Bariatric Surgery Patient and Endoscopic Treatment

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Sept. 2011
Agenda

- Bariatric Basics
- Endoscopic Repair of Surgical Complications
- New Endoscopic Paradigm
Obesity

- Obesity is a metabolic disease
- Severe toll of comorbid illness
- Obesity more prevalent hunger
- Underserved group that requires a multidisciplinary treatment approach
## Obesity

<table>
<thead>
<tr>
<th>Class</th>
<th>BMI Kg/m²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>18</td>
</tr>
<tr>
<td>Normal</td>
<td>18-24.9</td>
</tr>
<tr>
<td>Overweight</td>
<td>25-29.9</td>
</tr>
<tr>
<td>Obesity I</td>
<td>30-34.9</td>
</tr>
<tr>
<td>Obesity II</td>
<td>35-39.9</td>
</tr>
<tr>
<td>Obesity III</td>
<td>&gt;40</td>
</tr>
</tbody>
</table>

**Qualify for surgery**

- BMI ≥ 35 with co-morbid illness
- BMI ≥ 40

NIH Consensus Conference, 1985

NIH Clinical Guidelines pub# 98-4083, Sept 1998
Pathophysiology

- Obesity is complex and multifactorial
- We don’t understand mechanisms of action for obesity treatments
  - Surgery likely hit multiple mechanisms
Diets and Medications Have Limited Efficacy

- 3-5% of dieters can maintain weight loss for 5 years

- Medication can achieve better weight loss than diet and exercise alone (3-5 kg), but with high rates of attrition (30-40%)

Bariatric Surgical Approaches

Lower Morbidity / Lower Risk
Less Effective

Higher Morbidity / Higher Risk
More Effective
Morbidity 23-77%
- 5-10% early
  - PE, resp failure, bleeding, infection, ulceration, bowel obstruction, leaks
- 15-40% late
  - ulcers, strictures, stasis, nutritional, hernias, and fistula

Mortality 0.5-1.5%

Morbidity 5-20%
- Pouch dilation 4%
- Ulceration 4%
- Migration 1.6%
- Band erosion 1.7%
- Port migration / abscess

Mortality 0.22%
Gastric Bypass Revision

- **Open Revision**
  - Early morbidity 15 to 50%
  - Emergent re-operation in 5%
  - Mortality 2%
  - Similar late complication rates

- **Laparoscopic Revision**
  - Technically challenging / arduous learning process
  - Conversion rates as high as 48% reported
  - More complications requiring early surgery vs. open revision

- Requires in-patient hospital stay

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Endoscopic Evaluation

- Preparation
  - Require high doses for sedation
  - Difficult airway
  - Obstructive sleep apnea
  - Pulmonary hypertension

Anesthesia Consult
Normal Gastric Bypass Anatomy
Complications

- Anastomotic Ulcers
- Strictures
- Band Complications
- Fistulae and Leaks
- Weight Regain
Anastomotic Ulcers

- **Incidence:** 0.6 – 16%
- **Diagnosis:** 
  - EGD
  - Pouch PH
  - H. pylori fecal antigen
- **Most common source of delayed hemorrhage**
- **Most common first 3 months post op**
- **Etiology:** acid, fistula, NSAIDs, H. pylori, ischemia, FB reaction
- **Treatment:** soluble PPI, sucralfate, remove contributory factors (NSAIDs, H. pylori, FB, ischemia)
- Surgery

Risk factor for marginal ulcer (MU) in a logistic regression model (100 MU and 90 controls)

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Univariate Analysis</th>
<th>Multivariate Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Odds Ratio [CI]</td>
<td>P Value</td>
</tr>
<tr>
<td>Years from Surgery</td>
<td>0.8 [0.7-0.9]</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Diabetes</td>
<td>2.5 [1.1-6]</td>
<td>0.03</td>
</tr>
<tr>
<td>Smoking</td>
<td>2.5 [1.5-5]</td>
<td>0.02</td>
</tr>
<tr>
<td>NSAID use</td>
<td>0.9 [0.4-2]</td>
<td>0.7</td>
</tr>
<tr>
<td>Inhaled steroid use</td>
<td>2.3 [1-5]</td>
<td>0.055</td>
</tr>
<tr>
<td>SSRI use</td>
<td>0.7 [0.4-1.2]</td>
<td>0.2</td>
</tr>
<tr>
<td>Gastric pouch length</td>
<td>1.2 [1.03-1.5]</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Abu Dayyeh, B. et al. DDW 2011
Postoperative Hemorrhage

- 1.5% incidence at endoscopy in under 24 hours for early postgastric bypass hemorrhage
- Slightly more common with laparoscopic approach
- Source typically at staple line
- Injection therapy
- Clips

Complications

- Anastomotic Ulcers
- Strictures
- Band Complications
- Fistulae and Leaks
- Weight Regain
Clinical Case

- Etiology: ulceration, ischemia, band complication
- Sites of stenosis and incidence:
  - Gastrojejunual anastomosis
  - Jejunjejunal anastomosis
  - Gastric band

- Treatment:
  - Balloon dilation: 66-93% successful, 2-3 sessions
  - Injection / steroid: often required
  - Jejunjejunal anastomotic stricture. She presents for second opinion. Next steps?

- Surgical revision
- FB removal

- Durable resolution of symptoms was achieved


Don’t Over Dilate!
Complications

- Anastomotic ulcers
- Strictures
- Band complications
- Fistulae andLeaks
- Weight Regain
Band Erosion

- Incidence 2%
- Due to inflammatory reaction
- Symptoms: Severe pain, nausea, emesis
- Treatment: Endoscopic removal, surgical revision

Different approach required
Clinical Case

- 48 y/o female who had 'obesity surgical' in 2005 in Mexico.
- Abdominal CT showed a foreign body in the jejunum and partial erosion of the adjustable gastric band.
- Presents with abdominal pain and small bowel obstruction.
- Suggestive of recent GI bleeding. No records are available.
- Surgical removal of part of the band would be able to be done to view buckle area.
- Pass lap wire thru band and apply mechanical lithotriptor.
- Remove with snare.
Complications

- Anastomotic ulcers
- Strictures
- Band complications
- Fistulae and Leaks
- Weight Regain
Leaks

- **Initial management**: Overall success rate 75-87%.
  - Radiologic drainage
  - Control leakage
  - Bowel rest
  - TPN
  - Fistulectomy
  - Low complication rates
  - Tissue preparation
  - Mucosal stripping
  - Other (fistulotomy with debridement, endoscopic spot welding, tissue adhesives)

- **Factors associated with poor outcome**:
  - Fistula to peritoneum
  - Esophageal or mediastinal fistula
  - High output infection (>200cc per day)
  - Diversion obstruction, persistent obstruction, high output, sepsis
  - Tissue adhesives (fibrin glue, plugs, matrix)
  - Other etiology

- **Treat infection**
  - Octreotide

- **Malignant, radiation, Crohn’s**

- **Other**
  - Duct stents and luminal stents

Rabago, LR Endoscopy 2002, 34:632
Lang, V. Surgical Endoscopy 1990, 4:212
Merrifield B, et al. GIE 2006 63;4 710-14
## Leak Meta-analysis

<table>
<thead>
<tr>
<th>Author</th>
<th>Year of Publication</th>
<th>No of Patients</th>
<th>Type of Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fukumoto et al</td>
<td>2007</td>
<td>4</td>
<td>Polyflex stent</td>
</tr>
<tr>
<td>Babor et al</td>
<td>2009</td>
<td>7</td>
<td>Ella Boubella Esophageal Stent</td>
</tr>
<tr>
<td>Eubanks et al</td>
<td>2008</td>
<td>19</td>
<td>Alveolus and Polyflex Stents</td>
</tr>
<tr>
<td>Serra et al</td>
<td>2007</td>
<td>6</td>
<td>Hanarostent and Polyflex Stent</td>
</tr>
<tr>
<td>Eisendrath et al</td>
<td>2007</td>
<td>21</td>
<td>Ultraflex and Silky Esophageal Stent</td>
</tr>
<tr>
<td>Salinas et al</td>
<td>2006</td>
<td>17</td>
<td>Ultraflex Stent</td>
</tr>
<tr>
<td>Casella et al</td>
<td>2009</td>
<td>3</td>
<td>Ultraflex and NITI-S Esophageal Stent</td>
</tr>
</tbody>
</table>

Puli S, et al. DDW 2010
### Forest Plot Showing Proportion of Leak Closure with SES

<table>
<thead>
<tr>
<th>Study</th>
<th>Proportion (95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fukumoto et al 2007</td>
<td>0.75 (0.19, 0.99)</td>
</tr>
<tr>
<td>Babor et al 2009</td>
<td>1.00 (0.59, 1.00)</td>
</tr>
<tr>
<td>Eubanks et al 2006</td>
<td>0.84 (0.60, 0.97)</td>
</tr>
<tr>
<td>Serra et al 2007</td>
<td>0.67 (0.22, 0.96)</td>
</tr>
<tr>
<td>Eisendrath et al 2006</td>
<td>0.81 (0.58, 0.95)</td>
</tr>
<tr>
<td>Salinas et al 2006</td>
<td>0.94 (0.71, 1.00)</td>
</tr>
<tr>
<td>Casella et al 2006</td>
<td>1.00 (0.29, 1.00)</td>
</tr>
<tr>
<td><strong>Combined</strong></td>
<td><strong>0.85 (0.76, 0.91)</strong></td>
</tr>
</tbody>
</table>

Puli S, et al. DDW 2010
Gastrogastric Fistula

- **Etiology**
  - Mechanical
  - Nutritional
  - Emesis
  - Staple gun failure
  - Stricture

- **Complications**
  - Acid reflux
  - Epigastric pain
  - Jejunal ulceration
  - Stricture
  - Weight regain
  - No fistula over 2 cm remained closed
  - Fistula < 1 cm predicts better response with durable closure in over 30% (mean f/u 395 days)
  - 65% re-open at avg 177 days

- **Conservative Treatment**
  - Avg 2.2 sutures placed

New Larger Clips

OTSC® System
Clinical Case

- 40 year old female 5 years post-RYGB with iron deficient anemia and heme positive stools
- Normal EGD and colonoscopy
- Capsule study normal

Next steps?
Accessing the PB Limb

- **Standard enteroscope**
  - Challenging
    - Length of Roux limb
    - Acute angle of JJ anastomosis

- **Alternate techniques**
  - Double balloon enteroscope
  - ShapeLock enteroscope
  - Spirus
  - Surgical assistance
Complications

- Anastomotic ulcers
- Strictures
- Band complications
- Fistulae and Leaks
- Weight Regain
Revision: Weight Regain after RYGB

Revision: Weight Regain after RYGB

- Mechanisms not clearly understood
  - Hormonal changes
  - Dietary noncompliance
  - Alteration in gut flora
  - Anatomic considerations

- Surgical revision carries high rate of morbidity and mortality
Gastrojejunal stoma diameter is associated with weight regain after RYGB

Diagnosis

- Careful history
  - Dietary indiscretion?
  - Soft calories?
  - Nutrition consult
- UGI series
  - Fistulae
- Endoscopy
  - Stoma / pouch size
  - Length of Roux limb
Endoscopic Solutions for Dilated Anastomosis

- Sclerotherapy

- Suturing Devices
  - LSI ESD
  - Bard EndoCinch
  - EES Spiderman
  - USGI IOP
  - Endogastric Solutions StomaphyX
  - Apollo OverStitch

Thompson C. DDW AB, 2004
Anastomosis Reduction: Sclerotherapy

- **Spaulding, et al.**
  - 20 of 20 patients achieved diminished size of gastrojejunostomy to 10 mm
  - 15 of 20 patients achieved 9% EWL at 6 months

- **Abu Dayyeh, et al.**
  - 231 consecutive patients
  - 575 sessions of ST
  - 36% weight regain from nadir
  - Avg pre-op stoma size–19mm
  - Avg 2 session (1-3)
  - Avg 16 cc injected per session

Spaulding L Obes Surg 2003;13:254
Abu Dayyeh, et al. DDW 2011
Sclerotherapy: BWH

Mean 10 Lb
95th CI [7.7 – 11.8]
17% of weight gain

Mean 26 Lb
95th CI [23.5 – 29]
61% of weight gain
Sclerotherapy: BWH

Kaplan-Meir Plot of Time to Continuation of Weight Regain

Log-Rank 0.0032
Stratified log-Rank 0.01

2 or 3 Sessions

1 Sessions
# Sclerotherapy: BWH

## Total number of sclerotherapy sessions: 575

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal perforation</td>
<td>0</td>
</tr>
<tr>
<td>Admissions for post-procedural abdominal pain</td>
<td>3 (0.5%)</td>
</tr>
<tr>
<td><strong>Bleeding</strong></td>
<td>14 (2.4%)</td>
</tr>
<tr>
<td>• Stopped spontaneously</td>
<td>4</td>
</tr>
<tr>
<td>• Epinephrine injection</td>
<td>2</td>
</tr>
<tr>
<td>• Epinephrine and endoscopic clipping</td>
<td>8</td>
</tr>
<tr>
<td><strong>Transient diastolic blood pressure elevation</strong></td>
<td></td>
</tr>
<tr>
<td>• &gt; 105 mmHg</td>
<td>64 / 425 (15%)</td>
</tr>
<tr>
<td>• &gt; 25 mmHg from pre-procedure reading</td>
<td></td>
</tr>
</tbody>
</table>
Revision: RESTORE

- **Double blind**
- **Sham controlled**
- **2:1 randomization**
- **359 screened**
- **129 enrolled**
- **77 randomized**
- **% EWL at 6 months**
  - DGJR: 15.9 ±20.9
  - Sham: 7.7 ±20.18

Thompson CC, et al. DDW 2010
Obesity Treatment Options

- Diet/Draugs
  - Low Risk
  - High Effectiveness

- Bridge
  - High Risk
  - High Effectiveness

- Early Intervention
  - High Risk
  - High Effectiveness

- Revision

- Gastric Balloon

- Laparoscopic Gastric Bypass
- Sleeve Gastrectomy

- Gastric Banding
  - BPD/DS
  - Primary Metabolic Therapy

- Metabolic Surgery
  - Primary Therapy
# Early Intervention: Spectrum of Care

<table>
<thead>
<tr>
<th>Non-invasive</th>
<th>Minimally invasive</th>
<th>Surgical</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Orthopedics</strong>&lt;br&gt;Exercise / PT Meds</td>
<td>Arthroscopy&lt;br&gt;Exercise / Diet Meds</td>
<td>Joint replacement&lt;br&gt;Endoscopy&lt;br&gt;Surgical Procedures&lt;br&gt;CABG&lt;br&gt;Banding, RYGB</td>
</tr>
<tr>
<td><strong>Cardiology</strong>&lt;br&gt;Exercise / Diet Meds</td>
<td>Angioplasty&lt;br&gt;Exercise / Diet Meds</td>
<td></td>
</tr>
<tr>
<td><strong>Obesity</strong>&lt;br&gt;Exercise / Diet Meds</td>
<td>Endoscopy</td>
<td></td>
</tr>
</tbody>
</table>
Early Intervention: Endolumenal Suturing

- **Endoluminal Vertical**

![Graph showing %EWL for Subjects Completing 12M Follow-Up](image)

- **TRIM Trial**

<table>
<thead>
<tr>
<th>BMI (Kg/m²)</th>
<th>&lt;35</th>
<th>35-40</th>
<th>&gt;40</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Excess Weight Loss</td>
<td>85.1</td>
<td>56.5</td>
<td>48.9</td>
</tr>
</tbody>
</table>

Thompson Ceta, DDW 2009 M1259
Metabolic: Implantable Sleeves

Randomized blinded pilot study (N=18)
- 12 sleeve
- 6 sham
- 24 week follow-up

Endpoints
- Primary HbA1c
  - DJBL Week 12 (n=8)
  - Sham Week 12 (n=3)
  - DJBL Week 24 (n=9)
  - Sham Week 24 (n=4)

7 point glucose profile
- 42% off OAD meds v. 17% sham

OAD medication use
- Weight loss - no sig change between groups

Conclusion

- Obesity is a major health concern that requires multidisciplinary care.

- Bariatric surgery is being performed more frequently and GIs will continue to see complications of surgery.

- Gastroenterologists should better integrate into bariatric centers of excellence and start taking a more active role in caring for these patients.
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