Supplementary Online Content

**Late Thrombotic Events after Bioresorbable Scaffold Implantation: A Systematic Review and Meta-analysis of Randomized Clinical Trials**

Carlos Collet1 MD\*; Taku Asano1 MD\*; Yosuke Miyazaki2 MD, PhD; Yuki Kataguiri MD1; Yohei Sotomi1 MD; \*; Erhan Tecknecioglu2, MD; Rafael Cavalcante2 MD\*, PhD; Robbert de Winter1 MD, PhD; Takeshi Kimura3 MD, PhD; Runlin Gao4 MD, PhD; Serban Puricel5 MD; Stéphane Cook5 MD; Davide Capodanno6 MD, PhD; Yoshinobu Onuma2 MD, PhD; Patrick W. Serruys7 MD, PhD.

1. Department of Cardiology, Academic Medical Center, University of Amsterdam, The Netherlands;
2. Department of Interventional Cardiology, Erasmus Medical Center, Rotterdam, The Netherlands;
3. Kyoto University Hospital, Kyoto, Japan;
4. Fu Wai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences, Beijing, China
5. Cinterventions. ative assessmentias arrows at the level of the radiopaque markers) eous coronary interventions. ative assessmentDepartment of Cardiology, Fribourg University and Hospital, Fribourg, Switzerland.
6. Cardio-Thoracic-Vascular Department, Ferrarotto Hospital, University of Catania, Catania, Italy
7. Imperial College of London, United Kingdom.

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**Table 1.** Preferred reporting items for systematic reviews and meta-analysis checklist. 1





**Table 2.** Risk of bias assessments for randomized clinical trials. 2

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Random sequence generation (selection bias) | Allocation concealment (selection bias) | Blinding of participants and researchers (performance bias) | Blinding of outcome assessment (detection bias) | Incomplete outcome data (attrition bias) | Selective reporting (reporting bias) | Other bias | Overall |
| ABSORB II3 | LOW | LOW | HIGH | LOW | LOW | LOW | LOW | LOW |
| ABSORB Japan4, 5 | LOW | LOW | HIGH | LOW | LOW | LOW | LOW | LOW |
| ABSORB China6, 7 | LOW | LOW | HIGH | LOW | LOW | HIGH | LOW | LOW |
| TROFI II8, 9 | LOW | LOW | HIGH | LOW | LOW | HIGH | LOW | LOW |
| EVERBIO II10, 11 | LOW | LOW | HIGH | LOW | LOW | HIGH | LOW | LOW |

The risk of bias was assessed according to Cochrane Collaboration’s handbook. For the assessment of selection bias, assessing the random sequence generation, the method used to generate the allocation sequence was assessed. It was described in detail in all publications, and it produced comparable groups. Therefore, low risk of bias was ascribed in all RCTs. For the allocation sequence concealment, studies protocols prevented foreknowledge of the forthcoming allocations. Therefore, all trials included in this meta-analysis showed low risk of selection bias. Regarding the performance bias, where measures used to blind study participants and personnel from knowledge of which intervention a participant received are assessed. A high risk of bias was ascribed, due to the fact that all studies were designed as open-label trials. Concerning the blinding of outcome assessment, it was graded as low since the outcomes of interest were clinical events (i.e., myocardial infarction, new percutaneous coronary intervention, cardiac death, etc.) which are objectives and well-defined end-points. The attrition bias also was low given that clinical follow-up data at two years was available in 95% (n=1642) of the population (94% [950/1015] Absorb BVS vs. 97% [692/715] EES). Also, the total the number of interventions was the same of the total number of participant included. Regarding the selective reporting of outcomes, all trials were consistent in reporting the primary and secondary end-point according to the Academic Research Consortium. 12Nevertheless, due to the fact that the long-term outcomes of three studies were assessed in a abstracts format a high risk of bias was attributed to these studies.

**Table 3.** Clinical, device, procedural and outcomes of patients presenting with scaffold thrombosis.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Days after implantation | Gender | Age | Target vessel | Scaffold size diameter-length (mm) | Post dilatation | Post procedural MLD in scaffold (mm) | Post procedural %DS | Clinical presentation at the time of thrombosis | Antiplatelet therapy at the time of thrombosis | Death after thrombotic event |
| 0 | M | 53 | Diagonal | 2.5-18 | Yes | 1.94 | 19% | STEMI | DAPT | No |
| 2 | M | 46 | LAD | 3-18\*2 | Yes | 2.19 | 19% | STEMI | DAPT | No |
| 4 | M | 64 | RCA | 2.5-18 | Yes | 2.27 | 11.50% | NSTEMI | DAPT | No |
| 4 | M | 55 | LAD | 3.0-18 | Yes | 2.4 | 9.90% | STEMI | DAPT | No |
| 5 | M | 64 | LCX | 2.5-18 | No | 1.69 | 19.80% | STEMI | DAPT | No |
| 6 | M | 70 | LAD | 3.0-N/A | Yes | 2.04 | 14.0% | STEMI | DAPT | No |
| 139 | F | 75 | LAD | 2.5-28 | No | 1.84 | 6.80% | STEMI | None | No |
| 335 | M | 75 | LAD | 3.0-18 | No | 2.36 | 14% | STEMI | None | No |
| 400 | M | 56 | RCA | 3.5-12/3.5-18 | Yes | 3.14 | 13.5% | STEMI | SAPT | No |
| 447 | M | 44 | LAD | 3.0-18 | Yes | 2.24 | 21% | STEMI | SAPT | No |
| 494 | M | 79 | LAD | 3.5-28 | Yes | 2.57 | 18% | STEMI | None | No |
| 536 | M | 44 | RCA | 3.5-18 | No | 2.79 | 16.20% | STEMI | SAPT | No |
| 595 | M | 72 | RCA | 3.0-18 | Yes | 2.19 | 20.5 | STEMI | DAPT | No |
| 602 | M | 54 | RCA | 3.0-18 | No | 2.16 | 21% | STEMI | SAPT | No |
| 679 | M | 59 | RCA | 3.5-18 | No | 3.12 | 7.60% | STEMI | SAPT | No |
| 967 | M | 58 | LAD | 3.0-18 | Yes | 2.38 | 24% | STEMI | SAPT | No |
| 981 | M | 76 | OM2 | 3.0-18 | No | 2.28 | 28% | STEMI | SAPT | No |
| 1022 | M | 65 | LAD | 3.0-18 | No | 2.43 | 13% | STEMI | SAPT | No |
| 1082 | M | 63 | OM1 | 3.0-18 | Yes | 2.29 | 17% | STEMI | SAPT | Yes |

M = Male. F = Female. LAD = Left Anterior Descending Artery. RCA: Right Coronary Artery. LCX = Left Circunflex Artery. N/A = Not Available. STEMI = ST- elevation Myocardial Infarction. NSTEMI = Non-ST-elevation Myocardial Infarction. DAPT = Dual Antiplatelet Therapy. SAPT = Single Antiplatelet Therapy.

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