

## Biodegradable polymer stents vs second generation drug eluting stents: A meta-analysis and systematic review of randomized controlled trials

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**Author contributions:** Pandya B and Gaddam S were involved in acquisition of data, analysis and interpretation of data, drafting the manuscript; Raza M, Asti D and Nalluri N interpreted data; Vazzana T, Kandov R and Lafferty J critically revised the manuscript, provided their expertise and approved the manuscript.

**Conflict-of-interest statement:** The authors deny any conflict of interest.

**Data sharing statement:** No data were created so no data are available.

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Received: September 3, 2015  
Peer-review started: September 8, 2015  
First decision: September 23, 2015  
Revised: September 25, 2015  
Accepted: November 23, 2015

Article in press: November 25, 2015  
Published online: February 26, 2016

### Abstract

**AIM:** To evaluate the premise, that biodegradable polymer drug eluting stents (BD-DES) could improve clinical outcomes compared to second generation permanent polymer drug eluting stents (PP-DES), we pooled the data from all the available randomized control trials (RCT) comparing the clinical performance of both these stents.

**METHODS:** A systematic literature search of PubMed, Cochrane, Google scholar databases, EMBASE, MEDLINE and SCOPUS was performed during time period of January 2001 to April 2015 for RCT and comparing safety and efficacy of BD-DES vs second generation PP-DES. The primary outcomes of interest were definite stent thrombosis, target lesion revascularization, myocardial infarction, cardiac deaths and total deaths during the study period.

**RESULTS:** A total of 11 RCT's with a total of 12644 patients were included in the meta-analysis, with 6598 patients in BD-DES vs 6046 patients in second generation PP-DES. The mean follow up period was 16 mo. Pooled analysis showed non-inferiority of BD-DES, comparing events of stent thrombosis (OR = 1.42, 95%CI: 0.79-2.52,  $P = 0.24$ ), target lesion revascularization (OR = 0.99, 95%CI: 0.84-1.17,  $P = 0.92$ ), myocardial infarction (OR = 1.06, 95%CI: 0.86-1.29,  $P = 0.92$ ), cardiac deaths (OR = 1.07, 95%CI: 0.82-1.41,  $P = 0.94$ ) and total deaths (OR = 0.96, 95%CI: 0.80-1.17,  $P = 0.71$ ).

**CONCLUSION:** BD-DES, when compared to second generation PP-DES, showed no significant advantage

and the outcomes were comparable between both the groups.

**Key words:** Stent design; Drug eluting stent; Zotarolimus eluting stent; Cobalt-chromium stent; Biodegradable drug eluting stent

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**Core tip:** No direct comparison has been done so far with biodegradable polymers in drug eluting stent compared to permanent alloy in second-generation drug eluting stent. We explored the efficacy of these two stents via meta-analysis of randomized control trials in terms of definite stent thrombosis, target lesion revascularization, myocardial infarction, cardiac deaths and total deaths.

Pandya B, Gaddam S, Raza M, Asti D, Nalluri N, Vazzana T, Kandov R, Lafferty J. Biodegradable polymer stents vs second generation drug eluting stents: A meta-analysis and systematic review of randomized controlled trials. *World J Cardiol* 2016; 8(2): 240-246 Available from: URL: <http://www.wjgnet.com/1949-8462/full/v8/i2/240.htm> DOI: <http://dx.doi.org/10.4330/wjc.v8.i2.240>

## INTRODUCTION

It's been more than two decades since the introduction of coronary stents and during this period the stent designs have been modified to improve patient safety. Bare metal stents (BMS) were trailed by first generation permanent polymer drug eluting stents (PP-DES) (Paclitaxel and Sirolimus) then followed by second generation PP-DES (Everolimus and Zotarolimus) and now biodegradable polymer DES (BD-DES) are envisaging potentially improved patient outcomes.

Stent designing is the crux of interventional cardiology research and the changes have been dynamic. Initial BMS used a simple expandable metal alloy frame work, while PP-DES use an anti-proliferative drug coating on the metal platform, glued by a binding durable polymer to hold and elute the drug over time. Beyond any uncertainty, PP-DES are superior to BMS in decreasing restenosis, however PP-DES require longer duration of dual-antiplatelet therapy to avert the risk of stent thrombosis<sup>[1]</sup>. It is now understood, the metal alloy and the permanent polymer are among the culprits for prolonged inflammation leading to very late stent thrombosis and late restenosis (termed late catch-up phenomena) and henceforth the unremitting search for safer stents<sup>[2]</sup>. The second generation PP-DES introduced few years ago, have superior metal frame work (cobalt-chromium and platinum-chromium) with thinner metal struts, enhanced biocompatible binding polymer and these stents have proven improved patient outcomes compared to its predecessors<sup>[3]</sup>. Nevertheless, the potential need for dual-antiplatelet therapy beyond one year is still an

apprehension among cardiologists and patients with second generation PP-DES. The BD-DES, unlike second generation PP-DES, will elute the anti-proliferative drug and the biodegradable polymer subsequently dissolves leaving behind a bare metal stent<sup>[4]</sup>. BD-DES is introduced with an anticipation to decrease the stent thrombosis events (especially very late events) and evading the need for prolonged dual-antiplatelet therapy.

Several randomized control trials and registries have been published in last few years, with most trials comparing first generation PP-DES to BD-DES. As anticipated, long term follow up data has shown superiority of BD-DES in decreasing very late stent thrombosis events when compared with Sirolimus (first generation) PP-DES<sup>[5]</sup>. However, there are only fewer studies comparing second generation PP-DES to BD-DES. Since second generation PP-DES is current standard of care in United States, it is of immense importance to study if the newer BD-DES offer any better outcomes. We performed a meta-analysis and systematic review of randomized control trials comparing efficacy and safety of BD-DES to second generation PP-DES (Everolimus and Zotarolimus).

## MATERIALS AND METHODS

### Literature search

Two independent investigators systematically searched PubMed, Cochrane and Google scholar database from January 2001 to April 2015. We used following keywords: "biodegradable stent", "biodegradable polymer", "biodegradable polymer drug eluting", and "biodegradable stent coronary". Reference lists from selected studies were manually searched for potentially relevant studies. Whenever available, the most recent follow up data on a study was included. The PRISMA statement was used as guidance for selection of studies to be included in the meta-analysis and is depicted in Figure 1. Randomized control trials comparing BD-DES vs second generation DES with a primary end point of definite stent thrombosis, target lesion revascularization, myocardial infarction, cardiac deaths and total death were included in the study. We found 11 trials comparing BD-DES to second generation (Everolimus or Zotarolimus) PP-DES. In ISAR-TEST 4 trial, both first generation Sirolimus and second generation Everolimus DES were used, but in our meta-analysis we only used data pertinent to second generation Everolimus DES. Given the low incidence of stent thrombosis and other outcomes, a meta-analysis was performed to prove treatment differences between these two stents.

### Study selection

Two authors screened all relevant literature by their abstract and title found by electronic search. Only trials published in English were taken into consideration. Inclusion criteria were (1) randomized control trials; (2) comparing biodegradable polymers to second generation drug eluting stents; and (3) reporting outcomes as

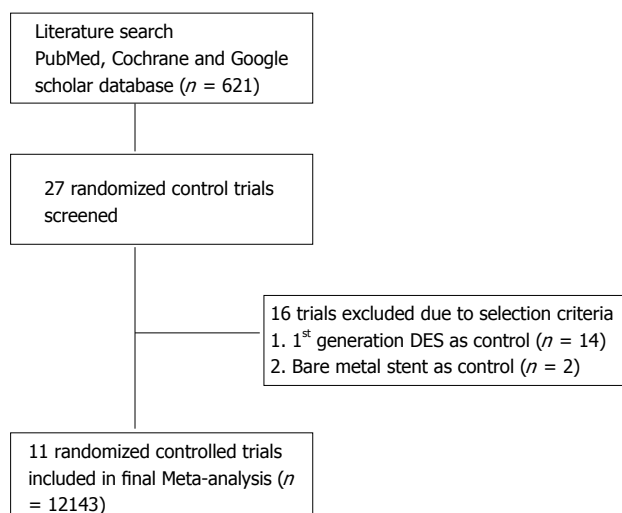


Figure 1 Study selection. DES: drug eluting stents.

a target lesion revascularization [target lesion revascularization (TLR)], definite stent thrombosis (DST), myocardial infarction (MI), cardiac deaths and total deaths. We excluded studies with first generation drug eluting stents and bare metal stents as controls and also studies performed on select population, like complex lesions or on bifurcating lesions. Randomized control trials comparing BD-DES to second generation PP-DES were only included in this study.

#### Data extraction

Data from all 11 trials were extracted by same two authors in regards to first author, year of publication, total No. of patients and No. of patients in each group (Table 1). Authors also extracted mean age group of patients, patients with DM and HTN, follow up duration and duration of use of dual antiplatelet therapy (Table 2).

#### Outcome measures

Clinical end points compared were definite stent thrombosis (DST), target lesion revascularization (TLR), myocardial infarction (MI), cardiac deaths and total deaths during the study period.

#### Statistical analysis

The results for each trial were obtained on an intention-to-treat analysis. The dichotomous and continuous endpoints from individual trials were analyzed using the odds ratio (OR) and the standard difference in mean (SDM) respectively as a parameter of efficacy with its 95%CI. We assessed heterogeneity with  $I^2$  that describes the percentage of total variation across trials due to heterogeneity rather than chance.  $I^2$  can be calculated as  $I^2 = 100\% \times (Qv - df)/Q$ , where  $Q$  is Cochran's heterogeneity statistics and  $df$  the degrees of freedom. Negative values of  $I^2$  are put equal to 0, so  $I^2$  lies between 0% (no heterogeneity) and 100% (maximal heterogeneity). The continuous outcomes were analyzed using the standard difference in mean.

Binary outcomes from individual studies were combined and the summary estimators of treatment effect were calculated using fixed-effect method. Weighting of trial data in the models was based on the inverse variance weight computed as the inverse of the squared standard error value of the effect size. A  $P$  value of  $\leq 0.05$  was regarded as significant. All analyses were performed using Review Manager (RevMan) Version 5.3 for Windows Oxford, England.

## RESULTS

### Study selection

A total of 11 RCT's with a total of 12644 patients were included in the meta-analysis, with 6598 patients in BD-DES vs 6046 patients in second generation PP-DES. The mean follow up period was 16 mo. Table 1 shows the main characteristics of the included studies. Table 2 shows the main characteristics of the BD-DES patients included in the studies. The final summary of clinical end points is depicted in Table 3.

### DST

The forest plot for summary effect is shown in Figure 2. There were a total of 34 (0.6%) stent thrombosis events in BD-DES group and 24 (0.46%) stent thrombosis in PP-DES group. The forest plot is shown in the Figure 2, with pooled OR of 1.42 (95%CI: 0.79-2.52),  $P = 0.24$ , and  $I^2$  for heterogeneity 0%.

### TRL

The forest plot for summary effect is shown in Figure 3. There were a total of 294 (4.77%) TLR in BD-DES group vs 350 (6.05%) TLR in PP-DES group. The forest plot is shown in the figure, with pooled OR of 0.99 (95%CI: 0.84-1.17),  $P = 0.92$ , and  $I^2$  for heterogeneity 0%.

### MI

The forest plot for summary effect is shown in Figure 4. There were a total of 202 (3.27%) myocardial infarctions in BD-DES group vs 238 (4.11%) myocardial infarctions in PP-DES group. The forest plot is shown in the Figure 4, with pooled OR of 1.06 (95%CI: 0.86-1.29),  $P = 0.59$ , and  $I^2$  for heterogeneity 0%.

### Cardiac deaths

The forest plot for summary effect is shown in Figure 4. There were a total of 108 (1.78%) cardiac deaths in BD-DES group vs 124 (2.18%) cardiac deaths in PP-DES group. The forest plot is shown in the figure, with pooled OR of 1.07 (95%CI: 0.82-1.41,  $P = 0.60$ ), and  $I^2$  for heterogeneity 0%.

### Total deaths

The forest plot for summary effect is shown in Figure 5. There were a total of 229 (3.65%) deaths in BD-DES group vs 236 (4.01%) deaths in PP-DES group. The

Table 1 Summary of included trials

Ref.	Trial acronym	Yr	BD-DES type	PP-DES type	Total patients	BD-DES patients	PP-DES patients
Natsuaki <i>et al</i> <sup>[8]</sup>	NEXT	2013	Biolimus	Everolimus	3235	1617	1618
Smits <i>et al</i> <sup>[9]</sup>	COMPARE 2	2013	Biolimus	Everolimus	2707	1795	912
Gao <i>et al</i> <sup>[10]</sup>	TARGET 1	2013	Sirolimus	Everolimus	458	227	231
Byrne <i>et al</i> <sup>[11]</sup>	ISAR-TEST 4	2011	Sirolimus	Everolimus	2603	652	1304
Xu <i>et al</i> <sup>[12]</sup>		2011	Sirolimus	Zotarolimus	324	168	156
Separham <i>et al</i> <sup>[13]</sup>		2011	Biolimus	Everolimus	200	100	100
Meredith <i>et al</i> <sup>[14]</sup>	EVOLVE	2012	Biolimus	Everolimus	192	98	94
Pilgrim <i>et al</i> <sup>[15]</sup>	BIOSCIENCE	2014	Sirolimus	Everolimus	2119	1063	1056
Serruys <i>et al</i> <sup>[7]</sup>	ABSORB 2	2014	Everolimus	Everolimus	501	335	166
Lee <i>et al</i> <sup>[16]</sup>		2014	Biolimus	Everolimus	500	245	255
Windecker <i>et al</i> <sup>[17]</sup>	BIOFLOW 2	2014	Sirolimus	Everolimus	452	298	154

BMS: Bare metal stents; PP-DES: Permanent polymer drug eluting stents; BD-DES: Biodegradable polymer drug eluting stents.

Table 2 Main characteristics of biodegradable polymer drug eluting stents patients in the study

Ref.	Mean age	Male %	Diabetes %	Inclusion criteria	Exclusion criteria	DAPT mo	Follow up mo
Natsuaki <i>et al</i> <sup>[8]</sup>	69	77	46	SA <sup>1</sup> /ACS <sup>2</sup>	Major surgery in 30 d, cardiogenic shock	3	12
Smits <i>et al</i> <sup>[9]</sup>	63	74	22	SA/ACS	Major surgery in 30 d, cardiogenic shock	12	12
Gao <i>et al</i> <sup>[10]</sup>	59	69	14	SA/UA <sup>3</sup>	AMI <sup>4</sup> < 1 wk, CT <sup>5</sup> , LM <sup>6</sup> bifurcation, ISR <sup>7</sup>	12	12
Byrne <i>et al</i> <sup>[11]</sup>	67	75	29	SA/ACS	LM. shock, malignancy, life expectancy < 1 yr	6	36
Xu <i>et al</i> <sup>[12]</sup>	57	70	26	SA/UA	AMI < 1 wk, LM, CTO	6	24
Separham <i>et al</i> <sup>[13]</sup>	61	66	28	SA/ACS	Allergy to aspirin, plavix, heparin, stainless steel, everolimus, biolimus or contrast and pregnancy	12	12
Meredith <i>et al</i> <sup>[14]</sup>	62	80	22	Symp CAD <sup>8</sup> , Silent Ischemia	AMI, LM CAD, ISR, thrombus in target vessel	6	6
Pilgrim <i>et al</i> <sup>[15]</sup>	66	77	24	Stable CAD/ACS	Pregnancy, intolerance to aspirin, plavix, planned surgery in 6 mo	12	12
Serruys <i>et al</i> <sup>[7]</sup>	61	76	24	Evidence of myocardial Ischemia	AMI, unstable arrhythmias, LVEF <sup>9</sup> < 30	NA	12
Lee <i>et al</i> <sup>[16]</sup>	63	68	32	SA/UA/NSTEMI <sup>10</sup>	STEMI <sup>11</sup> , cardiogenic shock, allergy to aspirin/plavix/heparin/stainless steel/biolimus/everolimus, HD pts, LM CAD	≥ 12	12
Windecker <i>et al</i> <sup>[17]</sup>	63	78	28	SA/UA/Clinical evidence of myocardial Ischemia	MI within 72 h, LM CAD, triple vessel CAD, LVEF < 30%	≥ 6	9

<sup>1</sup>Stable angina; <sup>2</sup>Acute coronary syndrome; <sup>3</sup>Unstable angina; <sup>4</sup>Acute myocardial infarction; <sup>5</sup>Complete total occlusion; <sup>6</sup>Left main; <sup>7</sup>In stent restenosis; <sup>8</sup>Coronary artery disease Left ventricular ejection fraction; <sup>9</sup>Left ventricular ejection fraction; <sup>10</sup>Non ST elevation myocardial infarction; <sup>11</sup>ST elevation myocardial infarction; BMS: Bare metal stents; PP-DES: Permanent polymer drug eluting stents; BD-DES: Biodegradable polymer drug eluting stents; NA: Not available.

Table 3 Summary of clinical end points

Events	BD-DES (n = 4459)	PP-DES (n = 4221)	ODD S RATIO (95%CI)	P-value
Definite stent thrombosis	34	24	1.42 (0.79-2.52)	0.24
Target lesion revascularization	294	350	0.99 (0.84-1.17)	0.92
Myocardial infarction	202	238	1.06 (0.86-1.29)	0.59
Cardiac deaths	108	124	1.07 (0.82-1.41)	0.6
Total deaths	229	236	0.96 (0.80-1.17)	0.71

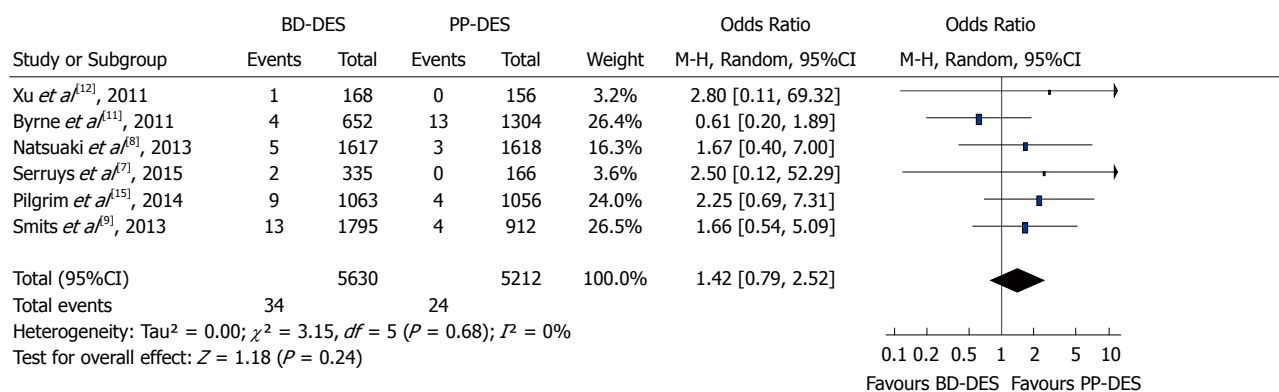
PP-DES: Permanent polymer drug eluting stents; BD-DES: Biodegradable polymer drug eluting stents.

forest plot is shown in the figure, with pooled OR of 0.96 (95%CI: 0.80-1.17,  $P = 0.71$ ), and  $I^2$  for heterogeneity 0%.

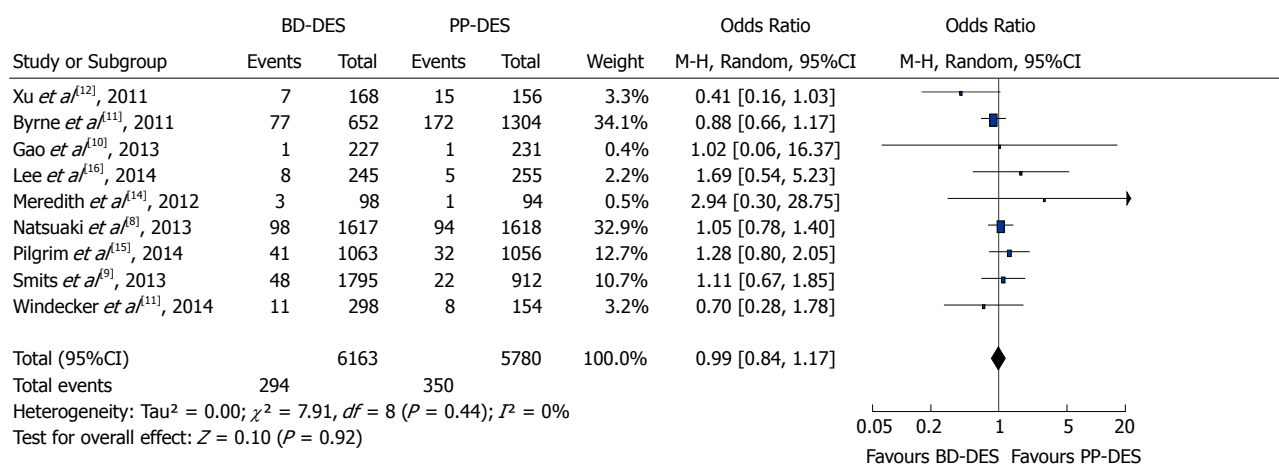
## DISCUSSION

From our study, at a mean follow up of 16 mo, BD-

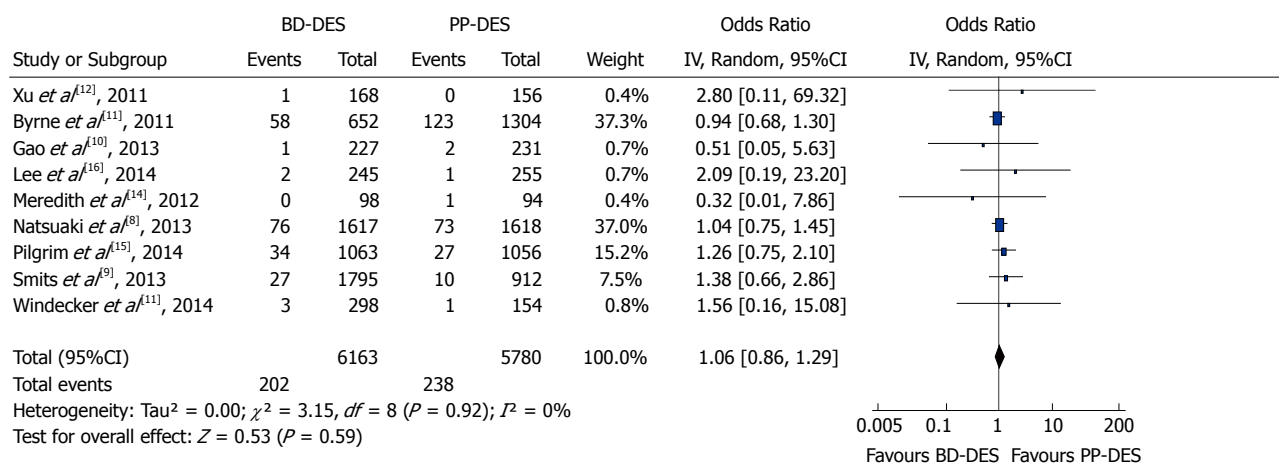
DES use did not significantly decrease mortality (OR = 0.96,  $P = 0.71$ ) or myocardial infarction events (OR = 1.06,  $P = 0.59$ ). Rates of stent thrombosis (OR = 1.42,  $P = 0.24$ ) and target lesion revascularization (OR = 0.99,  $P = 0.92$ ) were comparable between both the stents. In this study the results for BD-DES, against contrary belief, failed to show any significant



**Figure 2 Definite stent thrombosis.** BMS: Bare metal stents; PP-DES: Permanent polymer drug eluting stents; BD-DES: Biodegradable polymer drug eluting stents.



**Figure 3 Target lesion revascularization.** BMS: Bare metal stents; PP-DES: Permanent polymer drug eluting stents; BD-DES: Biodegradable polymer drug eluting stents.

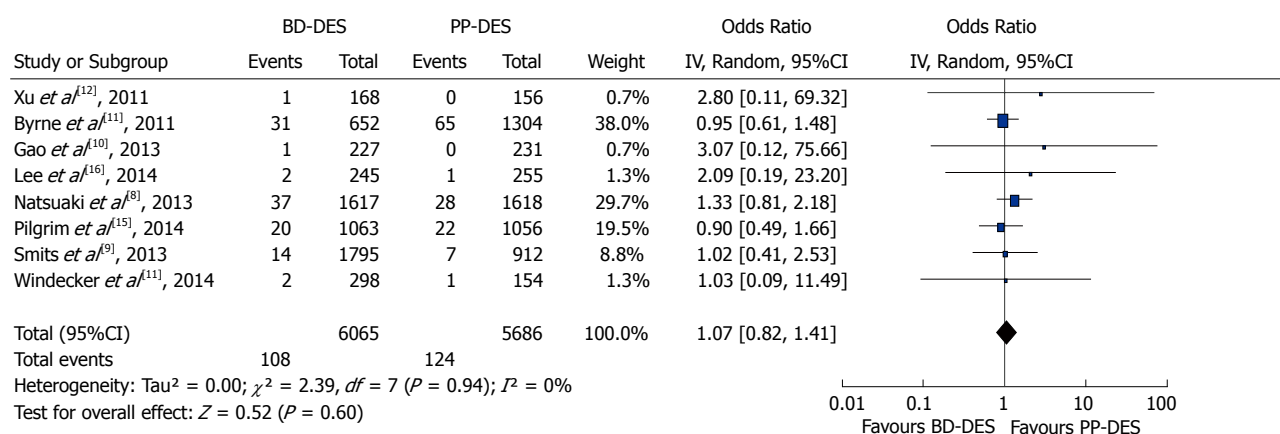


**Figure 4 Myocardial infarction.** BMS: Bare metal stents; PP-DES: Permanent polymer drug eluting stents; BD-DES: Biodegradable polymer drug eluting stents.

decrease in stent thrombosis. Looking at individual study results, except for ISAR-TEST 4, all trials showed non-significant increase in odds of stent thrombosis compared to second generation PP-DES. However it should be remembered, BD-DES are anticipated to have decreased stent thrombosis events at long term follow up, especially after the biodegradable polymer

dissolves and leaves behind a bare metal stent. It is important to wait for long term follow up data on these trials, to observe if the very late stent thrombosis rates are lower, as seen in long term follow up data of ISAR-TEST 4. It is also crucial and remains to be observed, if the stent thrombosis events would be lower even after discontinuing dual anti-platelet therapy and the when





**Figure 5 Cardiac deaths.** BMS: Bare metal stents; PP-DES: Permanent polymer drug eluting stents; BD-DES: Biodegradable polymer drug eluting stents.

event rates are adjusted for dual-antiplatelet therapy use between both the groups. Henceforth, it is too early to come to any firm conclusions in regards to superiority of BD-DES to currently used second generation PP-DES. A recent network meta-analysis comparing BD-DES, first and second generation PP-DES and bare metal stents, concluded BD-DES are not superior to second generation BD-DES<sup>[6]</sup>. In our study, we systematically reviewed all the studies and believe long term follow up of the trials are needed before we can make any such firm conclusions.

A pooled analyses comparing ISAR-TEST3, ISAR-TEST-4 and LEADERS trial showed decreased risk of stent thrombosis with BD-DES at 4 year follow up<sup>[5]</sup>. It is likely because those trials used first generation Sirolimus DES, and the first generation stents are known to have increased late restenosis and stent thrombosis events. However, the second generation DES, use different metal alloy framework with thin struts and the binding polymer is biocompatible and hence the results of such studies cannot be extrapolated to second generation PP-DES. The time for dual anti-platelet therapy with the biodegradable stent is shorter. In fact, in some trials (Table 2), the time for DAPT is reduced to 3-6 mo, while for the drug-eluted stents can be longer. This can be an advantage in any case, since patients on DAPT may have an increased risk of bleeding, especially if unplanned surgery is needed or in case oral anticoagulation is needed for concomitant disease (atrial fibrillation or deep venous thrombosis).

Interventional cardiologists have always been welcoming to newer technology and novel stent designs. The early enthusiasm of most stents, introduced in the past, could not meet the expectations during long-term follow up. With new BD-DES being studied across the globe, we need to analyze the data more closely before drawing conclusions on their superiority to currently used second generation PP-DES.

### Limitation

The major limitation of this study is the wide variation of follow-up period. In particular, the ISAR-TEST 4 study

had the longest mean follow-up period (36 mo), and the odds ratio was completely opposite to all other included studies as pointed out. The results may change with long-term follow-up. Second, Serruys *et al*<sup>[7]</sup> included a study investigating a bioresorbable scaffold into the analysis because you aimed to compare BD-DES and PP-DES. Other minor issues are described below. BD-DES used in the RCT was of various types (Biolimus and Sirolimus) and the results should be interpreted with caution in generalizing our results to all types of BD-DES. The patient population in all these studies did vary to some degree (as described in Table 2). Also, the lesions treated and characteristics of stents used- like length and diameter along with lesion complexity could have affected the outcomes.

BD-DES when compared to second generation PP-DES, showed no significant advantage and the outcomes were comparable between both the groups. Long term follow up data is needed, to demonstrate any decrease in very late stent thrombosis events with BD-DES compared to second generation PP-DES.

## COMMENTS

### Background

Biodegradable polymer stent are currently used in Europe for PCI. Despite that there is no clear-cut evidence in literature comparing the efficacy of these two types of stent.

### Research frontiers

Now a day every effort is made to find the new design of stents, which will minimize the need for longer duration of dual antiplatelet therapy, which can be responsible for their notorious side effect in some situations.

### Innovation and breakthrough

In present study, the authors compared the efficacy of novel biodegradable drug eluting stent with the standard of care second-generation drug eluting stents in the form of meta-analysis of current randomized control trials.

### Application

The present results allow authors to think the role of biodegradable drug eluting stent in stent thrombosis, interests them in further investigating the long term outcomes in form of late stent thrombosis and duration of dual antiplatelet therapy.

## Peer-review

The present meta-analysis provides more insight into clinical practice in regards to usage of different stent designs.

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**P- Reviewer:** De Ponti R, Kettering K, Petix NR, Said SA, Vermeersch P **S- Editor:** Qiu S **L- Editor:** A **E- Editor:** Lu YJ





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