

Effectiveness and safety of the ABSORB bioresorbable vascular scaffold for the treatment of coronary artery disease: systematic review and meta-analysis of randomized clinical trials

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Background: In the last years bioresorbable vascular scaffold (BVS) become a new therapeutic option for interventional cardiologists, with the advantage of a scaffold inducing a possible vessel wall restoration. Nevertheless, several trials tried to prove the safety and efficacy profile of scaffolds, but with conflicting results.

Methods: A systematic review and meta-analysis was performed. The search was carried out in PubMed, Google Scholar, Biomed Central and Cochrane Library between January and March 2017. Inclusion criteria: randomized clinical trials (RCT) comparing the Absorb BVS versus durable polymer cobalt-chromium Everolimus Eluting Stent. The outcomes analysed were all-cause mortality, cardiac death, ischemia-driven target lesion revascularization, target vessel myocardial infarction (MI), target lesion failure (TLF)/device oriented composite endpoints (DOCE), and device thrombosis. Fixed-effect meta-analysis was performed. Data were expressed as odds ratio (OR).

Results: Overall 5,674 patients were included (mean age 62.2±1.31 in drug eluting stents (DES) group *vs.* 62±1.47 in BVS group; P=0.942). DOCE (OR 1.16, 95% CI: 0.90–1.48; P=0.259, I²=0%), cardiac death (OR 0.86, 95% CI: 0.52–1.40; P=0.537, I²=0%) and all-cause death (OR 0.78, 95% CI: 0.53–1.15; P=0.205, I²=15%) did not differ between BVS and DES. Conversely, ischemia-driven target lesion revascularization was more frequent in the BVS group (OR 1.32, 95% CI: 1.01–1.73; P=0.039, I²=0%), as well as device thrombosis (2.2% *vs.* 0.6%, OR 2.94, 95% CI: 1.71–5.05, P=0.0001, I²=0%) and target-vessel MI (5.4% *vs.* 3%, OR 1.66, 95% CI: 1.25–2.21, P=0.001, I²=0%).

Conclusions: The implantation of BVS is associated with an increased risk of device thrombosis, ischemia-driven target lesion revascularization and target vessel MI. If longer follow-up or different implantation technique may change these findings should be addressed in future trials.

Keywords: Bioresorbable vascular scaffold (BVS); absorb; meta-analysis

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Introduction

Routinary use of second generation drug eluting stents (DES) is nowadays a consolidate practice. Many studies provided evidence on efficacy and safety of these devices but warning concerns still arise from cardiological community regarding the increased risk of late and very late stent thrombosis (1). Several studies showed that the presence of several uncovered struts was related with the presence of persistent inflammatory reaction around the device (2-4). Moreover, after DES implantation the anatomy and physiology of the endothelium seem to remain abnormal, with increased vasoconstriction in response to some stimuli (e.g., acetylcholine) (5,6).

In this framework, the new bioresorbable vascular scaffolds (BVS) were introduced as a promising technology. Nevertheless, the efficacy and safety profile of BVS remains unclear. Such type of stent can potentially overcome the long-term limitations of permanent stent implantation, restoring physiological vasomotion and endothelial function of the treated vessel without precluding future surgical revascularization at the same lesion. Bioresorbable scaffolds consist of a polymer or bioresorbable metal alloy (7). Currently, several polymers are available, each with different chemical compositions, mechanical properties, and subsequently bioabsorption times. The most frequently used polymer in the current generation of BVS is poly-L-lactic acid (PLLA), which form the backbone of the BVS device while the coating consists of poly D,L-lactide acid (PDLLA). PLLA is a random copolymer of D and L-lactic acid with lower crystallinity (7) and it is responsible of the release of the anti-proliferative drug everolimus (7).

The current and most used BVS is the absorb BVS (Abbott Vascular, Santa Clara, CA, USA) which had been yet the subject of several randomized clinical trial (RCT) (8,9), which evaluated clinical outcomes from BVS implantation, but being underpowered to detect differences in treated lesion efficacy and to value safety endpoints. The aim of this review is to compare bioresorbable scaffold implantation versus everolimus drug eluting stent in term of efficacy and safety lesion related outcomes.

Methods

Search strategy

A systematic search of RCT comparing Absorb BVS versus durable polymer cobalt-chromium everolimus eluting stent (EES) was performed. The search was carried out

in PubMed, Biomed Central, Google Scholar and the Cochrane library. The search was performed according to the preferred reporting items for systematic reviews and meta-analyses (PRISMA) amendment to the quality of reporting of meta-analyses (QUOROM) statement (10-13). The search strategy terms included “BVS” and “absorb” and it was carried between January and March 2017. Two reviewers (MS, RP) analysed the records, valuing the ones deserving a full-text analysis (*Figure 1*).

Selection criteria

Inclusion criteria were:

- ❖ Studies with randomized design comparing the Absorb BVS versus durable polymer cobalt-chromium Everolimus Eluting Stent;
- ❖ Studies reporting the number of events for the outcomes of interest at 6-month follow-up and over: all-cause death, target lesion failure (TLF), cardiac death, target vessel myocardial infarction (MI), ischemia driven target lesion revascularization (ID-TLR), device oriented composite endpoints (DOCE), definite or probable device thrombosis (ST). DOCE was defined as the composite endpoint for TLF (cardiac death, ID-TLR, target vessel MI). The ST was defined according to the Academic Research Consortium (ARC) criteria (14);
- ❖ Study published in English.

Exclusion criteria were:

- ❖ Non-randomized trial (e.g., review, editorials, meta-analysis, case report/series, propensity score matching analysis, observational studies);
- ❖ Duplicate study, duplicate of the sample study;
- ❖ Follow-up duration less than 6-months;
- ❖ Comparison between BVS to a non-permanent polymer DES (e.g., bioabsorbable or bioresorbable polymer DES).

Data abstraction, endpoints, subgroup analyses

The reviewers completed a database with data regarding: the journal, year of publication, population characteristics and endpoint of interest. The endpoints of the analysis were the odds ratio (OR) of all-cause mortality, cardiac death, ischemia-driven target lesion revascularization, DOCE, target vessel MI, definite or probable device thrombosis. Subgroup analysis according to the length of the follow-up (≤ 1 vs. > 1 year) was performed.

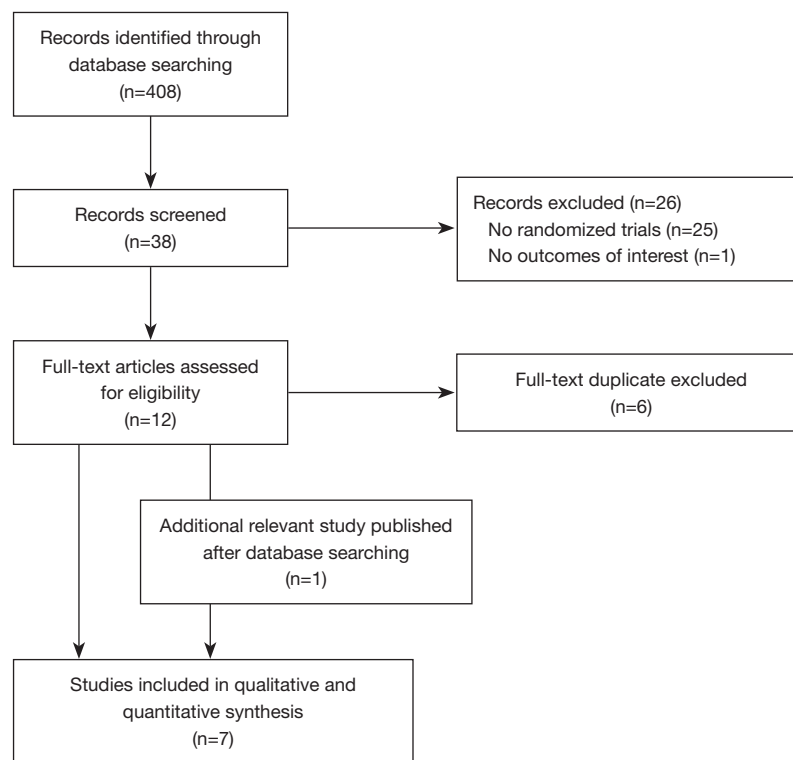


Figure 1 Outline of the search strategy.

Internal validity and quality appraisal

Two unblinded reviewers evaluated the quality of included studies. The presence of low or high risk of selection, analytical, adjudication, attrition and detection bias was evaluated. The divergences were resolved by consensus.

Statistical analysis

Continuous variables were summarized as mean (\pm standard deviation) or median (interquartile range) while the categorical ones were expressed as percentage or number. To convert median (interquartile range) to mean (standard deviation) we used formula accepted in the literature (15). The endpoints were expressed as OR. Statistical heterogeneity was appraised with I^2 statistic. A value of I^2 of 0 to 25% was considered insignificant, 26 to 50% low, 51 to 75% moderate, and $>75\%$ high (16). When the I^2 was $<50\%$ a fixed effect model was used, while if the I^2 was $>50\%$ a random effect model was chosen. The Chi^2 test has been used to test the difference between sub-group analyses. Finally, meta-regression analysis was performed to weigh the effect of some potential confounding factors (demographical

characteristics of the population, previous MI, previous percutaneous coronary intervention, cardiovascular risk factors, coronary artery treated, clinical presentation). Publication bias was evaluated by funnel plots analysis with Duval and Tweedie trim and fill, Begg and Mazumdar rank correlation, Egger's regression intercept (17). Prometa software 3 (Internovi, Cesena, Italy) and RevMan 5 (The Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen, Denmark) were the statistical software used.

Results

Search strategy

A total of 408 records were analysed (*Figure 1*). After a first evaluation of titles and abstracts 38 records were screened and 26 of these were excluded because they did not meet the inclusion criteria and 6 because they were duplicate (*Figure 1*). A total of seven studies were included in the meta-analysis (18-24), one of which was added after the publication in March 2017 (AIDA trial) (25). We also decided to use the data at two years, recently published in clinicaltrial.org for ABSORB III trial (26).

Population characteristics

Population characteristics for each studies are listed in *Table 1*. The whole study population was of 5,674 patients. The mean age of the population was 62.2 ± 1.31 in the DES group and 62 ± 1.47 in the BVS group ($P=0.942$). Overall, males were 74%, 26% were smokers, 24% had diabetes and finally hypertension and dyslipidaemia were present in 64% of the study population. The majority of patients enrolled had a diagnosis of stable coronary artery disease (48%) or of unstable angina (21%). Left anterior descendent artery was the most treated vessel (51%).

Outcomes

The rate of DOCE was 7% for patients treated with DES and 9% in the group treated with BVS (OR 1.16, 95% CI: 0.90–1.48; $P=0.259$, $I^2=0\%$) (*Figure 2*). The occurrence of cardiac death was similar between patients treated with both DES and BVS (OR 0.86, 95% CI: 0.52–1.40; $P=0.537$, $I^2=0\%$) (*Figure 2*) while ischemia-driven target lesion revascularization was more incident in the BVS group (OR 1.32, 95% CI: 1.01–1.73; $P=0.039$, $I^2=0\%$) (*Figure 3*).

No difference was found in all-cause mortality between the two groups (OR 0.78, 95% CI: 0.53–1.15; $P=0.205$, $I^2=15\%$) (*Figure 3*). Device thrombosis was more frequent in patient treated with BVS (2.2% *vs.* 0.6%, OR 2.94, 95% CI: 1.71–5.05, $P=0.0001$, $I^2=0\%$) as well as target-vessel MI (5.4% *vs.* 3%, OR 1.66, 95% CI: 1.25–2.21, $P=0.001$, $I^2=0\%$) (*Figure 4*).

Meta-regression and subgroup analysis

Meta-regression analysis showed that no-one of clinical patients' characteristics affected the outcomes considered. After stratification of study according the length of the follow-up (≤ 1 *vs.* >1 year) the results for all the outcomes considered did not change.

Publication bias

Tests for the detection of publication bias were negative for all the outcomes considered (*Table 2*) (*Figures 5–7*).

Discussion

The present meta-analysis valued BVS versus DES selecting only RCT. Data show that there is not any advantage

between BVS and DES implantation in terms of mortality, cardiac death, and DOCE. However, the rate of ID-TLR, device thrombosis and of target vessel MI is higher in the group of patients treated with BVS. This confirm the trend of the single big trials (ABSORB III and AIDA), recently published and which failed to demonstrate a safety profile of these scaffolds (25,26). Meta-regression analysis showed that the main clinical characteristics of the patients are not influencing the outcomes analysed. Moreover, the heterogeneity was insignificant in all the analyses, showing a good reliability of the data obtained.

The implantation technique of BVS is different from the one used for common DES. In the last years, a European expert consensus (GHOST-EU registry) has proposed a specific protocol to be followed for the correct apposition of scaffolds, the so called "PSP technique" (27). This technique consists in preparation of the lesion, with Pre-dilatation, accurate vessel Sizing (28,29), and mandatory post-dilatation (PSP) (30). Unfortunately, all data coming from big trials are on patients treated with BVS, enrolled between November 2011 and December 2015 (*Figure 8*). The PSP technique was firstly reported in the late 2014, so only few data coming from trials reflect the correct technique for BVS implantation. Moreover, a recent study on GHOST-registry population demonstrated that a specific model of PSP translated in a score, was an independent predictor of DOCE, and that patients with high PSP score had less events, particularly MI (31). The limit of this technique are several; first of all, costs: the correct sizing requires the use of intracoronary imaging; secondly the time for the procedure will increase. Thirdly, there are no data coming from RCT. In the AIDA trials, in 26 over 31 stent thrombosis occurred in the BVS group, the post dilatation was performed, but with only 16 ATM (25). In addition, only in ten cases the post-dilatation was performed with a balloon ≥ 0.5 mm the diameter of the scaffold (25). New data showed best results with a post dilation at 18–20 ATM (32). Hence, if with PSP the BVS implantation will became a safety technique it still has to be proven. Nevertheless, several registries showed that a scrupulous implantation technique is associated with a better outcome, similar to that observed with second generation DES, also in complex clinical scenario (33). As a matter of fact, the mechanical structure of second generation DES, ensures a good result of stent deployment even if post-dilatation results in under-expansion. This is not equally true in the setting of scaffold, where a careful implantation with some tips and tricks could significantly change the long-term performance. It

Table 1 Sample study characteristics

Study title	Absorb II	Absorb III	Absorb China	Absorb Japan	Trofi II	Everbio II	AIDA
General study characteristics							
Population	501	2008	475	400	191	158	1845
Follow-up	3 years	2 years	1 years	1 years	6 months	9 months	2 years
Group	DES BVS	DES BVS	DES BVS	DES BVS	DES BVS	DES BVS	DES BVS
No. of patients	335 166	1,322 686	238 237	134 266	191 96	80 78	921 924
CV risk factors							
Age (mean ± SD)	61.5 (±10)	63.5 (±10.6)	57.2 (±11.4)	67.1 (±9.4)	59.1 (±10.7)	65 (±11)	64 (±10.5)
Male [%]	253 [76]	132 [79]	171 [71]	99 [74]	147 [77]	64 [80]	700 [76]
Smoking habits [%]	79 [23]	281 [21]	78 [33]	29 [21]	22 [23]	30 [38]	273 [32]
Diabetes [%]	22 [7]	40 [24]	60 [25]	48 [36]	18 [19]	13 [16]	153 [17]
Hypertension [%]	231 [69]	1,122 [85]	140 [59]	107 [80]	41 [44]	51 [64]	464 [51]
Dyslipidaemia [%]	252 [75]	1,140 [86]	101 [42]	110 [82]	60 [64]	50 [63]	350 [38]
Previous MI [%]	48 [14]	150 [22]	38 [16]	32 [23]	3 [3]	14 [18]	172 [19]
Previous PCI [%]	5 [1]	/	19 [8]	7 [5]	3 [3]	25 [32]	184 [20]
Coronary lesion							
LAD [%]	84 [46]	301 [42]	132 [52]	58 [46]	44 [45]	78 [34]	528 [44]
CX [%]	42 [23]	218 [31]	61 [24]	36 [26]	41 [42]	21 [19]	318 [26]
RCA [%]	56 [31]	194 [27]	59 [23]	43 [31]	13 [13]	40 [36]	348 [29]
Clinical presentation							
STEMI [%]	0 [0]	0 [0]	0 [0]	0 [0]	96 [100]	6 [8]	225 [24]
NSTEMI [%]	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]	16 [20]	192 [21]
UA [%]	37 [22]	168 [25]	152 [64]	26 [10]	0 [0]	5 [6]	87 [9]
SCAD [%]	107 [64]	417 [61]	50 [17]	88 [66]	0 [0]	47 [59]	370 [40]
SI [%]	19 [11]	70 [10]	13 [6]	24 [18]	0 [0]	6 [8]	9 [12]

DES, drug eluting stents; BVS, bioresorbable vascular scaffold; SI, silent ischemia; STEMI, ST elevation myocardial infarction; NSTEMI, non ST elevation myocardial infarction; UA, unstable angina; SCAD, stable coronary artery disease; RCA, right coronary artery; CX, circumflex artery; LAD, left anterior descending artery; MI, myocardial infarction; PCI, percutaneous coronary intervention; CV, cardiovascular; SD, standard deviation.

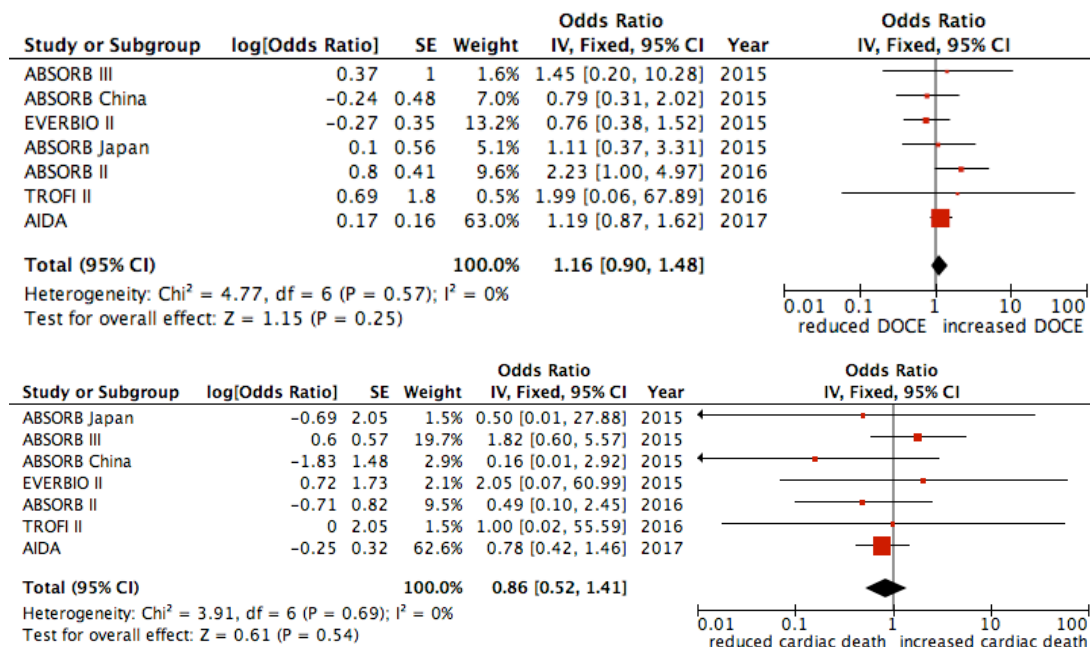


Figure 2 Forest plot for DOCE and cardiac death. Data are displayed as OR (95% CI). DOCE, device oriented major adverse cardiac events.

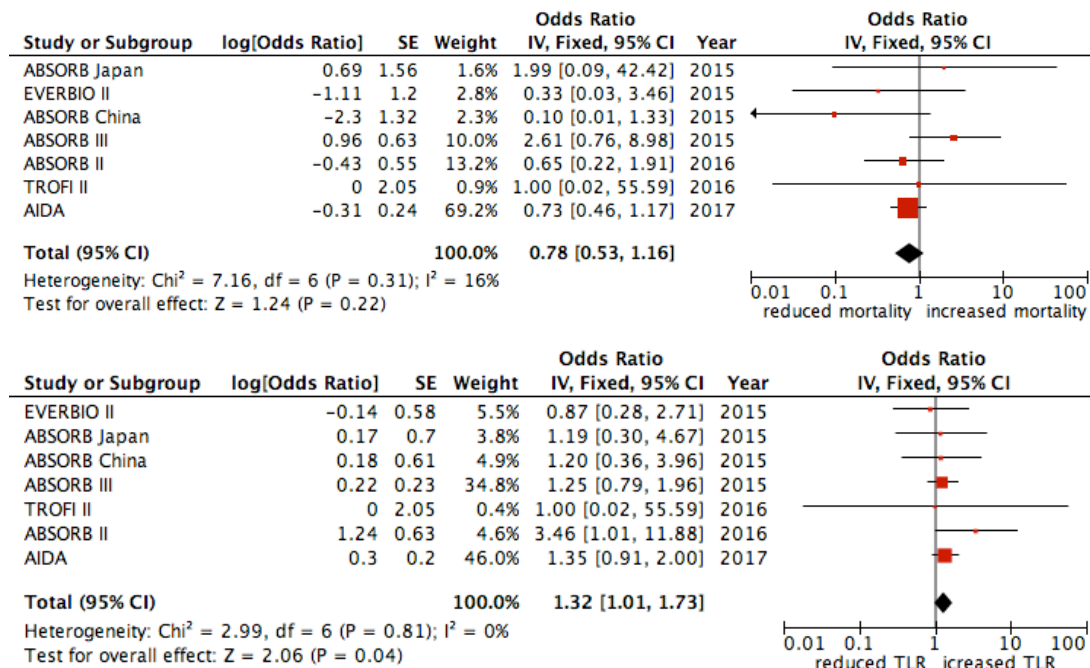


Figure 3 Forest plot for all-cause death and ischemia driven target lesion failure. Data are displayed as OR (95% CI).

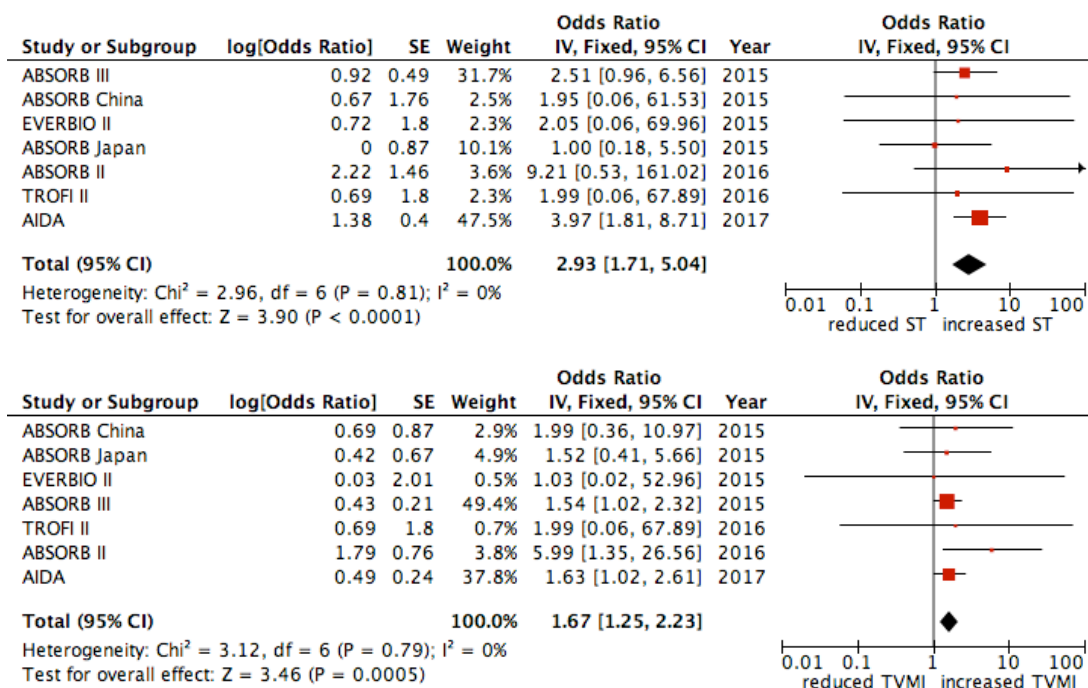


Figure 4 Forest plot for device thrombosis and target vessel myocardial infarction. Data are displayed as OR (95% CI).

Table 2 Publication bias analysis

Statistical test	Efficacy outcome						Safety outcome					
	DOCE		All-cause death		Cardiac death		Ischemia driven TVR		Stent thrombosis		Target vessel MI	
Eggers linear regression test												
Intercept	0.09	P=0.89	-0.08	P=0.92	-0.18	P=0.75	0.09	P=0.87	-0.32	P=0.56	0.42	P=0.38
t	0.14		-0.11		-0.33		0.17		-0.63		0.96	
Begg and Mazumdar's rank correlation test												
Z value for Kendall's tau	1.05	P=0.29	-0.15	P=0.88	-0.15	P=0.88	0.45	P=0.65	-0.45	P=0.65	0.45	P=0.65
Trim and fill test												
OR estimated	1.07	P=0.56	1	P=0.99	0.86	P=0.54	1.32	P=0.04	2.94	P>0.0001	1.58	P=0.001
No. trimmed studies	2		0		0		0		1		1	

DOCE, device oriented major adverse cardiac events.

is important to underline that: (I) the scaffold struts are thicker and post-dilation helps in the correct deliverability process; (II) scaffolds have not radial strength, because of the absence of a metallic structure; (III) the delivery balloon used for BVS is usually more compliant than the ones used with other DES. For these and other under-investigation reasons, a proper sizing followed by post-dilatation should be considered mandatory and the absence of compliance

with this behaviour might justify the clinical failure in the first RCTs involving scaffolds.

In the first three months after BVS implantation there is mainly the delivery of the drug; in the first year the mechanical support of the scaffold disappears, but the full mass loss and reabsorption of the scaffold require up to three years (34). The physiological process of scaffold dissolution may be related to an increased thrombotic risk

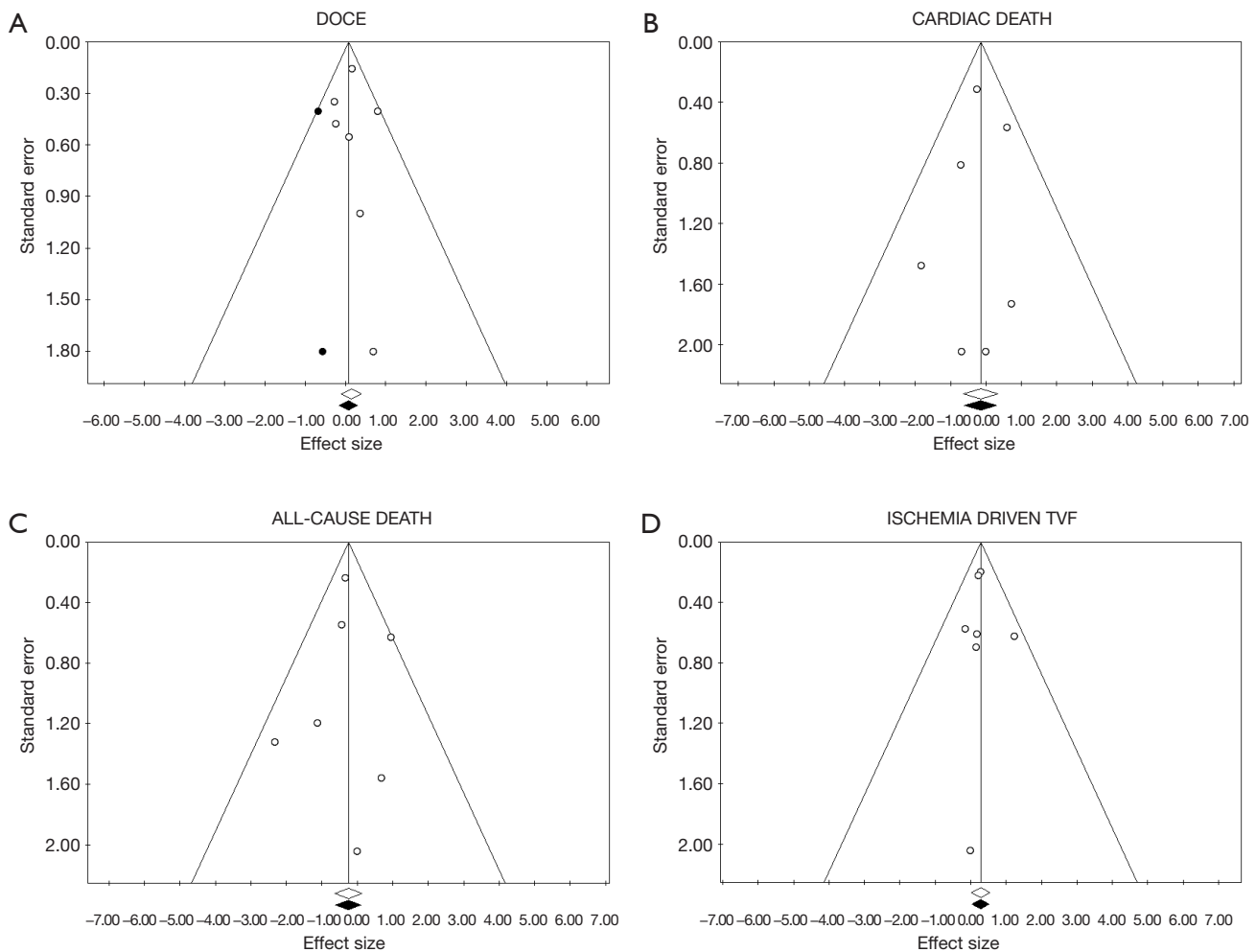


Figure 5 Funnel plot and trim and fill analysis for publication bias detection for all-cause death, ischemia driven target vessel failure (TVF), DOCE and Cardiac death. On x axis is reported the value of OR for the effect sizes in (A) DOCE, (B) cardiac death, (C) all-cause death, (D) ischemia driven TVF. On y axis is reported the standard error for each studied included in the meta-analysis. Every point represents a trial included in the meta-analysis. White points are observed effect size, black points are estimated effect size. DOCE, device oriented major adverse cardiac events.

compared to DES design, and this could be overpassed with stronger or prolonged regimen of antiplatelet therapy until the complete reabsorption of the scaffold (35). Finally, all the data we analysed were on a follow-up of maximum three years, where, the real advantage of the design of scaffolds are related to the complete restoration of the physiology of vessel wall (34), which happens in three years, but if there is an advantage in the full restoration of the vessel wall, only a longer follow-up will be able to verify the benefit of BVS implantation versus DES.

New trials are needed to explore these three hypothesis

and to definitely understand if there is any advantage in BVS implantation. In particular, ABSORB IV (36) will answer some of this question.

Study limitation

This is a study level meta-analysis. We calculated the OR using single event data from each paper considered, so data obtained are not weighted for other factors even if meta-regression analysis was negative for the main clinical characteristics of the study population.

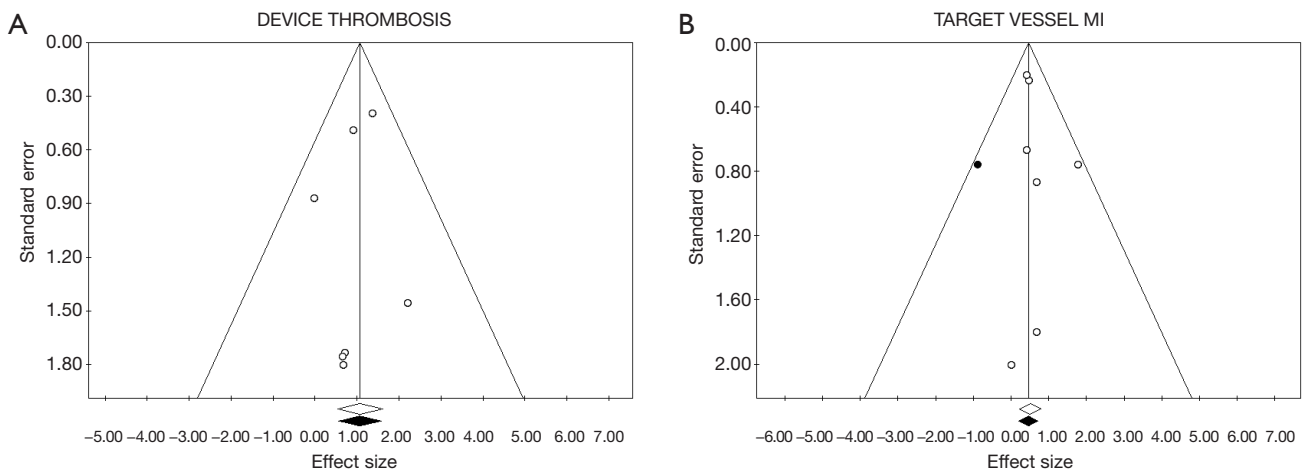


Figure 6 Funnel plot and trim and fill analysis for publication bias detection for device thrombosis and target vessel myocardial infarction (MI). On x axis is reported the value of OR for the effect sizes in (A) device thrombosis, (B) target vessel MI. On y axis is reported the standard error for each studied included in the meta-analysis. Every point represents a trial included in the meta-analysis. White points are observed effect size; black points are estimated effect size.

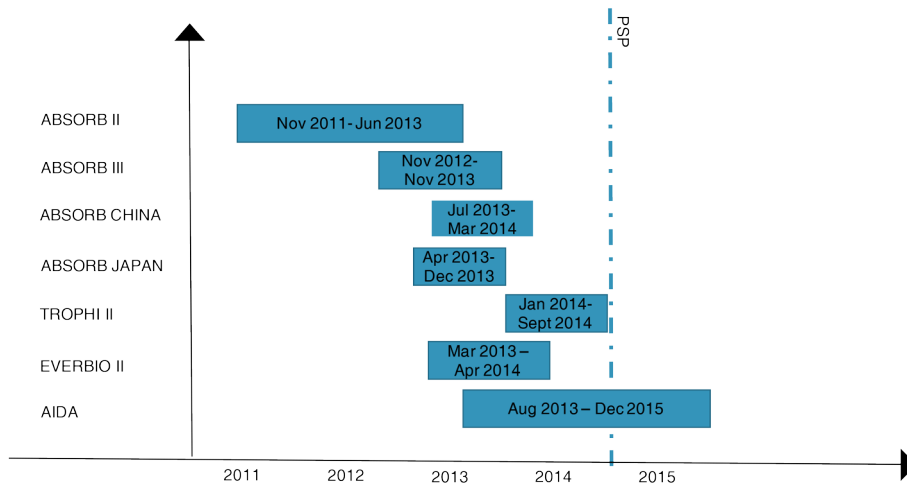


Figure 7 Risk of bias graph.

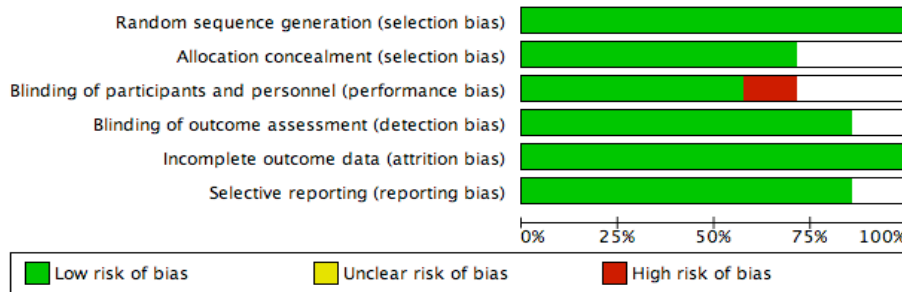


Figure 8 Time-line of the enrollment time. PSP, pre-dilatation, sizing, post-dilatation. The dotted line indicates the moment in which various publications and advisory boards have stressed the need to apply the PSP technique in BVS implantation. BVS, bioresorbable vascular scaffold.

Conclusions

The implantation of BVS is related to an increased risk of device thrombosis, ischemia-driven target lesion revascularization and target vessel MI, while the rate of DOCE, cardiac death and all-cause death do not differ for patients treated with BVS or DES. New trials valuing if a different implantation technique may change these findings are clearly on demand. Similarly, longer follow-up is needed to analyse the benefit of BVS implantation.

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None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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