Are We Too Afraid to Operate on Kids – What's the Data?

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Disclosures

Co-Founder Data Dissect Pty Ltd
(A Learning Healthcare System Company)

Are We Too Afraid to Operate on Kids ?

Yes.....

ASMBS / IFSO Guidelines 2022

Consideration of MBS in children/adolescents with

- Evidence suggests that MBS does not negatively impact pubertal development or linear growth, and therefore a specific Tanner stage and bone age should not be considered a requirement for surgery.
  - BMI >120% of the 95th percentile (class II obesity) and major comorbidity;
  - BMI >140% of the 95th percentile (class III obesity)

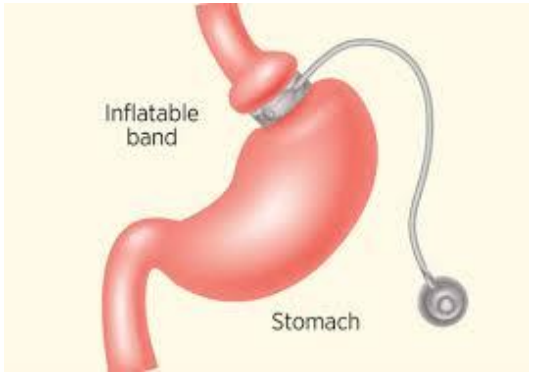
Increasingly, syndromic obesity, developmental delay, autism spectrum, or history of trauma is not considered a contraindication to MBS in adolescents .

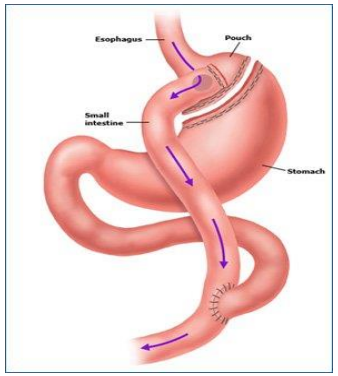
What's the Data?

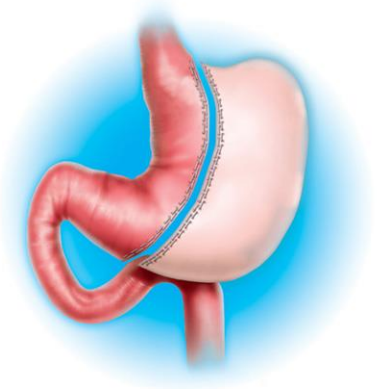
How good is the data?

Are We Too Afraid to Operate on Kids – What's the Data?

Does it really matter today?







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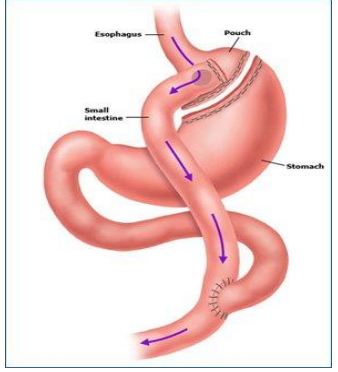

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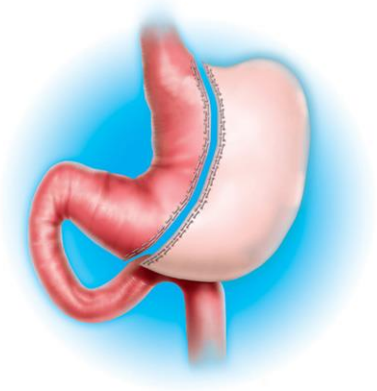

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Laparoscopic sleeve gastrectomy in children and adolescents with Prader-Willi syndrome: a matched-control study

Aayed R Alqahtani [1], Mohamed O Elahmedi [2], Awadh R Al Qahtani [2], Jaehoon Lee [3], Merlin G Butler [4]

ORIGINAL SCIENTIFIC ARTICLES

Ten-Year Outcomes of Children and Adolescents Who Underwent Sleeve Gastrectomy: Weight Loss, Comorbidity Resolution, Adverse Events, and Growth Velocity

Check for updates

Aayed R Alqahtani, MD, FRCSC, Mohamed Elahmedi, MBBS, Hanan Y Abdurabu, MBBS, Sultan Alqahtani, MD

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Long-term Outcomes Following Adolescent Metabolic and Bariatric Surgery
Andrew J. Beamish et al

The Journal of Clinical Endocrinology & Metabolism, 2023, **108**, 2184–2192
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Mini-Revi

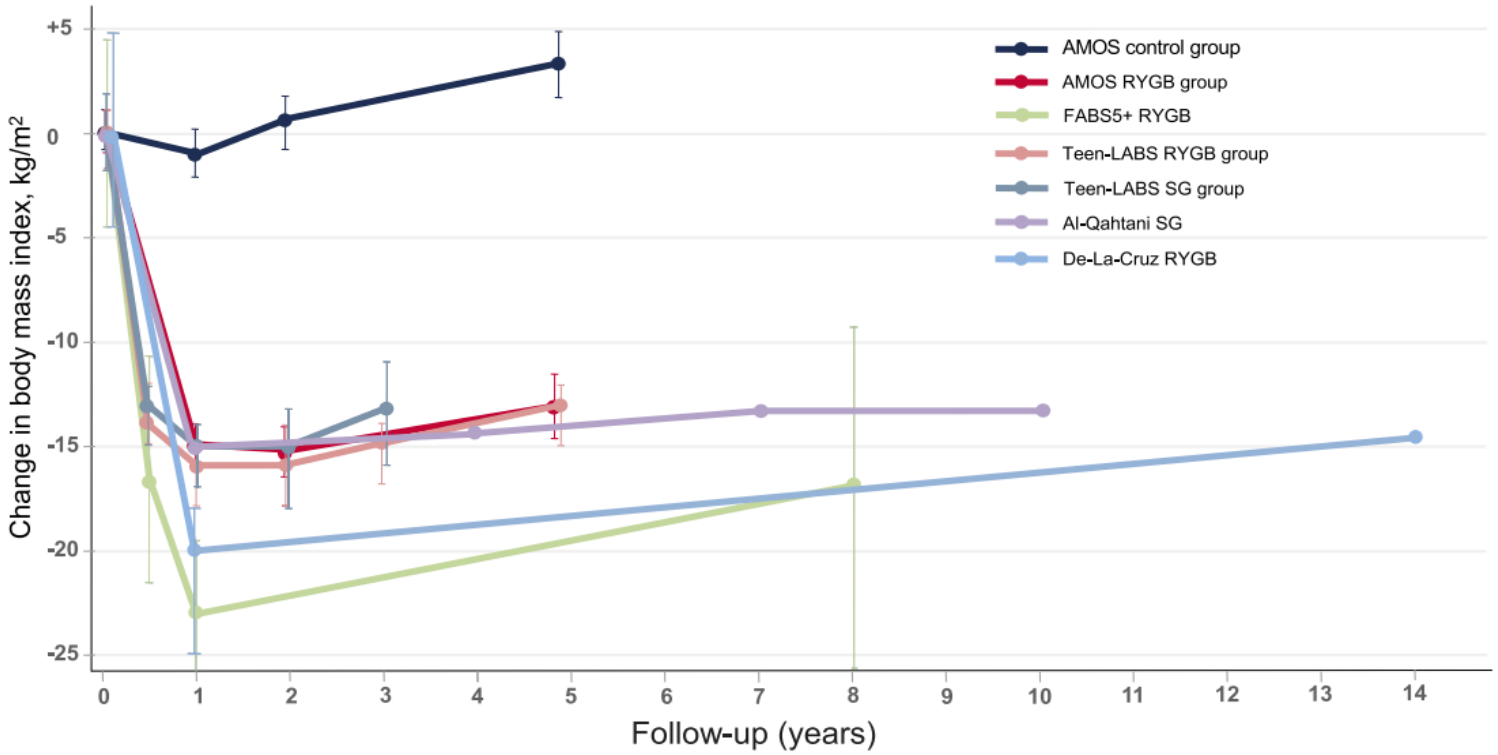

Figure 2. Change in BMI in in studies reporting outcomes to medium to long-term outcomes after adolescent metabolic and bariatric surgery (7, 8, 22, 46, 47). AMOS, Adolescent Morbid Obesity Surgery study; RYGB, Roux-en-Y gastric bypass; FABS-5+, Follow-up of Adolescent Bariatric Surgery after 5+ years study; Teen-LABS, Teen-Longitudinal Adolescent Bariatric Surgery study; SG, sleeve gastrectomy.

Variable	Baseline					Maximal Follow-up					Resolution at longest follow-up				
	Teen-LABS	AMOS	FABS-5+	Alqahtani et al	de la Cruz-Munoz et al	Teen-LABS	AMOS	FABS-5+	Alqahtani et al	de la Cruz-Munoz et al	Teen-LABS	AMOS	FABS-5+	Alqahtani et al	de la Cruz-Munoz et al
Follow-up (years)	—	—	—	—	—	5	5	8	7 to 10	14.3	5	5	8	7-10	14.3
n	242[a] 161[b]	81	58	2504	96	141	81	58	559	96	—	—	—	—	—
Sex (f)	75%[a] 78%[b]	65%	64%	55%	83%	79%	65%	64%	—	83%	—	—	—	—	—
Age (years)	17	16.5	17.1	15.7	18.8	22	18.5	25.1	—	—	—	—	—	—	—
BMI (kg/m^2)	53[a] 50[b]	46	59	44.8	44.9	37	46	42	31.8	31.7	—	—	—	—	—
Elevated hs-CRP	75%	87%[c] 59%[d]	—	—	—	—	25%[c]	—	—		71%	74%[c]	—	—	—
Hypertension	43%[a] 57%[b]	15%	47%	15%	14%	11%	3%	16%	—	1%	68%[b]	100%	76%	58%	92%
Impaired fasting glucose	26%	20%	—	—	—	—	0%	—	—	—	76%[a]	100%	—	—	—
Hyperinsulinemia	74%	71%	—	—	—	—	4%	—	—	—	79%	94%	—	—	—
Type 2 diabetes	13%[a] 14%[b]	4%	16%	11%	5%	2%	100%	2%	—	0%	86%[b]	100%	88%	72%	100%
Dyslipidemia	76%[a] 36%[b,e]	69%	86%	9%	15%	6%[e]	15%	38%	—	0%	81%[e]	83%	64%	57%	100%
Renal dysfunction	17%[a]	—	—	—	—	—	—	—	—	—	86%[a]	92%	—	—	—
Liver dysfunction	—	31%	—	—	—	—	5%	—	—	—	—	92%	—	—	—

Missing data within studies resulted in some follow-up resolution percentages that differ from the sum of baseline and follow-up values.
Abbreviations: BMI, body mass index; hs-CRP, high-sensitivity C-reactive protein.
[a]Value based on all Teen-LABS participants.
[b]Value based on Teen-LABS participants undergoing Roux-en-Y gastric bypass and included in 5-year follow-up analyses
[c]hsCRP ≥2 mg/dL.
[d]hsCRP ≥5 mg/dL.
[e]Hypertriglyceridemia reported, not dyslipidemia.

Long-term Outcomes in Cardiovascular Risk Factors following Adolescent MBS

Long-term Outcomes Following Adolescent Metabolic and Bariatric Surgery

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Mini-Review

Complications

- (Micro)nutritional deficiencies –
- Further procedures
- GOR
- Barretts oesophagus
- Oesophageal motility disorders

5-year mental health and eating pattern outcomes following bariatric surgery in adolescents: a prospective cohort study

www.thelancet.com/child-adolescent Vol 4 March 2020

Kajsa Järvholm, Gustaf Bruze, Markku Peltonen, Claude Marcus, Carl-Erik Flodmark, Pia Henfridsson, Andrew J Beamish, Eva Gronowitz, Jovanna Dahlgren, Jan Karlsson, Torsten Olbers**

- Non randomised matched control study
  - (AMOS STUDY and Swedish Childhood Obesity Treatment Register)
- Adolescents 13 – 18 years
- Data Linkage
  - Use of psychiatric drugs
  - Treatment with mental health specialists

	Surgical group (n=81)	Control group (n=80)	p value
Sex	..	..	0·2605
Female	53 (65%)	45 (56%)	..
Male	28 (35%)	35 (44%)	..
Age at baseline, years	16·5 (1·2)	15·8 (1·2)	0·0002
BMI at baseline	45·5 (6·1)	42·2 (5·2)	0·0002
BMI at 5 years	32·3 (6·3)	41·7 (10·4)*	<0·0001

Data are n (%) or mean (SD). BMI=body-mass index. *Available for 72 patients at follow-up.

Table 1: **Characteristics of adolescents at baseline and 5 years after either Roux-en-Y gastric bypass (surgical group) or conservative treatment (control group)**

	Pre-baseline*				After treatment (to 5-year follow-up)			
	Surgical group (n=81)	Control group (n=80)	Absolute risk difference	p value	Surgical group (n=81)	Control group (n=80)	Absolute risk difference	p value
Psychiatric drug treatments ever								
Any psychiatric drugs (N05 or N06)	16 (20%)	12 (15%)	5% (−7 to 16)	0·4263	35 (43%)	27 (34%)	10% (−6 to 24)	0·2175
Psycholeptics (N05)	8 (10%)	9 (11%)	−1% (−11 to 8)	0·7768	28 (35%)	17 (21%)	13% (0 to 27)	0·0597
Psychoanaleptics (N06)	15 (18%)	7 (9%)	10% (−1 to 20)	0·0712	27 (33%)	20 (25%)	8% (−6 to 22)	0·2449
Psychiatric diagnoses ever (ICD-10 codes F00–F99)								
Any†	16 (20%)	14 (18%)	2% (−10 to 14)	0·7135	29 (36%)	17 (21%)	15% (1 to 28)	0·0410
Inpatient‡	6 (7%)	4 (5%)	2% (−5 to 10)	0·5269	9 (11%)	2 (2%)	9% (1 to 16)	0·0304
Outpatient§	14 (17%)	12 (15%)	2% (−9 to 14)	0·6938	29 (36%)	17 (21%)	15% (1 to 28)	0·0410

Frequency data are n (%). Between-group differences are absolute risk difference (95% CI), based on an intention-to-treat analysis. Registration, which is automatic and mandatory, generated complete data. ICD-10=International Classification of Diseases, tenth revision. *From July 1, 2005 (for psychiatric treatments) or from Jan 1, 2001 (for psychiatric diagnoses), to start of gastric bypass or conventional treatment. †From inpatient or outpatient specialist treatment. ‡Hospitalisation with a psychiatric diagnosis as the main diagnosis. §Specialist outpatient treatment with a psychiatric diagnosis as the main diagnosis.

Table 2: **Psychiatric drug treatment and psychiatric diagnoses in adolescents undergoing Roux-en-Y gastric bypass (surgery group) and matched conservatively managed adolescents (controls group)**

"…bariatric surgery does not improve adolescents mental health problems

www.thelancet.com/child-adolescent Vol 4 March 2020

5-year mental health and eating pattern outcomes following bariatric surgery in adolescents: a prospective cohort study

Kajsa Järvholm, Gustaf Bruze, Markku Peltonen, Claude Marcus, Carl-Erik Flodmark, Pia Henfridsson, Andrew J Beamish, Eva Gronowitz, Jovanna Dahlgren, Jan Karlsson*, Torsten Olbers*

	Baseline	Follow-up			p value (5-year follow-up *vs* baseline)	Standardised response mean*
		1 year	2 years	5 years		
Self-esteem (RSE score)	18·9 (17·4–20·4), n=78	22·6 (21·1–24·1), n=80	22·3 (20·8–23·8), n=72	21·6 (19·9–23·4), n=73	0·0059	0·26
Pleasantness (MACL score)	2·9 (2·7–3·0), n=78	3·1 (3·0–3·2), n=79	3·0 (2·9–3·2), n=71	3·0 (2·8–3·1), n=74	0·2367	0·08
Activation (MACL score)	2·6 (2·5–2·7), n=78	2·8 (2·7–2·9), n=79	2·7 (2·6–2·8), n=72	2·8 (2·6–2·9), n=75	0·0185	0·25
Calmness (MACL score)	2·6 (2·5–2·7), n=78	2·8 (2·7–3·0), n=79	2·8 (2·6–2·9), n=72	2·7 (2·6–2·9), n=75	0·2155	0·08
Overall mood (MACL score)	2·7 (2·6–2·8), n=78	2·9 (2·8–3·0), n=79	2·8 (2·7–2·9), n=72	2·8 (2·7–2·9), n=75	0·0737	0·16
Binge eating (BES score)	15·0 (13·3–16·5), n=77	7·1 (5·8–8·5), n=79	8·8 (7·4–9·1), n=71	9·3 (7·9–10·8), n=75	<0·0001	0·55
Emotional eating (TFEQ score)	39·7 (34·5–44·9), n=77	20·8 (15·7–25·9), n=80	25·2 (19·8–30·5), n=72	24·8 (18·7–30·8), n=75	<0·0001	0·47
Uncontrolled eating (TFEQ score)	44·9 (41·0–48·8), n=77	25·4 (19·5–27·4), n=80	27·1 (21·9–32·4), n=72	27·3 (22·5–32·2), n=75	<0·0001	0·70
Cognitive restraint (TFEQ score)	39·5 (35·2–43·8), n=77	46·5 (42·1–50·8), n=80	43·8 (39·1–48·5), n=72	49·9 (44·5–55·3), n=75	0·0007	0·37

Data are mixed-model mean (95% CI), n. Higher RSE scores represent higher self-esteem (range 0–30). Higher MACL scores represent better mood (range 1–4). Higher BES scores represent more binge eating (range 0–46). Higher TFEQ scores represent more emotional or uncontrolled eating or cognitive restraint (range 0–100). RSE=Rosenberg Self-Esteem. MACL=Mood Adjective Checklist. BES=Binge Eating Scale. TFEQ=Three-Factor Eating Questionnaire-R21. *Mean change divided by SD of change between baseline and 5-year follow-up.

Table 3: **Self-reported mental health and eating-related problems in adolescents at baseline and at 1 year, 2 years, and 5 years after Roux-en-Y gastric bypass**

Relative changes in BMI were not associated with presence or absence of binge eating disorders at baseline

Long-Term Outcomes after Adolescent Bariatric Surgery

Nestor de la Cruz-Muñoz, MD, Luyu Xie, PHARMD, Hallie J Quiroz, MD, Onur C Kutlu, MD, FACS, Folefac Atem, PhD, Steven E Lipshultz, MD, M Sunil Mathew, MS, Sarah E Messiah, PhD, MPH

J Am Coll Surg

Vol. 235, No. 4, October 2022

- 96/130 Patients (2002-2010)
  - Age at surgery <21 years
  - Min 10 years post surgery,
  - 'lost to follow up'
  - Not enrolled in a research study

- 87 RYGB
- 8 LAGB
- 1 LSG

- 2 BANDS WERE REMOVED
- 1 REPOSITIONED
- 1 DEFLATED AND LEFT IN SITU
- 4 LEFT UNTOUCHED

- *"Majority patients were referred by parents who were successful MBS completers".*

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Table 1. Baseline Characteristics Among Those Who Had Metabolic and Bariatric Surgery at 21 Years of Age or Younger (n = 130) by Contact Status

Characteristic	Patients consented (n = 96)	Patients not consented (n = 34)	p Value*
Age at surgery, y, mean (SD)†	18.8 (1.6)	19.1 (1.4)	0.269
Sex, n (%)			
Male	16 (16.7)	8 (23.5)	0.376
Female	80 (83.3)	26 (76.5)	
Race/ethnicity, n (%)			
NHW	16 (16.7)	2 (5.9)	
NHB	9 (9.4)	0 (0)	0.023
Hispanic	71 (73.9)	31 (91.2)	
Native American	0 (0)	1 (2.9)	
Procedure type, n (%)			
RYGB	87 (90.6)	30 (88.2)	0.642
Lap band	8 (8.3)	4 (11.8)	
Sleeve gastrectomy	1 (1.0)	0 (0)	
Insurance type, n (%)			
Commercial	65 (67.7)	20 (58.8)	0.724
Government	9 (9.4)	4 (11.8)	
Self-pay	20 (20.8)	9 (26.5)	
Not available	2 (2.1)	1 (2.9)	
BMI at surgery, median [kg/m^2, (IQR)]	45.0 (41.0-49.0)	45.5 (42-49.0)	0.758

*Mann-Whitney U test for continuous variables; Pearson Chi-square or Fisher's exact test for categorical variables.
†Patients consented: median age 19 years (range 15–21 years); Patients not consented: median age 19 years (range 16–21 years).
IQR, interquartile range; NHB, non-Hispanic Black; NHW, non-Hispanic White; RYGB, Roux-en-Y gastric bypass.

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Table 3. Patient Comorbidities from Baseline (pre-MBS) to Long-Term Follow-Up (post-MBS) Among Those Who Had Metabolic and Bariatric Surgery at 21 Years of Age or Younger (n = 96).

Comorbidity	Pre-MBS, n (%)	Post-MBS, n (%)	p value*
Anemia	3 (3.1)	65 (67.7)	<0.001
Asthma	10 (10.4)	0	0.002
Anxiety	7 (7.3)	2 (2.1)	0.169
Back pain	32 (33.3)	4 (4.2)	<0.001
Depression	26 (27.1)	4 (4.2)	<0.001
Diabetes or hyperglycemia	5 (5.2)	0	0.059
GERD	13 (13.5)	3 (3.1)	0.016
Hyperlipidemia	14 (14.6)	0	<0.001
Hypertension	13 (13.5)	1 (1.0)	0.001
Sleep apnea	16 (16.7)	1 (1.0)	<0.001
Transfusion	0	23 (24.0)	<0.001

*Fisher's exact test.

GERD, gastroesophageal reflux disease; MBS, metabolic and bariatric surgery.

Long-Term Outcomes after Adolescent Bariatric Surgery

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J Am Coll Surg

Vol. 235, No. 4, October 2022

- 67% Anaemia
- 40% Further procedures
  - Cosmetic 19%
  - Cholecystectomy 8%

- 84% were currently employed
- 59% had (or were pursuing a college degree)
- 67% females had a successful pregnancy

- Only predictor of success was ethnicity

ORIGINAL SCIENTIFIC ARTICLES

Ten-Year Outcomes of Children and Adolescents Who Underwent Sleeve Gastrectomy: Weight Loss, Comorbidity Resolution, Adverse Events, and Growth Velocity

Check for updates

Aayed R Alqahtani, MD, FRCSC, Mohamed Elahmedi, MBBS, Hanan Y Abdurabu, MBBS, Sultan Alqahtani, MD

J Am Coll Surg

Vol. 233, No. 6, December 2021

Table 1. Descriptive and Clinical Characteristics of Children and Adolescents Who Underwent Laparoscopic Sleeve Gastrectomy

	Age group		
Characteristic	**5–14 y**	**15–18 y**	**19–21 y**
Patients, n (%)	801 (32)	1,517 (61)	186 (7)
Age, y, mean ± SD	11.3 ± 2.5	16.9 ± 0.9	19.0 ± 0.6
Sex, male, n (%)	343 (43)	681 (45)	89 (47)
Height, cm, mean ± SD	152.1 ± 14.5	165.3 ± 10.2	166.0 ± 10.0
Weight, kg, mean ± SD	101.3 ± 26.5	124.1 ± 24.5	127.5 ± 27.7
Percent of 95th percentile, mean ± SD	177 ± 38	—	—
BMI, kg/m^2, mean ± SD	43.4 ± 7.9	45.4 ± 8.1	46.3 ± 8.2
BMI *z*-score,* mean ± SD	3.2 ± 0.7	2.4 ± 0.4	3.0 ± 0.4
Height *z*-score,* mean ± SD	1.4 ± 1.2	0.6 ± 1.1	0.6 ± 1.0

*The *z*-scores were calculated based on national growth charts.

ORIGINAL SCIENTIFIC ARTICLES

Ten-Year Outcomes of Children and Adolescents Who Underwent Sleeve Gastrectomy: Weight Loss, Comorbidity Resolution, Adverse Events, and Growth Velocity

Aayed R Alqahtani, MD, FRCSC, Mohamed Elahmedi, MBBS, Hanan Y Abdurabu, MBBS, Sultan Alqahtani, MD

Table 2. Anthropometric Changes Experienced by Children and Adolescents Who Underwent Laparoscopic Sleeve

Table 3. Growth Rate Experienced by Children and Adolescents Who Underwent Laparoscopic Sleeve Gastrectomy

	Age group, mean ± SD					
	5–14 y		15–21 y			
Growth rate	Height *z*-score	Height *z*-score change	Height *z*-score	Height *z*-score change	p Value	Total, n
Baseline	1.4 ± 1.2	—	0.5 ± 1.1	—	—	2,504
Follow-up					—	
1–3 y	1.3 ± 1.1	0.1 ± 0.5	0.6 ± 1.1	0.1 ± 0.6	0.95	2,051
4–6 y	1.3 ± 1.2	0.1 ± 1.0	0.5 ± 1.0	0.0 ± 1.2	0.21	1,268
7–10 y	1.2 ± 1.1	0.0 ± 0.9	0.5 ± 1.1	0.0 ± 1.0	0.40	632

The *z*-scores were calculated based on national growth charts.

cohort is sequential, and so was their follow-up. For this reason, the numbers of eligible patients, attended patients, and the attendance rate at each follow-up stage is different. "n" represents the number of patients eligible for follow-up based on time elapsed since operation. Those who actually attended were included in "n." The follow-up rate was obtained as a ratio of n/N representing the attendance rate.

[†]The *z*-scores were calculated based on national growth charts.

%EWL, % excess weight loss; %TWL, % total body weight loss.

ORIGINAL SCIENTIFIC ARTICLES

Ten-Year Outcomes of Children and Adolescents Who Underwent Sleeve Gastrectomy: Weight Loss, Comorbidity Resolution, Adverse Events, and Growth Velocity

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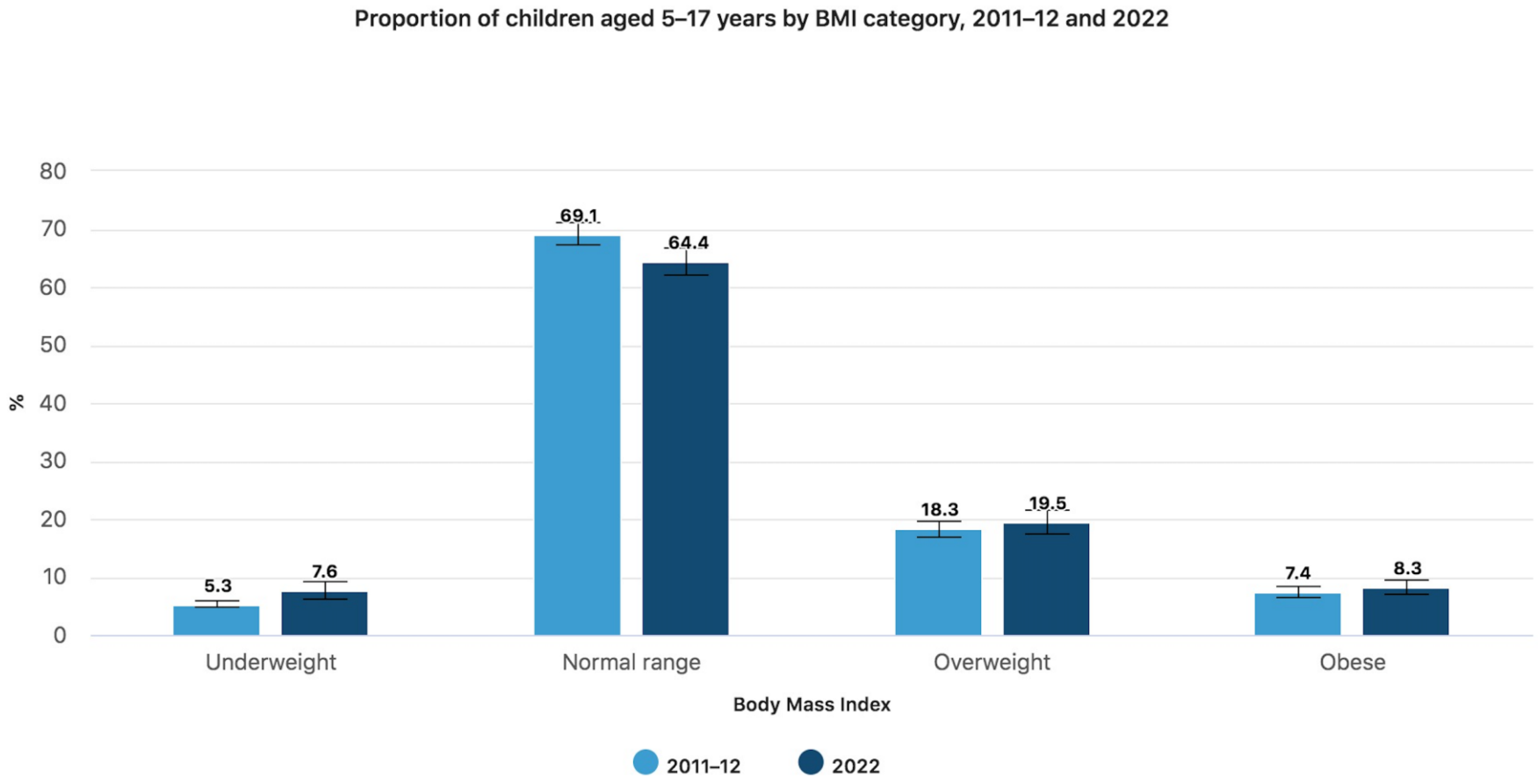
Table 4. Adverse Events Observed in Children and Adolescents Who Underwent Laparoscopic Sleeve Gastrectomy

Event	n	%	Management
Staple line leak	2	0.09	Conservative management; revision to Roux-en-Y gastric bypass
Metabolic neuropathy	3	0.1	IV thiamine, long-term thiamine supplementation
Nausea and vomiting	22	1.0	Analgesia, proton pump inhibitor, IV rehydration

NO PROBLEMS WITH GOR!!

What about Australia?!



Source: Australian Bureau of Statistics, Waist circumference and BMI 2022

RESEARCH ARTICLE

Trends in the Prevalence of Morbid and Severe Obesity in Australian Children Aged 7-15 Years, 1985-2012

PLOS ONE | DOI:10.1371/journal.pone.0154879 May 12, 2016

Sarah P. Garnett[1,2]*, Louise A. Baur[2,3], Aimee M. D. Jones[1], Louise L. Hardy[3]

Table 1. Characteristics and BMI status of Australian children age 7 to 15 years 1985, 1995, 2007 and 2012.

	AHF85	NNS95	NCNPAS07	NHS12
	n (%)	n (%)	n (%)	n (%)
Sex				
Boys	4301 (50.7)	815 (52.9)	1275 (49.3)	1480 (50.3)
Girls	4185 (49.3)	726 (47.1)	1310 (50.7)	1460 (49.7)
Total	8486	1541	2585	2940
Age (years)—Boys				
7 to 11	2419 (28.5)	457 (29.6)	603 (23.4)	812 (27.6)
12 to 15	1882 (22.2)	358 (23.3)	672 (25.9)	668 (22.7)
Age (years)—Girls				
7 to 11	2439 (28.7)	438 (28.4)	634 (24.6)	770 (26.2)
12 to 15	1746 (20.6)	288 (18.7)	676 (26.1)	690 (23.5)
IOTF BMI category				
Healthy weight[a]	7472 (88.1)	1200 (77.9)	1927 (74.6)	2142 (72.9)
Overweight[b]	864 (10.2)	256 (16.6)	468 (18.1)	567 (19.3)
Obesity[c]	133 (1.6)	74 (4.8)	144 (5.6)	179 (6.1)
Morbid obesity[d]	17 (0.2)	11 (0.7)	46 (1.8)	52 (1.8)
AHA Severe obesity				
Class 2[e]	24 (0.3)	16 (1.0)	49 (1.9)	58 (2.0)
Class 3[f]	5 (0.1)	2 (0.1)	10 (0.4)	16 (0.5)

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AHF85, Australian Health and Fitness Survey 1985; NNS95, National Nutrition Survey 1995 NCNPA07, Australian National Children's Nutrition and Physical Activity Survey 2007; NHS12, National Health Survey 2012; IOTF, International Obesity Taskforce; AHA American Heart Association.

[a]Equivalent to age and sex adjusted BMI <25 at 18 years

[b]Equivalent to age and sex adjusted BMI $\geq$ 25 & <30 at 18 years

[c]Equivalent to age and sex adjusted BMI $\geq$ 30 & <35 at 18 years

[d]Equivalent to age and sex adjusted BMI $\geq$ 35 at 18 years

[e]BMI $\geq$120% and <140% 95th centile or BMI $\geq$35 and <40

[f]BMI $\geq$140% 95th centile or BMI $\geq$40

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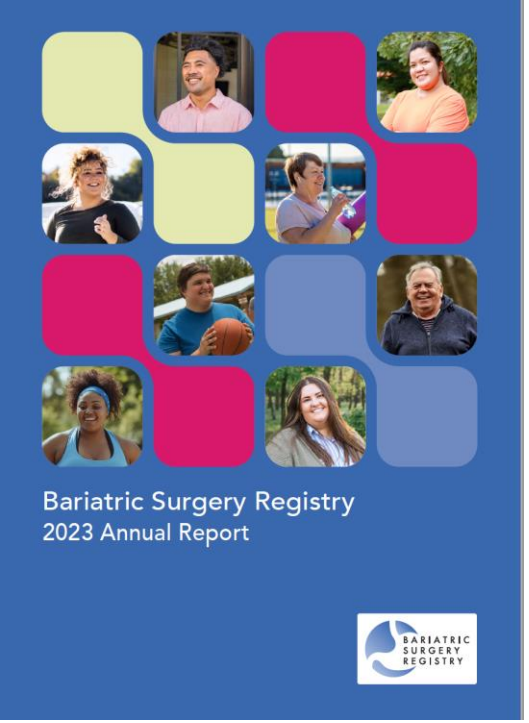
- **30,000* 14-18 yrs old Australians in June 2023 with AHA class 2 Severe Obesity**

(BMI 120% and <140% 95th centile or BMI 35 ≤ 40)

- **8,000* 14-18 yrs old Australians in June 2023 with AHA class 3 Severe Obesity**

(BMI 140% 95th centile or BMI ≥ 40)

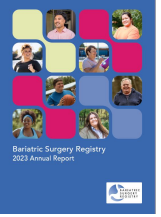
*1,614,369 Australian Children aged 14-18 years in June 2023
https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/dec-2023



AGE AT PROCEDURE

Year of enrollment	No. of patients enrolled ge less than 18 years	Min age of patient (yrs)
2023	8	16.6
2022	18	14.1
2020-21	275	15.4
2019-20		14.4
2018-19		14.3
2017-18		13.7

Excludes participants where sex is described as "other", n= 3



WEIGHT OUTCOMES

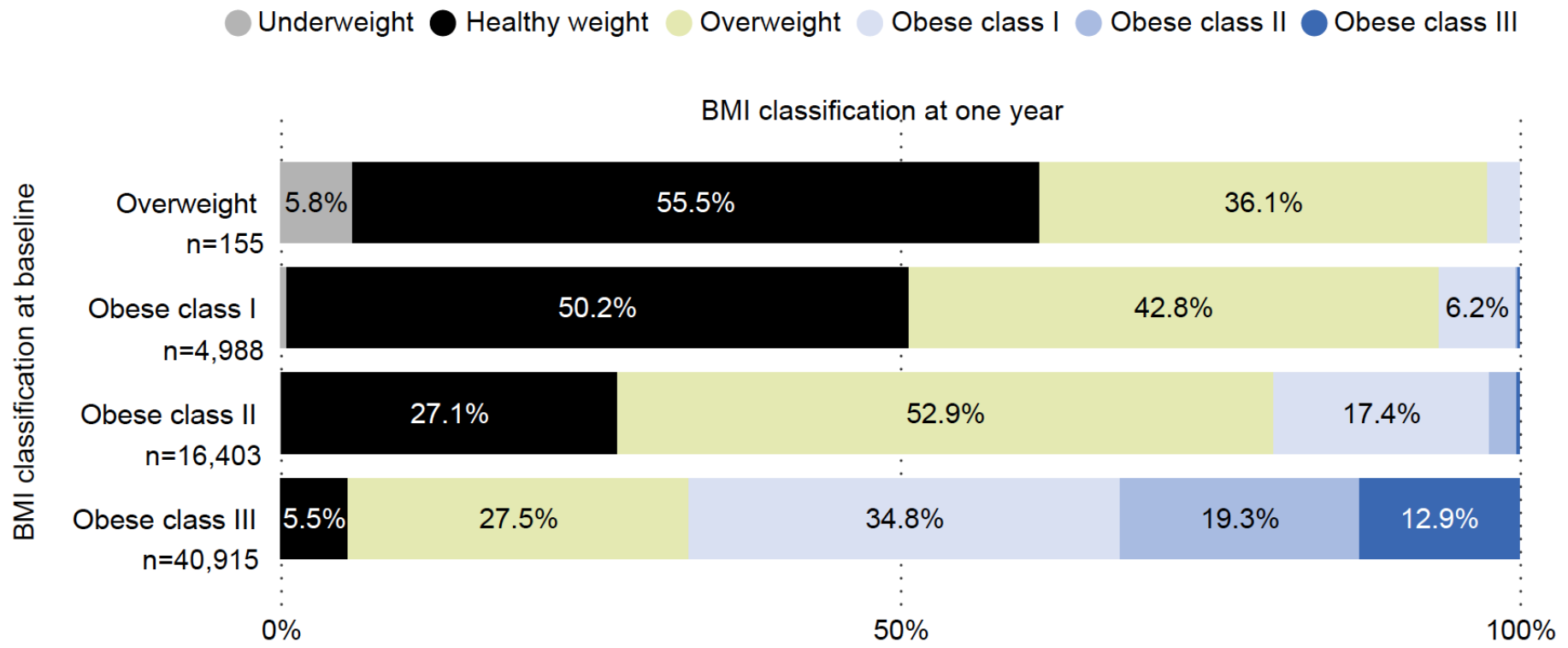


Figure 20 - Initial BMI range and one-year BMI for adult primary participants, Australia, n= 62,461

Excludes participants <18 years at age at primary procedure, participants for whom baseline and/or one-year weight is not available, participants who have a verified initial BMI <25. Percentages not shown: in the overweight at baseline group 2.6

Lessons Learnt from adolescent bariatric surgery for Severely Obese Adolescents

- Reliably effective
- Predictable profile of adverse effects
- Better than ‘no intervention’
- No reliable prediction model (yet) for patient selection
- ? No reason to deny prepubertal adolescents

NO AUSTRALIAN DATA!!

Future of Adolescent Bariatric Surgery?

AUSTRALIAN PRODUCT INFORMATION

Wegovy® (semaglutide) solution for injection

Wegovy® FlexTouch® (semaglutide) solution for injection

1 NAME OF THE MEDICINE

Paediatric population

In a clinical trial conducted in adolescents of 12 years to below 18 years with obesity or overweight with at least one weight-related comorbidity, 133 patients were exposed to Wegovy. The trial duration was 68 weeks.

Overall, the frequency, type and severity of adverse reactions in the adolescents were comparable to that observed in the adult population. Cholelithiasis was reported in 3.8% of patients treated with Wegovy.

Semaglutide did not appear to affect growth or pubertal development during the trial period.

To date, there are no long-term (beyond 68 weeks) clinical trial data on safety or efficacy in adolescents.

Future of Adolescent Bariatric Surgery

- Integrate with a comprehensive adolescent obesity registry.
- Actively engage with paediatric community to commence comparative trials.

THANK YOU!