Bariatric Endoscopic Interventions

Barham K. Abu Dayyeh, M.D. MPH
Consultant in Gastroenterology and Hepatology
Director of Bariatric and Metabolic Endoscopy
Mayo Clinic, Rochester, MN
Disclosures

- Consultant: Apollo Endosurgery
- Consultant: Metamodix
- Research Support: Aspire Bariatrics
- Research Support: GI Dynamics
Treatments for obesity

1-2% patients receive surgery

SOARD 2013, 9: 159-91
Treatments for obesity

Efficacy

Treatment Gap

Risk

1-2% patients receive surgery

SOARD 2013; 9: 159-91
Obesity Disease Burden

Body Mass Index

Obesity Burden

Obesity Distribution

Moderate Obesity Burden

Moderate

Severe
<table>
<thead>
<tr>
<th>OBESITY COMPLICATION</th>
<th>% wt loss for Rx benefit</th>
<th>Notes</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>T2DM Prevention</td>
<td>3-10%</td>
<td>Maximum benefit at 10%</td>
<td>DPP (Lancet, 2009); SEQUEL (Garvey et al, 2013)</td>
</tr>
<tr>
<td>T2DM (HbA1c)</td>
<td>3-15%</td>
<td>HA1c still decreasing at &gt;15%</td>
<td>Look AHEAD (Wing, 2011)</td>
</tr>
<tr>
<td>Dyslipidemia (TG/HDL)</td>
<td>3-15%</td>
<td>TG still decreasing at &gt;15%</td>
<td>Look AHEAD (Wing, 2011)</td>
</tr>
<tr>
<td>HTN</td>
<td>5-15%</td>
<td>BP still decreasing at &gt;15%</td>
<td>Look AHEAD (Wing, 2011)</td>
</tr>
<tr>
<td>NAFLD</td>
<td>10%</td>
<td>Improved steatosis, inflammation, mild fibrosis</td>
<td>Assy et al, 2007; Dixon et al, 2004; Anish et al, 2009</td>
</tr>
<tr>
<td>Sleep Apnea</td>
<td>10%</td>
<td>Little benefit at ≤ 5%</td>
<td>Sleep AHEAD (Foster, 2009); Winslow et al, 2012</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>5-10%</td>
<td>Improved symptoms and joint stress mechanics</td>
<td>Christensen et al, 2007; Felson et al, 1992; Aaboe et al, 2011</td>
</tr>
<tr>
<td>Stress Incontinence</td>
<td>5-10%</td>
<td></td>
<td>Burgio et al, 2007; Leslee et al, 2009</td>
</tr>
<tr>
<td>GERD</td>
<td>5-10% (F) 10% (M)</td>
<td></td>
<td>Singh et al, 2013; Tutujian R, 2011</td>
</tr>
</tbody>
</table>
Endoscopic Bariatric Therapies
Gastric EBTs

1. Balloons
2. POSE
3. ESG
4. Others

MAYO CLINIC
Small Bowel EBTs

Duodenal Sleeves

Gastroduodenojejunal Sleeves

Duodenal Mucosal Resurfacing
Other EBTs

Aspiration Therapy

Full Sense Device

Self-assembling Magnets for Endoscopy
EBTs: Efficacy of FDA approved devices
Intragastric Balloons
Intragastric Balloons

- Orbera
- Reshape Duo
- Obalon

FDA approved in the US
%TBWL with the Orbera IGB: Published International Experience
N=6845
%TBWL with the Orbera IGB: US Pivotal Trial (ITT)
N=255

**Graph:**
- **X-axis:** Month
- **Y-axis:** Percent total body weight loss (%TBWL)
- Two lines represent different groups:
  - Blue line: Control
  - Red line: Orbera
- *P<0.001 for difference between treatment groups

**Source:** Abu Dayyeh, Courcoulas, Eaton, et al. DDW 2015
%TBWL with the Orbera IGB: Mayo Clinic experience post FDA approval N=30

<table>
<thead>
<tr>
<th>Months</th>
<th>Pre-IBG BMI (Kg/m²)</th>
<th>%TBWL</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>36.8 ± 1.4</td>
<td>12.8 ± 1.0</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>14.1 ± 1.6</td>
</tr>
</tbody>
</table>
ReShape Duo IGB Pivotal US RCT: REDUCE Trial (N=326)

%EWL at 24 weeks (balloon removal)

<table>
<thead>
<tr>
<th>Group</th>
<th>Percent Excess Weight Loss (%EWL)</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>DUO Intent-to-Treat</td>
<td>25.1%</td>
<td>187</td>
</tr>
<tr>
<td>DIET</td>
<td>11.3%</td>
<td>139</td>
</tr>
<tr>
<td>DUO Completed Cases</td>
<td>27.9%</td>
<td>167</td>
</tr>
<tr>
<td>DIET</td>
<td>12.3%</td>
<td>126</td>
</tr>
</tbody>
</table>

Δ = 13.9% for DUO vs DIET

7.5% superiority margin for DUO

p = 0.0041

Ponce et al. Surg Obes Relat Dis. 2015;11(4):874-81
Endoscopic Sleeve Gastroplasty
Endoscopic Sleeve Gastroplasty
ESG Multi-Center Study: 242 Patients

%TBWL

Months

Lopez-Nava, Sharaiha, Acosta, Topazian, Gostout, Abu Dayyeh. DDW 2016
ESG Multi-Center Study: 242 Patients

%TBWL per center

- Mean(TBWL6)
- Mean(TBWL12)
- Mean(TBWL18)

P=0.35

%TBWL

Madrid
New York
Rochester

Lopez-Nava, Sharaiha, Acosta, Topazian, Gostout, Abu Dayyeh. DDW 2016
Aspiration Therapy
Aspiration Therapy
Aspiration Therapy: US Pivotal Trial Results
N=207
Summary

1- Endoscopic bariatric therapies can potentially offer effective weight loss at lower cost and risk in a select group of patients with mild to moderate obesity

2- EBTs should be utilized as part of a structured program that includes dietary intervention, exercise therapy, and behavioral modification

3- EBTs should be offered as part of the continuum of obesity care. Patients should be prospectively followed to identify poor responders and offer them alternative therapy including bariatric surgery
"I look through a half opened door into the future, full of interest, intriguing beyond my power to describe."

William J. Mayo, M.D.
1931