**STENT THROMBOSIS: IS THE ACHILLES HEEL OF BIORESORBABLE SCAFFOLDS EMERGING? A META-ANALYSIS OF RANDOMIZED CLINICAL TRIALS**

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**Objective & Background**: bioresorbable polyactic acid stents (BVS) are a promising technology but concerns regarding its radial strength are a matter of debate. Whether BVS are associated with an increased risk of stent thrombosis when compared to metallic drug eluting stents (DES) is not established.

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### Materials & Methods

**Search Strategy**
- Medline, Embase and Scopus databases search of randomized clinical trials comparing polyactic bioresorbable scaffolds with drug eluting stents.
- Search Criteria:
  - "POLYLACTIC" or "BIORESORBABLE" or "SCAFFOLDS" or "BIOABSORBABLE" or "ABSORB"
  - "CORONARY" or "PERCUTANEOUS INTERVENTION"

- Performed by two independent reviewers (FVS & MVS).
- Discrepancies were resolved by consensus.

**Search Results**

<table>
<thead>
<tr>
<th>Study</th>
<th>Ref</th>
</tr>
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<tbody>
<tr>
<td>ABSORB II</td>
<td></td>
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<tr>
<td>ABSORB III</td>
<td></td>
</tr>
<tr>
<td>ABSORB China</td>
<td>J Am Coll Cardiol 2015;66(21):1967-75</td>
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<tr>
<td>ABSORB Japan</td>
<td></td>
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<tr>
<td>EVERBIO II</td>
<td>J Am Coll Cardiol 2013;62(20):1967-75</td>
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<tr>
<td>TROFI</td>
<td>J Am Coll Cardiol 2013;62:1967-75</td>
</tr>
</tbody>
</table>

**Studies Included**: 6

**Initial references identified**: 1387

**Studies Assessed for Eligibility**: 20

**Excluded**: 192 studies and abstracts; 1406 studies and abstracts.

**Outcomes & Definitions**
- Efficacy outcomes extracted were:
  - Overall and Cardiac
  - Myocardial Infarction: Target Vessel Related or not
  - ST Thrombosis: Acute, Subacute, Late

- Efficacy outcomes definitions were those of the individual trials.

**Statistical Analysis**
- Outcomes were analyzed by the intention-to-treat data provided.
- Fixed-effects models were performed to estimate pooled relative risk of events, with StatsDirect 3 software.
- To quantify the statistical heterogeneity I² statistic was applied.

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### Results I

**Overall**

- There were 30 overall deaths, being 13 cardiac in origin. The risk of overall and cardiovascular death was similar between groups.

**Death**

- There were 30 overall deaths, being 13 cardiac in origin. The risk of overall and cardiovascular death was similar between groups.

**Cardiovascular**

- There were 30 overall deaths, being 13 cardiac in origin. The risk of overall and cardiovascular death was similar between groups.

**Myocardial Infarction**

- There were 169 overall myocardial infarctions, 129 being target vessel related and 23 non related. There was a trend towards an increased risk of MI associated with the use of BVS, mainly determined by an increased risk of target vessel related myocardial infarction.

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### Results II

**Overall Stent Thrombosis**

- BVS was associated with significant increases in the risk of overall ST with a low degree of heterogeneity (I²=0%). Similar trends were present in random effect models.

<table>
<thead>
<tr>
<th>Study</th>
<th>Relative Risk (95% confidence interval)</th>
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</thead>
<tbody>
<tr>
<td>ABSORB II</td>
<td>1.08 (0.91-1.30)</td>
</tr>
<tr>
<td>ABSORB III</td>
<td>1.00 (0.82-1.22)</td>
</tr>
<tr>
<td>ABSORB Japan</td>
<td>1.35 (0.31-6.00)</td>
</tr>
<tr>
<td>EVERBIO II</td>
<td>1.15 (0.41-3.38)</td>
</tr>
<tr>
<td>Combined (Fixed)</td>
<td>2.12 (1.02-4.41)</td>
</tr>
</tbody>
</table>

**ST According to Timing**

- Acute
  - Relative Risk (95% confidence interval): 2.12 (1.02-4.42)
  - No Device associated risk
- Subacute
  - Relative Risk (95% confidence interval): 0.43 (0.11-1.75)
  - No Device associated risk
- Late
  - Relative Risk (95% confidence interval): 3.55 (1.36-9.59)
  - No Device associated risk

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### Conclusion:

**THESE RESULTS SUGGEST THAT, WHEN COMPARED WITH DES, BVS MAY BE ASSOCIATED WITH AN INCREASED RISK OF STENT THROMBOSIS. COMPLETE SAFETY DATA IS NEEDED PRIOR TO THE IMPLEMENTATION OF BVS IN DAILY CLINICAL PRACTICE.**

There are no potential COI in relation with this presentation.