

MEDCAC Meeting

Health Outcomes after Bariatric Surgical Therapies
Laparoscopic Adjustable Gastric Banding (LAGB)

August 30, 2017

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Disclosure

Sid Rohrscheib, MD

Relationships with commercial Interests:

- Apollo Endosurgery, Inc. (minor association)
 - Consultant
 - Clinical Investigator

Outline

- Health outcomes data for LAGB
- Special populations of interest to Medicare
- Where LAGB “fits” on the spectrum of surgical options
- Patient selection, proper setting, and good aftercare is key to success with bariatric surgery, including LAGB
- LAGB can help reduce barriers to bariatric surgery, and offer opportunities for further cost savings for CMS

Substantial Outcomes Data Exists for LAGB

- Durable Weight Loss (50% EWL at 6 years, 47% EWL at 15 years)

Weichman K, Ren C, Kurian M, et al. The effectiveness of adjustable gastric banding: a retrospective 6-year U.S. follow-up study. *Surg Endosc.* 2011;25:397-403.

O'Brien PE, MacDonald L, Anderson M, et al. Long-term outcomes after bariatric surgery. *Annals of Surgery.* 2013 Jan;257(1):87-94.

- Postoperative Complications (Comparatively lower complication/re-op rates and shorter hospital stays)

Hutter MM, Schirmer BD, Jones DB, et al. First report from the American College of Surgeons Bariatric Surgery Center Network. *Ann Surg.* 2011;254(3):410-22.

DeMaria Eric, Pate Virginia, Warthen Michael, Winegar Deborah. Baseline data from American Society for Metabolic and Bariatric Surgery-designated Bariatric Surgery Centers of Excellence using the Bariatric Outcomes Longitudinal Database. *Surgery for Obesity and Related Diseases* 6. 2010.

Arteburn D, Powers JD, Toh S, et al. Comparative Effectiveness of Laparoscopic Adjustable Gastric Banding vs. Laparoscopic Gastric Bypass. *JAMA Surg.* 2014; 149(12):1279-1287.

Substantial Outcomes Data Exists for LAGB

- Co-morbidity resolution/improvement (metabolic syndrome)

Ooi GJ, Doyle L, Tie T, et al. Weight loss after laparoscopic adjustable gastric band and resolution of the metabolic syndrome and its components. *JAMA Surg.* 2017. 41:902-908.

- Quality of Life (improvements in SF-12 and IWQOL-Lite scores)

Dixon JB, Eaton L, Cobourn C, Curry T. 2016. Health outcomes from the HERO study: a prospective, multi-center, non-randomized study of health outcomes and the rates of explants after 5 years of treatment with laparoscopic adjustable gastric banding. (Poster) Obesity Week, New Orleans.

- Health Economics (LAGB favorable compared to RYGB and LSG)

Finkelstein EA, Allaire BT, Globe D, Dixon JB. 2013. The business case for bariatric surgery revisited: a non-randomized case-control Study. *Plos One.* 8(9): 1-8.

Telem DA, Talamini M, Gesten F, Patterson W, Peoples B, Gracia G, Yang J, Zhang Q, Altieri M, Pryor AD. 2014. Hospital admissions greater than 30 days following bariatric surgery: patient and procedure matter. *Surg Endosc.* 29(6): 1310-5.

Special Populations

- Patients over 60 benefit from LAGB

Clough A, Layani L, Shah A, Wheatley L, Craig T. Laparoscopic Gastric Banding in Over 60s. *Obesity Surgery*. 2010 May 19. doi 10.1007/s11695-0100158-3.

- LAGB may be best option for many with BMI 30-40

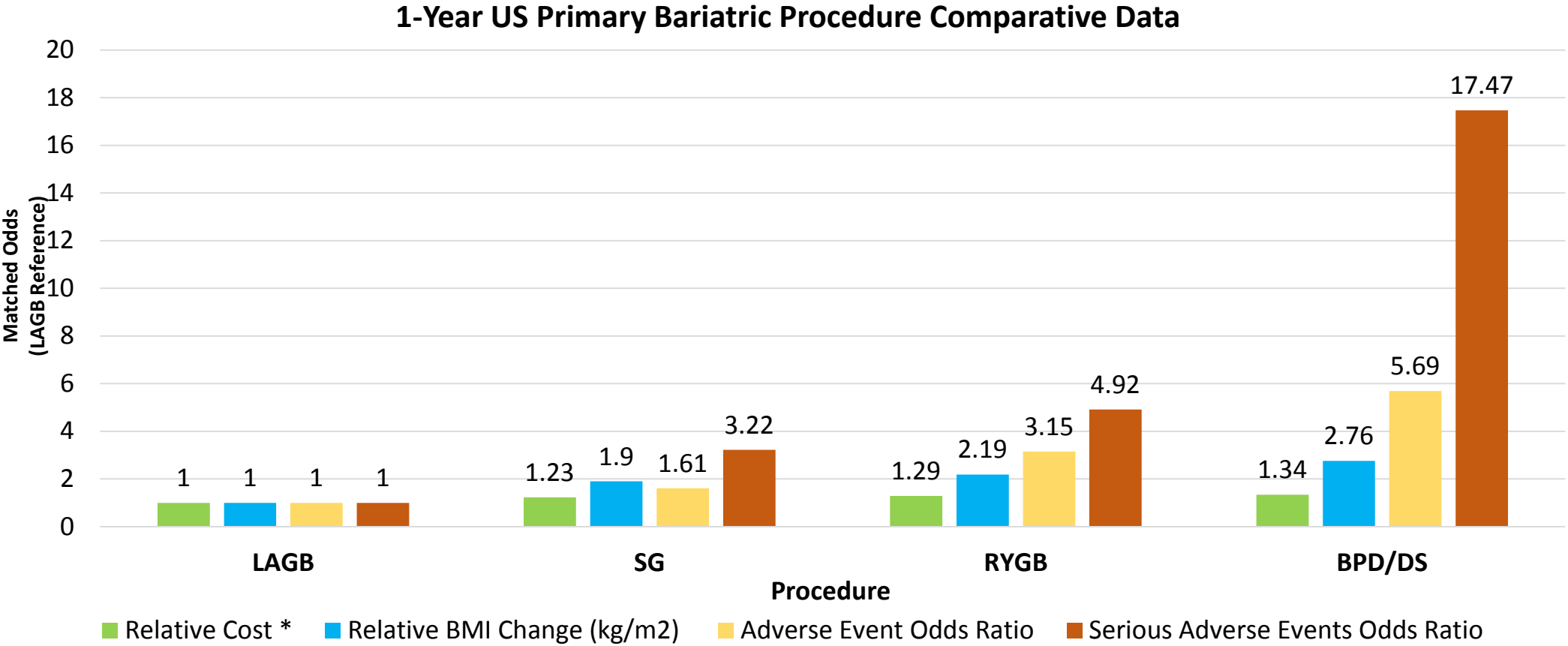
Michaelson R, Murphy DK, Gross TM, Whitcup SM. Lap-band for lower BMI: 2-year results from the multicenter pivotal study. *Obesity*. 2013;21(6):1148-58.

Courcoulas AP, Belle SH, Neiberg RH, et al. Three-year outcomes of bariatric surgery vs. lifestyle intervention for type 2 diabetes mellitus treatment. *JAMA Surg*. 2015. doi: 10.1001/jamasurg.2015.1534.

Dixon JB, O'Brien PE, Playfair J, et al. Adjustable gastric banding and conventional therapy for Type 2 diabetes: a randomized controlled trial. *JAMA*. 2008 Jan. 23;299(3):316-22.

Dixon JB, Eaton LL, Vincent V, et al. LAP-BAND for BMI 30-40: 5-year health outcomes from the multicenter pivotal study. *Int J Obes*. 2015; 1-8.

Bariatric Procedure Comparative Data



Sudan R, Maciejewski ML, Wilk AR, Nguyen NT, Ponce J, Morton JM. Comparative effectiveness of primary bariatric operations in the United States. *Surg Obes Relat Dis (SOARD)*. DOI: <http://dx.doi.org/10.1016/j.soard.2017.01.021>.

*Based on CMS 2017 Final Ruling for HOPPS and IPPS using DRG 619, 620, 621 and CPT 43770

Patient Selection and Aftercare is Critical

- All bariatric procedures have their place in the right patient
- Aftercare and proper follow up is critical for all procedures

Sivagnanam P, Rhodes M. The importance of follow-up and distance from centre in weight loss after laparoscopic adjustable gastric banding. *Surg Endosc*. March 2010. DOI 10.1007/s00464-010-0970-9.

Kaiser KA, Franks SF, Smith AB. Positive relationship between support group attendance and one-year postoperative weight loss in gastric banding patients. *Surg Obes Relat Dis (SOARD)*. 7(2011) 89-93.

Barriers to Bariatric Surgery

- Fear of complications is the greatest barrier

Fung M, Wharton S, Macpherson A, Kuk JL. Receptivity to Bariatric Surgery in Qualified Patients. *J Obes*. 2016; 2016: 5372190.

- LAGB is safest and least invasive procedure and should continue to be offered as a primary option

O'Brien PE, MacDonald L, Anderson M, et al. Long-term outcomes after bariatric surgery. *Annals of Surgery*. 2013 Jan;257(1):87-94.

Flum DR, Belle SH, King WC, et al. Perioperative safety in the Longitudinal Assessment of Bariatric Surgery. *N Engl J Med* 2009; 361:445-54.

Inabnet WB, Belle SH, Bessler M, et al. Comparison of 30-day outcomes after non-LapBand primary and revisional bariatric surgical procedures from the Longitudinal Assessment of Bariatric Surgery study. *Surg Obes Relat Dis (SOARD)*. 6(2010) 22-30.

Summary

- LAGB outcomes are well established in the literature over many years
- Improvements in long-term weight loss, QOL and co-morbid conditions have also been shown with patients over 60
- Risk/benefit ratio makes LAGB the logical choice for low BMI indications, and is better received by patients fearful of surgery
- Patient selection and aftercare is crucial for success
- LAGB is the safest and least invasive option, with a unique mechanism of effect compared to alternative surgical therapies