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Three-year outcomes of bioresorbable vascular scaffolds versus second-generation drug-eluting stents

Meta-analysis of randomized trials

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Abstract

Background: Bioresorbable vascular scaffolds (BVS) completely resorb within 3 years after placement into the coronary artery. The safety and effectiveness of bioabsorbable scaffolds are of critical importance during this 3-year period.

Objective: We performed a meta-analysis to compare the safety and efficacy of BVS and second-generation drug-eluting stents (DES) at 3 years after implantation.

Methods: Published randomized trials comparing BVS to second-generation DES for the treatment of coronary artery disease were identified within PubMed, EMBASE, Cochrane Library, Web of Science, and relevant Web sites with publication dates through June 2019. The primary efficacy endpoint was target lesion failure. The primary safety endpoint was definite/probable stent/scaffold thrombosis. Secondary outcomes were cardiac death, target vessel myocardial infarction, ischemia-driven target lesion revascularization, and a patient-oriented composite end point.

Results: Six randomized controlled trials, with a total of 5,412 patients (BVS n=3,177; DES n=2,235), were included. At 3 years, BVS was associated with higher rates of target lesion failure (OR=1.33, 95%CI: 1.10–1.60, $P=0.003$) and definite/probable stent/scaffold thrombosis (OR=3.75, 95% CI: 2.22–6.35, $P<.00001$)compared with DES. The incidence of target vessel myocardial infarction (OR=1.68, 95% CI: 1.30–2.17, $P<.0001$), ischemia-driven target lesion revascularization (OR=1.46, 95% CI: 1.14–1.86, $P=.003$), and the patient-oriented composite end point(OR=1.20, 95% CI: 1.04–1.39, $P=.01$) were higher for those treated with BVS compared with DES. However, there was no significant difference in risk of cardiac death (OR=0.94, 95%CI: 0.61–1.45, $P=.79$) between treatment groups.

Conclusions: At the 3-year follow-up, BVS was inferior to second-generation DES in both safety and efficacy.

Abbreviations: BVS = bioresorbable vascular scaffolds, CAD = coronary artery diseases, DAPT = dual antiplatelet therapy, DES = drug eluting stents, MI = myocardial infarction, PCI = percutaneous coronary intervention, RCT = randomized controlled trial, ST = stent/scaffold thrombosis, TLF = target lesion failure.

Keywords: bioresorbable vascular scaffold, coronary artery diseases, drug-eluting stent, Meta-analysis

1. Introduction

Bioresorbable scaffolds are designed to mitigate the late-stage risks associated with metal stents by providing mechanical support only during the time required for vascular remodeling before undergoing complete bioabsorption. In theory, bioresorbable scaffolds can restore the vasomotor function of target vessels in the treated area, reduce the incidence of late restenosis, stabilize plaques, and bypass grafts after stent reabsorption.[1,2]

The Absorb bioresorbable vascular scaffold (BVS) (Abbott Vascular, Santa Clara, CA, USA) was the most widely used bioabsorbable scaffold. It consisted of a balloon-expandable, 157-μm-thick BVS made of a poly-L-lactide backbone with a poly-D,L-lactide coating in a 1:1 ratio with the anti-proliferative drug everolimus. Previous studies[3,4] have verified the effectiveness and safety of BVS in the treatment of coronary artery diseases (CAD). However, subsequent clinical studies[5,6] have shown higher rates of target vessel myocardial infarction (MI) and stent/scaffold thrombosis (ST) with the BVS than with second-generation drug-eluting stents (DES), raising concerns about its effectiveness and safety.

The BVS is designed to completely resorb within 3 years after implantation. We performed a meta-analysis on the available randomized controlled trials (RCTs) comparing long-term outcomes for patients treated with BVS compared with DES.

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The datasets generated during and/or analyzed during the current study are publicly available.

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2. Methods

2.1. Search strategy and Selection criteria

We searched PubMed, Cochrane Library, EMBASE, Web of Science, and relevant Web sites (https://www.clinicaltrials.gov; https://www.pcronline.com/) without language restrictions from their inception to June 30, 2019. The following keywords were used in various search combinations: bioresorbable vascular scaffold(s), bioresorbable scaffold(s), absorb stent(s), everolimus eluting stent(s), drug eluting stent(s). Studies were included in the meta-analysis when they met the following criteria:

(1) the study design was a prospective randomized controlled clinical trial;
(2) the study compared the clinical efficacy of the BVS and second-generation DES in the treatment of CAD;
(3) There was at least 1 of the following clinical endpoints: target lesion failure (TLF), definite/probable ST, target vessel MI, ischemia-driven target lesion revascularization, patient-oriented composite end point, cardiac death;
(4) report on clinical outcome with a follow-up time = 3 years.

2.2. Outcomes

The primary efficacy endpoint was TLF (the device-oriented composite endpoint of cardiac death, target vessel MI, or ischemia-driven target lesion revascularization). The primary safety endpoint was definite/probable ST. Secondary endpoints included cardiac death, target vessel MI, ischemia-driven target lesion revascularization, and patient-oriented composite end point(consisting of all-cause mortality, all MI, or all revascularization; all-cause mortality); Definite/probable ST was classified according to the academic research consortium.[7]

2.3. Data extraction and assessment of risk of bias

Data were independently extracted from the relevant articles by 2 physician reviewers after determining their eligibility for inclusion. Discrepancies and disagreements regarding data incorporation were resolved through consensus among all authors. We collected information about the study design, clinical and procedural characteristics, and clinical outcomes. The Cochrane Collaboration's tool was used to assess risk of bias.[8] Publication bias was estimated using a funnel plot.

2.4. Statistical analyses

The summary measure used for this analysis was the Odds Ratio (OR) with 95% confidence intervals. Heterogeneity was assessed by Q-statistic and I^2 tests. For low or moderate heterogeneity ($P > .10$ and $I^2 < 50\%$), a fixed-effects model was used, and for high heterogeneity ($P < .10$ or $I^2 > 50\%$), a random-effects model was used. Sensitivity analysis was performed to detect the influence of a single study on the overall estimate by omitting each study in turn. RevMan software (version 5.3.5) was used for all statistical analyses.

2.5. Data availability

All data generated during and/or analyzed in this study are included in this published article (and its supplementary information files, http://links.lww.com/MD/E661).

2.6. Ethical approval

This article does not contain any studies with human participants or animals performed by any of the authors.

2.7. Informed consent

For this type of study, formal consent is not required.

3. Results

3.1. Study Selection and Characteristics

Flow diagram illustrates the search strategy. Our initial search yielded 2,451 studies for possible inclusion in this analysis. After rigorous examination, 6 studies[5,9–13] enrolling a total 5412 patients with CAD undergoing percutaneous coronary intervention (PCI) with either BVS (n = 3,177) or DES (n = 2,235) implantation were included for analysis. The duration of dual antiplatelet therapy (DAPT) prescribed by each study was at least 12 months. The main characteristics of the included studies are reported in Table 1. Baseline clinical and procedural characteristics across studies are summarized in Table 2.

3.2. Assessment of study quality

There was no evidence of statistical heterogeneity ($P > .10$, $I^2 < 50\%$) at the clinical endpoints in any study, so fixed-effects models were used. During the sensitivity analysis, wherein we excluded studies 1-by-1 from the analysis, there was no significant change in outcomes, suggesting that the study results were relatively stable across reports. The funnel plots for TLF and definite/probable ST were basically symmetrical, suggesting that there was little publication bias (Fig. 1). Quality assessments for the RCTs are provided in the Table 3. All included studies were high quality with low risk of bias.

Table 1

Main characteristics of the included studies.

Study	Year	Centres, n	BVS/DES treated Patients, n	Study type	Clinical presentation	BVS/DES Scaffold type	Follow-up, Yrs
ABSORB China[9]	2018	24	235/232	RCT	SAP, UA, AMI	Absorb BVS /EES	3
ABSORB II[5]	2016	46	335/166	RCT	SAP, UA, SMI	Absorb BVS /EES	3
ABSORB III[10]	2017	193	1322/686	RCT	SAP, UA, SMI	Absorb BVS /EES	3
ABSORB Japan[11]	2017	38	266/134	RCT	SAP, UA SMI	Absorb BVS /EES	3
AIDA[12]	2019	5	924/921	RCT	SAP, UA, SMI, STEMI, NSTEMI	Absorb BVS /EES	3
TROFI II[13]	2018	8	95/96	RCT	STEMI	Absorb BVS /EES	3

ACS = acute coronary syndrome, AMI = acute myocardial infarction, BVS = bioresorbable vascular scaffolds, DES = drug eluting stents, EES = everolimus-eluting stents, NSTEMI = non-ST-segment elevation myocardial infarction, RCT = randomized controlled trial, SAP = stable angina pectoris, SMI = silent myocardial ischemia, STEMI = ST-elevation myocardial infarction, UA = unstable angina.

Table 2

Baseline characteristics and procedural characteristics of included studies (presented as BVS vs DES).

	ABSORB China[9]	ABSORB II[5]	ABSORB III[10]	ABSORB Japan[11]	AIDA[12]	TROFI II[13]
Patients, n	235/232	335/166	1322/686	266/134	924/921	95/96
Age, yr	57.2/57.6	61.5/60.9	63.5/63.6	67.1/67.3	64.3/64.0	59.1/58.2
Male (%)	71.8/72.6	76/80	70.7/70.1	78.9/73.9	72.5/76.0	76.8/87.5
Diabetes (%)	25.2/23.2	24/24	31.5/32.7	36.1/35.8	18.5/16.6	18.9/14.7
Hypertension (%)	58.8/60.3	69/72	84.9/85.0	78.2/79.9	50.9/50.5	44.1/36.5
Dyslipidemia (%)	42.4/38.4	75/80	86.2/86.3	82/81.1	37.6/38.3	63.8/57.3
Previous MI (%)	16.8/16.0	28.0/29.0	21.5/22.0	16.0/23.9	18.0/18.7	2.1/3.1
Previous PCI (%)	9.7/8.0	12.0/9.0		3.4/5.2	21.9/20.0	4.2/3.1
Lesions, n	251/252	364/182	1385/713	275/137	1237/1209	95/98
Infarct-related artery						
LAD (%)	55.4/52.4	44.8/46.2	44.5/42.2	46.2/42.3	42.5/43.7	35.8/41.8
LCx (%)	19.5/24.2	29.1/23.1	26.2/30.6	22.9/26.3	24.0/26.3	17.9/13.3
RCA (%)	25.1/23.4	26.1/30.1	29.2/27.2	39.9/31.4	32.4/28.8	46.3/44.9
ACC/AHA B2/C (%)	74.9/72.1	46/49	68.7/72.5	76/75.9	55.0/51.0	NA
Bifurcation(%)	50.2/48.6	0/0	0/0	0/0	5.0/6.0	NA
Lesion length (mm)	14.1/13.9	13.8/13.8	12.6/13.1	13.5/13.3	19.1/18.8	12.9/13.4
Lesion length (mm)	2.81/2.82	2.6/2.6	2.67/2.65	2.72/2.79	NA	2.86/2.76
Pre-dilatation (%)	99.6/98.0	100/99.0	NA	100/100	96.9/91.2	55.8/51.0
Post-dilatation (%)	63.0/54.4	60.7/58.8	65.5/51.2	82.2/77.4	74.0/49.1	50.5/25.5
OCT/IVUS guidance (%)	0.4/0.4	100/100	11.2/10.8	68.8/68.7	NA	NA
Stent diameter (mm)	3.1/3.1	3.01/3.01	3.18/3.12	3.09/3.13	2.73/2.88	3.25/3.12
Stent length (mm)	22.8/22.3	21.1/20.9	20.5/20.7	20.3/19.5	31.1/29.7	20.6/20.7

BVS = bioresorbable vascular scaffolds, DES = drug eluting stents, IVUS = intra-vascular ultrasound, LAD = left anterior descending artery, LCx = left circumflex artery, MI = myocardial infarction, NA = not available, OCT = optical coherence tomography, PCI = percutaneous coronary intervention, RCA = right coronary artery.

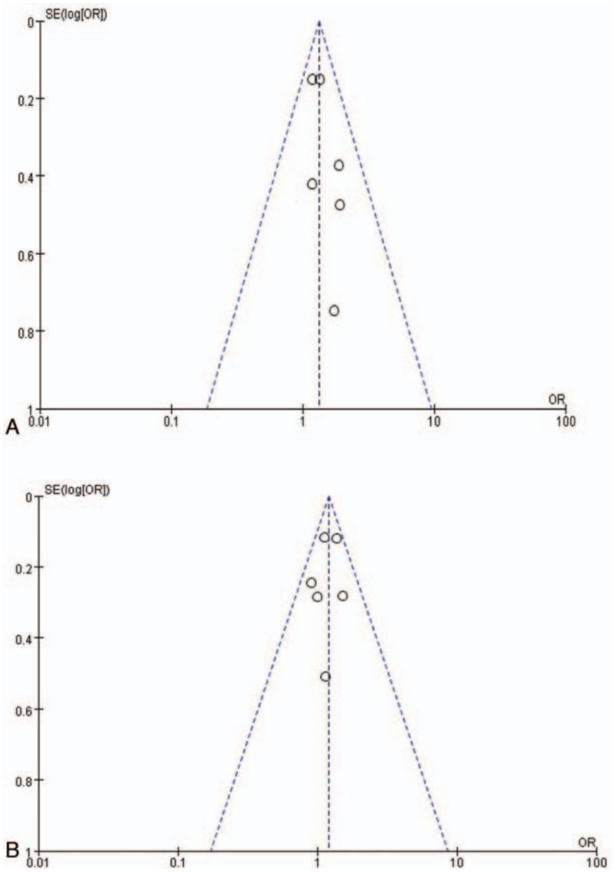

Figure 1. Funnel plot analysis for TLF(A), definite/probable ST(B). ST = stent/scaffold thrombosis, TLF = target lesion revascularization. Meta-analysis flowchart. Flow diagram demonstrating the studies selection process for this meta-analysis.

3.3. Clinical outcomes

3.3.1. TLF. The collected studies [5,9–13] were compared for TLF between the BVS group and the DES group. The rates of the TLF were higher with BVS compared with DES (2.7% vs 0.7%, OR = 1.33, 95% CI: 1.10–1.60, $P = .003$, Fig. 2A).

3.3.2. Definite/probable ST. All studies [5,9–13] reported definite/probable ST. Patients treated with BVS had a significantly higher risk of definite/probable ST compared with those receiving DES (2.7% vs 0.7%, $OR = 3.75$, 95% CI: 2.22–6.35, $P < .00001$, Fig. 2B).

3.3.3. Ischemia-driven target lesion revascularization. Six studies [5,9–13] compared ischemia-driven target lesion revascularization between the BVS and the DES groups. The ischemia-driven target lesion revascularization occurred more commonly with BVS than DES (6.6% vs 4.7%; OR = 1.46, 95% CI: 1.14–1.86, $P = .003$, Fig. 2C).

3.3.4. Target vessel MI. Target vessel MI was reported by 6 studies[5,9–13] included in the analysis and was greater with BVS compared with DES(6.8% vs 3.9%, OR = 1.68, 95% CI: 1.30–2.17, $P < .0001$, Fig. 2D).

3.3.5. Patient-oriented composite end point. All studies [5, 9–13] reported incidence of POCE. The rates of the patient-oriented composite end point were higher with BVS compared with DES (20.3% vs17.2%, OR = 1.20, 95% CI: 1.04–1.39, $P = .01$, Fig. 2E).

3.3.6. Cardiac death. Cardiac death was also reported by all studies [5, 9–13] included in the analysis and was similar in both groups. (1.5% vs 1.7%, OR = 0.94, 95% CI: 0.61–1.45, $P = .79$, Fig. 2F).

4. Discussion

In this comprehensive meta-analysis of 6 high-quality trials of 5,392 patients with coronary artery disease who underwent PCI,

Table 3

Assessment of risk of bias for randomized controlled trials.

Trial	Random sequence generation	Allocation concealment	Blinding of participants	Blinding of outcome assessment	Incomplete outcome data	Selective outcome reporting
ABSORB China	IWRS	Yes	Yes (independent CEC)	Yes	Yes	No
ABSORB II	IWRS	Yes	Yes (independent CEC)	Yes	Yes	No
ABSORB III	IWRS	Yes	Yes (independent CEC)	Yes	Yes	No
ABSORB Japan	IWRS	Yes	Yes (independent CEC)	Yes	Yes	No
AIDA	IWRS	Yes	Yes (independent CEC)	Yes	Yes	No
TROFI II	IWRS	Yes	Yes (independent CEC)	Yes	Yes	No

CEC = clinical event committee, IWRS = interactive web-based response system.

we demonstrated that BVS was associated with an increased risk of TLF and ST at 3 years of follow-up, relative to DES. There was a higher risk of ischemia-driven target lesion revascularization, target vessel MI, and patient-oriented composite end point for patients treated with BVS, compared with DES. However, the risk of cardiac death was similar in both groups. Previous meta-analyses have similarly found that BVS is associated with increased rates of TLF and ST cumulatively at 2 years and between 1 and 2 years of follow-up, compared with second-generation DES.[14,15] Generally, the use of BVS appears to be associated with both lower efficacy and lower safety over time. In the ABSORB III trial, the rate of adverse events was increased at the 5-year follow-up in patients treated with BVS, relative to DES. However, between 3 and 5 years, there was a significant reduction in annualized adverse event rates and relative rates in patients treated with BVS, relative to DES.[16] The BVS completes the reabsorption process within 3 years after PCI. Therefore, it is important to improve the clinical outcome before the BVS is completely absorbed.

BVS are inferior to second-generation DES in terms of safety and effectiveness, potentially due to factors at every stage of the production and implementation of BVS, i.e., ranging from device design to procedural specifics and vascular properties at the site of implantation.[17,18] Compared with DES, BVS have thicker struts, lower tensile strength and stiffness, lower mechanical strength, and lower ductility.[19]The thick struts lead to greater protrusion and turbulent flow, delayed reendothelialization, and unfavorable dismantling during the resorption process.[20] Given their nature, in order to avoid strut rupture or abnormal decomposition, BVS require accurate lesion identification and placement, judicious patient selection, and experienced implantation technique. In other words, implantation strategies are of crucial importance for clinical outcomes. The PSP (Pre-dilatation, Sizing, Post-dilatation) strategy is currently used to optimize stent placement, including proper lesion preparation, accurate vessel sizing, and mandatory high-pressure post-dilation.[21] We observed a strong relationship between vessel size and adverse events. The 3-year follow-up results of the ABSORB China trial found no significant difference between the BVS and DES groups in terms of TLF (5.5% vs 4.7%, $P = .71$) or stent thrombosis (0.8% vs 0%, $P = .16$).[9] Such a good clinical outcome is related to the relatively low proportion of small vessels (< 2.25 mm) in the patients included in the study.[9] In the study by Sabato et al, which carried out BVS deployment at 12 atmospheres of pressure

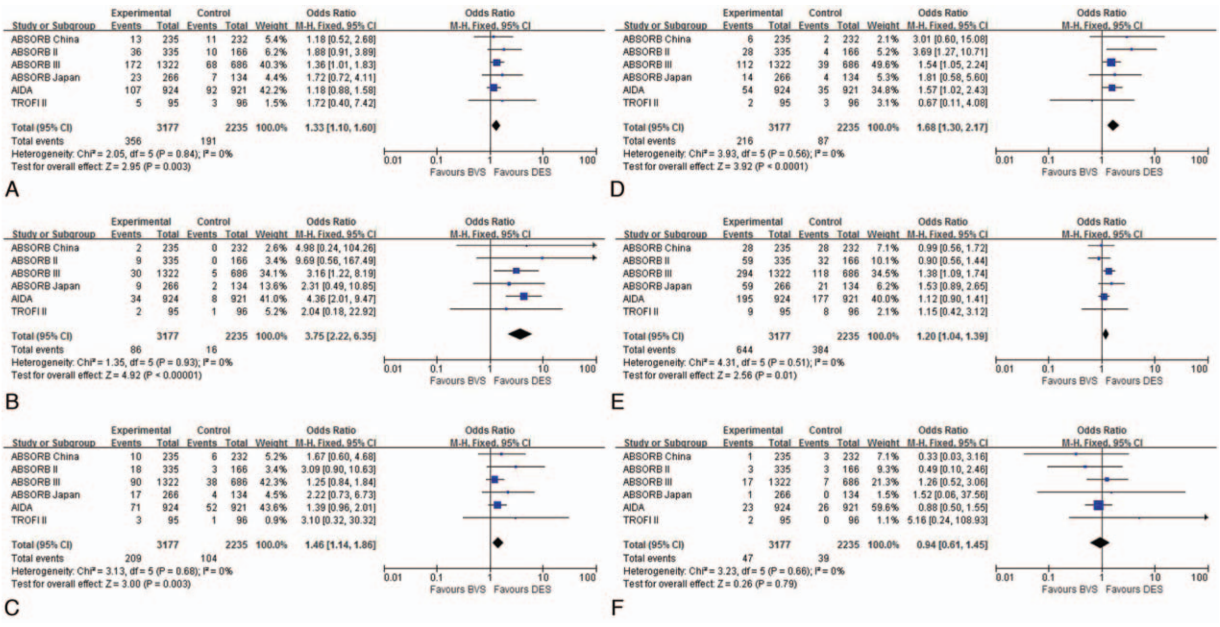

Figure 2. Forest plots for the clinical endpoint. TLF(A), definite/probable ST(B), Ischemia-driven target lesion revascularization (C), Target vessel myocardial infarction (D), Patient-oriented composite end point (E), cardiac death(F). BVS = bioresorbable vascular scaffolds, DES = drug-eluting stents, ST = stent/scaffold thrombosis, TLF = target lesion failure.

(ATM) the balloon was first rapidly deflated, then inflated again and maintained at 12 ATM for 30 seconds. Subsequent quantitative coronary angiography confirmed significant increases in the minimal luminal diameter-to-reference scaffold diameter ratio from 0.70 ± 0.10 after initial stent deployment to 0.79 ± 0.10 after the 30-second balloon dilation ($P < .001$).[22] In contrast, the proportion of patients that received post-expansion in the ABSORBII study was relatively low (only 61%),which was closely related to the high thrombosis rate (3%) at the 3-year follow-up.[5] The application of PSP technology was Emphasized in the study of ABSORB IV. At 1-year follow-up, the target vessel failure of BVS was 7.8%, which was not statistically different from the new-generation DES(6.4%, $P > .05$), and there was no statistical difference in stent thrombosis (BVS 0.7% vs the XIENCE stent 0.3% $P > .05$).[23] In addition, the use of optical coherence tomography to guide BVS placement allows microscopic observation of the diseased vessels and better implantation of the stent. The use of optical coherence tomography allows the physician to accurately assess the condition of the stent and vessels after implantation, reducing the occurrence of adverse events.[24]

After stent implantation, procedural disintegration of the polymeric scaffold struts occurs, potentially leading to stent discontinuity and subsequent adverse events if not adequately constrained by neointima.[25] Further, BVS can cause an inflammatory reaction during polymer degradation, which may be 1 of the causes of delayed adverse events.[26] The use of DAPT is important for the prevention of ST after coronary stent implantation. In a study by Collet et al, 92% of the cases of very late ScT occurred in patients that were not on DAPT at the time of the event.[27] Prolongation of DAPT, especially during the active bioresorption phase, may represent an effective strategy to reduce the risk of device-related thrombosis and MI.[28] Published reviews recommend that patients with BVS be put on DAPT for at least 12 months and that prasugrel or ticagrelor is superior to clopidogrel after BVS implantation.[29,30]

In summary, several design- and procedure-based changes will be necessary to optimize outcomes for patients treated with BVS. Specifically, reducing the strut thickness of the scaffold, exploring new materials with superior mechanical properties and faster degradation, and developing an improved implant technique may increase the long-term advantages of BVS.

Data from RCTs[5,6] and meta-analyses[31,32] of other study types with long durations of follow-up have shown that BVS is associated with a higher incidence of TLF and scaffold thrombosis. On the basis of these findings, the FDA has restricted the use of BVS to clinical trials/registries, and the devices are no longer manufactured. However, the exploration of improved bioresorbable scaffolds is an ongoing field of study. The new generation of BVS has a smaller strut size, faster absorption process, and superior mechanical properties. Some of the newer BVS have also shown encouraging results in clinical trials. Impressively, in the BIOSOLVE-II study, at 24 months of follow-up, DREAMS 2G BVS had 0% ScT and 3.4% of target lesion revascularization.[33]

BVS represents a revolutionary concept in interventional cardiology and has the potential to induce the anatomical and functional restoration of the vasculature after coronary revascularization. Despite current technical challenges, the considerable clinical potential of BVS means that it will likely be a topic of significant interest in the cardiovascular field for years to come.

4.1. Limitations

This study had several key limitations. First, even though the present analysis only included high quality, randomized studies, there may still be potential sources of bias. Second, no detailed subgroup analysis was made on stable angina pectoris and acute coronary syndrome to clarify the comparison of the 2 outcomes in different types of CAD. Third, routine intracoronary imaging was not necessary in the included studies. Therefore, it is not possible to distinguish between successful and unsuccessful device implantations. Finally, only 1 type of bioresorbable scaffold was evaluated in this study, and the results of this meta-analysis cannot be generalized to all types of bioresorbable scaffolds.

5. Conclusions

BVS were associated with worse long-term clinical outcomes compared with DES in patients with CAD in the studies included in this analysis. The clinical results from these high-quality RCTs will provide valuable a reference for shaping the next generation of bioabsorbable scaffolds in terms of product design, material application, and implantation technology.

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