures are safe also for pediatric patients (complication rates of 22%–33% for RYGB, 4.3% for SG, and 10%–48% for AGB) [12–13].

Choosing the best procedure is of primary importance and, although RYGB is currently the gold standard for adults, for adolescents many authors suggest the use of non-malabsorptive techniques, especially in younger morbidly obese patients. In a recent report from a Swedish nationwide study for bariatric surgery it was reported that the use of gastric bypass in severe obesity had good results also in adolescents. They reported that the Laparoscopic Roux en Y gastric bypass is well tolerated with a positive five-year follow-up [14–15].

Probably the main problem is that many studies reported procedures on a pediatric or adolescent population within the age range of 18–21 years. In fact, the pediatric age should be considered as ranging between 13 and 18 years or less than 16 years. A large series of adolescents undergoing RYGB showed BMI reduction of 13.3 kg/m<sup>2</sup> at 2 years, with 93% achieving >50% excess BMI loss [16].

This is a good result but only few patients aged between 13 and 15 years were reported in literature as treated with RYGB. In literature, the resolution rates following AGB were wide-ranging and very limited data were available on SG. Intragastric balloon or AGB, both considered as reversible procedures, demonstrated good tolerance, with low complications and satisfactory weight loss after a 2-year follow-up [11–17].

Published papers also reported that the rate of adolescents with bands still in place decreased to 87%, 76%, and 53% at 3, 4, and 5 years respectively. After 5 years, a limited number of patients remained banded. But probably the most important factor is that Lap band surgery is reversible and allows time for the adolescent to mature and make a more informed decision with regard to a permanent surgical procedure if required later in life. Lap band is used also for severe obesity with good results at 3 years.

Recent evidence has demonstrated that SG is a viable option also in adolescents and in very young children, with short weight outcomes similar to RYGB but with lower risks of long-term nutritional deficiencies. However, no data are available for long-term weight loss outcome. It is clear that a suitable population of patients, following the international guidelines, is essential to achieve good long-term results [16–26].

Ejaz et al. reported their results in 18 patients treated with SG; after 2 years (in only 3 patients) the %EWL was 50.2% [22].

Moreover, Serrano OK et al. recently reported their results in patients younger than 21 comparing laparoscopic gastric bypass and SG; they concluded that these procedures seem to offer a comparable weight loss benefit with acceptable surgical morbidity [23].

In the pediatric/adolescent age it is clear that non-surgical options should be explored first, including lifestyle interventions and behavioral modifications; however, in this population it is more difficult than in adults to achieve good motivation, especially when the parents decide about their child's health. In literature, as reported by a recent review, there are no studies demonstrating a correlation between patients' motivation and the outcome [24–28].

Our study reports interesting findings, comparing different procedures with long-term follow-ups. The study population is one of the few pediatric populations ever reported in medical literature with a satisfactory distribution per procedure. Data from our database and the results of the study showed that SG seems to be a promising technique in terms of weight loss, safety, low complication rate and resolution of comorbidities.

Although a national surgical register should be introduced for the whole country, the data included should be as correct and complete as possible; however, this represents a limit to this study. As for surgical

complications, only a limited number of centers recorded the data regarding complications and, for this reason, it was not possible to collect report and compare them. On the other hand, the register was carefully completed with data regarding weight, %EWL and resolution of comorbidities. Probably, keeping in mind that the focus is to investigate the main outcomes of bariatric surgery, it is better to have results about weight loss rather than the more common strictly surgical and technical aspects or complications that are already well known and similar to those already reported in most of the published papers.

## 4. Conclusion

There is emerging literature about bariatric surgery in adolescents, but data remain limited. Based on current evidence, as reported for adults, bariatric surgery offers weight loss and improvements also in adolescent patients' health.

Bariatric surgery seems to be an effective method for weight loss in adolescents. Considering the different techniques available in this field, in adolescent patients the authors advocate the use of those techniques preserving an intact gastrointestinal tract. As reported in recent literature as well as in this study, the use of sleeve gastrectomy is safe and useful to achieve high and stable %EWL. Other less invasive techniques, such as AGB or intragastric balloon insertion, offer satisfactory results and could be used as an alternative to SG or in those patients who require immediately reversible procedures. It remains crucial that these patients have access to an experienced surgeon as part of a multidisciplinary pediatric team to ensure that there is a long-term regular follow-up.

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