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Comparison of the biodegradable polymer everolimus-eluting stent with contemporary drug-eluting stents: A systematic review and meta-analysis

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ABSTRACT

Aims: Despite similar efficacy and safety profile in pilot studies, bioresorbable polymer drug-eluting stents (BP-DES) could have potential benefit over latest generation durable polymer (DP)-DES by facilitating vessel healing, therefore reducing inflammation and neoatherosclerosis leading to enhanced clinical safety. Therefore, we sought to perform a meta-analysis of randomized clinical trials (RCTs) comparing the safety and efficacy of everolimus-eluting BP-DES (BP-EES) to second-generation DP-DES.

Methods and results: We conducted a systematic review and meta-analysis to examine the safety and efficacy of BP-EES in patients treated for coronary artery disease. We searched PubMed, Scopus, and the Cochrane Library through February 2018 for RCTs that included outcome data on BP-EES. We identified four eligible studies, which included a total of 4631 patients. Three studies reported a follow-up of one year and one study of five years. The BP-EES group, included 2315 patients and the DP-DES group included 2316 patients (1143 treated with DP-EES and 1173 treated with zotarolimus eluting DP-DES). Patient's characteristics were comparable between the two groups except for higher prevalence of prior MI in the DP-DES group (25.7 vs 22.5%, respectively, $p = 0.001$). Procedural characteristics were comparable among groups except for slightly longer lesions in the BP-EES group compared to the DP-DES group (mean 15.1 vs 14.9 mm, $p = 0.04$). No significant differences were observed for cardiac mortality ($p = 0.72$), occurrence of MI ($p = 0.64$), any TLR ($p = 0.93$), ST ($p = 0.85$) or major adverse cardiac events ($p = 0.43$).

Conclusion: Overall, based on the available data BP-EES had similar one-year outcomes to contemporary DP-DES. Whether these devices could enhance clinical safety remains to be evaluated at longer follow-up.

1. Introduction

The implantation of a drug-eluting stent (DES) is now considered the standard approach for percutaneous coronary intervention (PCI) [1]. While the addition of a drug-eluting polymer to the coronary stent marked a major advance in reducing restenosis, the lifelong presence of a durable polymer (DP) in a coronary artery induces vessel wall inflammation, delayed arterial healing, and occasionally cause serious complications such as stent thrombosis (ST) and myocardial infarction (MI) [2]. These drawbacks motivated the development of stents with biodegradable coatings that leave only a bare metal stent after polymer resorption and raise the obvious question of whether development

Abbreviations: BP, biodegradable polymer; DES, drug-eluting stent; DP, durable polymer; EES, everolimus-eluting stent; MI, myocardial infarction; PCI, percutaneous coronary intervention; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; PtCr, platinum chromium; ST, stent thrombosis; ZES, zotarolimus-eluting stent.

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of biodegradable-polymer drug-eluting stents (BP-DES) will improve outcomes [2]. Metal alloy coronary stent platforms with biodegradable polymers are associated with comparable clinical outcomes when compared with newer DP-DES [3,4]. The possible influence of additional factors, including polymer composition and stent strut thickness [5], have been topics of debate [6]. It is important to note that there is significant variability in the strut thickness of available BP-DES, which may partly account for the failure of BP-DES to demonstrate superiority over DP-DES. Today, novel biodegradable polymer stents are available with uncoated struts and up to half as thick as the struts of the first generation BP-DES [2]. The Synergy™ stent (Boston Scientific Corporation) is a thin-strut (74-79 μm) platinum chromium (PtCr) metal alloy stent that elutes everolimus from a bioabsorbable poly(D,L-lactide-*co*-glycolide) polymer only applied to the abluminal surface (BP-EES) [7].

The results of the recently published EVOLVE II trial [8] are encouraging and suggest that PCI with BP-EES or with DP-DES (Promus™, Boston Scientific Corporation) results in similar outcome. We sought to investigate the efficacy of this BP-EES in the present meta-analysis of randomized controlled trials (RCTs) comparing clinical outcomes of patients treated with BP-EES compared to latest generation DP-DES.

2. Methods

2.1. Search methods

MEDLINE, Scopus, and the Cochrane Library database were systematically searched for manuscripts through February 2018. Articles were recorded by using the following search strategy: "Synergy" OR "everolimus" AND "stent" AND "bioabsorbable polymer" OR "bioresorbable polymer" OR "biodegradable polymer". The systematic review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement [9]. We limited our search to articles published in English. Reference lists of the original papers were retrieved and meticulously hand-searched to identify other relevant studies. This study is registered with PROSPERO, number CRD42018088511.

We limited our data to studies on the Synergy™ stent (Boston Scientific Corporation). We included all RCTs which: 1) examined the use of BP-EES in adult humans, 2) were compared to a durable-polymer DES and, 3) reported on at least one of the following safety and efficacy outcomes: vessel restenosis, ST, target-lesion revascularization (TLR), myocardial infarction (MI), cardiac death, all-cause mortality, and major adverse cardiac events (MACE) or device oriented clinical endpoints (DOCE). Inclusion was restricted to studies published in English. In cases of duplicate publications, the most recent one including the outcomes of interest was selected. We excluded non-randomized studies, animal studies, letters to the editor, editorials, poster or oral presentations, reviews, and studies that did not examine BP-EES as an intervention. Relevant abstracts from conference proceedings were included to provide interim results from ongoing investigations.

2.2. Data extraction

Two investigators (FP and MP) independently reviewed the studies and reported the results in a structured database. Disagreements between the investigators regarding the inclusion of each trial were resolved by consensus by a third independent investigator (OV). Pre-specified data were extracted from each study including: study design and period, demographic and clinical characteristics of the study population, and duration of the follow-up. Outcomes of interest including cardiac death, MI, TLR, TLF, ST, all-cause mortality, vessel restenosis, and MACE, were extracted as counts and percentages and recorded according the intention-to-treat principle. The quality of the studies included in the present analysis was assessed according to the National Heart, Lung, and Blood Institute (NHLBI) quality assessment tool (https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools).

2.3. Data synthesis and analysis

Baseline risk factors and outcomes are reported as pooled proportions or mean differences with 95% confidence intervals (CI). The average effects for the outcomes (odd ratios, ORs) and 95% confidence intervals (CIs) were calculated by using a random-effects method [8]. Heterogeneity among trials were estimated with I^2 statistics ($I^2 > 40\%$ indicating

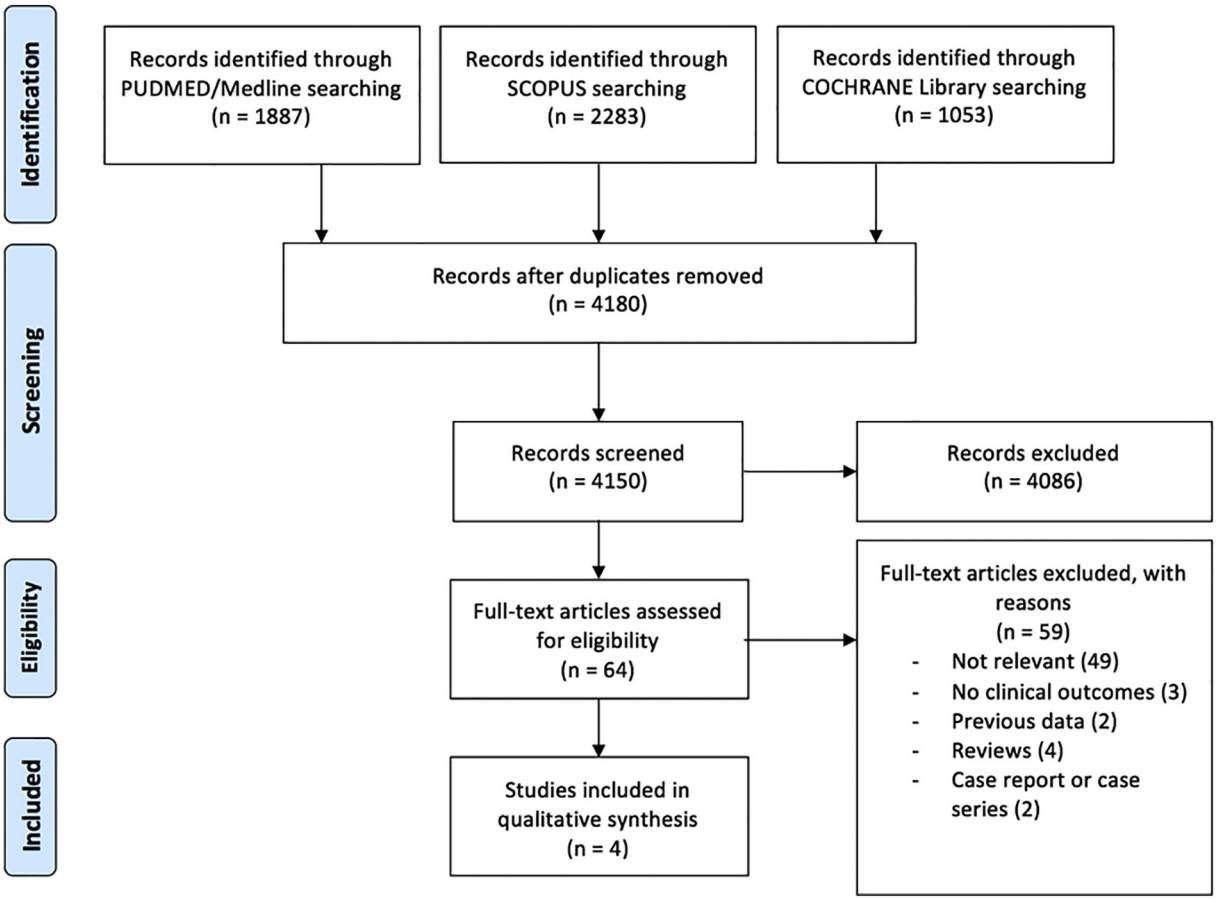

Fig. 1. Study flowchart which illustrates the study selection process in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.

Table 1
Patients and procedural characteristics.

Baseline characteristics	No. of studies	BP-EES	DP-DES	Random-effects estimates	*p*-Value	I^2
Age, years	4	61.7 (57.8–65.6)	61.9 (59.6–64.3)	−0.39, −2.15-1.37	0.67	85%
Male	4	71.4 (0.70–0.73)	72.8 (70.9–64.6)	0.94, 0.83–1.07	0.33	0%
Smoking habit	3	37.5 (12.1–63.0)	40.3 (15.4–65.2)	0.93, 0.82–1.06	0.34	0%
Diabetes	4	22.6 (14.4–30.8)	23.5 (15.9–31.1)	0.98, 0.86–1.13	0.84	0%
Hypertension	4	60.9 (41.2–80.7)	61.3 (0.44–0.78)	1.01, 83.5–1.21	0.98	41%
Dyslipidaemia	4	51.0 (26.1–76.0)	51.7 (27.2–76.1)	0.94, 0.83–1.07	0.36	0%
Prior CABG or PCI	4	30.1 (20.2–40.0)	30.1 (18.4–41.8)	0.98, 0.86–1.11	0.72	0%
Prior myocardial infarction	4	22.5 (16.0–29.0)	25.7 (20.0–31.4)	**0.80, 0.69–0.92**	**0.001**	0%
Unstable angina	4	25.5 (16.3–54.8)	36.0 (17.6–54.3)	0.93, 0.81–1.06	0.26	0%
Treated vessels						
LAD	4	46.9 (39.8–54.0)	47.0 (40.5–53.7)	1.03 (0.92–1.16)	0.45	0%
Cx	4	28.0 (21.7–34.2)	29.1 (24.1–34.0)	0.91 (0.75–1.10)	0.18	40%
RCA	4	37.2 (30.9–43.4)	34.0 (24.7–43.4)	1.07 (0.89–1.28)	0.15	43%
Left main	4	0.7 (0.0–1.6)	0.8 (0.0–1.7)	0.87 (0.51–1.48)	0.95	0%
Reference vessel diameter, mm	4	2.7 (2.6–2.8)	2.7 (2.6–2.8)	0.01 (−0.03–0.04)	0.76	0%
Minimal lumen diameter, mm	4	0.8 (0.7–0.9)	0.8 (0.6–0.9)	0.0 (−0.02–0.02)	0.99	38%
Total lesion length, mm	4	15.1 (14.0–16.2)	14.9 (14.0–15.8)	**0.5 (0.0–0.9)**	**0.04**	35%
Stenosis diameter	3	71.4 (65.3–77.5)	70.8 (65.9–75.8)	0.7 (−0.5–1.8)	0.29	68%
Stent length, mm	3	27.3 (18.6–36.0)	27.3 (17.7–36.9)	−0.02 (−0.92–0.87)	0.96	64%

Bold values showing statistical significant difference.
Values are proportions, mean differences or odds ratios with 95% confidence intervals (in parentheses). BP-EES, biodegradable polymer everolimus-eluting stent; DP-DES, durable polymer drug-eluting stent; CI, confidence interval; CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention; LAD, left anterior descending artery; Cx, circumflex artery; RCA, right coronary artery.

substantial heterogeneity). Funnel plots were used to test for small study effects. Statistical significance for hypothesis testing was set at the 0.05 level. Statistical analysis was performed using Reviewer Manager version 5.3 (The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) and Open Meta-analyst (http://www.cebm.brown.edu/openmeta/, accessed on March 4th, 2018) statistical softwares.

3. Results

3.1. Search results

Our search identified a total of 4180 potentially relevant publications. Following our exclusion criteria, 64 publications were retrieved and evaluated for eligibility. A total of 4 RCTs met our inclusion criteria [7,8,10,11]. We used the published data with the longest available follow-up. Our study flowchart summarizing the study selection process in accordance with the PRISMA Statement is shown on Fig. 1.

These four RCTs were of good quality (Suppl. Table 1) according to the NHLBI criteria and included a total of 4631 patients. Among these patients, 2315 were randomized to receive a BP-EES, and 2316 patients to receive a DP-DES (DP-EES (n = 1143) and DP-zotarolimus eluting stent (ZES), n = 1173). The characteristics of these RCTs are presented in Supplemental Tables 1 and 2.

3.2. Patients and procedural characteristics

Baseline patient's characteristics are reported in Table 1. There was no difference in age (pooled mean, 61.7 vs 61.9 years, $p = 0.67$), male sex (71.4 vs 72.8%, $p = 0.33$), smoking habit (37.5 vs 40.3%, $p = 0.34$), diabetes (22.6 vs 23.5%, $p = 0.84$), hypertension (60.9 vs 61.3%, $p = 0.98$) or dyslipidaemia (51.0 vs 51.7%, $p = 0.36$). Patients who received DP-DES had a higher prevalence of prior MI (25.7 vs 22.5%, $p = 0.001$) compared to BP-EES.

Procedural characteristics are presented in Table 1. There was no difference among treated vessels (46.9 vs 47%, $p = 0.45$ were treated on the left anterior descending artery; 28.0 vs 29.1%, $p = 0.18$ on the left circumflex artery; 37.2 vs 34%, $p = 0.15$ on the right coronary artery; and 0.7 vs 0.8%, $p = 0.95$ on the left main coronary artery). Reference vessel diameter, minimal lumen diameter, stenosis diameter and stent length were similar among the study groups, whereas in BP-EES group the treated lesions were slightly longer (pooled mean, 15.1 vs 14.9 mm, $p = 0.04$).

3.3. BP-EES vs. DP-DES on efficacy outcomes

Study-level outcomes at longest available follow-up for MACE, the individual components of MACE, TLR, and ST are summarized in

Table 2
Pooled outcomes.

Outcomes	No. of studies	BP-EES	DP-DES	Odds ratio (95%-CI)	*p*-Value	I^2
All-cause death	4	1.4 (0.6–2.2)	1.1 (0.6–1.6)	1.18 (0.71–1.97)	0.52	2%
Cardiac death	4	0.6 (0.3–0.9)	0.7 (0.3–1.0)	0.88 (0.44–1.77)	0.72	0%
Myocardial infarction	4	3.3 (1.5–5.1)	2.8 (1.4–4.2)	1.02, (0.74–1.42)	0.64	0%
TLR	4	1.8 (1.2–2.4)	1.8 (1.0–2.6)	0.97 (0.53–1.79)	0.93	36%
TVR	4	2.7 (1.6–3.8)	3.6 (2.1–5.1)	0.77 (0.50–1.19)	0.25	26%
Non-TLR TVR	3	1.3 (0.2–2.3)	2.1 (0.1–3.1)	0.70 (0.38–1.30)	0.60	0%
Stent thrombosis	4	0.4 (0.1–0.6)	0.5 (0.2–0.8)	0.68 (0.28–1.65)	0.85	0%
TVF	4	5.5 (4.1–5.9)	6.1 (4.8–7.3)	0.90 (0.71–1.16)	0.78	0%
TLF	3	4.2 (3.2–5.3)	4.6 (3.3–5.7)	0.90 (0.63–1.28)	0.95	0%
MACE	4	7.0 (4.4–9.6)	6.2 (4.5–7.8)	1.10 (0.87–1.39)	0.43	0%

Values are proportions or odds ratios with 95% confidence intervals (in parentheses). BP-EES, biodegradable polymer everolimus-eluting stent; DP-DES, durable polymer drug-eluting stent; CI, confidence interval; TLR, target lesion revascularization; TVR, target vessel revascularization; TVF, target vessel failure; TLF, target lesion failure; MACE, major adverse cardiac event.

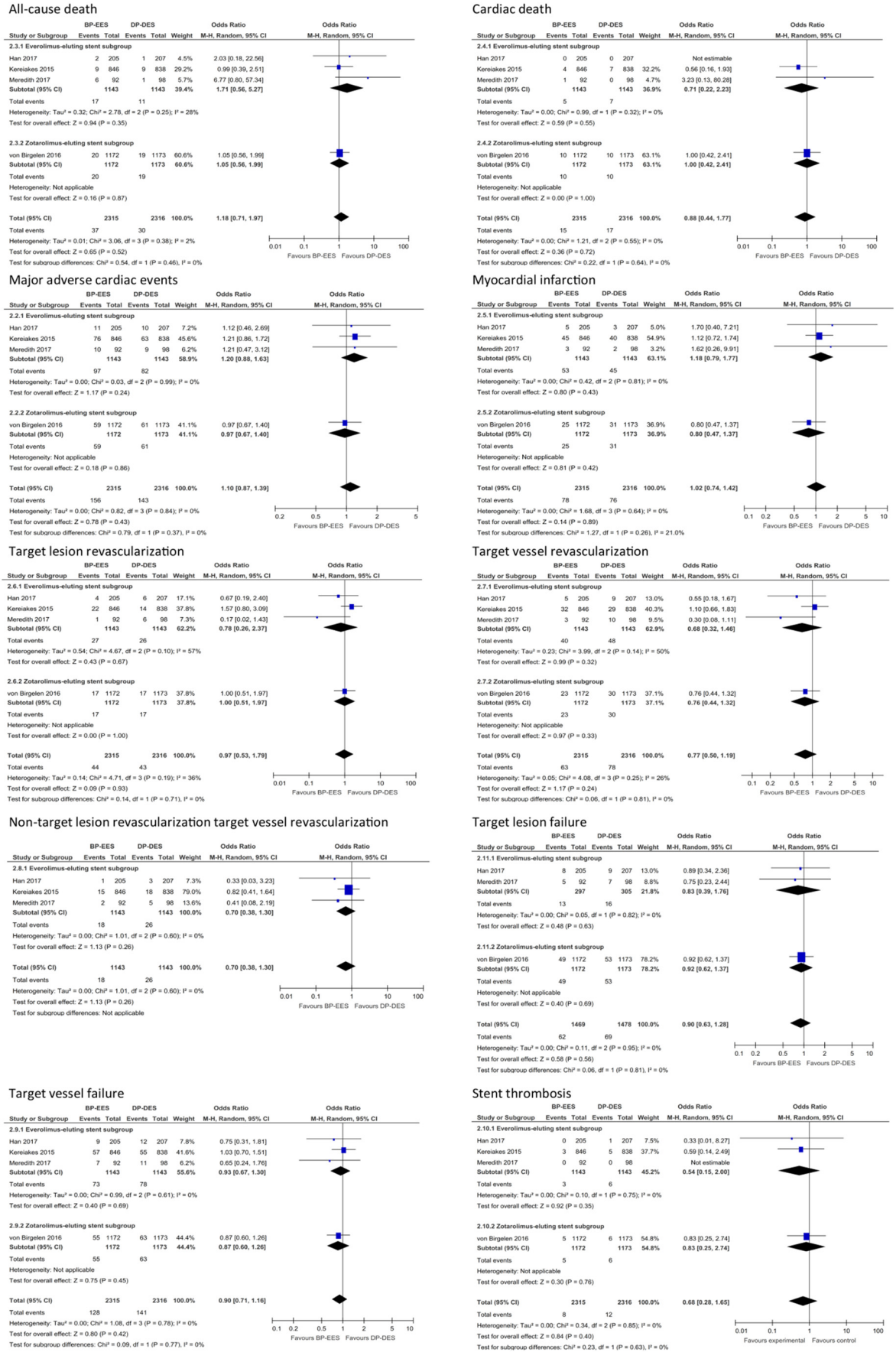

Fig. 2. Forest plots comparing the outcomes of patients undergoing biodegradable polymer everolimus-eluting stent (BP-EES) or durable polymer drug-eluting stents (DP-DES). The forest plots are presented by subgrouping the trials according to their comparator stent.

Table 2 and Fig. 2. Three studies reported a follow-up of one year and one study of five years.

MACE occurred in 7.0% of the patients treated with BP-EES and in 6.2% of the patients treated with DP-EES (OR 1.10, 95%-CI: 0.87–1.39, $p = 0.43$; heterogeneity: $I^2 = 0\%$).

The rate of cardiac death and TLR were also similar for patients treated with BP-EES and DP-DES (OR 0.88, 95%-CI 0.44–1.77, $p = 0.72$ and OR 0.97, 95%-CI 0.53–1.79, $p = 0.93$, respectively).

3.4. BP-EES vs DP-DES on safety outcomes

During the follow-up, the rate of definite-or-probable stent thrombosis was similar among both groups (0.4% vs. 0.5%; OR 0.68, 95%-CI: 0.28–1.65, $p = 0.85$; heterogeneity: $I^2 = 0$). In addition, target lesion failure and MI were also similar among groups (4.2% vs 4.6%; OR 0.90, 95%-CI: 0.63–1.28, $p = 0.95$; heterogeneity: $I^2 = 0\%$ and 3.3% vs. 2.8%; OR 1.02, 95%-CI: 0.74–1.42, $p = 0.64$; heterogeneity: $I^2 = 0\%$, respectively). There was no difference in dual antiplatelet therapy duration between BP-EES and DP-DES groups in these studies.

4. Discussion

This meta-analysis showed no significant differences in clinical outcomes at one-year follow-up in patients treated with BP-EES or DP-DES. While there was a numerical reduction in definite or probable ST with BP-EES, this was not statistically significant, with low rates in both groups. There was also no difference in cardiac death, MI, TLR and TLF when comparing the BP-EES with all DP-DES. There was a numerically higher rate of MACE in the BP-EES group, non-significant either.

Interestingly, there was a trend for less TVR associated with BP-EES in the EVOLVE study [7], while the present meta-analysis of all available RCTs did not show any significant difference among BP-EES and DP-DES. These data, while not demonstrating superiority of BP-EES, suggest that the BP-EES is comparable to contemporary, widely used DP-DES. Furthermore, given the concerns regarding scaffold thrombosis seen with the Absorb™ (Abbott Vascular) bioresorbable vascular scaffold [12], this data does not raise safety concerns for the BP-EES. Indeed, whether metal alloy coronary stent platforms with BP are associated with improved clinical outcomes when compared with newer DP-DES has been a topic of debate [6] and may be influenced by additional factors, including polymer composition and stent strut thickness [5]. It is important to note that there is significant variability in the strut thickness of available BP-DES, which may account for the failure of BP-DES to demonstrate improvement over DP-DES [13]. Today, some new drug coated stents are available with uncoated struts and up to half as thick as the struts of the early BP-DES [2]. In addition, the benefits of thin struts and BP are appealing and may be very useful in certain clinical scenarios, such as in-stent restenosis or small-vessel PCI. However, the push toward reduction in strut thickness must be tempered against the need to maintain adequate radial support to prevent late lumen loss. Thin struts may reduce the incidence of side branch closure and periprocedural MI.

The present meta-analysis is unable to provide information on the potential benefits of bioresorbable versus durable polymers on the reduction of late/very late stent thrombosis. Indeed, three-out-of four of the trials included in the study present a follow-up limited to one-year post implantation. Therefore, based on our results no inference can be made on the theoretical advantage of this platform at long-term. Early RCTs as well as meta-analyses suggested that BP-DES were associated with lower rates of late/very late stent thrombosis when compared with either first generation DES or bare metal stents [13]. Conversely, more recent network meta-analyses and observational studies have suggested that the newer generation cobalt chromium (CoCr) and PtCr durable polymer (polyvinylidene fluoride) EES are associated with even lower rates of ST when compared with other durable polymer DES, early biodegradable polymer DES, and bare metal stents [6,14]. Finally, a large-scale RCT comparison of the CoCr EES versus the Nobori™ (Terumo) BP-DES demonstrated similar long-term outcomes for both stents [15]. These apparent inconsistencies may be partially explained by differences in BP-DES platform design. Both the time course and extent of endothelial stent coverage, as well as the function and maturation of endothelial cells may be influenced by multiple factors, including metal alloy, stent strut thickness, polymer composition, distribution and the time course for polymer bioresorption [5,16]. These aspects highlight the importance of performing device specific rather than stent class analyses.

There are several limitations related to this study. The present meta-analysis is limited to few studies, matching the inclusion/exclusion criteria, which present a considerable difference in size. Therefore, the results of the present work are most likely driven by the EVOLVE and BIORESORT trials. While a patient-level meta-analysis could allow a more accurate comparison, our data are limited to a study-level comparison. Another limitation is the lack of raw or uniform data. Our study demonstrated very low heterogeneity when comparing clinical outcomes among different trials with the use of random-effects pooling. As we included only RCTs and utilized all available study data, the likelihood of publication bias appears to be low. While a large number of patients ($n = 4631$) were included in this meta-analysis, the sample size may still be too small to assess minor differences in the occurrence of rare adverse events such as ST. This study does not provide long-term data while DP-DES already has available long-term clinical data. The BP-EES technology is still relatively new. The majority (3/4) of the randomized trials included in the present study collected outcome data at 12 months from the index procedure and only one characterized by a small population (190 patients) provides data at a longer follow-up (five years). Therefore, the results of the present meta-analysis as to be interpret with caution, underlying the need for a longer follow-up to assess the long-term safety and efficacy of BP-EES beyond the first year after treatment.

5. Conclusion

In conclusion, BP-EES has similar clinical outcomes compared with the latest generation DP-DES at one year follow-up. These results support the safety of the BP-EES in patients undergoing PCI. Further studies, with long-term results are warranted to evaluate whether a reduction in ST could be observed.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2018.11.113.

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