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Original Research

Strut biodegradable polymer sirolimus-eluting stent versus the durable polymer everolimus-eluting stent in patients with myocardial infarction

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***ABSTRACT*:**
Background: The first generation drug eluting stents (DES) coated with a permanent polymer reduced the rates of restenosis when compared to bare metal stents (BMS). The present study was conducted to compare strut biodegradable polymer sirolimus-eluting stent (BP-SES) versus the durable polymer everolimus-eluting stent (DP-EES) in patients with myocardial infarction. **Materials & Methods:** The present study was conducted on 84 cases of myocardial infarction of both genders. Patients were divided into 2 groups of 42 each. Group I patients received thin strut biodegradable polymer sirolimus-eluting stent (BP-SES) and in group II patients received durable polymer everolimus-eluting stent (DP-EES). **Results:** The mean stents used per patients was 1.53 in group I and 1.52 in group II, maximum implantation pressure was 14.21 in group I and 14.30 in group II, direct stent implantation was seen in 34.2 % in group I and 36.1% in group II, post- dilatation was seen in 24.1% in group I and 27.6% in group II, thrombectomy was observed in 10.4% in group I and 10.2% in group II. The difference was significant (P< 0.05). Mortality was observed 6 in group I and 7 in group II. **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, everolimus-eluting stent, myocardial infarction

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INTRODUCTION

The first generation drug eluting stents (DES) coated with a permanent polymer reduced rates of restenosis when compared to bare metal stents (BMS).[1] Although DES succeeded in suppressing neointimal hyperplasia, the presence of durable polymers was implicated in delayed vessel healing, hypersensitivity reactions, chronic inflammation with the added risks of stent thrombosis (ST) due to delayed healing and prolonged re-endothelialization. Use of second-generation drug eluting stents resulted in reduction in the rates of stent thrombosis with preserved low restenosis rates. However, very late stent thrombosis and neo-atherosclerosis 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. 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 stent thrombosis 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 stent thrombosis and reinfarction.[3]

In comparison with first-generation drug eluting stents, contemporary second-generation stents have thinner struts and have polymers which are more biocompatible. They have been found to reduce vascular injury and inflammation and promote faster endothelialization, thereby decreasing the neointimal proliferation and thrombogenicity. If event-free survival can be improved further by modifications in stent design is uncertain.[4] When compared with durable polymers, the drug elution from bioresorbable polymers and polymer-free systems offer theoretical advantage only, that to date, have not been shown to confer improved clinical outcomes. In the same way, outcomes with first-generation bioabsorbable scaffolds have also been discouraging. Thus, clinical outcomes with contemporary second generation DES, while outstanding have plateaued and largely remained steady over the past decade.[5] The present study was conducted to compare 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 was conducted at a tertiary care apex facility for cardiological services at Patna. It comprised of 84 cases of myocardial infarction of both genders. All patients were informed about the study and prior written consent was obtained. Ethical clearance was not required as the results of the study insured the confidentiality of each subject and publishing such result was for the benefit of society at large.

General information such as name, age, gender etc. was recorded. All patients underwent coronary angiography with following or postponed PCI using standard devices. Patients were divided into 2 groups of 42 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- 84		
Gender	**Males**	**Females**
Number	52	32

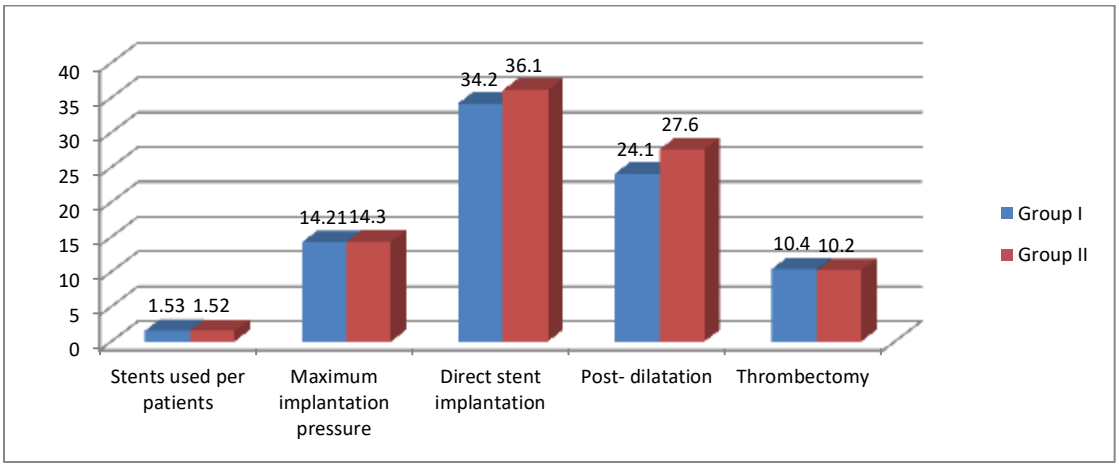
Table I shows that out of a total of 84 patients, 52 were males and 32 were females.

Table II Angiographic and procedural characteristics

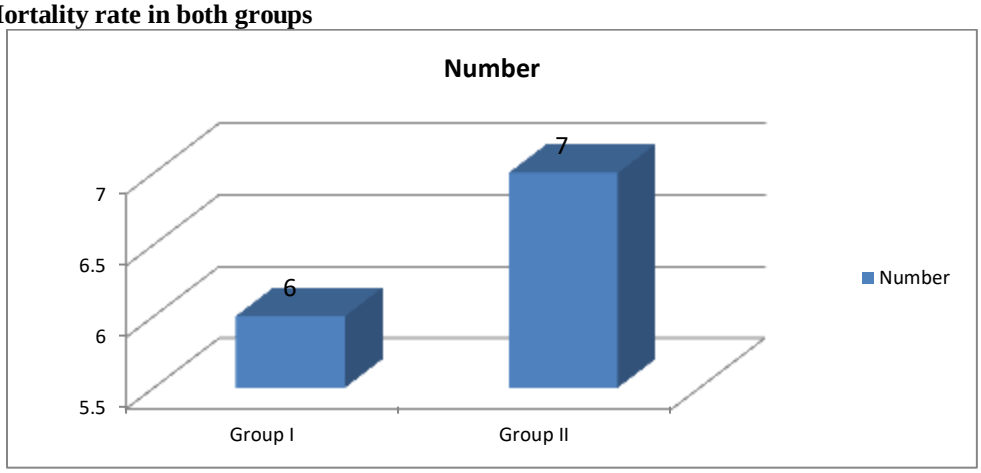
Characteristics	Group I	Group II	P value
Stents used per patient	1.53	1.52	0.91
Maximum implantation pressure	14.21	14.30	0.92
Direct stent implantation	34.2	36.1	0.13
Post- dilatation	24.1	27.6	0.15
Thrombectomy	10.4	10.2	0.81

Table II, graph I shows that mean stents used per patients was 1.53 in group I and 1.52 in group II, maximum implantation pressure was 14.21 in group I and 14.30 in group II, direct stent implantation was seen in 34.2 % in group I and 36.1% in group II, post- dilatation was seen in 24.1% in group I and 27.6% in group II, thrombectomy was observed in 10.4% in group I and 10.2% in group II. The difference was significant (P < 0.05).

Graph I Angiographic and procedural characteristics



Graph II Mortality rate in both groups



Graph II shows that mortality was observed 6 in group I and 7 in group II.

DISCUSSION

Acute thrombogenicity and long-term vascular healing in DES have been attributed not only to drug pharmacokinetics, durable polymer biocompatibility, composition distribution, and, in the case of BP-DES, duration of bioresorption, but also to the platform material and stent strut thickness.[6] Recently, ultrathin strut DES have been introduced with the potential to further reduce vascular injury and accelerate endothelialization.[7] In the BIOFLOW V trial (Biotronik- Safety and Clinical Performance of the Drug Eluting Orsiro Stent in the Treatment of Subjects With Single De Novo Coronary Artery Lesions), the 60-µm strut thickness Orsiro sirolimus-eluting stent (SES) reduced target lesion failure (TLF) in comparison with a widely used 81-µm strut thickness everolimus-eluting stent (EES).[8] The present study was conducted to compare 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 84 patients, males were 52 and females were 32. Bangalore et al[9] compared newer-generation ultrathin strut DES (defined as strut thickness <70 µm) versus thicker strut second-generation DES and reported clinical outcomes. The primary outcome was target lesion failure (composite of cardiovascular death, target vessel myocardial infarction or ischemia driven target lesion revascularization) evaluated at 1-year follow-up. Authors identified 10 trials that randomly assigned 11 658 patients and evaluated 3 newer-generation ultrathin strut DES: Orsiro stent (60 µm), MiStent (64 µm), and BioMime (65 µm). In comparison with thicker strut second-generation DES, newer-generation ultrathin strut DES were associated with a 16% reduction in target lesion failure driven by less myocardial infarction. Ultrathin strut DES were also associated with qualitatively lower rates of any stent thrombosis. Tests for subgroup effects based on the ultrathin strut DES type (P=0.58) and the comparator DES type (P=0.98) were not significant, suggesting consistent outcomes across the 3 ultrathin strut DES and with the different DES comparators.

We found that mean stents used per patients was 1.53 in group I and 1.52 in group II, maximum implantation pressure was 14.21 in group I and 14.30 in group II, direct stent implantation was seen in 34.2 % in group I and 36.1% in group II, post- dilatation was seen in 24.1% in group I and 27.6% in group II, thrombectomy was observed in 10.4% in group I and 10.2% in group II. The mortality was observed 6 in group I and 7 in group II.

Bioabsorbable polymers may facilitate stent healing, thus enhancing clinical safety. Gasior et al[10] sought to determine the 1-year clinical follow-up in patients treated with the thin strut (71 µm) bioabsorbable polymer-coated sirolimus-eluting stent (BP-SES) vs durable coating everolimus eluting stent (DP-EES) in daily clinical routine. They analyzed 4,670 patients treated with either a BP-SES (ALEX, Balton, Poland) or DP-EES (XIENCE, Abbott, USA) with available 1-year clinical follow-up using propensity-score matching. Outcomes included target vessel revascularization (TVR) as efficacy outcome and all cause death, myocardial infarction (MI), and definite/probable stent thrombosis as safety outcomes. Results showed that after propensity score matching, 1,649 patients treated with BP-SES and 1,649 patients treated with DP-EES were selected. Procedural and clinical characteristics were similar between both groups. There was no significant difference between tested groups in in-hospital mortality. One-year follow-up demonstrated comparable efficacy outcome, TVR (BP-SES 5.9% vs DP-EES 4.6% P = 0.45), as well as comparable safety outcomes, all cause death, MI and definite/probable stent thrombosis.

They concluded that BP-SES thin strut biodegradable polymer-coated sirolimus-eluting stent demonstrated comparable clinical outcomes at 1-year after implantation to the DP-EES. These data support the relative safety and efficacy of DP-SES in a broad range of patients undergoing percutaneous coronary intervention.

CONCLUSION

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

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