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ORIGINAL ARTICLE

A comparative analysis of Strut BP-coated sirolimus-eluting stent versus the durable coating everolimus-eluting stent in patients with myocardial infarction

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ABSTRACT:

Background: When compared to bare metal stents (BMS), the first generation drug eluting stents (DES) covered with a permanent polymer had lower restenosis rates. The present study compared strut BP-coated sirolimus-eluting stent (BP-SES) versus the durable coating everolimus-eluting stent (DP-EES) in patients with myocardial infarction. **Materials & Methods:** 70 cases of myocardial infarction of both genders were divided into 2 groups of 35 each. Group I patients received thin strut biodegradable polymer-coated sirolimus-eluting stent (BP-SES) and in group II patients received durable coating everolimus-eluting stent (DP-EES). **Results:** Out of 70 patients, males were 40 and females were 30. The mean stents used per patients was 1.56 in group I and 1.54 in group II, post- dilatation was seen in 22.5% in group I and 27.8% in group II, thrombectomy was observed in 12% in group I and 10.4% in group II, maximum implantation pressure was 14.8 in group I and 14.2 in group II, direct stent implantation was seen in 40% in group I and 48% in group II. The difference was significant (P< 0.05). Mortality was observed 5 in group I and 8 in group II. The difference was significant (P< 0.05). **Conclusion:** Authors found both strut BP-coated sirolimus-eluting stent (BP-SES) and the durable coating everolimus-eluting stent (DP-EES) were equally effective in patients with myocardial infarction.

Key words: sirolimus-eluting stent, myocardial infarction, hypersensitivity reactions

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INTRODUCTION

When compared to bare metal stents (BMS), the first generation drug eluting stents (DES) covered with a permanent polymer had lower restenosis rates.[1] The presence of durable polymers was linked to delayed artery healing, hypersensitivity reactions, chronic inflammation, and the increased risk of stent thrombosis (ST) due to delayed healing and protracted re-endothelialization, despite the fact that DES was successful in decreasing neointimal hyperplasia. Second-generation DES had lower ST rates while maintaining low restenosis rates.[2]

However, very late ST and neoatherosclerosis have been recently observed also with second-generation DES.[2] To address the limitations of the durable polymer DES, new platforms that make use of biodegradable polymers have been developed.[3] The safety and effectiveness of biodegradable polymer coated DES (BP-DES) over BMS and first-generation DES has been proven previously in reducing the risk of very late ST and restenosis. Patients with acute coronary syndromes (ACS) constitute a challenging subset with poorer outcomes after percutaneous coronary interventions (PCI) as compared to stable coronary artery disease, with an increased risk of ST and reinfarction.[4]

Modern second-generation DES include thinner struts and more biocompatible polymers than first-generation DES, which reduce vascular damage and inflammation and speed up endothelialization while reducing neointimal proliferation and thrombogenicity. Further improvements to stent design may be able to increase event-free survival, however this is questionable.[5]Drug elution from bioresorbable polymers and polymer-free systems has theoretical advantages over drug elution from durable polymers, but these advantages have not yet been demonstrated to lead to better clinical outcomes.[6] Similar results have been obtained with first-generation bioabsorbable scaffolds. As a result, despite being excellent, clinical outcomes with modern second generation DES have basically plateaued over the past ten years.[7] The present study compared strut BP-coated sirolimus-eluting stent (BP-SES) versus the durable coating everolimus-eluting stent (DP-EES) in patients with myocardial infarction.

MATERIALS & METHODS

The present study comprised of 70 cases of myocardial infarction of both genders. All patients were informed regarding the study and written consent was obtained.

Data such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 35 each. Group I patients received thin strut biodegradable polymer-coated sirolimus-eluting stent (BP-SES) and in group

II patients received durable coating everolimus-eluting stent (DP-EES). All interventional strategies such as the use of stents, choice of stent type and periprocedural antithrombin and antiplatelet therapy was recorded. Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

RESULTS

Table I Distribution of patients

Total- 70		
Gender	**Males**	**Females**
Number	40	30

Table I shows that out of 70 patients, males were 40 and females were 30.

Table II Assessment of parameters

Characteristics	Group I	Group II	P value
Stents used per patients	1.56	1.54	0.91
Post- dilatation (%)	22.5	27.8	0.38
Thrombectomy (%)	12	10.4	0.94
Maximum implantation pressure	14.8	14.2	0.94
Direct stent implantation (%)	40	48	0.12

Table II shows that mean stents used per patients was 1.56 in group I and 1.54 in group II, post- dilatation was seen in 22.5% in group I and 27.8% in group II, thrombectomy was observed in 12% in group I and 10.4% in group II, maximum implantation pressure was 14.8 in group I and 14.2 in group II, direct stent implantation was seen in 40% in group I and 48% in group II. The difference was significant (P< 0.05).

Table III Assessment of mortality rate in both groups

Groups	Number	P value
Group I	5	0.05
Group II	8	

Table III shows that mortality was observed 5 in group I and 8 in group II. The difference was significant (P< 0.05).

DISCUSSION

Acute thrombogenicity and long-term vascular healing in DES have been linked to the platform material and stent strut thickness in addition to drug pharmacokinetics, durable polymer biocompatibility, composition distribution, and, in the case of BP-DES, duration of bioresorption.[8] Recent developments in vascular injury prevention and endothelialization speed have led to the introduction of ultrathin strut DES.[9]

Modern second-generation DES include thinner struts and more biocompatible polymers than first-generation DES, which reduce vascular damage and inflammation and speed up endothelialization while reducing neointimal proliferation and thrombogenicity.[10]Further improvements to stent design may be able to increase event-free survival, however this is questionable. Drug elution from bioresorbable polymers and polymer-free systems has theoretical advantages over drug elution from durable polymers, but these advantages have not yet been demonstrated to lead to better clinical outcomes.[11] Similar results have been obtained with first-generation bioabsorbable scaffolds. As a result, despite being excellent, clinical outcomes with modern second generation DES have basically plateaued over the past ten years.[12] The present study compared strut BP-coated sirolimus-eluting stent (BP-SES) versus the durable coating everolimus-eluting stent (DP-EES) in patients with myocardial infarction. We found that out of 70 patients, males were 40 and females were 30. Windecker et al[13] in their study, 452 patients were randomly assigned 2:1 to treatment with O-SES (298 patients, 332 lesions) or X-EES (154 patients, 173 lesions) in a multicenter, noninferiority trial. The primary end point was in-stent late loss at 9 months. O-SES was noninferior to X-EES for the primary end point (0.10±0.32 versus 0.11±0.29 mm). Clinical outcome showed similar rates of target-lesion failure at 1 year (O-SES 6.5% versus X-EES 8.0%; hazard ratio=0.82; 95% confidence interval, 0.40-1.68; log-rank test: P=0.58) without cases of stent thrombosis. A subgroup of patients (n=55) underwent serial optical coherence tomography at 9 months, which demonstrated similar neointimal thickness among lesions allocated to O-SES and X-EES (0.10±0.04 mm versus 0.11±0.04 mm; -0.01 [-0.04, -0.01]; P=0.37). Another subgroup of patients (n=56) underwent serial intravascular ultrasound at baseline and 9 months indicating a potential difference in neointimal area at follow-up (O-SES, 0.16±0.33 mm(2) versus X-EES, 0.43±0.56 mm(2); P=0.04).

We found that mean stents used per patients was 1.56 in group I and 1.54 in group II, post- dilatation was seen in 22.5% in group I and 27.8% in group II, thrombectomy was observed in 12% in group I and 10.4% in group II, maximum implantation pressure

was 14.8 in group I and 14.2 in group II, direct stent implantation was seen in 40% in group I and 48% in group II. We found that mortality was observed 5 in group I and 8 in group II. Dores et al[14] in their study a total of 3806 patients were submitted to percutaneous coronary intervention (PCI) with only 1stGEN or 2ndGEN DES: 2388 patients (62.7%) were treated with 1stGEN DES only (sirolimus-eluting stent [SES] = 1295 [34.0%]; paclitaxel-eluting stent [PES] = 943 [24.8%]; both stent types were used in 150 patients) and 1418 patients (37.3%) were treated with 2ndGEN DESs only. The total incidence of definite ST (as defined by the Academic Research Consortium) at 12 months was 1.2% (n = 46). After correction for baseline differences between study groups and other variables deemed to influence the occurrence of ST, the use of 1stGEN DES was associated with a significant 2.4-fold increase in the risk of definite ST (95% confidence interval [CI], 1.05-5.42; P=.039) at 12 months; adjusted risk was higher with PES (hazard ratio [HR], 3.6; 95% CI, 1.48-8.70; P=.005) than with SES (HR, 2.3; 95% CI, 0.92-5.65; P=.074). Total mortality (3.7% vs 3.5%) did not differ significantly between groups (adjusted HR, 1.2; 95% CI, 0.81-1.84, P=.348).

CONCLUSION

Authors found in patients with myocardial infarction both strut BP-coated sirolimus-eluting stent (BP-SES) and the durable coating everolimus-eluting stent (DP-EES) were equally effective.

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