Why Staple Line Reinforcement Is Beneficial

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Why Staple Line Reinforcement is Beneficial

As previously disclosed, these are the companies with which I have a financial or other relationship(s):

<table>
<thead>
<tr>
<th>Company Name (s)</th>
<th>Nature of Relationship (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enteromedics</td>
<td>CMO, Consulting</td>
</tr>
<tr>
<td>Baxter Healthcare Co.</td>
<td>Consulting</td>
</tr>
<tr>
<td>Obesity Surgery Journal</td>
<td>Editor-in-Chief</td>
</tr>
<tr>
<td>Medtronic</td>
<td>Consulting</td>
</tr>
</tbody>
</table>

Introduction

- Although consistently reliable, staple line complications can and do occur and can result in significant morbidity
- Reducing staple line complications would be beneficial
- The literature is divided as to whether staple line reinforcement (SLR) is beneficial
- This presentation will support SLR in bariatric surgery
Why Staple Line Reinforcement is Beneficial

Major Staple Line Complications

- Present day staple lines are very safe and have few complications
  - Bleeding – approximately 0.5-1%
  - Leakage - approximately 2-3%

Carlin A et al, Ann Surg 2013

- However both complications can result in significant cost, morbidity, and even mortality
Why Staple Line Reinforcement is Beneficial

Leaks Are Costly

• Chronic disability (fistula, wound issues, etc)
• Prolonged or recurrent hospitalizations
• Personal financial
• Medical bills – Mean hospital charges
  • Uncomplicated sleeve leak = $137,417
  • Sleeve leak with sepsis = $400,000
  • Multisystem organ failure = $$$$$$

Why is There a Controversy?

- The literature concerning staple line complications is inconclusive
- Complication rates are low
- Most studies are small, retrospective, and underpowered
- Few studies compared different buttressing materials or techniques
- There is no consensus on indications, staple cartridge size or even operative technique
Why Staple Line Reinforcement is Beneficial

Reinforcement Options

- Fibrin glue and other sealants
- Suture oversewing
- Buttressing
  - Permanent (no longer in use)
  - Non-permanent
  - Tissue
  - Synthetic

Why Staple Line Reinforcement is Beneficial

Staple Line Oversewing

- The cheapest option
- Can be technically challenging
- Can be time consuming which will increase OR costs
- May increase the risk of leak secondary to ischemia or tissue tearing

Baker R, Obes Surg, 2004
Why Staple Line Reinforcement is Beneficial

Staple Line Buttressing

- Potential advantages
  - Spreads tension across entire staple line
  - Decrease staple line bleeding
  - Increase staple line burst pressure

- Potential disadvantages
  - They add thickness to the tissue
  - Time of application
  - Cost – per case ($650 to $1,300)
Why Staple Line Reinforcement is Beneficial

Staple Line Buttressing Options

- **Synthetic - Bioabsorbable**
  - SEAMGUARD®
  - Medtronic PRELOADED
- **Tissue – Nonpermanent / Remodelable**
  - SURGISIS
  - PERI STRIPS DRY® WITH VERITAS® COLLAGEN MATRIX
Why Staple Line Reinforcement is Beneficial

Reinforcement May Increase Leaks

- MBSAQIP registry
- 189,477 LSG from 2012-2014
- Results (30 day)
  - 78% of patients had oversewing, buttressing or both
  - Leaks – 0.96% (SLR) vs 0.65% (no SLR)
  - Bleeding – 0.75%(SLR) vs. 1.00%(no SLR)

### Why Staple Line Reinforcement is Beneficial

Reinforcement May Increase Leaks

<table>
<thead>
<tr>
<th>Technique</th>
<th>No. Patients (%)</th>
<th>Overall Leak (%)</th>
<th>Overall Bleed (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>189,186</td>
<td>0.90</td>
<td>0.81</td>
</tr>
<tr>
<td>Neither</td>
<td>22</td>
<td>0.65</td>
<td>1.00</td>
</tr>
<tr>
<td>Oversew</td>
<td>11</td>
<td>0.59</td>
<td>0.96</td>
</tr>
<tr>
<td>Reinforcement</td>
<td>48.4</td>
<td>0.96</td>
<td>0.75</td>
</tr>
<tr>
<td>Both</td>
<td>18.6</td>
<td>1.22</td>
<td>0.67</td>
</tr>
</tbody>
</table>

Why Staple Line Reinforcement is Beneficial

Why the Opposite Results?

- MBSAQIP registry
- 189,477 LSG from 2012-2014
- Results (30 day)
  - Retrospective - only data from 2012-2014
  - No information on buttress type or application technique
  - No information on stapler type or cartridge size
  - The oversewing technique was not described

Why Staple Line Reinforcement is Beneficial

Staple Line Buttresses

• Several studies have demonstrated that buttressing reduces bleeding and bleeding related complications (blood loss, OR time, LOS)
• The literature concerning leaks is inconclusive
  • Leak rate is low
  • Most studies are retrospective, small, and underpowered
  • Few studies compared the different buttressing materials
Does Staple Line Reinforcement Decrease Bleeding?
Buttressing Decreases Bleeding

- PRCT 98 patients undergoing lap GBP
  - Group A – PeriStrips Dry
  - Group B - control
- Results
  - Less clips used (5 vs 23, p < 0.001)
  - Less intraop leaks (0 vs 7, p < 0.001)
  - Decreased OR time (120 min vs 220 min, p < 0.01)

Angrisoni L, et al, Obes Surg, 2005
Why Staple Line Reinforcement is Beneficial

Reinforcement Meta-Analysis

- 1570 articles pulled, 282 papers selected
- 2000 – August 2014
- 66,751 unique patients (leak-57,244, bleed-42,783)
- Includes lap RYGBP and Sleeve procedures
- Papers must include information regarding if reinforcement was used, and if so, what type of reinforcement or buttressing
- Incidence of bleeding and leaks

Shikora SA, Mahoney CB, Obes Surg 2015
Why Staple Line Reinforcement is Beneficial

Reinforcement Meta-Analysis – Bleed

All Cases

<table>
<thead>
<tr>
<th>Reinforcement</th>
<th># of Patients</th>
<th># of Studies</th>
<th>Bleed (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>17,548</td>
<td>82</td>
<td>3.45</td>
</tr>
<tr>
<td>Oversew</td>
<td>14,368</td>
<td>58</td>
<td>2.69</td>
</tr>
<tr>
<td>Seamguards</td>
<td>2,864</td>
<td>43</td>
<td>2.48</td>
</tr>
<tr>
<td>Peristrips</td>
<td>7,684</td>
<td>31</td>
<td>1.251</td>
</tr>
</tbody>
</table>

Shikora SA, Mahoney CB, Obes Surg 2015
### Reinforcement Meta-Analysis – Bleed

#### Laparoscopic Sleeve Gastrectomy

<table>
<thead>
<tr>
<th>Reinforcement</th>
<th># of Patients</th>
<th># of Studies</th>
<th>Bleed (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>2,865</td>
<td>25</td>
<td>4.94</td>
</tr>
<tr>
<td>Oversew</td>
<td>4,682</td>
<td>33</td>
<td>2.41</td>
</tr>
<tr>
<td>Seamguards</td>
<td>1,997</td>
<td>28</td>
<td>2.09</td>
</tr>
<tr>
<td>Peristrips</td>
<td>1,632</td>
<td>14</td>
<td>1.16</td>
</tr>
</tbody>
</table>

Differences significant at p < 0.05 are: None-Peri, None-Seam, None-Over, Over-Peri, Peri-Seam

Shikora SA, Mahoney CB, Obes Surg 2015
Why Staple Line Reinforcement is Beneficial

Buttressing Decreases Bleeding

There may be an inherent difference in the intrinsic hemostatic properties of the buttressing materials

Does Staple Line Reinforcement Decrease Leakage?
### Why Staple Line Reinforcement is Beneficial

#### Meta-Analyses and Systematic Reviews

<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th>Patients</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Giannopoulos-2010</td>
<td>SR/MA</td>
<td>3299 SG,GBP,BPD-DS</td>
<td>No benefit</td>
<td>Did not include oversewing</td>
</tr>
<tr>
<td>Sajjid-2011</td>
<td>MA</td>
<td>180 GBP</td>
<td>Decreased leaks</td>
<td>Small series - 3 studies</td>
</tr>
<tr>
<td>Choi-2012</td>
<td>MA</td>
<td>1345 SG</td>
<td>Decreased leaks</td>
<td>Oversewing increased bleeding</td>
</tr>
<tr>
<td>Knapps-2013</td>
<td>SR</td>
<td>4881 SG</td>
<td>No benefit</td>
<td>Did not look at types of reinforcement</td>
</tr>
<tr>
<td>Parikh-2013</td>
<td>SR/MA</td>
<td>9991 SG</td>
<td>No benefit</td>
<td>56% bioabsorbable</td>
</tr>
</tbody>
</table>
Why Staple Line Reinforcement is Beneficial

Sleeve Leak Systematic Review

- 659 articles pulled, 88 papers selected
- PRISMA search – until March 2012
- 8,920 patients – 2.1% leak rate - Sleeves

<table>
<thead>
<tr>
<th></th>
<th>% Leaks</th>
<th>Patients</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seamguards</td>
<td>1.09</td>
<td>1,462</td>
<td>-</td>
</tr>
<tr>
<td>Oversew</td>
<td>2.04</td>
<td>4,214</td>
<td>0.002</td>
</tr>
<tr>
<td>No Reinforcement</td>
<td>2.60</td>
<td>2,579</td>
<td>0.001</td>
</tr>
<tr>
<td>Peri Strips</td>
<td>3.30</td>
<td>665</td>
<td>0.0006</td>
</tr>
</tbody>
</table>
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Reinforcement Meta-Analysis – Leak

All Cases

<table>
<thead>
<tr>
<th>Reinforcement</th>
<th># of Patients</th>
<th># of Studies</th>
<th>Leaks (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>25,943</td>
<td>115</td>
<td>2.76</td>
</tr>
<tr>
<td>Seamguards</td>
<td>3,634</td>
<td>51</td>
<td>2.61</td>
</tr>
<tr>
<td>Oversew</td>
<td>19,755</td>
<td>92</td>
<td>2.45</td>
</tr>
<tr>
<td>Peristrips</td>
<td>7,793</td>
<td>43</td>
<td>1.25</td>
</tr>
</tbody>
</table>

Shikora SA, Mahoney CB, Obes Surg 2015
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### Laparoscopic Sleeve Gastrectomy

<table>
<thead>
<tr>
<th>Reinforcement</th>
<th># of Patients</th>
<th># of Studies</th>
<th>Leaks (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>3,958</td>
<td>35</td>
<td>3.27</td>
</tr>
<tr>
<td>Seamguards</td>
<td>1,860</td>
<td>33</td>
<td>3.25</td>
</tr>
<tr>
<td>Oversew</td>
<td>6,141</td>
<td>47</td>
<td>2.70</td>
</tr>
<tr>
<td>Peristrips</td>
<td>1,678</td>
<td>16</td>
<td>1.83</td>
</tr>
</tbody>
</table>

Differences significant at $p < 0.05$ are: None-Peri, Peri-Seam, and Over-Peri,
Shikora SA, Mahoney CB, Obes Surg 2015
So Why Do I Use SLR?

- Makes good handles – reduces serosal tears
- Decreases significant staple line bleeding
- May possibly decrease staple line leaks
Conclusions

- SLR has been shown to decrease the likelihood of bleeding and (??) leaking
- Unfortunately, the published studies have conflicting results
- It will therefore be up to each surgical practice to determine if SLR is worth the added cost
Thank You !!!