AIDA Study: Prophylactic Onlay Mesh Implantation Prevents Incisional Hernia following AAA Repair – a Multicenter Randomized Trial

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Disclosures

I have the following potential conflicts of interest to report:

• Receipt of grants/research support (BBraun)
• Participation in a company sponsored speakers’ bureau
• Employment in industry
• Shareholder in a healthcare company
• Owner of a healthcare company

I do not have any potential conflict of interest


Metaanalysis 757 Patients: postoperative midline incisional hernia

• AAA 10-37%  2.9 fold increased risk


Systematic Review: 1132 Patients (719 AAA)

• Incidence of postoperative incisional hernia AAA 21%
• Pooled analysis: 5.4 fold risk

Prophylactic mesh placement is associated with an 85% postoperative incisional hernia risk reduction when compared to primary suture closure in at-risk patients undergoing elective, midline laparotomy closure. This technique appears to be safe with comparable complication profiles, barring an increased risk of seroma, especially with the onlay technique.

Abdominal Incision Defect following AAA Surgery

• A prospective, multicenter (11), randomized, controlled clinical investigation
• Elective aortic aneurysm repair (OR)
• Hypothesis: Insertion of an onlay mesh is superior to suturing alone
**Secondary objectives**
- wound complications
- safety / AE, SAE
- VAS
- Quality of life (EQ-5D)
- Non-inferiority of MonoMax suture material

**Study design**

**Group A**
- monofile Polydioxanine
- running suture Technique
- Large bite 2.5cm

**Group B**
- Polydioxanine Plus Polypropylene Elastic Mesh
- Overlap 5cm

**Group C**
- Monofil Poly 4-Hydroxybutyrate
  (long lasting, absorbable & flexible)
- Continuous
- Large bite

**Endpoints**
Reduced herniation rate in the 24 months after mesh implantation (assumption: 30% incidence decreased to 10%)

**Study enrollement 2011 - 2013**

<table>
<thead>
<tr>
<th>Group</th>
<th>n=36</th>
<th>n=34</th>
<th>n=35</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>10.00</td>
<td>15.38</td>
<td>13.04</td>
</tr>
<tr>
<td>Group B</td>
<td>6.67</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Group C</td>
<td>6.67</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

**Exclusion criteria n=34**
- Refused
- Total cohort

**Patients characteristics & risk factors**

<table>
<thead>
<tr>
<th>Group</th>
<th>Age (years)</th>
<th>Weight [kg]</th>
<th>Height [cm]</th>
<th>BMI [kg m²]</th>
<th>Systolic RR [mmHg]</th>
<th>Diastolic RR [mmHg]</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>55.62 ± 16.16</td>
<td>75.2 ± 16.16</td>
<td>176.5 ± 16.16</td>
<td>30.5 ± 16.16</td>
<td>180.5 ± 16.16</td>
<td>110.5 ± 16.16</td>
</tr>
<tr>
<td>B</td>
<td>55.62 ± 16.16</td>
<td>75.2 ± 16.16</td>
<td>176.5 ± 16.16</td>
<td>30.5 ± 16.16</td>
<td>180.5 ± 16.16</td>
<td>110.5 ± 16.16</td>
</tr>
<tr>
<td>C</td>
<td>55.62 ± 16.16</td>
<td>75.2 ± 16.16</td>
<td>176.5 ± 16.16</td>
<td>30.5 ± 16.16</td>
<td>180.5 ± 16.16</td>
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</tr>
</tbody>
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**Study design**

- Non-inferiority of MonoMax suture material
- Quality of life (EQ-5D)
- VAS
- safety / AE, SAE
- wound complications

- Assumption: 30% incidence decreased to 10%

**Reduced herniation rate in the 24 months after mesh implantation**

<table>
<thead>
<tr>
<th>Group</th>
<th>24 months follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>12.66 %</td>
</tr>
<tr>
<td>B</td>
<td>3.85 %</td>
</tr>
<tr>
<td>C</td>
<td>0.00 %</td>
</tr>
</tbody>
</table>

**Exclusion criteria n=34**

- Refused
- Total cohort

**No significant differences**

**Suture vs mesh technique**

<table>
<thead>
<tr>
<th>Group</th>
<th>12 months p-value</th>
<th>24 months p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>A and C vs. B</td>
<td>0.086</td>
<td>0.026</td>
</tr>
</tbody>
</table>
Postoperative pain VAS (mm)

Frequency of wound healing disorders (%)

Overall: 12%

Formation of seromas: Exclusively using a mesh 18% (6/34)

Quality of Life

No difference in mean patient health status

Serious Adverse Event

27 SAE
7 patients died (6.8%), 2 in Mesh Group

11 (10.7%) reoperation
6 (5.8%) re-laparotomy
• 2x ileus, 1x ischemic bowel, 1x dehiscence of abdominal wall, 2x incisional hernias
• 2x Seromas, 1x post Op bleeding, 2 ischaemic leg

Prophylactic Onlay Mesh:
significant reduction of hernia rate after 24 months
Easy to perform
Seroma more frequent with onlay mesh
Wound infection did not differ
Glue versus stitches for mesh fixture?
Comparison small bite technique?
Thank you!

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