SYSTEMATIC REVIEW

Comparative efficacy of drug-eluting balloon and drug-eluting stent for treatment of in-stent restenosis: a systematic review and meta-analysis

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Abstract

Objective: To compare the efficacy of drug-eluting stents and drug-eluting balloons in treating in-stent restenosis.

Method: The systematic review was conducted from January to February 2022, and comprised literature search on PubMed, ProQuest, Cochrane Library and Google Scholar databases with relevant key words to locate randomised controlled trials and observational studies published between 2000 and 2022 that compared drug-eluting balloons and drug-eluting stents in the treatment of in-stent restenosis. The outcomes were all-cause death, cardiovascular death, major adverse cardiovascular events, myocardial infarction, stent thrombosis, stroke and target vessel revascularisation. The pooled risk ratio for each outcome was analysed. Data was analysed using Review Manager 5.1.

Results: Of the 1,105 studies identified, 11(0.99%) were analysed in detail; 7(63.6%) randomised controlled trials and 4(36.4%) observational studies. There were 2,437 patients with in-stent restenosis. There was no significant difference between drug-eluting balloons and drug-eluting stents with respect to all-cause death, cardiovascular death, stroke, stent thrombosis, myocardial infarction and major adverse cardiovascular events (p>0.05). Drug-eluting stents significantly caused more target vessel revascularisation compared to drug-eluting balloons (p=0.004).

Conclusions: Except for target vessel revascularisation, the drug-eluting balloons and drug-eluting stents had no difference in terms of clinical outcomes related to in-stent restenosis patients.

Key Words: Eluting stents, Coronary restenosis, Myocardial infarction, Thrombosis.

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Introduction

One of the biggest problems with percutaneous coronary intervention (PCI) has been in-stent restenosis (ISR). Injury to the endothelium and the vessel wall due to barotrauma may result in PCI. Inflammatory response due to vascular injury will increase in circulating biomarkers, such as fibrinogen, amyloid A, and C-reactive protein (CRP).[1] In the period of bare metal stents (BMSs), ISR lesions were mainly accountable for 10.6% of all PCIs. There is some controversy regarding the effectiveness of drug-eluting stents (DES) and drug-eluting balloons (DEB) in managing ISR.[1,2]

One of the causes of restenosis following stent implantation that DES has significantly reduced is neointimal proliferation.[3] European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS) recommend repeat revascularisation for patients with ISR plus symptoms of myocardial ischaemia. In this recommendation, coronary intervention with DES implantation and DEB angioplasty are considered equivalent therapies.[4] Even with DES techniques, ISR and stent thrombosis are still the main problems. A DEB technique is currently the alternative treatment for this condition.[5]

In the treatment of ISR, prior research has demonstrated that second-generation DES and DEB provide the best clinical and angiographic results in patients with ISR.[5] Nevertheless, DEB and DES have been the issue of a lot of research examining their effectiveness and safety, but the results are still unclear. The current systematic review and meta-analysis was planned to compare the efficacy of DES and DEB in treating ISR.

Materials and Methods

The systematic review comprised literature search in January and February 2022 on PubMed, ProQuest, Cochrane Library and Google Scholar databases to locate randomised controlled trials (RCTs) and observational studies published between 2000 and 2022 that compared DEB and DES technique in the treatment of ISR. The review was registered with the international prospective

register of systematic reviews (PROSPERO) with registration number CRD42023453061 (https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=453061). Two investigators searched articles using key words "in-stent restenosis," "drug-eluting balloons," and "drug-eluting stents".

Major adverse cardiovascular events (MACE), total vessel revascularisation (TVR), cardiovascular mortality, thrombosis of the stent, all-cause mortality, myocardial infarction (MI) and stroke were the targetted variables.

Two researchers independently extracted the data. Disagreements between the researchers were settled through discussion mediated by a third researcher. Data, including the name of the corresponding author, publication year, study design, major endpoints, and the number of patients, was gathered for each study, and documented using Excel spreadsheet.

Each endpoint's treatment effect was represented by a pooled risk ratio (RR) and 95% confidence interval (CI). In order to examine heterogeneity, I2 statistic was calculated. A random effect model was used. All analyses were performed using Review Manager 5.1.

Results

Of the 1,105 studies identified, 11(0.99%) were analysed

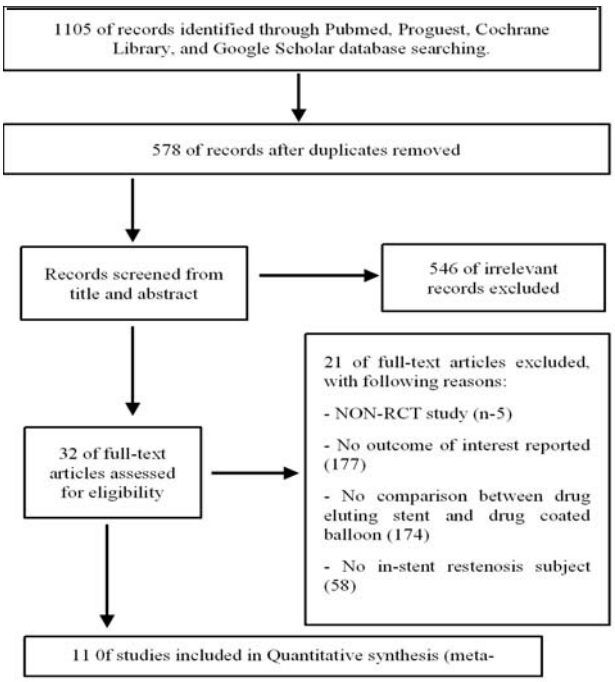


Figure-1: Flow diagram.

Table: Baseline data of the studies analysed.

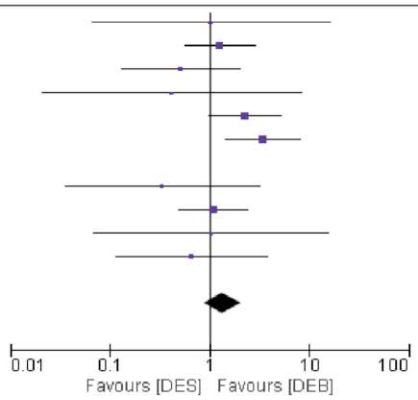
Trial	Location	Number of patients (DES/DEB)	Clinical presentation	Included outcome	Follow up
PEPCAD, 2014[6]	China	110/110	UA, SA, and SI	All-cause death, CV Death, Myocardial Infarction, TVR	12 months
ISAR-DESIRE 3, 2012[7]	Germany	131/137	SA	All-cause death, CV Death, Myocardial Infarction, TVR	12 months
SEDUCE, 2014[8]	Belgium	25 / 24	ACS, SA and SI	All-cause death, ST, Myocardial Infarction, TVR	12 months
RIBS IV, 2018[9]	Spanish	155 / 154	UA and SA	All-cause death, CV Death, ST, Myocardial Infarction, TVR, MACE	36 months
DARE, 2018[10]	Germany	141/137	ACS	All-cause death, CV Death, Stroke, ST, Myocardial Infarction, TVR	12 months
Fang, 2018[11]	Taiwan	42 / 75	STEMI and NSTEMI	All-cause death, CV Death, Stroke, Myocardial Infarction, TVR, MACE	12 months
Lee, 2017[12]	Korea	409 / 219	ACS, SA and SI	All-cause death, CV Death, ST, Myocardial Infarction, TVR	13 months
Marquis-Gravel, 2017[13]	Canada	409 / 219	ACS and SA	All-cause death, Stroke, ST, Myocardial Infarction, TVR, MACE	12 months
RESTORE, 2017[14]	Korea	186 / 184	SA, UA, NSTEMI	All-cause death, ST, Myocardial Infarction, TVR, MACE	12 months
Kook, 2020[15]	South Korea	51 / 24	UA and SA	All-cause death, CV Death, ST, Myocardial Infarction, TVR, MACE	868 days
Unverdorben, 2009[16]	Germany	65/66	UA and SA	All-cause death, CV Death, ST, Myocardial Infarction	12 months

ACS: Acute coronary syndrome, STEMI: ST-elevation myocardial infarction, NSTEMI: Non-ST-elevation myocardial infarction, SA: Stable angina, UA: Unstable angina, SI: Silent ischaemia, CV: Cardiovascular, TVR: Target vessel revascularisation, ST: Stent thrombosis, MACE: Major adverse cardiovascular events.

A. All-cause death.

Study or Subgroup	DEB Events	DEB Total	DES Events	DES Total	Weight	Risk Ratio M-H, Random, 95% CI
DARE 2018[10]	1	137	1	141	2.3%	1.03 [0.07, 16.29]
Fang, 2018[11]	16	75	7	42	19.4%	1.28 [0.57, 2.87]
ISAR-DESIRE 3, 2012[7]	3	137	6	141	8.5%	0.51 [0.13, 2.02]
Kook 2020[15]	0	24	2	51	2.0%	0.42 [0.02, 8.34]
Lee, 2017[12]	12	219	10	409	18.8%	2.24 [0.98, 5.10]
Marquis-Gravel, 2017[13]	21	91	6	89	17.7%	3.42 [1.45, 8.08]
PEPCAD 2014[6]	0	110	0	110		Not estimable
RESTORE, 2017[14]	1	86	3	86	3.5%	0.33 [0.04, 3.14]
RIBS IV, 2018[9]	12	154	11	155	19.9%	1.10 [0.50, 2.41]
SEDUCE, 2014[8]	1	24	1	25	2.4%	1.04 [0.07, 15.73]
Unverdorben, 2009[16]	2	66	3	65	5.5%	0.66 [0.11, 3.80]
Total (95% CI)		**1123**		**1314**	**100.0%**	**1.35[0.88, 2.08]**
Total events	69		50			

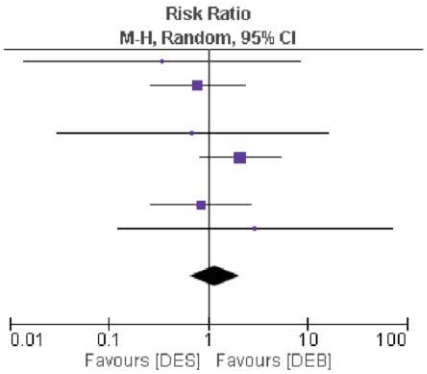
Heterogeneity: $Tau^2 = 0.08$, $Chi^2 = 10.90$, df = 9 (P = 0.28): $I^2 = 17\%$
Test for overall effect: Z = 1.38 (P=0.017)



B. Cardiovascular death.

Study or Subgroup	DEB Events	DEB Total	DES Events	DES Total	Weight	Risk Ratio M-H, Random, 95% CI
DARE 2018[10]	0	137	1	141	3.2%	0.34 [0.01, 8.35]
Fang, 2018[11]	7	75	5	42	28.2%	0.78 [0.27, 2.32]
ISAR-DESIRE 3, 2012[7]	0	137	0	141		Not estimable
Kook 2020[15]	0	24	1	51	3.3%	0.69 [0.03, 16.42]
Lee, 2017[12]	9	219	8	409	37.6%	2.10 [0.82, 5.37]
PEPCAD 2014[6]	0	110	0	110		Not estimable
RIBS IV, 2018[9]	5	154	6	155	24.4%	0.84 [0.26, 2.69]
Unverdorben, 2009[16]	1	66	0	65	3.3%	2.96 [0.12, 71.24]
Total (95% CI)		**922**		**1114**	**100.0%**	**1.35[0.88, 2.08]**
Total events	22		21			

Heterogeneity: $Tau^2 = 0.00$, $Chi^2 = 3.33$, df = 5 (P = 0.65): $I^2 = 0\%$
Test for overall effect: Z = 0.53 (P=0.59)



C. Major adverse cardiovascular events (MACE).

Study or Subgroup	DEB Events	DEB Total	DES Events	DES Total	Weight	Risk Ratio M-H, Random, 95% CI
Fang, 2018[11]	24	75	15	42	22.4 %	0.90 [0.53, 1.51]
Kook 2020[15]	6	51	13	24	18.6 %	0.22 [0.09, 0.50]
Marquis-Gravel, 2017[13]	33	91	17	89	22.6 %	1.90 [1.14, 3.15]
RESTORE, 2017[14]	6	86	4	86	14.0%	1.50 [0.44, 5.13]
RIBS IV, 2018[9]	31	154	19	155	22.4 %	1.64 [0.97, 2.78]
Total (95% CI)		**457**		**396**	**100.0%**	**1.00 [0.51, 1.98]**
Total events						

Heterogeneity: $Tau^2 = 0.47$, $Chi^2 = 21.82$, df = 4 (P = 0.0002): $I^2 = 82\%$
Test for overall effect: Z = 0.01 (P=0.99)

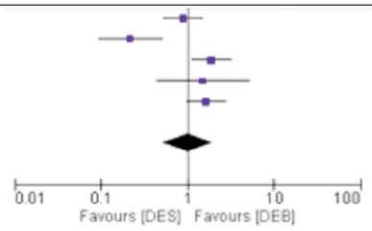


Figure 2-A-C: Comparison of study parameters between DES and DEB groups.
DES: Drug-eluting stents, DEB: Drug-eluting balloons, M-H: Mantel–Haenszel, CI: Confidence interval.

in detail; 7(63.6%) RCTs and 4(36.4%) observational studies (Figure 1). Characteristics of the included studies were noted in detail[6-16], and there were overall 2,437 IRS patients (Table).

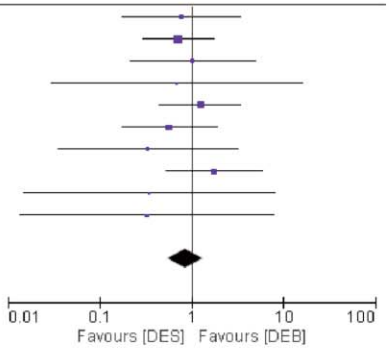
There was no significant difference between DEB and DEB groups with respect to all-cause death, cardiovascular death, stroke, stent thrombosis, MI and MACE (Figure 2-A-F).

DES significantly caused more target vessel revascularisation (TVR) events compared to DEB (Figure 3).

D. Myocardial infarction (MI).

Study or Subgroup	DEB Events	DEB Total	DES Events	DES Total	Weight	Risk Ratio M-H, Random, 95% CI
DARE 2018[10]	3	137	4	141	9.3%	0.77 [0.18, 3.39]
Fang, 2018[11]	9	75	7	42	24.5%	0.72 [0.29, 1.79]
ISAR-DESIRE 3, 2012[7]	3	137	3	141	8.2%	1.03 [0.21, 5.01]
Kook 2020[15]	0	24	1	51	2.0%	0.69 [0.03, 16.42]
Lee, 2017[12]	6	219	9	409	19.6%	1.25 [0.45, 3.45]
PEPCAD 2014[6]	4	110	7	110	14.2%	0.57 [0.17, 1.90]
RESTORE, 2017[14]	1	86	3	86	4.1%	0.33 [0.04, 3.14]
RIBS IV, 2018[9]	7	154	4	155	14.0%	1.76 [0.53, 5.90]
SEDUCE, 2014[8]	0	24	1	25	2.1%	0.35 [0.01, 8.12]
Unverdorben, 2009[16]	0	66	1	65	2.0%	0.33 [0.01, 7.92]
Total (95% CI)		**1032**		**1225**	**100.0%**	**0.86 [0.54, 1.34]**
Total events	33		40			

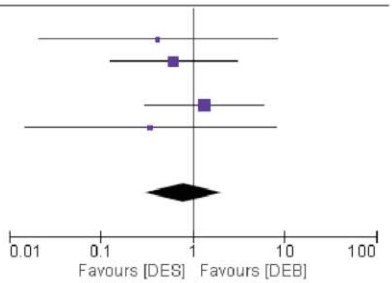
Heterogeneity: $Tau^2 = 0.00$, $Chi^2 = 3.89$, df = 9 (P = 0.92); $I^2 = 0\%$
Test for overall effect: Z = 0.68 (P=0.50)



E. Stent thrombosis.

Study or Subgroup	DEB Events	DEB Total	DES Events	DES Total	Weight	Risk Ratio M-H, Random, 95% CI
DARE 2018[10]	0	137	0	141		Not estimable
Kook 2022[15]	0	24	2	51	2.0%	0.42 [0.02, 8.34]
Lee, 2017[12]	2	219	6	409	18.8%	0.62 [0.13, 3.06]
RESTORE, 2017[14]	0	86	0	86	3.5%	Not estimable
RIBS IV, 2018[9]	4	154	3	155	19.9%	1.34 [0.31, 5.90]
SEDUCE, 2014[8]	0	24	1	25	2.4%	0.35 [0.01, 8.12]
Unverdorben, 2009[16]	0	66	0	65	5.5%	Not estimable
Total (95% CI)		**710**		**932**	**100.0%**	**0.79 [0.30, 2.07]**
Total events	6		12			

Heterogeneity: $Tau^2 = 0.00$, $Chi^2 = 1.02$, df = 3 (P = 0.80); $I^2 = 0\%$
Test for overall effect: Z = 0.49 (P=0.63)



F. Stroke.

Study or Subgroup	DEB Events	DEB Total	DES Events	DES Total	Weight	Risk Ratio M-H, Random, 95% CI
DARE 2018[10]	1	137	2	141	49.6%	0.51 [0.05, 5.61]
Fang, 2018[11]	2	75	1	42	50.4%	0.72 [0.10, 11.99]
RESTORE, 2017[14]	0	86	0	86		Not estimable
Total (95% CI)		**298**		**269**	**100.0%**	**0.76 [0.14, 4.10]**
Total events	33		40			

Heterogeneity: $Tau^2 = 0.00$, $Chi^2 = 0.21$, df = 1 (P = 0.65); $I^2 = 0\%$
Test for overall effect: Z = 0.32 (P=0.75)

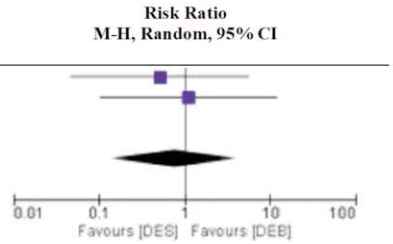


Figure 2-D-F: Comparison of study parameters between DES and DEB groups.
DES: Drug-eluting stents, DEB: Drug-eluting balloons, M-H: Mantel–Haenszel, CI: Confidence interval.

Discussion

The findings showed that DES demonstrated similar efficacy in the primary outcome, including all-cause death, cardiovascular death, MACE, MI, stent thrombosis and stroke compared to the DEB group. There was a satisfactory efficacy of lowering TVR in the DEB group.

The fact that DES inhibits neointimal development as a side effect has led to it becoming the conventional treatment for ISR.[12] The incidence of restenosis was decreased following the implantation of early-generation DES releasing paclitaxel (PES) or sirolimus (SES) in ISR.[13] However, the techniques created many layers of metal on the vascular wall, increasing the potential risk of stent thrombosis, and necessitating lengthened dual antiplatelet therapy (DAPT), which raises the potential of bleeding.[14] There is ongoing debate regarding the best way to treat ISR lesions. For managing patients with ISR, DEBs present a prospective substitute. A retrospective study conducted at a single centre in a real-world setting provided evidence for the effectiveness and safety of utilising DEBs in treating ISR.[17]

DEB and DES are equally effective, but the late loss should be considered. The use of DEB would significantly reduce

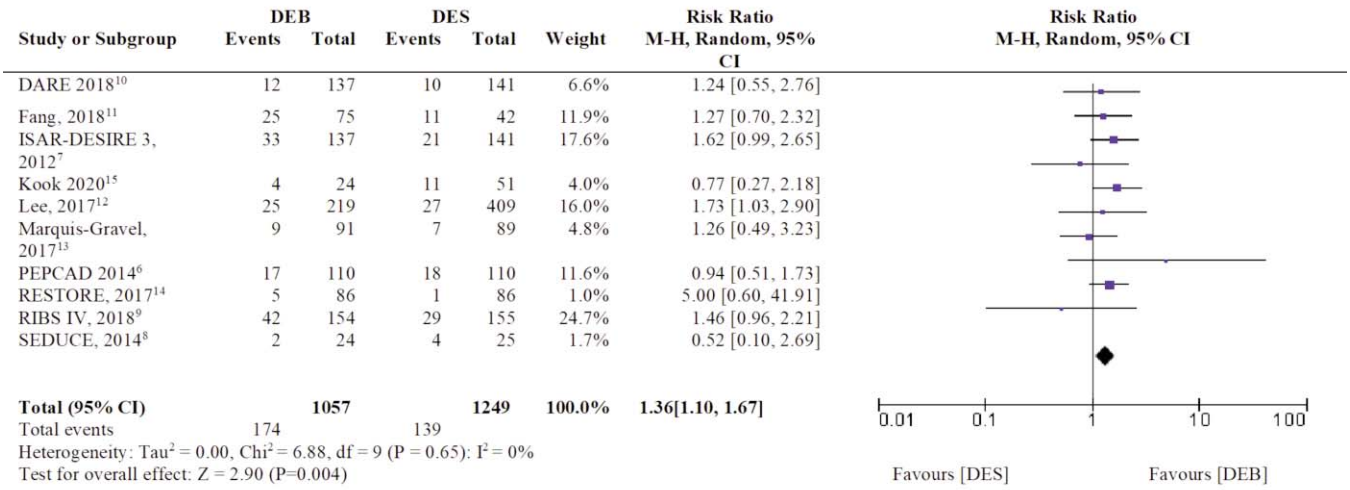


Figure-3: Comparison of target vessel revascularisation (TVR) outcome in DES and DEB groups.
DES: Drug-eluting stents, DEB: Drug-eluting balloons, M-H: Mantel–Haenszel, CI: Confidence interval.

the amount of newly generated tissue or thrombus deposition caused by introducing a second metal structure into the ISR lesion. Late loss following DEB would be lower than with DES. According to the a trial using DEB to treat DES-ISR, it was found to be as effective as DES implantation[18] and without the need to implant extra metal layers for drug release. In patients with BMS-ISR or DES-ISR, research revealed that DEB outperformed standard balloon angioplasty and may have been comparable to early-generation DES implantation.[18,19]

A study showed that in ISR patients, the newer generation of DES produced better long-term clinical and angiographic results than DEB.[7] Nevertheless, a study showed that regarding clinical outcomes, DEB surpassed more recent DES techniques when treating DES-ISR.[15] These findings suggest that the debate over the best care for ISR patients is still alive.

The advantages of the DEB method include the capacity to deliver drugs directly to the site without introducing additional stent struts to already restenosis lesions. This, in turn, prevents the initiation of fresh vessel inflammation and restenosis triggers, thereby mechanistically leading to a reduction in minimal lumen area.[20,21]

The current systematic review had limitations. There was variability in study characteristics. Besides, several trials had a small sample size and shorter follow-up period, which leads to inadequate balance in randomisation. Further research with larger sample sized and more specific focus are recommended.

Conclusion

Except for target vessel revascularisation, the drug-eluting balloons and drug-eluting stents had no difference in terms of clinical outcomes related to in-stent restenosis patients. The ideal treatment plan should be carefully chosen because ISR is important for prognosis.

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Conflict of Interest: None.

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