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# Safety of Laparoscopic Adjustable Gastric Banding

An Evidence Update

Presented to the Ontario Health Technology Advisory Committee in September 2009

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Medical Advisory Secretariat Ministry of Health and Long-Term Care

## About this Update

This report updates the following evidence-based analysis:

Medical Advisory Secretariat. Bariatric surgery: an evidence-based analysis. Ont Health Technol Assess Series [Internet] 2005 August [cited 2009 09 01]; 5(1). 1-148. Available at: <u>http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev\_baria\_010105.pdf</u>

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## **Background and Methodology**

A literature search was conducted on June 29, 2009 to update the 2005 evidence-based review by the Medical Advisory Secretariat (MAS)<sup>1</sup> on the use of bariatric surgery for the treatment of morbid obesity (search details described in Appendix). Due to concerns regarding complications following laparoscopic adjustable gastric band (LAGB) insertion, safety was the focus of this Evidence Update.

Inclusion criteria for the literature search consisted of:

- 1. Comparative studies of LAGB vs. laparoscopic roux en y gastric bypass (LRYGB) with at least 1 year of follow-up in morbidly obese patients.
- 2. Single arm studies with  $\geq 100$  morbidly obese patients.
- 3. Studies that account for and stratify modifications in LAGB device and implantation techniques.

## **Results of Evidence Review**

The updated literature search identified three systematic reviews (see Table 1). (1-3) Detailed results of the most recent systematic review by Tice et al. (1) and an observational study (4) that was published after the literature search cut-off date used by Tice et al. are shown in Tables 2 to 5. Notably, the quality of the majority of the studies included in Tice et al. was very low (see Table 6).

Across the studies, it is important to note that:

- Some studies steered higher risk patients into their LAGB arms instead of the LRYGB arms.
- The duration of follow-up varied across studies
  - Follow-up periods in the LAGB arms were longer than those of the LRYGB arms.
  - LAGB patients were followed-up more frequently.
  - Overall, follow-up was generally poor in terms of length and completeness.
- Complications were defined differently across studies
  - Some studies included emesis/dehydration when determining total complication rates but did not provide a definition for such in terms of severity or frequency;
  - Some studies considered LAGB slippage, erosion, and port problems to be "major" complications, others considered them to be "minor" complications;
  - There was a general lack of systematic reporting on the entire range of potential complications
- Weighing the trade-off between complications can be problematic (e.g., port leak vs. anastomotic leak)
- The studies included in Tice et al. (1) that used the perigastric technique exhibited higher rates of slippage/dilation (36% and 20%) than those that used the pars flaccida technique (1% to 14%; see Tables 3 and 6).
- Some studies switched techniques or carried out device modifications midway, such as:
  - Change in band length to avoid stomal obstruction
  - Access port modifications
  - Fat pad removal to avoid stomal obstruction

<sup>&</sup>lt;sup>1</sup> <u>http://www.health.gov.on.ca/english/providers/program/mas/tech/ohtas/tech\_baria\_010105.html</u>

Concerning surgical technique, a randomized trial was identified that compared the perigastric (n=101) and pars flaccida (n=101) techniques for LAGB. (5) Patient outcomes were followed for 2 years and those who were treated using pars flaccida exhibited significantly less LAGB slippage than those who had undergone surgery using the perigastric procedure (16% vs. 4%, p=0.004).

## Conclusions

- The rates of short-term complications are lower with LAGB than with LRYGB.
- Long-term complication rates (i.e., band slippage and erosion) vary considerably, although studies using updated modifications to the implantation procedure or device show a decrease in the rate of these complications.

Study	Overall Safety Results					
Tice et al. 2008 (1)	<ul> <li>The complication rates of each procedure differed markedly from study to study. This likely reflects different lengths of follow-up and different definitions of significant complications across studies.</li> <li>It is difficult to weight the tradeoffs between complications. For example, a port leak that requires a minor reoperation is less important than an anastomotic leak that causes peritonitis and sepsis.</li> </ul>					
Blue Cross Blue Shield Technology Evaluation Center 2008 (2)	<ul> <li>Short-Term Complications</li> <li>Very uncommon and occur less frequently with LAGB than with LRYGB</li> </ul>					
	Long-Term Complications					
	<ul> <li>Higher frequency than short-term complications</li> </ul>					
	<ul> <li>Uncertainty due to wide range of reported values</li> </ul>					
	<ul> <li>Poor follow-up in terms of length and completeness</li> </ul>					
	<ul> <li>Lack of systematic reporting on entire range of potential complications</li> </ul>					
Canadian Agency for Drugs and Technology in Health 2007 (3)	<ul> <li>LAGB may not result in the most weight loss but it may be an option for bariatric patients who prefer, or who are better suited to, less invasive and reversible surgery with lower perioperative complication rates.</li> <li>One caution with LAGB is the uncertainty about whether the low complication rate extends past 3 years, given the possibility of increased band-related complications that necessitate re-operation (e.g., erosion and slippage).</li> </ul>					

## Table 1: Results of Systematic Reviews Identified in the Updated Literature Search for LAGB

Study	Arm	N	Death (%)	Conversion to Open (%)	Total Short-Term Complications (%)
Weber et al. 2004 (6)	LAGB	103	0	0	18
	LRYGB	103	0	1.0	21
Jan et al. 2005 (7)	LAGB	154	0.6	0.6	3.9
	LRYGB	219	0.5	0.5	5.0
Mognol 2005 (8)	LAGB	179	0.6	0	0.0
	LRYGB	111	0.9	3.6	0.1
Parikh 2005 (9)	LAGB	197	0	0.5	4.7
	LRYGB	97	0	2.1	11
Bowne 2006 (10)	LAGB	60	0	1.7	18
	LRYGB	46	0	0	17
Cottam 2006 (11)	LAGB LRYGB	181 181	No separation of short and long term complications.		
Galvani 2006 (12)	LAGB	470	0	0.2	3.6
	LRYGB	120	0.8	2.5	6.6
Kim 2006 (13)	LAGB	160	0	0	0.6
	LRYGB	232	0	0	5.2
Parikh 2006 (14)	LAGB	480	0	0	3.3
	LRYGB	235	0	0.9	9.4
Rosenthal 2006 (15)	LAGB	152	0	0	4.6
	LRYGB	849	0	0.6	4.4
Angrisani 2007 (16)	LAGB	27	0	0	0
	LRYGB	24	0	4.2	8.3
Jan 2007 (17)	LAGB	406	0.2	0.7	7.9
	LRYGB	492	0.2	0.2	15

Table 2: Laparoscopic Adjustable Gastric Banding Short-Term Complication Rates (≤30 days) Reported in Tice et al. (1)

					LAGB specific (%)			
Study	Arm	N	Death (%)	Reoperation (%)	Slippage/ dilation (%)	Erosion (%)	Port (%)	Total Long-Term Complications (%)
Weber 2004 (6)	LAGB LRYGB	103 103	0 0	26 9	36	2	1	45 14
Jan 2005 (7)	LAGB LRYGB	154 219	0 0	20 14	10	1	7	27 26
Mognol 2005 (8)	LAGB LRYGB	179 111	0 0	25 10	20	1	3	25 16
Parikh 2005 (9)	LAGB LRYGB	197 97			Long term compli	cations not repor	ted	
Bowne 2006 (10)	LAGB LRYGB	60 46	0 0	25 7	2	0	18	78 28
Cottam 2006 (11)	LAGB LRYGB	181 181	0 0	23 19	6	0	9	17 13
Galvani 2006 (12)	LAGB LRYGB	470 120	0 0	8 8	14	0.2	3	17 14
Kim 2006 (13)	LAGB LRYGB	160 232	0 0	0 0	0	0	4	4 0.4
Parikh 2006 (14)	LAGB LRYGB	480 235	0 0.4	NR NR	NR NR	NR NR	NR NR	5 14
Rosenthal 2006 (15)	LAGB LRYGB	152 849	0 0	14 0	1	1	0	9 9
Angrisani 2007 (16)	LAGB LRYGB	27 24	0 0	15 13	8	0	0	8 4
Jan 2007 (17)	LAGB LRYGB	406 492	0.2 0.6	17 17	8	1	5	19 23

## Table 3: Laparoscopic Adjustable Gastric Banding Long-Term Complications (>30 days) Reported in Tice et al. (1)

Study	Arm	N	Death (%)	Perforation (%)	Conversion to Open (%)	Total (%)
Te Riele 2008 (4)	LAGB	53	0	0	0	7.5
	LRYGB	53	0	0	0	15.1

Table 4: LAGB Study Published After Literature Search Cut-off in Tice et al.: Short-Term Complications (≤30 days)

## Table 5: LAGB Study Published After Literature Search Cut-off in Tice et al.: Long-Term Complications (>30 days)

					LAGB specific (%)			_
Study	Arm	N	Death (%)	Reoperation (%)	Slippage/ Dilation (%)	Erosion (%)	Port (%)	Total (%)
Te Riele 2008 (4)	LAGB LRYGB	53 53	0 0	3.8 18.9	1.9	0	0	3.8 7.5

Study	LAGB Implant Technique	LAGB Device Modifications Reported During Study	Comment
Weber 2004 (6)	<ul> <li>1995-2003</li> <li>Perigastric</li> <li>10cm band used</li> <li>Fat pad removal not reported</li> </ul>	No	<ul> <li>Mean follow-up 17.6 ± 8.3 months for LRYGB and 41.9 ± 21.4 months for LAGB</li> <li>Unclear if consecutive LAGB patients examined.</li> </ul>
Jan 2005 (7)	<ul><li>2000-2003</li><li>Pars flaccida</li><li>Fat pad routinely excised</li></ul>	No	<ul> <li>Highest risk patients (older, male, 'super-obese') recommended to undergo LAGB.</li> <li>Significantly more males and older patients in LAGB group.</li> <li>"Most of theband slippage complications occurred early in our learning curve"</li> </ul>
Mognol 2005 (8)	<ul> <li>1994-2004</li> <li>Perigastric (n=115)</li> <li>Switched to pars flaccida (n=64)</li> </ul>	10cm then 11cm band used.	<ul> <li>All super obese patients (BMI&gt;50 kg/m2).</li> <li>"Band slippage rate was significantly higher with the perigastric technique than the pars flaccida technique (p&lt;0.001)".</li> </ul>
Parikh 2005 (9)	<ul> <li>2000-2004</li> <li>Pars flaccida</li> <li>10 cm band</li> <li>After 143 bands, perigastric fat pads routinely removed to avoid stomal obstruction.</li> </ul>	No	<ul> <li>All super obese patients (BMI&gt;50 kg/m2).</li> </ul>
Bowne 2006 (10)	<ul><li> 2001-2004</li><li> Pars flaccida</li><li> Fat pad removal not reported.</li></ul>	No	<ul> <li>All super obese patients (BMI&gt;50 kg/m2).</li> </ul>
Cottam 2006 (11)	<ul> <li>2001-2004</li> <li>Pars flaccida</li> <li>10 cm band</li> <li>Fat pad removal not reported.</li> </ul>	Redesigned LAGB access port introduced in 2002 by manufacturer.	<ul> <li>Significantly more males in LAGB arm.</li> <li>Authors attribute decline in reoperations following LAGB to redesigned access port, increasing experience securing access port to fascia and ability to eliminate endoscopy except when symptoms suggest erosion or gastroesophageal reflux.</li> </ul>

## Table 6: LAGB Technique and Modifications Reported in Studies Included in Tice et al. and Te Riele et al.

Study	LAGB Implant Technique	LAGB Device Modifications Reported During Study	Comment
Galvani 2006 (12)	<ul><li> 2000-2004</li><li> Pars flaccida</li><li> Removal of fat pad started 2004.</li></ul>	10cm band used, then 11cm used in 2004 (to avoid stomal obstruction)	<ul><li>Included 14-17 year olds half way through study.</li><li>Significantly more males in LAGB than LRYGB.</li></ul>
Kim 2006 (13)	<ul> <li>2001-2004</li> <li>Started with perigastric then changed to Pars flaccida with fat pad removal and anterior fixation.</li> <li>10cm band</li> </ul>	Used redesigned port in 2004	<ul> <li>Significantly more males and older patients in LAGB than LRYGB</li> <li>Bulk food eaters (mostly males) and older high risk patients encouraged to undergo LAGB</li> <li>LAGB patients followed up more frequently</li> </ul>
Parikh 2006 (14)	<ul> <li>2000-2003</li> <li>Pars flaccida</li> <li>After 143 bands, perigastric fat pads were consistently removed</li> <li>9.75cm and 10cm bands used</li> </ul>	No	<ul> <li>Patients BMI ≥35 kg/m2</li> <li>Patient overlap with Parikh et al. 2005 (which focused specifically on super obese)</li> </ul>
Rosenthal 2006 (15)	<ul><li> 2000-2003</li><li> Pars flaccida</li><li> Fat pad removal not reported</li></ul>	No	<ul> <li>No comparison of baseline characteristics.</li> </ul>
Angrisani 2007 (16)	<ul><li>Jan to Nov 2000</li><li>Pars flaccida</li><li>Fat pad removal not reported</li></ul>	No	•
Jan 2007 (17)	<ul><li> 2000-2005</li><li> Pars flaccida</li><li> Fat pad removal not reported</li></ul>	No	<ul> <li>LAGB recommended to highest risk patients (significantly older, male, super obesity)</li> </ul>
Te Riele 2008 (4)	<ul><li> 2002-2005</li><li> Pars flaccida</li><li> Fat pad removal not reported</li></ul>	No	<ul> <li>Retrospective; matched sex, age and BMI</li> <li>Unclear if consecutive patients were selected for case control study from database.</li> <li>Median follow-up 23 months for LAGB and 18 months for RYGB.</li> </ul>

# Appendix

## Final Search – Laparoscopic Adjustable Gastric Banding

Search date: June 29, 2009

Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, OVID EMBASE, Wiley Cochrane, Centre for Reviews and Dissemination/International Agency for Health Technology Assessment

Database: Ovid MEDLINE(R) <1996 to June Week 3 2009>

- Search Strategy:
- 1 exp Gastroplasty/ (2003)

2 (lap band\* or lapband\* or (swedish adj3 band\*)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (262)

3 ((intragastric or intra-gastric or gastric or adjustable or soft) adj2 band\*).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (1396)

- 4 (lagb or sagb).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (381)
- 5 or/1-4 (2448)
- 6 exp Anastomosis, Roux-en-Y/ (1506)
- 7 exp Gastric Bypass/ (2664)

8 (gastrojejunostom\* or stomach bypass or gastric bypass or gastroileal bypass).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (3553)

- 9 roux en y.mp. (2924)
- 10 or/6-9 (4955)
- 11 10 and 5 (800)
- 12 limit 11 to (english language and humans and yr="2005 2009") (369)
- 13 ("200409\*" or "200410\*" or "200411\*" or "200412\*").ed. (185582)
- 14 11 and 13 (40)
- 15 12 or 14 (409)
- 16 limit 15 to (case reports or comment or editorial or letter) (37)
- 17 15 not 16 (372)
- 18 from 17 keep 1-372 (372)

Database: EMBASE <1980 to 2009 Week 26> Search Strategy:

1 exp Gastroplasty/ (1644)

2 (lap band\* or lapband\* or (swedish adj2 band\*)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (204)

- 3 ((intragastric or intra-gastric or gastric or adjustable or soft) adj2 band\*).mp. (2112)
- 4 (lagb or sagb).mp. (382)
- 5 or/1-4 (3357)
- 6 exp Roux y Anastomosis/ (2856)
- 7 exp Stomach Bypass/ (3164)
- 8 (gastrojejunostom\* or stomach bypass or gastric bypass or gastroileal bypass).mp. (5082)
- 9 roux en y.mp. (2958)
- 10 or/6-9 (7294)
- 11 10 and 5 (1085)
- 12 limit 11 to (human and english language and yr="2004 2009") (616)
- 13 limit 12 to (editorial or letter or note) (73)
- 14 Case Report/ (1042653)
- 15 12 not (13 or 14) (507)

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