Clinically Meaningful Outcomes for Weight Loss Procedures and Devices

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Obesity

- Treating an epidemic
- Creating options that can help stem the tide of obesity
- Durable
- Reproducible
- “Repeatable”

Outcomes

- Historically for any procedure

  safety

  efficacy
- Propel greater acceptance
- Increase penetration

Obesity

- Safety/Efficacy: short and long term
  - Recidivism or weight regain
  - 20-30% in gastric bypass longterm
  - 22% -55% in sleeve at five years
    - Felsenreich DM(1), Langer FB(1), Kefurt R(1),et al. Weight loss, weight regain, and conversions to Roux-en-Y gastric bypass: 10-year results of laparoscopic sleeve gastrectomy. Surg Obes Relat Dis. 2016 Feb 26. pii: S1550-7289(16)00066-6.
- Co Morbidity Resolution
- Weight loss
  - Measured against surgery (25% Total body weight loss)
  - Measured against medicines (5% Total body weight loss)

Obesity

- Excess Weight Loss
- Total Body Weight Loss
- Excess % BMI loss
- Total % BMI loss
- Standardize internationally and across specialties
  - Brethauer SA(1), Kim J(2), el Chaar M(3), Papasavas P(4), Eisenberg D(5), Rogers A(6), Ballem N(7), Kligman M(8), Kothari S(9); ASMBS Clinical Issues Committee. Standardized outcomes reporting in metabolic and bariatric surgery. Surg Obes Relat Dis. 2015 May-Jun;11(3):489-506

Obesity

- Chronic Disease
- Multiple modalities to treat
- Alterations to GI anatomy
- Impact on Further Therapies
- Reversability
- Risks of removal or explantation

GERD/Achalasia

- Endoscopic
- Laparoscopic/open procedures
  - Botox, dilation, ablation, plication (sutures, fasteners) all add to the risk of surgical revision

- Address the success and failure rates, need for additional intervention, risk of further intervention

Chronic Disease Models

- Cardiac
  - angioplasty
  - Coronary stents to bypass
  - Endovascular valves to valve replacement
- Peripheral Vascular
  - Angioplasty
  - Stents and endovascular grafts
  - bypass
- Orthopedic
  - Injections, arthroscopy to replacements
  - Replacements of the replacement

Weight Loss: By hook or by …

- Weight loss and adverse events:
  - Medications
  - Surgical techniques have evolved to minimally invasive techniques
  - Clinical pathways, standardization, team building have resulted in significant reduction in morbidity and mortality
- MBSAQIP
- Endoscopic methods should have a safety record that is better than surgical procedures

Intragastric Balloon

- The estimates for weight lost at balloon removal for BIB® were the following: 14.7 kg, 12.2% of initial total body weight, 5.7 kg/m^2 in BMI, and 32.1% of excess weight. Complications of IGBs reported in a large case series and a meta-analysis include esophagitis (1.27%), gastric perforation (0.19- 0.21%) with a higher incidence post gastric surgery, gastric outlet obstruction (0.76%), gastric ulcer (0.2%), balloon rupture (0.36%), and death (0.07%). Overall complication rate was of 2.85%. BIB® is relatively safe, the majority of complications reported were mild and the early removal rate was 4.2%.
  - Dumonceau JM. Evidence-based review of the Bioenterics intragastric balloon for weight loss. Obes Surg 2008;18:1611-7.

SAE, complication rate, weight loss

Co-Morbidity Resolution

- Duoedeno jejunal liner
- Duodenal resurfacing

- Treating diabetes and lipid metabolism more than weight loss
- Metabolic Syndrome
- Non Cosmetic
- Preventive

Co-Morbidity Resolution

- Duodenal-jejunal liner
  - 22 patients w type 2 DM, mean BMI 44.8
  - 52 weeks duration
  - Fasting blood glucose, Hgb A1C, insulin levels
  - 13/22 completed study- early retrieval for migration, GI bleed, pain…
  - 16/22 had HgbA1c<7 (1/22 pre procedure)
  - AE: upper abd pain, back pain, nausea, vomiting
  - DJBL improves glycemic status in obese pts w diabetes
    - deMoura EG, Martins BC, Lopes GS et al. Metabolic improvements in obese type 2 diabetes subjects implanted for 1 year with an endoscopically deployed duodenal-jejunal bypass liner. Diabetes Technol Ther 2012 feb; 14(2):183-9.

Obesity Treatment

- Few short term studies
- Very few long term studies on weight maintenance or weight regain in endoscopic therapies*
  - *Some Orbera data with weight regain and repeat balloon
    - Maintenance and weight regain are metrics we should look at
  - Other Metrics: Pt satisfaction, ease of use, quality of life, impact of repeatability

Framing the Discussion

- Surgery, medication and endoscopy are different
- Try to obtain outcomes that are in line with each other
- Treat patients at different stages of obesity
- Offer opportunities to provide care for a spectrum of patients
- NOT designed to replace each other but to complement the treatment of a complicated disease that progressively worsens untreated.