Alexia Sophie Peña, Tarik Delko, Richard Couper, Kerri Sutton, Stamatiki Kritas, Taher Omari, Jacob Chisholm, Lilian Kow, Sanjeev Khurana

Laparoscopic adjustable gastric banding in Australian adolescents : should it be done?

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Laparoscopic Adjustable Gastric Banding in Australian adolescents:

Should it be done?

Authors

* Alexia Sophie Peña, MD, FRACP, PhD [1,2] (Email: alexia.pena@adelaide.edu.au)

* Tarik Delko, MD [3] (tarik.delko@gmail.com)

Richard Couper MChB, FRACP [4] (richard.couper@adelaide.edu.au)

Kerri Sutton, CN [3] (kerri.Sutton@sa.gov.au)

Stamatiki Kritas, BSc (Hon) [4] (stamatiki.kritas@gmail.com)

Taher Omari, PhD [4, 5] (taher.omari@flinders.edu.au)

Jacob Chisholm, MBBS, FRACS, MS [3] (Jacob.Chisholm@sa.gov.au)

Lilian Kow, BMBS, PhD, FRACS [3] (lilian.kow@flinders.edu.au)

Sanjeev Khurana, MBBS, MS, FRCSI, FRACS [1, 6] (sanjeev.khurana@sa.gov.au)

* *Both equal contribution for 1st authorship*

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[1] Robinson Research Institute and Discipline of Paediatrics, The University of Adelaide, Adelaide, South Australia

[2] Endocrinology and Diabetes Department, [4] Gastroenterology Department [6] Paediatric Surgery Women's and Children's Hospital (WCH), North Adelaide, South Australia

[3] Department of Gastrointestinal Surgery, Flinders Medical Centre, Adelaide, Australia

[5] Human Physiology, Medical Science and Technology, School of Medicine, Flinders University, Adelaide, South Australia

Corresponding author: Alexia Sophie Peña - E-mail: alexia.pena@adelaide.edu.au

Address: Discipline of Paediatrics, Women's and Children's Hospital,

72 King William Road, North Adelaide, SA 5006, Australia

Telephone/ Facsimile: + 61 8 81616402 / + 61 8 81617759

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Abstract

Objective: There are very few studies on laparoscopic adjustable gastric banding (LAGB) in obese adolescents with follow up for more than 36 months, let alone good prospective data beyond 24 months in Australian adolescents. We aimed to evaluate medium term (>36 months) safety and efficacy of LAGB in adolescents with severe obesity.

Methods: Prospective cohort study (March 2009–December 2015) in one tertiary referral hospital including obese adolescents (14-18 years) with a body mass index (BMI) >40 (or ≥35 with comorbidities) who consented to have LAGB. Exclusion criteria were syndromal causes of obesity, depression and oesophageal motility disorders. Main outcome measures include change in weight and BMI at 6, 12, 24, 36 and 48 months post LAGB. Postoperative complications and admissions.

Results: 21 adolescents (median [Interquartile range (IQR)] 17.4 [16.5-17.7] years, 9 males, mean ± SD BMI 47.3 ± 8.4 kg/m^2) had a median follow up of 45.5 [32-50] months post LAGB. Follow up data were available for 16 adolescents. Weight and BMI improved significantly at all follow up times (all $p < 0.01$). The median maximum BMI loss was 10 [7.1-14.7] kg/m^2. There were 4 minor early complications. Seven bands were removed due to weight loss failure/regain (2 had also obstructive symptoms).

Conclusions: We have shown in the longest prospective LAGB postoperative follow up study of Australian adolescents, that LAGB improves BMI in the majority of adolescents without significant comorbidities. LAGB is still a reasonable option to be considered as a temporary procedure to manage severe obesity during adolescence.

Key words: Adolescents, obese, bariatric surgery, Lap Band, longitudinal study

Introduction

The obesity epidemic is a global phenomenon [1]. In Australia 25% of children aged 6 to18 years have been identified as either overweight or obese and around 5% as obese [2]. Childhood obesity is linked to serious physical, psychologic and social comorbidities, and may result in reduced life expectancy due to early onset of disorders such as type 2 diabetes, hypertension, non-alcoholic steatohepatitis, obstructive sleep apnoea, depression accompanied by anxiety and low self-esteem. These comorbidities are becoming more prevalent in adolescents and young adults [3,4].

A multidisciplinary approach underpins obesity treatment and can result in improvement in weight and comorbidities. This approach includes lifestyle interventions such as dietary modification, increased physical activity, reduced sedentary activity, behaviour modification, family therapy and targeted medications [5,6]. Meta-analyses have shown that non-pharmacological and pharmacological management strategies evaluated in adolescents over a period of 6 to 12 months are only mildly effective in reducing body mass index (BMI) [5]. For example behavioural interventions reduce BMI by 3 kg/m^2 [5] and metformin reduces BMI by 1 kg/m^2 [7]. As opposed to these therapies it has become apparent that bariatric surgery is the most effective treatment for obese adults [8] and recent studies including a meta-analysis indicate similar benefits can be expected in adolescents in the short term [9–14]. According to Australian and New Zealand recommendations and revised National Health and Medical Research Council guidelines for obesity management laparoscopic adjustable gastric banding (LAGB) should be considered in post-pubertal adolescents with a BMI > 40 kg/m^2 or BMI $\geq$ 35 kg/m^2 with obesity-related comorbidities [6,15].

A recent meta-analysis of bariatric surgical procedures including mostly short term follow up studies in 538 adolescents undergoing LAGB reported a BMI loss of 11 kg/m^2, improvement of comorbidities, no deaths and minor complications [12]. Medium to long-term studies (more than 36 months post-surgery) regarding the efficacy of LAGB in adolescents are scarce [16] and there is no prospective data beyond 24 months in Australian adolescents [13,17,18]. Therefore, we aimed to evaluate longitudinally safety and medium term effects of LAGB in severely obese adolescents in the South Australian Health Service.

Materials and Methods

Design and Subjects

This prospective single centre observational study (March 2009–December 2015) was designed to determine the efficacy and safety of LAGB in adolescents. The study was approved by the Hospital Research Ethics Committee (HREC 2168/5/15). Written informed consent was obtained from all parents of participants and written assent from all participants.

Adolescents who were referred by paediatricians for LAGB assessment to a single Paediatric Surgeon from March 2009 until May 2013 were recruited consecutively after they were considered eligible for LAGB. Inclusion criteria for LAGB were age 14 to 18 years with a BMI 40 or 35 with co-morbidities, Tanner pubertal development stage 4, and documented failure of medical management over 6 months. Inclusion criteria for the study were consent for the LAGB procedure as well as physiological oesophageal and gastric studies prior to LAGB and 6 months post LAGB (Data on these studies were not included in this manuscript). Exclusion criteria for the study were syndromal causes of obesity, depression and oesophageal motility disorders.

All adolescents received preoperative multidisciplinary evaluation from a paediatrician, paediatric surgeon, dietitian and psychologist, and were advised to consider LAGB as an interim measure. The rationale behind this advice was that as a constricting foreign body, the chances of band related complications such as erosion, reflux, esophageal dismotility disorder, pouch dilation or slippage would increase with longer time exposure. Preoperative psychological evaluation included two reviews to screen for depression, underlying motivation and to ensure there was adequate comprehension of LAGB procedure.

Surgical Technique

All procedures were performed laparoscopically by a single paediatric surgeon mentored by 2 experienced bariatric surgeons. All adolescents were operated on after 4 weeks of exclusive preoperative very low calorie diet (Optifast® VLCD™, Nestlé, Switzerland). The pars flaccida technique with the insertion of the Swedish Adjustable Gastric Band (SAGB-VC, Ethicon INC, Somerville, USA) was used in all adolescents. Two to three anterior gastro-gastric serosa-to-serosa sutures using non-absorbable Ethibond Excel® 2-0 (Ethicon INC, Somerville, USA) secured the band. The band was left empty without volume adjustment for at least 6 weeks postoperatively.

Postoperative Management

The fitness for discharge was determined by independent ambulation, pain well controlled on oral analgesia and travel time longer than 1 hour between home and hospital. The postoperative follow up protocol included monthly follow up for the first 6 months and then follow up was based on clinical progress with a review at least once a year. Missed visits did not necessary indicate withdrawal from the study as adolescents returned for later visits even after missing a previous visit. Subjects were not followed up after the gastric band was removed. Postoperative reviews by paediatric surgeon and dietitian included evaluation of food selection, weight, subjective assessment of band restriction, band fluid adjustments and postoperative complications. Band adjustments were driven primarily by clinical assessments of food intake restriction as reported by adolescents and the presence or absence of obstructive and/or reflux symptoms. Amount of weight loss was not taken into consideration for band adjustments. There was a relatively low threshold for consideration of band removal in keeping with the preoperative advice. Transition to adult care was organised after a minimum of 3 years of follow up by a single paediatric surgeon.

Outcome measures

Outcome measures included changes in weight and BMI, development of early (< 30 days) and late (> 30 days) postoperative complications which were classified according to the Clavien - Dindo classification, [19] and presence of comorbidities. All admissions to hospital were documented over the follow up period.

Weight was measured in light clothing using Wedderburn digital scales (Wedderburn, Sydney, Australia) at baseline, 6, 12, 24, 36 and 48 months post LAGB. Baseline measurements were defined as measurements obtained prior to Optifast. Height was measured on a wall stadiometer to the nearest 0.1 cm. BMI Z score was calculated using EpiInfo database version 3.5.1 (www.cdc.gov/epiinfo). Maximum BMI loss was defined as the maximum BMI loss at any time point during the follow up. Health-related quality of life was assessed at baseline and 6 month post LAGB using the Pediatric Quality of Life Inventory (PedsQL TM 4.0 MAPI, Research Institute, Lyon, France). Adolescents completed the Child Self-Report for ages 13 to 18 years and their parents completed Parent Proxy-Report for ages 13 to 18 years. The PedsQL consists of 23 items describing physical, emotional, social and school performance aspects from which a total score is derived. Comorbidities evaluated pre and postoperative included presence of Type 2 diabetes using HbA1c and/or oral glucose tolerance test as diagnostic criteria, abnormal liver function defined as alanine transaminase (ALT) above the reference range; and at least one abnormality in fasting lipid profile including triglycerides, total cholesterol and/or LDL cholesterol above the reference range and HDL cholesterol below the reference range.

Statistics

Categorical data were summarized with the use of frequency of distributions. Continuous data were summarized as mean ± SD or median (interquartile range [IQR)]) according to normality. Comparison of weight and BMI changes was performed using the paired-samples Student's t-test. Statistical analyses were performed using MedCalc for Windows, version 12.5 (MedCalc Software, Ostend, Belgium).

Results

Twenty nine adolescents were referred for assessment of LAGB in the South Australian Health Service. Eight adolescents did not participate in the study (7 did not have LAGB after surgical evaluation and 1 did not consent to be part of the study). 21 adolescents (9 males, 20 Caucasians and 1 Asian) with a median age of 17.3 (minimum 14.2 and maximum 18.2) years, a median [IQR] BMI of 47.1 [39.9-52.5] and a median [IQR] BMI z score of 2.7 [2.4-3.0] underwent LAGB between March 2009 and May 2013. 16 out of 21 adolescents had a BMI over 40 kg/m^2. Preoperative comorbidities included: Pre-diabetes (n=2), high ALT (n=10), abnormal lipid profile (n=10), use of atorvastatin (n=1), use of continuous positive airway pressure for obstructive sleep apnoea (n=1) and hypertension on antihypertensive medication (n=1). None were taking antidepressants. The mean length of stay in hospital after LAGB was 2.8±0.6 days. Nine out of 21 adolescents improved in at least one comorbidity after LAGB. Two adolescents had resolution of their pre diabetes with normal glucose tolerance test and HbA1c below 5.7% post LAGB. ALT improved significantly after LAGB (Pre LAGB Median [IQR] of 39 [33.1-68.9] U/L vs post LAGB Median [IQR] 21.5 [20.4-38.7] U/L, p=0.02). Mean ± SD overall quality of life scores improved significantly after 6 months as reported by both adolescents (60±20.5 vs 74.9±16.3, p=0.03) and parents (52.8±22.9 vs 74±16.3, p=0.02).

Multiple phone calls and appointments with phone calls and short message service reminders were made to optimize follow up of adolescents, one of which moved overseas. Complete follow up data for weight over the study period was available for 16/21 adolescents (76%). Three adolescents did not come back post LAGB (2 after 12 months, 1 after 18 months), but phone contact with families and new treating private adult bariatric surgeon confirmed their bands were still in situ. Two adolescents who missed the 48 months follow up visit came at 60 months.

Weight and BMI loss changes

Pre and postoperative BMI for each individual during the study period is included in Table 1. Median [IQR] BMI at last follow up was 39.2 [31.7-50.3] kg/m^2 after a median follow up 45.5 [32-50] months. Median [IQR] post LAGB maximum BMI loss was 10 [7.0-14.6] kg/m^2 after a median follow up of 13 [6- 41.2] months. Weight and BMI changes over time including number of available/eligible adolescents at every time point are included in Table 2. In uni-variable generalized estimating equation models, BMI post LAGB at all time follow up visits (3, 6, 12, 24, 36 and 48 months) improved significantly compared to BMI pre LAGB (all $p<0.001$).

Early and late postoperative complications

There were 4 early minor and 12 late band or weight loss related complications (Table 3). Seven adolescents had their band removed after 3.5±1.0 years. Two bands were removed due to weight loss failure and 5 due to weight regain. Two adolescents had also obstructive symptoms combined with weight regain. Our reoperation rate including band removals was 42%. Two adolescents who had normal preoperative abdominal ultrasound developed symptomatic gall stone disease (one of which had a laparoscopic cholecystectomy 14 months after LAGB and the other endoscopic retrograde cholangiopancreatography and sphincterotomy 60 months after LAGB followed by laparoscopic cholescystectomy). There were no skin removal procedures during follow up. There were no life threatening postoperative complications during the early and late postoperative follow up and there were no slippages, band erosions or pouch dilatations (Table 3). None of the adolescents had another bariatric surgical procedure and none of the females had an unplanned pregnancy. There were 12 admissions to hospital related to band removals (n=7), gallstones (n=2), early postoperative fever and vomiting (1), early wound infection (n=1), and early postoperative epigastric pain (n=1).

Discussion

This is the first prospective Australian study reporting on safety and medium term outcomes of obese adolescents who have undergone LAGB in a public health service. We have shown that the use of LAGB in severely obese adolescents reduced BMI by 10 kg/m^2 over 45 months. This degree of BMI loss is comparable to previous studies and meta-analyses [9,12,16] even though short term BMI loss in our cohort was lower than previously reported in Australian adolescents participating in a randomized controlled trial over 24 months [13]. In spite of a lower reduction of BMI in comparison to other bariatric surgery procedures used in adolescents such as laparoscopic sleeve gastrectomy (LSG) or laparoscopic Roux-en-Y gastric bypass (LRYGB) [12], adolescents had improvement of quality of life and comorbidities without significant morbidity with LAGB.

There were no major operative complications in our cohort. Life threatening surgical complications after LAGB in adolescents are uncommon with no reported deaths [12]. The rate of major complications after LAGB such as bleeding and conversion to laparotomy is 0.8% compared to 0.7% after LSG and 5.1% after LRYGB [12]. Even though the incidence of major complications such as staple leaks after LSG is low, it is of much greater significance and can cause severe morbidity [11,12]. There were few minor perioperative complications in our study consistent with studies of bariatric surgery in adults and adolescents that showed lower minor perioperative complications after LAGB in comparison to LSG and LRYGB (1% compared to 2.4% and 2.5%, respectively) [12, 20].

There was a higher band removal rate in our cohort compared with the few studies that have reported on the morbidity of LAGB beyond 3 years in adolescents [16]. In contrast, an earlier study from Austria including 50 adolescents reported lower band removal rate over a similar period of follow up [16]. The higher band removal rate in our study was most likely related to an aggressive practice to remove bands in case of weight loss failure/ regain with or without band intolerance symptoms and in keeping with our preoperative advice to use the band as an interim procedure .Our band removal rate is consistent with adult studies. Reasons for band removal after LAGB in adults are weight loss failure, intolerable obstructive symptoms or band related complications such as erosion, slippage or pouch dilatation [21]. There were no band related complications such as erosion, slippage or pouch dilatation in our cohort.

In addition to band removal, one late morbidity leading to reoperation in our cohort was related to symptomatic gall stone formation which is known to be related to weight loss and has been previously described in adults and adolescents [13, 22, 23].

Our reoperation rate of 42% in the medium term follow up was not related to any severe and life threatening complications. Current alternatives to LAGB in adolescents are LRYGB or LSG. LRYGB is regarded as the golden standard by most bariatric surgeons and offers follow up data over 20 years [8]. Although it is a reversible procedure [24] it is malabsorptive and therefore requires indefinite follow up with multivitamin and calcium replacement. There is a significant reoperation rate and weight regain with LRYGB [25]. LSG is an irreversible procedure and long term data is currently not available. Furthermore there have been no reported deaths in adolescents post LAGB and there is less need for multivitamin supplementation post LAGB compared to other procedures such as LSG or LRYGB at a developmental stage when adherence to medications is suboptimal.

The strengths of the current study include the prospective single centre enrolment with a single paediatric bariatric surgeon and a standardized reporting method on all events post LAGB over a median period of 45 months. In addition, cohort maintenance was reasonable. Limitations of the study included limited data on other comorbidities such as obstructive sleep apnoea, however availability of sleep studies is limited as routine investigations for these children especially if they did not have symptoms. Another limitation of this study was the small sample size. However, long-term (beyond 36 months) results of LAGB in adolescents remain scarce [16]. In addition one of the largest prospective bariatric surgery studies in the U.S. (Teens LAB consortium) has provided 36 month follow up of only 11 adolescents post LAGB [22].

Even though LAGB is currently the least used bariatric surgical procedure in adults and in adolescents in the USA [8, 10, 22, 26], it is less invasive, it is reversible and has a lower rate of life threatening complications. Long term follow up beyond 5 years post LAGB in adults has shown an increased band removal rate due to complications [21, 27, 28]. In addition to the results of our study this supports the role of LAGB as a temporary management option to manage severe obesity during adolescence. After removal, conversion to more invasive bariatric procedures such as LSG or LRYGB is possible.

Conclusion

We have shown in the longest prospective post LAGB study in Australian adolescents with severe obesity, that LAGB improves BMI in the majority of adolescents with minimal complications. LAGB may be the preferred 'initial' operation for adolescents with severe obesity as part of a 'stepped up' surgical management plan.

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Compliance with ethical standards

Disclosure

There are no potential benefits in any form from a commercial party related directly or indirectly to the subject of this manuscript.

Conflict of interest

All authors declare that they have no conflict of interest.

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Ethical statement

Study was conducted in accordance to the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Consent Statement

Informed consent and assent was obtained from all parents of participants and all individual participants included in the study.

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Table 1: Individual preoperative and postoperative outcomes

	Gender	Age (years)	Baseline BMI (kg/m^2)	Maximum BMI loss (kg/m^2)	FU (months) to maximum BMI loss	BMI loss at last FU (kg/m^2)	Time to last FU (months)	Band status
1	Male	17.2	61.4	7.2	6	0.6	70	In situ
2	Male	18	45.1	14.1	12	6.1	48	Removed
3	Female	16.2	40.3	11.3	54	11.3	60	In situ
4	Female	17.3	51.4	6.4	6	1.4	48	Removed
5	Male	17.8	38.6	4.6	3	4.6	55	Removed
6	Female	17.6	52.5	9.5	12	0.5	50	Removed
7	Male	17.6	51	10	46	10	48	In situ
8	Female	14.2	37.3	12.3	24	7.3	46	In situ
9	Male	17.8	50	19	60	19	60	In situ
10	Female	17.3	40.3	15.3	50	15.3	50	In situ
11	Female	15.8	37.3	9.3	53	9.3	53	In situ
12	Female	16.2	58.6	6.6	6	5.6	45	Removed
13	Female	18.2	35	0.7	13	10.7	13	In situ
14	Female	15.9	47.1	15.1	6	12.1	41	In situ
15	Female	16.8	51.2	3.2	3	2.8	32	Removed
16	Male	18.3	52.7	20.7	39	20.7	39	In situ
17	Male	16.9	37.7	9.7	34	9.7	12	In situ
18	Male	17.2	44.4	3.4	3	0.6	31	Removed
19	Male	17.6	57.1	7.2	18	7.2	18	In situ
20	Female	18.1	42.5	14.5	6	10.5	27	In situ

21	Female	17.3	62.3	16.3	28	16.3	28	In situ

BMI, Body mass index; FU, follow up

Table 2: Weight and body mass index over the study period

FU post LAGB (months)	3m	6m	12m	24m	36m	48m
Available subjects (n)	21	19	19	14	11	9
Eligible subjects (n)	21	21	21	21	18	14
Weight (kg)	124 * [98, 143]	120 * [89, 148]	116 * [88,132]	118 * [91,141]	113 ** [90, 146]	121*** [85,140]
BMI (kg/m^2)	41 * [34,48]	42 * [32,49]	39 * [32,47]	40 ** 35,45]	36 ** [32,46]	35 ** [32,51]
BMI loss (kg/m^2)	5 [9,14]	6 [10,19]	7 [9,27]	7 6,27]	8 [5,23]	6 [7,24]
Body weight loss (%)	11 [9,14]	14 [10,19]	19 [10,28]	16 [7,28]	16 [7,28]	16 [7,24]
BMI loss (%)	11 [9, 14]	14 [10,19]	18 [9,27]	16 [6,27]	19 [5,23]	15 [7,24]

BMI, Body mass index; FU, follow up

Data are median (interquartile range; Q1 first quartile; Q3 third quartile)

* p<0.0001 ** p<0.01 *** p=0.01 (Follow up time vs baseline)

Table 3: Early and late postoperative complications according to the Clavien - Dindo Classification over the follow up period

Grade	Complication type	Less than 30 days	More than 30 days
I	Haematoma	1	0
I	Food Intolerance (no deflation)	2	0
II	Food intolerance (deflation)	0	2
III a	Endoscopy	0	1
III b	Technical device failure	0	0
III b	Removal	0	7
III b	Slippage	0	0
III b	Erosion	0	0
III b	Infection	1	0
III b	Cholescystectomy	0	2
III b	Plastic Surgery	0	0
IV	Leak	0	0
V	Death	0	0