Porcine Versus Polypropylene Sling For Stress Urinary Incontinence - Results Of A 10 Year Randomised Control Study

S. Lamb, A. Eldaly, M. Abdel-Fattah, J. Barrington
1. Tens of thousands of women pursuing compensation for transvaginal mesh injuries.
2. Incontinence operations that’s ruining women’s lives.
3. Mesh.
4. Say no to mesh.
5. TVT-No! Mesh Survivor Foundation.
6. The women left in agony after bladder mesh ops.
7. Your health.
10 year RCT comparing...

**Pelvicol™** (Bard Urology) - a natural, non-allergenic, flexible and strong biological matrix derived from porcine dermis

**TVT™** (Ethicon Inc.) - a macroporous type 1 polypropylene synthetic mesh

Declaration of interests – none
Methodology

142 patients randomised to Pelvicol™ (74) or TVT™ sling (68)

› 128 patients completed 3 year follow-up
  (90% response rate)

› 98 patients completed 10 year follow-up
  (69% response rate)
Outcome Measures

**Primary:** Patient determined continence status

(Success = cured or >90% improved)
(Improved = ≥75 <90% improved)
(Failed = <75% improved)

**Secondary:** Repeat continence surgery
Use of incontinence pads
Adverse events
Patient satisfaction
# Results - Primary Outcome

<table>
<thead>
<tr>
<th>Patient determined continence</th>
<th>3 Year Follow-Up</th>
<th>10 Year Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pelvicol™</td>
<td>TVT™</td>
</tr>
<tr>
<td></td>
<td>N=68</td>
<td>N=60</td>
</tr>
<tr>
<td>Success (≥90%)</td>
<td>56 (82.4%)</td>
<td>53 (88.3%)</td>
</tr>
<tr>
<td>Improved (≥75 &lt;90%)</td>
<td>7 (10.3%)</td>
<td>3 (5.0%)</td>
</tr>
<tr>
<td>Failed (&lt;75%)</td>
<td>5 (7.3%)</td>
<td>4 (6.7%)</td>
</tr>
</tbody>
</table>

\( p = 0.5 \) \( p = 0.03 \)
Results - Primary Outcome

Pelvicol™ cure rates at 10 year follow-up
- Success: 47%
- Improved: 35%
- Failed: 18%

TVTTM cure rates at 10 year follow-up
- Success: 62%
- Improved: 19%
- Failed: 19%

p = 0.03
Results – Secondary Outcomes

Need for repeat anti-incontinence surgery

Pelvicol™

TVT™

Further surgery
No further surgery

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Further surgery</th>
<th>No further surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvicol™</td>
<td>27.5</td>
<td>72.5</td>
</tr>
<tr>
<td>TVT™</td>
<td>8.5</td>
<td>91.5</td>
</tr>
</tbody>
</table>
## Results – Secondary Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>3 Year Follow Up</th>
<th>10 Year Follow Up</th>
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</tr>
<tr>
<td></td>
<td>Pelvicol™</td>
<td>TVT™</td>
</tr>
<tr>
<td></td>
<td>N=37</td>
<td>N=43</td>
</tr>
<tr>
<td>Intermittent self catheter</td>
<td>2 (2.9%)</td>
<td>2 (3.3%)</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Difficulty in voiding</td>
<td>4 (5.9%)</td>
<td>5 (8.3%)</td>
</tr>
<tr>
<td></td>
<td>2 (5.4%)</td>
<td>6 (13.0%)</td>
</tr>
<tr>
<td>Pelvic Pain</td>
<td>1 (1.5%)</td>
<td>1 (1.7%)</td>
</tr>
<tr>
<td></td>
<td>3 (8.1%)</td>
<td>4 (9.3%)</td>
</tr>
<tr>
<td>Dyspareunia</td>
<td>0 (0.0%)</td>
<td>2 (3.3%)</td>
</tr>
<tr>
<td></td>
<td>3 (8.1%)</td>
<td>3 (6.9%)</td>
</tr>
</tbody>
</table>
Results – Secondary Outcomes

A graph to show reported adverse events at 10 year follow up

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<tr>
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<th>TVT™</th>
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</thead>
<tbody>
<tr>
<td>ISC Use</td>
<td>5.4</td>
<td>6.9</td>
</tr>
<tr>
<td>Difficulty in voiding</td>
<td>13.9</td>
<td>9.3</td>
</tr>
<tr>
<td>Pelvic pain</td>
<td>8.1</td>
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</tr>
<tr>
<td>Dyspareunia</td>
<td>8.1</td>
<td>6.9</td>
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</table>
Results – Secondary Outcomes

Would you have the sling procedure again?

- Pelvicol™:
  - Yes: 62.2%
  - No: 29.7%
  - Don't know: 8.1%

- TVT™:
  - Yes: 76.7%
  - No: 20.9%
  - Don't know: 2.4%
Results – Secondary Outcomes

Would you recommend this procedure to a friend?

Pelvicol™

- Yes: 62.2%
- No: 10.8%
- Don't know: 27%

TVT™

- Yes: 72%
- No: 14%
- Don't know: 14%
Discussion

- 2015 Cochrane review concluded established effectiveness and a good safety profile
- Lack of long-term outcome data for sling procedures, especially those using materials other than polypropylene

Other 10 year follow-up studies of TVT slings:
  - Groutz et al – cure rate 65%
  - Aignmueller et al – cure rate 57%
  - Svenningsen et al – cure rate 76%

Our study: cure rate of 62% and improvement ≥75% of 81%
Discussion

- Data of long-term follow up of Porcine slings poor
- Some questions over it’s durability for SUI sling procedures

Our study: cure rate of 47.2% and improvement ≥75% of 65%

Both cure rates declined at 10 years compared to 3 years

Pelvicol 82% to 47%
TVT 88% to 62%

Note significantly greater reduction in the Pelvicol group
Discussion

- Our re-operation rate of 8.5% in TVT group comparable to other 10 year follow-up studies who reported 7.8%

- Re-operation rate of 27.5% significantly higher in the Pelvicol group, suggests Porcine slings inferior

- Pelvicol sling is no longer commercially available

- With increasing interest in use of other allogenic materials, our results can be useful for patient counselling
Conclusion

The 10 year success rate of synthetic TVT™ slings is superior to Pelvicol™ porcine slings
I’d be happy to answer any questions
Discussion:
2. Urinary incontinence in women: management, NICE Clinical guideline [CG171], September 2013

Images:
4. Victory for the Mail on surgery that left thousands in agony, Daily Mail Online, Associated Newspapers Ltd, December 2013
6. uk.pinterest.com, 2016
7. The women left in agony after bladder mesh ops, Daily Mirror Online, MGN Ltd, October 2016