Technology Assessment Program
Office of Patient Care Services

Bibliography* Update: Surgical treatments for morbid obesity—
laparoscopic adjustable gastric banding

*Selected, quality filtered, not subject to external review

This report is the third in a series of bibliographies produced to monitor the evidence base for surgical treatments for morbid obesity.

Policy Issue: The VA National Director of Surgery, in concert with the VA Central Office Bariatric Surgery Committee, asked the VA Technology Assessment Program (VATAP) to provide information on the safety, efficacy, effectiveness and cost effectiveness of laparoscopic adjustable gastric banding to support both evidence-based recommendations for the provision of the procedure in the veteran population and considerations for future research priorities.

To accomplish this, VATAP updated its 2004 bibliography report of quality filtered systematic reviews, meta-analyses and primary studies, focusing on evaluations of laparoscopic adjustable gastric banding as the technology of interest.

Background: Morbid obesity is chronic disease defined as a body mass index[1] (BMI) of at least 40 kg/m^2. Many conditions or risk factors associated with obesity (eg. coronary artery disease, other atherosclerotic diseases, sleep apnea, high fasting blood glucose levels and high cholesterol levels) place patients at high risk for subsequent mortality and require aggressive management[2]. In VA, 6.0% of female veterans and 3.3% of male veterans using VA medical facilities are classified as morbidly obese, which constitutes a substantial burden for both VA and the veterans it serves[3]. In response to this urgent health crisis, the VA National Center for Health Promotion and Disease Prevention developed a comprehensive approach to weight management called the *MOVE!* Program, based on the National Heart, Lung and Blood Institute *Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults* with guidance from the VA Weight Management Executive Council[4].

Bariatric surgery may be offered to appropriately selected patients with morbid obesity who meet the following criteria:

- Are well informed and motivated;
- Have a BMI ≥ 40 or BMI ≥ 35 with serious comorbid conditions, and;
- Have failed medical management approaches such as lifestyle modification through proper nutrition and increased exercise, behavioral modification and medication.

Various bariatric procedures exist, among which gastric bypass with Roux-en-Y anastomosis (done as a laparoscopic or open procedure) and vertical banded gastroplasty are most commonly performed in the US. Adjustable Gastric Banding (AGB) is a new surgical option for long-term treatment of morbid obesity. According to FDA, weight loss through AGB is induced by surgically implanting an adjustable silicone ring, either through an open procedure or laparoscopically, completely around the stomach opening below the junction of the stomach and

[1] BMI = weight in lbs x 703/height in inches^2 or kg/m^2
[2] *Practical Guide to the Identification, Evaluation and Treatment of Overweight and Obesity in Adults*, a joint publication of the National Institutes of Health National Heart, Lung, and Blood Institute, and the North American Association for the Study of Obesity. NIH Publication Number 00-4084. October 2000. http://www.nhlbi.nih.gov/guidelines/obesity/prctgd_c.pdf accessed March 2, 2007.
[3] Das, SR, Kinsinger LS, Yancy WS, et al. Obesity prevalence among veterans at Veterans Affairs medical facilities. American Journal of Preventive Medicine April 2005; 28(3):291-294.
[4] http://www.move.va.gov/whoDevelopedMove.asp accessed February 27, 2007.

esophagus to regulate food intake; adjustment can take place without the need for surgery by adding or removing sterile saline through a subcutaneous access port[5]. Today, AGB is most often performed laparoscopically. The LAP-BAND® Adjustable Gastric Banding (LAGB®) System (BioEnterics Corp., Carpinteria, California) has been approved by FDA for use in the US since 2001:

> *"LAGB® is indicated for use in weight reduction for severely obese patients with a BMI of at least 40 or a BMI of at least 35 with one or more severe comorbid conditions, or those who are 100 lbs. or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (using the midpoint for medium frame). It is indicated for use only in severely obese adult patients who have failed more conservative weight-reduction alternatives…"*

As a minimally invasive procedure, LAGB® reportedly carries less surgical risk than either open or laparoscopic gastric bypass procedures and is reversible, making it a potentially attractive alternative for the high-risk veteran population. However, early reports comparing LAGB® to gastric bypass procedures suggest that LAGB® is associated with more modest weight loss at one year, less effective comorbidity control, and higher costs associated with the procedure and maintenance in the outpatient setting. Complete long-term follow up data (greater than three years) have been lacking, making the risk/benefit profile of this procedure difficult to determine.

In 2006, the Centers for Medicare & Medicaid Services (CMS) expanded national coverage of bariatric surgery to include open and laparoscopic Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding, and open and laparoscopic biliopancreatic diversion with duodenal switch for Medicare beneficiaries who have a body-mass index (BMI) $\geq$ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity; CMS will cover these procedures only when performed at approved centers of excellence in bariatric surgery.[6]

VHA offers bariatric surgery to eligible veterans at 14 VA facilities, of which three perform LAGB® (E. Livingston: personal communication March 1, 2007). Increasing numbers of veteran patients are requesting placement of the LAGB® and management of LAGB® originally placed in private sector facilities. The rising popularity of this procedure and continued uncertainty about its risk/benefit profile call for evidence-based guidance on its use in the veteran population.

Methods: Not asked to undertake a formal literature synthesis of this topic, VATAP relied on the results of exiting systematic reviews and health technology assessments (HTA[7]) as the basis for this report supplemented with updated searches of recent clinical trial data from primary studies.

In January 2007, VATAP conducted comprehensive literature searches of MEDLINE®, EMBASE®, and Current Contents® electronic databases for systematic reviews, meta-analyses and primary studies published since 2005 comparing surgical interventions for morbid obesity. Search terms were used for controlled studies, meta-analyses, guidelines, consensus

[5] http://www.fda.gov/cdrh/pdf/P000008b.pdf. Accessed March 1, 2007.
[6] http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=160 accessed March 1, 2007.
[7] Health Technology Assessment (HTA) is a multidisciplinary field of policy analysis that systematically studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology.

development, recommendations crossed with terms for weight loss surgery, bariatric surgery, intragastric balloon, jejunoileal bypass, gastric bypass, biliopancreatic diversion, gastroplasty, and gastric banding. VATAP conducted separate searches of the Cochrane Library through Issue 4, 2006 for guidelines and studies using the same search terms.

Also in January 2007, VATAP queried the International Network of Agencies for Health Technology Assessment (INAHTA) via electronic mail for relevant completed or ongoing HTAs produced since 2005. VATAP supplemented the query with searches of the HTA database (www.inahta.org) using search terms for obesity, surgery, and bariatric in completed HTA reports and ongoing HTA projects. These queries resulted in several new, completed and ongoing HTAs on surgical treatments for obesity from INAHTA members and other organizations, which are included in Table 1.

VATAP screened search references using the following inclusion criteria:

- Adult, human subjects only;
- Sample size > 12 per treatment arm;
- Only FDA-approved devices used in bariatric surgery;
- Primary randomized, controlled or uncontrolled clinical studies comparing LAGB® to other bariatric surgical techniques;
- Only the most recent or largest studies reported data from the same population by the same investigators with the same objective (to eliminate redundancy);
- Systematic reviews or meta-analyses of bariatric procedures including LAGB® with full text available in public domain;
- Full text published in English.

Results: The searches and queries yielded a total of 374 citations. Based on review of title and abstract information, full text of 39 citations were retrieved as potentially meeting inclusion criteria or as relevant background information, of which 26 met inclusion criteria: eight non-randomized controlled trials, two randomized controlled trials, 12 completed systematic reviews or syntheses of systematic reviews supplemented with updated clinical trial data, and three systematic reviews or HTAs in progress (see Table 1).

The Blue Cross Blue Shield Technology Evaluation Center (BCBS TEC) produced the most recent, publicly available systematic review on LAGB® (2007) as of this writing and will constitute the basis for this bibliography. The systematic review was confined to comparative studies of LAGB® versus open or laparoscopic Roux-en-Y gastric bypass (LRYGB) with at least 25 evaluable patients per treatment arm, or large single arm series (N > 100) that reported outcomes of weight loss and/or adverse events with at least one year of follow-up. Searches were limited to English language articles reporting on human subjects published from January 1980 through September 2006.

VATAP searches identified all of the studies included in BCBS TEC (2007) comparing LAGB® to LRYGB, which are shaded in Table 1. VATAP identified one additional study by Jan (2005) comparing LAGB® to LRYGB, as well as three studies (Van Dielen 2005; Suter 2005; Collett 2005) comparing LAGB® to other interventions and two studies (Ballantyne 2006; Ledoux 2006) assessing outcomes that may be relevant to the veteran population. Data from single arm series were not the primary focus of this VATAP report; however, Suter (2006) was included

because it reported outcomes at 8 years follow up, and long-term follow up studies of bariatric surgery have been rare.

Conclusions: New data on the comparative safety and efficacy of LAGB® to other bariatric surgical techniques such as gastric bypass (GBY) from primary studies and other systematic reviews confirm the findings from BCBS TEC (2007), which are repeated here:

> *"…The current body of literature lacks high-quality clinical trials that directly compare outcomes between LAGB and GBY. Therefore, the conclusions in this Assessment are derived from other types of evidence, primarily comparisons of clinical series with or without matching.*
>
> *Weight loss at 1 year is less for LAGB compared with GBY, and conclusions on the comparative weight loss at longer time periods are not possible from these data. Some studies report that the difference in weight loss between these procedures diminishes, or disappears, with longer follow-up. However, the present data are mixed, and overall, do not confirm this hypothesis. It appears more likely from the current data that attrition bias may account for the diminution of the difference in weight loss over time, particularly when patients who have their band removed or deflated are excluded from analysis.*
>
> *The data on long-term complications remain suboptimal. The reporting of long-term complications in these trials is not systematic or consistent. As a result, highly variable rates of long-term outcomes are reported. It is not possible to determine the precise rates of long-term complications from these data, but it is likely that complications are under-reported in many studies due to incomplete follow-up and a lack of systematic surveillance. The high rates of long-term complications reported in some studies raise concern for the impact of these events on the overall benefit/risk ratio for LAGB.*
>
> *In comparing LAGB with GBY, there is a tradeoff in terms of risks and benefits. LAGB offers a less-invasive procedure that is associated with fewer procedural complications, a decreased hospital stay and earlier return to usual activities. However, the amount of weight loss will also be less for LAGB. The patterns of long-term complications also differ between the two procedures. For LAGB, longer-term adverse events related to the presence of a foreign body in the abdomen will occur, and will result in reoperations and removal of the band in a minority of patients. Patients who have their bands removed can later be offered an alternative bariatric surgery procedure, such as gastric bypass.*
>
> *For patients considering bariatric surgery, there is sufficient evidence to allow an informed choice to be made between gastric bypass and LAGB. An informed patient may reasonably choose either GBY or LAGB as the preferred procedure. Preoperative counseling should include education on the comparative risks and benefits of the two procedures in order to allow the optimal choice to be made based on patient and surgeon preferences."*

In light of the growing demand for LAGB® in VA and limitations in the existing knowledge base about the comparative risks and benefits of LAGB® versus other bariatric procedures particularly in patients similar to the veteran population, there is a need to study these bariatric procedures in the veteran population and monitor outcomes systematically over the long term.

Table 1. Evaluations of the Lap-Band® (LAGB®) procedure for treatment of morbid obesity published since 2005

RCT=randomized controlled trial; NCT=non-randomized controlled trial (multiple-arm case series of two or more treatment options); N=total study population

Shaded rows indicate studies met BCBS TEC 2007 inclusion criteria

Citation	Objective	LAGB® vs. ___	Follow up	Study design
Comparative studies				
Browne 2006	To compare demographic, comorbidity profiles and outcomes of super morbidly obese patients	LRYGB	1-40 months	NCT N=106
Rosenthal 2006	To compare safety and efficacy	LRYGB	1 year	NCT N=1,001
Kim 2006	To compare safety and efficacy	LRYGB	2 years	NCT N=392
Collam 2006	To compare safety and efficacy	LRYGB	3 years	NCT with matched-pairs N=362
Jan 2005	To compare safety and efficacy	LRYGB	1-41 months	NCT N=373
Ballantyne 2006	To compare short term changes in insulin resistance post op	LRYGB	3 months	NCT N=107
Ledoux 2006	To quantify and compare nutritional complications post op	LRYGB, Medical program	6 months to 5 years	NCT N=201
Van Dielen 2005	To compare safety and efficacy	Open VBG	2 years	RCT N=100
Suter 2005	To compare safety and efficacy	SAGB	3 years	RCT N=180
Collett 2005	To compare safety and efficacy	Minimizer® Band	2 years	NCT N=188
Other studies				
Van Mastrigt 2006	Cost effectiveness		1 year	Netherlands perspective
Suter 2006	To evaluate long-term safety and efficacy	None	8 years	Case series N=317
HTA, systematic reviews & meta-analyses				
BCBS TEC 2007 (USA)	To compare safety, efficacy	LRYGB		Systematic review through September 2006
Brand 2006	To evaluate effectiveness	Various surgical options		Sys reviews, meta-analyses, controlled trials and observational studies from 1980-May 2006
Lambert 2006 (Belgium)	Effectiveness, cost-effectiveness and societal consequences	Pharmaceutical and surgical		Review of reviews published through December 2005
Jacobs 2006 (IHE Canada)	Evaluates the economic aspects associated with LAGB® in the Alberta population	LAGB®		June 2006
Colquitt 2005	To compare safety, efficacy	Various surgical options		Systematic review through December 2004 (Cochrane review)
Maggard 2005	To evaluate effectiveness and adverse events	Various surgical options		Meta-analysis of RCT, observational studies and case series through July 2003
Manterola 2005	To identify the best bariatric surgical options	Various		All study types published from 1990- December 2002
ICSI 2005 (USA)	To compare safety and efficacy	LRYGB, VBG		Systematic review through early 2005
AETMIS 2005 (Montreal Canada)	To compare safety and efficacy	Various surgical options		Literature published 1998 to April 2005
AHFMR 2005 (Alberta, Canada)	To compare safety and efficacy	Various surgical options		Systematic review published literature from 2000 to early

Citation	Objective	LAGB® vs. ___	Follow up	Study design
				2005
NZHTA 2005 (New Zealand)	To compare safety and efficacy	Various surgical options		Literature published 2000 to September 2004
OHTAC 2005 (Ontario Canada)	To compare safety, effectiveness and cost-effectiveness	Various surgical options		Literature published April 2004-December 2004
INAHTA agency HTA and systematic reviews in progress				
CADTH 2007 (Canada)	To evaluate safety, efficacy, effectiveness	LABG		Synthesis of sys reviews, meta-analyses and HTA published since 2000 plus clinical trial data from 2004 onward Completion slated for end of spring
DACEHTA 2007 (Denmark)	To evaluate safety, efficacy, effectiveness	LAGB®		HTA on the obesity-topic in terms "surgical procedures", including laparoscopic adjustable gastric banding, will be conducted Completion slated for 2007
DAHTA@DIMDI 2007 (Germany)	To evaluate safety, efficacy, effectiveness	Gastric banding		Commissioned by industry Completion slated for end of spring

LRYGB, laparoscopic Roux-en-Y gastric bypass
VBG, vertical banded gastroplasty
SAGB, Swedish adjustable gastric band

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