PDAM-02

MEETING THE INCREASING INTEREST IN COVERAGE AND REIMBURSEMENT OF OBESITY TREATMENT: COMPARATIVE EFFECTIVENESS RESEARCH METHODS

Cheryl Hankin, PhD[1]; Maria Lopes, MD[2]; Jeffrey D. Dunn, PharmD[3]; Barbara Troupin, MD[4]

[1]BioMedEcon, Moss Beach, CA; [2]MMD Lopes, LLC, Cresskill, NJ; [3]SelectHealth, Inc., Salt Lake City, UT; [4]VIVUS Pharmaceuticals, Inc., Mountain View, CA

BACKGROUND

- **The U.S. obesity epidemic creates an enormous economic burden on the healthcare system.**
  - In 2008, 34% of U.S. adults were obese (BMI ≥30 kg/m^2).[1]
  - Current trends indicate that half of U.S. adults will be obese by 2030.[2]
  - The health-related costs of obesity are staggering:
    - Obesity accounts for 9.1% of U.S. annual total healthcare spending (~$147 billion).[3]
    - Healthcare costs attributable to obesity and overweight are expected to reach $956 billion, and account for up to 18% of total healthcare costs or $1 in every $6 spent on healthcare, by 2030.[2]
- **Given the rising burden of obesity-related medical expenditures, various stakeholders (payers, employers, policy makers, consumers) are increasingly interested in how coverage and reimbursement of obesity treatments are determined.**
- Currently, whereas weight loss behavioral modification and pharmacotherapy are rarely covered by health plans, bariatric surgery is often covered, albeit for a small proportion of the obese population.[4,5]
- The basis for making these coverage determinations is often unclear, and variation in coverage and reimbursement policies is widespread.
- **Comparative effectiveness research (CER) can facilitate a shift toward more evidence-based decision making regarding coverage and reimbursement of obesity treatments.**
  - CER is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care.[6]
  - One of the top national priorities for CER is to compare the effectiveness of treatment strategies for obesity (e.g., bariatric surgery, behavioral interventions, pharmacologic treatment).[6]
  - Because weight loss treatment studies have reported different weight loss outcomes, CER methods to compare outcomes across treatment modalities.

OBJECTIVES

- To provide a method of comparing published efficacy of weight loss procedures from various studies;
- To report CER for the two most common bariatric procedures performed in the U.S. in terms of average percent weight loss achieved at one year; and
- To report safety in terms of rates of reoperation and conversion to open surgery.

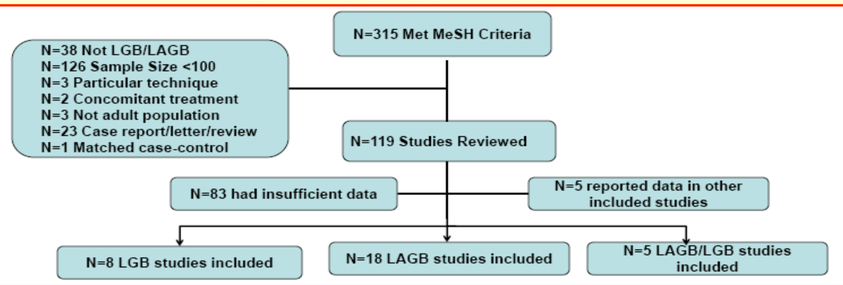
METHODS

- We conducted a systematic literature review of published studies of laparoscopic Roux-en-Y gastric bypass (LGB) and laparoscopic adjustable gastric banding (LAGB) to compare mean percent weight loss from baseline to one year, reoperation rate, conversion rate, and mortality rate.
- Inclusion criteria were prospective or retrospective consecutive patient series of surgical treatment with LAGB or LGB, English language, adult patients only (>18 years old), study reported the mean baseline weight and either percentage excess weight loss or absolute weight loss at one year, and sample size of ≥100 per LAGB/LGB arm at enrollment.
- Exclusion criteria included nonhuman studies; nonsurgical interventions; concomitant weight loss treatments; bariatric surgery procedures other than LGB or LAGB; studies of revisional surgeries only; studies that focused on a particular surgical technique; randomized or case-control design, and follow-up before one year.
- A MEDLINE search of studies published from 2000 to 2009 using the MeSH terms “bariatric surgery,” “laparoscopy,” and “weight loss” was conducted to identify relevant studies.
- Electronic papers were reviewed based on inclusion/exclusion criteria.
- Selected papers were then abstracted and entered into an Excel database.

METHODS: CALCULATION OF MEAN % WEIGHT LOSS AT ONE YEAR

- Studies of bariatric surgery often report weight loss in terms of percent excess weight loss (%EWL), defined as:
  - [(Preoperative Weight – Postoperative Weight)/(Preoperative Weight – Ideal Weight)] * 100
  - Ideal weight was derived from the 1983 Metropolitan insurance height and weight tables, which represent the weight for each height at which mortality was lowest and longevity was highest.
    - We assumed an “ideal” weight of 70 kg for males (69” tall, 154 lb) and 59.5 kg for females (64” tall, 131 lb), which corresponds to the midpoint of the large frame for the Metropolitan tables.[7]
- To calculate the mean percentage weight loss at one year based on the %EWL at one year:
  - The ideal average baseline weight for each group was calculated as:
    - [(Number of Males * 70 kg) + (Number of Females * 59.5 kg)]/Total Number of Male and Female Subjects
  - The average weight loss achieved was calculated as:
    - [(Mean Baseline Weight – Ideal Baseline Weight) * (% Excess Weight Loss at One Year)]

RESULTS: STUDY IDENTIFICATION



RESULTS: SUMMARY OF LGB STUDIES

Study	N	% EWL at 1 Year	Mean Weight Loss at 1 Year (kg)	Mean % Weight Loss at 1 Year	% Reoperation	% Conversion	Deaths
Ahmed, 2009[8]	100	60.0	45.0	32.6	–	–	–
Akkary, 2009[9]	309	–	49.3	34.4	–	–	1
Biertho, 2003[10*]	456	67.0	49.5	36.5	2.2	2.0	2
Christou, 2009[11*]	886	70.4	52.6	36.3	3.0	0.1	3
DeMaria, 2002[12]	69	70.0	47.7	36.8	–	–	0[a]
Harnisch, 2008[13]	203	63.7	53.0	36.8	–	5.9	0
Jan, 2006[14*]	492	64.9	49.6	35.6	–	0.2	1
Ma, 2006[15]	494	65.0	53.2	37.2	–	–	3
Marema, 2005[16]	1,077	–	55.3	42.0	–	–	1
Mognol, 2005[17*]	111	63.0	62.6	38.6	–	3.6	1
Perugini, 2003[18]	93	–	48.0	34.2	–	1.6	1[b]
Puzziferri, 2008[19*]	1,102	70.3	58.3	45.0	–	–	–
Weber, 2004[20]	103	54.8	38.4	29.2	6.8		1
TOTAL	**5,392**	**67.8%**	**53.6 kg**	**38.2%**	**3.0%**	**0.8%**	**0.3%**

[a]based on a sample size of 281; [b]based on a sample size of 188; *studies of both LGB and LAGB

RESULTS: SUMMARY OF LAGB STUDIES

Mean One-Year Percent Weight Loss for Bariatric Surgery

Study	N	% EWL at 1 Year	Mean Weight Loss at 1 Year (kg)	Mean % Weight Loss at 1 Year	% Reoperation	% Conversion	Deaths
Ahroni, 2005[21]	195	33.0	45.7	28.0	–	–	1
Biagini, 2008[22]	591	66.7	37.7	31.7	–	–	1
Bierto, 2003[10*]	805	33.0	18.3	15.6	–	3.0	0
Busetto, 2003[23]	379	41.5	25.3	19.4	25.9	3.5	0
Christou, 2009[11*]	149	42.8	18.5	14.6	15.4	0	0
Colles, 2008[24]	129	50.0	25.7	20.8	–	–	1
Favretti, 2007[25]	295	40.3	24.0	18.0	17.1	1.7	0
Frigg, 2004[26]	295	40.0	25.4	20.3	16.6	6.1	0
Gastaldelli, 2009[27]	159	–	21.0	17.9	–	–	–
Gravante, 2007[28]	400	48.2	32.8	26.6	–	0	1
Jan, 2006[14*]	406	34.0	27.0	18.6	–	0.7	1
Mittermair, 2009[29]	785	40.4	26.0	21.7	32.0	0	0
Mognol, 2005[17*]	179	41.0	34.4	25.9	–	0	1
Naef, 2007[31]	128	33.3	21.3	16.8	11.7	0	0
Nehoda, 2001[30]	250	72.0	35.0	25.8	8.8	0.8	0
O’Brien, 2002[33]	709	40.7	30.4	21.4	18.9	0	0
Paganelli, 2001[33]	156	42.5	24.0	20.3	3.8	2.6	0
Puzziferri, 2008[19*]	631	36.6	27.6	20.2	–	–	–
Rubin, 2003[34]	250	42.1	24.7	20.6	12.0	0	0
Steffen, 2003[35]	824	25.9	16.6	16.6	23.3	6.9	0
Toouli, 2008[36]	1,000	40.0	23.0	19.4	–	–	1
Vertruyen, 2002[37]	542	38.0	21.5	18.4	–	1.1	0
Zinzindohoue, 2003[38]	500	42.8	25.7	21.3	10.4	2.4	0
TOTAL	**11,059**	**42.4%**	**25.7 kg**	**20.6%**	**20.2%**	**1.9%**	**0.07%**

*studies of both LGB and LAGB

CONCLUSIONS

- One-year average percent weight loss was higher among 5,392 morbidly obese patients who received LGB (38.2%) compared with 11,059 morbidly obese patients who received LAGB (20.6%).
- The mortality rate was over four times greater for LGB (N=14; 0.3%) versus LAGB (N=7; 0.07%), but LAGB was associated with a higher reoperation rate than LGB (20.2% vs. 3.0%).
- As obesity rates continue to spiral, healthcare systems will encounter increasing demands to evaluate the comparative effectiveness of weight loss treatments.
- Although %EWL is the most commonly reported weight loss outcome in studies of bariatric surgery, it is not inherently meaningful and does not facilitate comparison to nonsurgical weight loss interventions, which do not report this outcome.
- We describe one CER method that can be used to compare weight loss effectiveness across various treatments for obesity.
- As research determines weight loss levels required to reduce obesity-related cardiometabolic risks, the relative benefits and risks of weight loss treatments can be more firmly established.

REFERENCES

See handout for list of references.

FOR FURTHER INFORMATION

Please contact: Cheryl Hankin, PhD, BioMedEcon, LLC.; P.O. Box 129, Moss Beach, CA 94038; 650-563-9475; cherylhankin@biomedecon.com; www.biomedecon.com

DISCLOSURES

Cheryl Hankin and Amy Bronstone are consultants to VIVUS, Inc. Research supported by VIVUS, Inc.

PRESENTED AT THE ACADEMY OF MANAGED CARE PHARMACY 2010 EDUCATIONAL CONFERENCE, ST LOUIS, MO; OCTOBER 13-15, 2010