Patient Perspective on the State of Evidence for Outcomes in the Medicare Population for Surgical and Endoscopic Procedures

Presented by:

Joe Nadglowski,
President/CEO,
Obesity Action Coalition (OAC)

Disclosures

Employee Obesity Action Coalition (OAC) >$10,000 I have no personal relationships with industry, but OAC does accept funding from a wide variety of industry members including those involved in the behavioral, medical, pharmaceutical, device and surgical treatment and prevention of obesity.

Minor - Other disclosures (all <$10,000):

- Former ASMBS Foundation Executive Director (role ended 6/30/2014)
- Former Member of the Data Access Committee of both the ASMBS and Surgical Review Corporation's Bariatric Outcomes Longitudinal Database (BOLD)
- PCORI Work:
  - PCORI Bariatric Surgery Study – Executive Stakeholder
  - PCORI LOBSTER PROM – Advisory Committee Member
  - One Florida Consortium (CDRN) – Steering Committee and Obesity Taskforce
- Participated in numerous FDA panels (both drug and device) during public comment periods
- ACTION (Awareness, Care and Treatment In Obesity Management) Study – Steering Committee Member (*Study funded by Novo Nordisk*)

Disclosures

Other disclosures continued (all <$10,000):

- AHRQ Reviewer (including current AHRQ review on bariatric surgery in those 65 and older)
- Serve on numerous committees, OAC committees and other organizations focused on access to care including as a non-voting member of the ASMBS Access to Care Committee
- STOP Obesity Alliance – Steering Committee Member
- Published research on weight bias/societal attitudes toward obesity and access to obesity care
- Participants in STOP, NQF and AMGA efforts to develop quality measures for obesity care including patient reported outcomes

Outline

- Obesity
- Weight Bias
- Seniors & Obesity
- Realities of Collecting Data on Bariatric Surgery
- Patient Centered Outcomes in Bariatric Surgery
- Conclusions

Obesity

- Obesity is a complex chronic disease with limited understanding of its pathogenesis.[1]

- Obesity is widespread and impacts many people though we see higher rates of obesity (40.4%) and especially severe obesity (9.9%) in women. Male rates are 35.0% and 5.5% respectively.[2]

1. Michael W. Schwartz, Randy J. Seeley, Lori M. Zeltser, Adam Drewnowski, Eric Ravussin, Leanne M. Redman, Rudolph L. Leibel; Obesity Pathogenesis: An Endocrine Society Scientific Statement. *Endocr Rev* 2017 er.2017-00111. doi: 10.1210/er.2017-00111

2. Flegal KM, Kruszon-Moran D, Carroll MD, Fryar CD, Ogden CL. Trends in Obesity Among Adults in the United States, 2005 to 2014. *JAMA.* 2016;315(21):2284-2291. doi:10.1001/jama.2016.6458

Obesity

For Your Consideration:

- People with obesity vary, as do their response to obesity interventions.[1] We have no one therapy that works for everyone.
- Success can and does look very different on an individual basis. For some, weight-loss is important, but for others, it is comorbidity resolutions, quality of life and/or improvements in functional status.
- Our healthcare system often treats obesity more like an acute illness and not a chronic disease. Comprehensive care is not the norm.

1. Kaplan, LM, Harvard Blackburn Course in Obesity Medicine, 2017.06.16 Accessed at http://conscienhealth.org/2017/06/one-size-fits-all-in-the-age-of-personalized-medicine/

Weight Bias

- Negative attitudes toward individuals with obesity
- Stereotypes leading to:
  - stigma
  - rejection
  - prejudice
  - discrimination
- Impacts Quality of Care and Quality of Life

1. Puhl, R. M., Phelan, S. M., Nadglowski, J., & Kyle, T. K. (2016). Overcoming weight bias in the management of patients with diabetes and obesity. Clinical Diabetes, 34(1), 44-50. DOI: 10.2337/diaclin.34.1.44

Weight Bias & Bariatric Surgery

- While bias experienced by those affected by obesity generally decreases after weight-loss, it doesn't necessarily do so after bariatric surgery.
- Prejudice is that many perceive bariatric surgery as the "lazy weight-loss option" because they believe that it "does not require the effort and discipline losing weight and dieting does."
- Please do not let the above attitudes impact your recommendations or review today.

Fardouly, J. Vartanian, L.R. Changes in weight bias following weight loss: the impact of weight-loss method. Int J Obes (Lond) 2012 Feb;36(2):314-9. doi: 10.1038/ijo.2011.26. Epub 2011 Mar 1.

Seniors & Obesity

The 65 and older population:

- Have matching views as those younger that obesity is a disease (66% 65+, 64% 18-64)
- Have significantly higher comorbidity prevalence (double in some cases)
- Specific medical events (heart attack, stroke, etc.) drove their desire for obesity care
- Have goals for obesity care focused on improving health conditions

Look, M, et al Insights and Perceptions of Obesity Management in Older People with Obesity ACE Annual Scientific & Clinical Congress, 5 May 2017, Austin, TX, USA

Seniors & Obesity

The 65 and older population:

- Were less likely to see their healthcare provider about obesity. 44% do not (35% for 18-64).
- Less likely to have a formal diagnosis of obesity despite meeting BMI requirements (50% 65+, 56% 18-64).

“Although similar in many ways, older PwO show important differences in how they perceive and manage their obesity compared with younger PwO.”

Look, M, et al Insights and Perceptions of Obesity Management in Older People with Obesity ACE Annual Scientific & Clinical Congress, 5 May 2017, Austin, TX, USA

Realities of Collecting Data on Bariatric Surgery

- Many studies require the patient and/or their insurer to pay the costs of surgery. Coverage for bariatric surgery is not universal.
- Most insurers, including Medicare, limit access to bariatric surgery based on conditions including BMI, co-morbidities, pre-surgical diets, etc. They can vary widely. They often exclude treatment types (gastric balloons under Medicare as an example).
- Under Medicare, if Palmetto is your Administrative Contractor, for hypertension to be considered a comorbidity it must be not well controlled with one medication. If First Coast, must have resistant hypertension on 3 medications. Differences exist on mandatory pre-surgical diets as well.[1]

1. CMS Medicare Coverage Database – Access week of July 24, 2017

Realities of Collecting Data on Bariatric Surgery

RCT's can be challenging as well:

- In general, we have few RCT's in the 65+ population across all trials not just bariatric surgery.[1]
- Patient preferences/choices make randomization difficult.
  - If as a patient, you've decided you want to have surgery being randomized to a non-surgical intervention and/or a different procedure, then your desire can cause opt-outs and/or skew the comparison group as patients seek their preferred treatment type.
  - Also, many patients are not open to a surgical/device intervention for their obesity.[2]

1. Zulman DM, Sussman JB, Chen X,et al. Examining the evidence: a systematic review of the inclusion and analysis of older adults in randomized controlled trials. J Gen Intern Med. 2011 Jul;26(7):783-90. doi: 10.1007/s11606-010-1629-x. PMID: 21286840

2. Stanford FC1, Kyle TK, Claridy MD, Nadglowski JF, Apovian CM. The influence of an individual's weight perception on the acceptance of bariatric surgery. Obesity (Silver Spring). 2015 Feb;23(2):277-81. doi: 10.1002/oby.20968. Epub 2014 Dec 28.

Realities of Collecting Data on Bariatric Surgery

Registry, Accreditation and Big Data Databases:

- Registry data and accreditation databases such as MBSAQIP hold potential to answer some of the important questions being posed.
    - Medicare no longer requires accreditation so not all Medicare recipients may be captured.
- PCORI Clinical Data Research Networks and other big data sources also hold potential with their combination of electronic health records and administrative/claims data.
    - Many of the networks still have data gaps and the common data available from each network is somewhat limited to start. Data verification can be a problem.

Realities of Collecting Data on Bariatric Surgery

Obesity Care, specifically bariatric care, being provided like acute care and not chronic care:

- Insurers and payors typically reimburse for the act of surgery itself, pre and post-care is more intermittently covered. Some allow only one bariatric procedure per lifetime.
- Many services post surgery such as required vitamins, visits with dieticians, exercise physiologists, support groups, etc. are either absorbed by the surgeon's practice/hospital or patients are charged an annual program fee and/or pay on a per-service basis.
- Often see challenges when patients move because of the payment system.
- While support groups are widely recognized as beneficial in behavioral weight management programs, there is little incentive to conduct them in bariatric practices.

Realities of Collecting Data on Bariatric Surgery

What does this mean for data collection and potentially outcomes?

- Reimbursement system discourages long-term care and easier data collection.
- Potentially harms outcomes and increases complications with patients not receiving critical follow-up care and services (malnutrition from lack of vitamin supplementation).
- Explanation for low follow-up rates post-bariatric surgery.
- Patients seeking support and advice post-surgery have flocked to the Internet where they sometimes get good advice but more often receive poor medical advice from non-medical professionals.

Patient-Centered Data on Bariatric Surgery

What outcomes of bariatric surgery are important to patients?

- Wide variation due to the wide variety of people.
- Desire for more focus beyond weight-loss and typical comorbidities such as quality of life, functional status and patient reported outcomes.
- Recent systematic review by Kolotkin and Andersen[1] showed consistent demonstration of improved quality of life post bariatric surgery. Also includes an in-depth discussion of potential improvement of future studies in this area.
- Ongoing PCORI funded LOBSTER PROMs (Longterm Outcomes of Bariatric Surgery Techniques and their Effect on Related Patient Reported Outcome Measures) study by Hutter and his colleagues should give us a greater collection of information to study on patient reported outcomes.

1. Kolotkin RL1,2,3,4,5, Andersen JR3,4. A systematic review of reviews: exploring the relationship between obesity, weight loss and health-related quality of life. https://www.ncbi.nlm.nih.gov/pubmed/28695722#

Conclusions

- Bias impacts people with obesity as well as people's perception about obesity treatments. Don't let bias enter today's conversations.
- Obesity is a chronic complex disease.
- Responses and treatment goals vary between patients.
- Seniors' views of obesity generally match the public with some exceptions.
- Data collection in bariatric surgery is difficult due to numerous circumstances.
- Patient-centered outcomes are important.