Current Status of Modified Duodenal Switch (SIPS/SADI-S/Loop DS/LDJB-S/SADJB-S) Best Candidates? Latest Evidence? Technique

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Disclosure

-Consultant and Speaker for BD (Carefusion)
-Speaker for Gore

No conflict with today’s presentation
# Estimate of Bariatric Surgery Numbers, 2011-2015 (ASMBS.org)

<table>
<thead>
<tr>
<th></th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>150,000</td>
<td>173,000</td>
<td>179,000</td>
<td>193,000</td>
<td>196,000</td>
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<tr>
<td><strong>RNY</strong></td>
<td>36.7%</td>
<td>37.5%</td>
<td><strong>34.2%</strong></td>
<td>26.8%</td>
<td>23.1%</td>
</tr>
<tr>
<td><strong>Band</strong></td>
<td>35.4%</td>
<td>20.2%</td>
<td><strong>14%</strong></td>
<td>9.5%</td>
<td>5.7%</td>
</tr>
<tr>
<td><strong>Sleeve</strong></td>
<td><strong>17.8%</strong></td>
<td>33%</td>
<td><strong>42.1%</strong></td>
<td><strong>51.7%</strong></td>
<td>53.8%</td>
</tr>
<tr>
<td><strong>BPD/DS</strong></td>
<td>0.9%</td>
<td>1%</td>
<td><strong>1%</strong></td>
<td>0.4%</td>
<td>0.6%</td>
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<tr>
<td><strong>Revisions</strong></td>
<td>6%</td>
<td>6%</td>
<td>6%</td>
<td>11.5%</td>
<td>13.6%</td>
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<tr>
<td><strong>Other</strong></td>
<td>3.2%</td>
<td>2.3%</td>
<td>2.7%</td>
<td>0.1%</td>
<td>3.2%</td>
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<tr>
<td><strong>Balloon</strong></td>
<td>~700 cases</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>V-Bloc</strong></td>
<td>18 cases</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</table>
History of Bariatric Procedures

- Gastric Bypass Mason and Ito 1967
- Wittgrove 1994 – Laparoscopic Gastric Bypass “Gold Standard” for next 22 years
- Recently Laparoscopic Sleeve has overtaken the field in volume (particularly in United States)
- Popular but high recidivism/ failure rate (20-25%) especially in very obese/comorbid population
- 1979 Scopinaro Biliopancreatic Diversion
- Marceau and Hess – Sleeve with Duodenal Switch
- Duodenal Switch best in terms of weight loss, comorbidity resolution and durability
Gastric Bypass ("Gold Standard")

Advantages
- ~85% DM resolution
- May lose more weight than sleeve or band
- Well known long term effects
- "Dumping" syndrome

Disadvantages
- Weight regain (esp. >150lbs EBW, >50 BMI) 8-25%
  - Pouch dilation, anastomosis dilation = less satiety
- Vitamin / Protein Deficiencies
- Dumping Syndrome, nisidioblastosis
- Ulcer risk (smokers, NSAIDS, Steroids) (1-16%)
- GJ anastomotic stricture (3-23%)
- Gastro-gastric fistula (1.5-6%)
- Internal Hernia (1-9%)
- Excluded pylorus
- Blind gastric remnant (ulcer/gastric cancer?)
- Variations in technique produces variations in weight loss
- No natural orifice access to biliary tree
Duodenal Switch

Advantages

• 90%+ DM Resolution
• Best for patients (BMI >50, >150lbs EBW) 5-8% weight regain
• No “dumping” syndrome
• Normal ulcer risk
• Intact pylorus retains control over gastric emptying
• No blind gastric remnant

Disadvantages

• Technically challenging
• More expensive materials/ longer operative time
• Vitamin / Protein Deficiencies (Fat Soluble Vitamins A,E,D,K)
• Calcium and micronutrient Deficiencies
• No natural orifice access to biliary tree
• GI complaints (gassy, frequent bowel movements)
Two Year Weight Loss

- BPD/DS
- LRYGB
- Sleeve
- Band

Non-Adoption of Switch

- Maurceau *et al.* and Hess *et al.* showed Switch to be safe and effective >15yr f/u, with proper management.
- IFSO 1.5% DS and ASMBS <1% DS
- Most technically difficult
- Long surgical times
- Higher cost in relation to OR time
- Longer hospitalization
- Greater consumption of disposables
- More complications/ morbidity
- Simpler procedures have good results
“Loop” DS (SADI-S/SIPS)

Perceived Advantages

- Benefits of sleeve, bypass and BPD/DS, without as many drawbacks
  - no dumping, no increased ulcer risk
  - less internal hernia (no mesenteric opening, only Petersen’s)
- Technically simpler than BPD/DS
  - Shorter operative time
  - One anastomosis vs two
- Less vitamin deficiency than BPD/DS, similar to bypass
- Less gassiness and less freq BM than BPD/DS (~2.5/day)
- Better in super morbid obesity than bypass
- Less appetite (ghrelin effect)
- No bile reflux

Perceived Disadvantages

- Need more time/data for efficacy and outcomes
- Afferent Loop syndrome?
- Twisting of anastomosis (volvulus)
“Loop” DS
(SADI-S, SIPS, MDS, SADJB-SG)
“...a rose by any other name...”

- SADI-S: Single Anastomosis Duodenal Ileostomy with Sleeve (250cm prox. to cecum)

- SIPS: Stomach Intestinal Pylorus Sparing (300cm prox. to cecum)
- MDS: Modified Duodenal Switch (SIPS new name)

- SADJB-SG: Single Anastomosis Duodeno-Jejunal Bypass with Sleeve Gastrectomy
New Kid on the Block

- The BPD/DS may be the most effective surgery for weight loss and diabetes/ metabolic syndrome resolution. However, due to technical difficulty and higher rates of complications it accounts for a minority of overall bariatric surgeries performed.

- In 2007, Sanchez-Pernaute and Torres suggested a technique to avoid the issues and technical challenges of BPD/DS. The SADI-S (single anastomosis duodenal-ileal end-to-side with sleeve gastrectomy), constructed with a single loop anastomosis with a 200cm common channel (later changed to 250cm).
Loop DS is not a Mini-bypass

Differences:

• Remnant stomach resected = reduced risk of ulcer, better for hunger suppression?

• Pylorus preserved = controlled solid emptying & reduced risk of bile reflux

• Bowel measured from ileum

• Preservation of pylorus reduces risk of diarrhea & dumping
BUT... Mini-bypass shows you do not need Roux limb

Overall, data suggests MGB equal or better wt. loss compared to RYGB, revision rate comparable, conversions secondary to bile reflux gastritis not high, risk of peptic ulcer lower.

- Laparoscopic Roux en Y Versus Mini Gastric Bypass for the Treatment of Morbid Obesity A Randomized Trial - Lee et al Annals of Surgery 2005
- Laparoscopic Roux en Y Versus Mini-Gastric Bypass for Morbid Obesity: A 10 year experience - Lee et al Obes Surg 2012
- One Thousand Consecutive Mini-Gastric Bypass: Short and Long Term Outcome - Noun et al: Obes Surg 2012
SADI-S/SIPS/SADJB-SG

- 2007, Sanchez-Perneute et al offered simplification of standard duodenal switch
- SADI-S 34-54Fr Sleeve with loop constructed 200cm from ileo-cecal valve, later 250cm due to hypoproteinemia in few patients
- Cottam and Roslin created SIPS with a 40-42Fr sleeve and a 300cm common channel to further combat hypoproteinemia and diarrhea
- Asian Experience SADJB-SG (38Fr Bougie and 200-300cm from Lig Trietz)
- Recently published literature review reports 1041 pts (304 SADI, 667 SIPS and 70 SADJB-SG) Topart et al. 2017 SORD
<table>
<thead>
<tr>
<th>No Deaths Reported</th>
<th>N</th>
<th>Type</th>
<th>Fr</th>
<th>Common Channel</th>
<th>Initial BMI</th>
<th>Operative time (min)</th>
<th>%EWL 1yr</th>
<th>%EWL 2yrs</th>
<th>%EWL 5yrs</th>
<th>BMI 1yr</th>
<th>BMI 2yrs</th>
<th>BMI 5yrs</th>
<th>Early Comp</th>
<th>30d Re-op</th>
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<tr>
<td>Huang, 2014</td>
<td>20</td>
<td>LDJB-SG</td>
<td>38Fr</td>
<td>200-300cm from LT</td>
<td>27.9</td>
<td>119</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>22.5</td>
<td>-</td>
<td>-</td>
<td>0.5% Major</td>
<td>0</td>
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<tr>
<td>Lee, 2014</td>
<td>50</td>
<td>SADJ-SG</td>
<td>45Fr</td>
<td>200cm CC/150cm BP</td>
<td>38.4</td>
<td>181</td>
<td>80.3%</td>
<td>-</td>
<td>-</td>
<td>25.9</td>
<td>-</td>
<td>-</td>
<td>6%</td>
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<tr>
<td>Nelson, 2016</td>
<td>69</td>
<td>SADI-S</td>
<td>34Fr</td>
<td>250cm</td>
<td>58.4</td>
<td>-</td>
<td>61.6%</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>13%</td>
<td>8</td>
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<tr>
<td>Sanchez-Pernaute, 2015</td>
<td>168</td>
<td>SADI-S</td>
<td>54Fr</td>
<td>200/250cm</td>
<td>44.3</td>
<td>-</td>
<td>91%</td>
<td>-</td>
<td>98%</td>
<td>-</td>
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<td>3%</td>
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<td>100</td>
<td>SADI-S</td>
<td>54Fr</td>
<td>200/250cm</td>
<td>44.6</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>87%</td>
<td>-</td>
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<td>27</td>
<td>14%</td>
<td>-</td>
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<tr>
<td>Cottam, 2016</td>
<td>61</td>
<td>SIPS</td>
<td>40Fr</td>
<td>300cm</td>
<td>50.1</td>
<td>70</td>
<td>78.7%</td>
<td>83.7%</td>
<td>-</td>
<td>30.8</td>
<td>29.1</td>
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<td>18 (total)</td>
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<td>Enochs, 2016</td>
<td>150</td>
<td>SIPS</td>
<td>40Fr</td>
<td>300cm</td>
<td>48.6</td>
<td>73</td>
<td>82.9%</td>
<td>87.2%</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>2</td>
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<td>Mitzman, 2016</td>
<td>123</td>
<td>SIPS</td>
<td>42Fr</td>
<td>300cm</td>
<td>49.4</td>
<td>96</td>
<td>72.3%</td>
<td>-</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>4.8%</td>
<td>1</td>
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<tr>
<td>Neichoy, 2016</td>
<td>135</td>
<td>SIPS</td>
<td>40Fr</td>
<td>300cm</td>
<td>52.9</td>
<td>83</td>
<td>68.9%</td>
<td>-</td>
<td>-</td>
<td>22.5</td>
<td>-</td>
<td>-</td>
<td>6.6%</td>
<td>2</td>
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<tr>
<td>Sabrudin, 2016</td>
<td>168</td>
<td>SIPS</td>
<td>42Fr</td>
<td>300cm</td>
<td>-</td>
<td>-</td>
<td>87%</td>
<td>-</td>
<td>27</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Surve, 2016</td>
<td>120</td>
<td>SIPS</td>
<td>40Fr</td>
<td>300cm</td>
<td>49.5</td>
<td>70</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>20</td>
<td>-</td>
<td>1.6%</td>
<td>0</td>
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<tr>
<td>Zaveri, 2016</td>
<td>291</td>
<td>SIPS</td>
<td>40Fr</td>
<td>300cm</td>
<td>-</td>
<td>-</td>
<td>86.1%</td>
<td>93.9%</td>
<td>93.3%</td>
<td>29.3</td>
<td>27.9</td>
<td>28.5</td>
<td>-</td>
<td>-</td>
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</table>
“Loop” DS (SADI-S)

Sanchez-Pernaute et al. SORD 2016 - 100pts – 5 year f/u mean BMI 27kg/m², mean EWL 87%, 8.2% did not achieve 50% EWL, 7 pts have been revised with common channel lengthening (? 200cm subgroup), 70% DM off treatment and 74% Hgb A1c below 6%.

Sanchez-Pernaute et al. SORD 2015 – SADI-S in obese diabetics

- 97 pts (mean pre-op BMI 44.3 kg/m²) - 28 pts 200cm common channel, 69 pts 250cm common channel
- Mean HgbA1c Pre-7.6%
- ~80% resolution DM @5yrs, 70-84% HgbA1c <6% post
“Loop” DS (SIPS)

Roslin and Cottam (US experience, 2 centers), SIPS (Stomach Intestinal Pylorus Sparing), 300cm Common Channel), > 1 year data

Roslin, Cottam et al. In press.

- 123 pts (mean pre-op BMI 49.4 kg/m²)
- Mean reduction 20 BMI points at 1 year
- Mean wt loss 122lbs at 1 year
- Mean EWL 38.6% at 1 year
- 2 pts developed diarrhea (1.6%)
- Vit A, B1, B12, D, and Alb normal in all pts at 1 year
“Loop” DS (SIPS)

- Cottam and Roslin, 2016 - 168pts (78 Utah and 90 NY), 96/168 pts with 2 year data BMI reduction ~22 units, EBWL 82%, 45/168 pts with 1 year nutritional data with average values wnl for Vits A, D, B1, B12, and Alb.
Cottam & Roslin Conclusion

• Early results show that SIPS is an effective weight loss procedure, with equivalent results across two separate centers

• Key beneficial aspects of procedure include:
  • Gastrectomy reducing ghrelin
  • Attachment 3 meters from colon activates hind gut receptors
  • Adequate Common Channel avoids consequences of short bowel syndrome

• Short term results did not show any negative aspect of a lack of roux limb
  • No evidence of afferent loop syndrome
  • No subjective bile reflux gastritis
Comparing other weight loss operations
“Loop” DS (SIPS)

Cottam

- Compared SIPS with matched cohorts (BPD/DS, LRYGB and LSG)
  - LSG v SIPS – 106 pts, 18mos f/u, EWL 72.5% and 95.3%, respectively (p<0.05).
  - LRYGB v SIPS – 108 pts, 18mos f/u, EWL 39.6% and 41%, respectively (p<0.05).
  - BPD/DS v SIPS – 182 pts (62 BPD/DS v 120 SIPS), 12 mos f/u, EBMIL 81.3% and 76.7% respectively (p=0.06).
Sleeve vs SIPS (Loop DS)
BPD/DS vs SIPS (Loop DS)
Garden State Bariatrics and Wellness Center Experience

- 59 Loop DS performed since 4/2014 (Primary, 2nd stage, RYGB to Loop)
- 52 primary Loop DS – 15/19pts with 10 mo data
- 2 surgeons at 3 centers
- 300cm-250cm loop measured proximally from cecum.
- Avg. Pre-op BMI 51.9, 3mos BMI 40.2 (17/19), 10mos BMI 33.6 (15/19) respectively (avg 18.3 BMI reduction @ 10 mos)
- One leak repaired POD 2 recovered w/o further incident
- One Mortality due to complications following an aspiration event
Nutritional Status after Loop DS

- Enoch et al., 2016 - protein and albumin deficiency @ 1 year 7.6% and 3.1%, respectively.
- Sabrudin et al., 2016 - 24/60 pts @ 6mos normal Vit A,D, and Iron, and normal alb
- Abd-Elatif et al., 2015 - Loop DS not associated with broad nutritional deficiencies. 37 pts BMI reduction 56.3 to 33.2. With proper supplementation and f/u: Fe, Hgb, Na, B12, Folic Acid, Copper, Zinc, K, Alb, AST, ALT, bilirubin wnl in all patients
- Other studies with varied nutritional outcomes (all have significant issues in term of length of study or follow-up %)
“Loop” DS for Revision

- **Bypass to “Loop” DS** - Sharma *et al.* SORD 2016 – Bypass to Loop DS one stage
  - 5 pts, with mean post bypass BMI 41.2, MEWL and MBMI at 1-mo (20.3% and 37.5 kg/m²), 3-mos (36.5% and 34.4 kg/m²), 7-mos (66.2% and 29.3 kg/m²) and one patient at 11-mos EWL 61.9% and BMI 30.2 kg/m²

- **Sleeve to “Loop” DS** - Sanchez-Pernaute *et al.* SORD 2015 - SADI-S as Second Step After Sleeve
  - 16 pts, with mean BMI 56.4 and mean EWL 39.5% after sleeve underwent SADI-S with 250 cm Loop
  - No immediate complications
  - Mean EWL 72% 2yrs after second step, 88% T2DM Remission, 60% HTN and 40% hyperlipidemia resolution, avg 2.1 BM/day one patient had isolated episode of hypo-proteinemia
Revision of "Loop" DS

- Convert to standard DS then perform DS reversal
- Lengthen/ Shorten Common Channel
  - Described by Cottam et al. SORD 2017
    - Divide DI anastomosis then Braun entero-enterostomy 15cm from loop anastomosis site and more proximal DI anastomosis
“Loop” DS

Easily reproducible operation
One anastomosis
No mesenteric defect
Internal hernias very rare @ T-colon
Intact Pylorus (no dumping, no additional ulcer risk)
Lower complication rates than bypass and BPD/DS?
Shorter operative times than BPD/DS
No Roux Limb complications
Similar weight loss as bypass and BPD/DS at 18mos
Better T2DM and cholesterol resolution than bypass, less than BPD/DS
Similar nutritional problems as bypass, treatable nutritional deficiencies
What is Next?

- Sleeve procedure gaining popularity over Bypass and Band (due to complications, side-effects and shortcomings)
- Standard deviation of sleeve suggests recidivism/failure
- Sleeve to Bypass for complications (GERD, stricture, Barrett’s)
- Sleeve to DS (or Loop DS) for inadequate weight loss/co-morbidity resolution
- Separation of bile from food is a significant benefit to diabetics (bypass forgut)
- No evidence for Roux limb necessity.
- Loop DS (SADI-S, SIPS, SADJB-SG) makes sense!
“Loop” DS (SADI-S, SIPS)

MORE DATA IS NEEDED (but early results are promising)

Medical trial .gov

Loop DS/SADI-S/SIPS may show:

• More weight loss than LSG, comparable weight loss with LRYGB, and less weight loss than BPD/DS

• Less side effects, less recidivism in Super MO and more overall durability than LRYGB

• Less complications and less surgical difficulty with similar outcomes as BPD/DS
Questions?