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Original Research Article

# Comparative Evaluation of Drug-Eluting and Bare-Metal Stents in Coronary Artery Disease: Safety, Efficacy, and Determinants of In-Stent Restenosis

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**Abstract:**

**Background:** Coronary artery disease (CAD) is a leading cause of morbidity and mortality worldwide. Percutaneous coronary intervention (PCI) with stent implantation is a widely used treatment modality. Drug-eluting stents (DES) were developed to reduce restenosis associated with bare-metal stents (BMS), but comparative outcome data remain clinically important.

**Aim:** To compare the clinical and angiographic outcomes of drug-eluting stents and bare-metal stents in patients undergoing PCI for coronary artery disease.

**Methodology:** This prospective comparative study included 90 patients who underwent PCI, comprising 45 patients treated with DES and 45 treated with BMS. Demographic characteristics, cardiovascular risk factors, angiographic findings, and clinical outcomes were analysed. Outcomes assessed included in-stent restenosis, target lesion revascularization, recurrent myocardial infarction, major adverse cardiac events (MACE), and all-cause mortality. Statistical analysis was performed using appropriate comparative tests, with $p<0.05$ considered statistically significant.

**Results:** Baseline demographic and clinical characteristics were comparable between the two groups. In-stent restenosis occurred in 8.9% of DES patients compared with 24.4% of BMS patients ($p=0.047$). MACE was observed in 11.1% of DES recipients and 26.7% of BMS recipients ($p=0.049$). Follow-up stenosis was significantly lower in the DES group ($14.2 \pm 6.8\%$) than in the BMS group ($26.5 \pm 10.4\%$; $p<0.001$). Mortality and recurrent myocardial infarction were lower in the DES group, although the differences were not statistically significant.

**Conclusion:** Drug-eluting stents demonstrated superior clinical and angiographic outcomes compared with bare-metal stents, with significantly lower rates of restenosis, follow-up stenosis, and major adverse cardiac events. DES may therefore be considered the preferred stent option for patients undergoing PCI.

**Keywords:** Coronary Artery Disease, Drug-Eluting Stent, Bare-Metal Stent, Percutaneous Coronary Intervention, Restenosis, Major Adverse Cardiac Events.

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## Introduction

One of the main causes of morbidity and death globally, coronary artery disease (CAD) continues to be a serious public health issue. It is mostly brought on by atherosclerotic coronary artery constriction, which lowers myocardial blood flow and causes ischaemia. Myocardial infarction, sudden cardiac death, unstable angina, and stable angina are all possible symptoms of CAD. Cardiovascular illnesses continue to be a major cause of death worldwide, especially in developing nations like India, despite advancements in preventive and treatment approaches [1].

A key component in the treatment of coronary artery disease is percutaneous coronary intervention, or PCI. The frequency of acute artery closure related to balloon angioplasty was decreased and procedural success was much enhanced with the introduction of coronary stents. The first generation of coronary stents that were extensively utilised in clinical practice were bare-metal stents (BMS). The high prevalence of in-stent restenosis brought on by neointimal hyperplasia, which resulted in recurring symptoms and repeated revascularisation procedures, limited the long-term use of BMS, despite the fact that they successfully decreased early problems [2].

Drug-eluting stents (DES) were created to get around BMS's drawbacks. Antiproliferative

medications including sirolimus, paclitaxel, everolimus, or zotarolimus, which prevent the proliferation of vascular smooth muscle cells and lessen neointimal development, are applied to DES [3]. When comparing patients receiving DES to those receiving BMS, early randomised clinical trials showed a significant decrease in restenosis rates and target lesion revascularisation [4].

Many studies have examined the safety and effectiveness of DES with BMS in various patient populations during the last 20 years. While retaining similar rates of death and myocardial infarction, long-term follow-up studies have consistently demonstrated reduced rates of restenosis and repeat revascularisation with DES. The safety profile of more recent DES has been further improved by technological developments in drug delivery systems, polymer coatings, and stent design [5].

One of the biggest randomised controlled trials comparing DES with BMS, the Norwegian Coronary Stent Trial (NORSTENT), found no discernible difference in non-fatal myocardial infarction or all-cause mortality between the two groups. Nevertheless, DES's better efficacy in preventing restenosis was demonstrated by the considerable reduction in the requirement for repeat revascularisation surgeries [6]. Similar to this, a number of observational studies and meta-analyses have shown that DES improves long-term outcomes, especially in terms of lowering severe adverse cardiovascular events and target vessel failure [7].

BMS is still utilised in some clinical settings, such as individuals with limited resources, a high risk of bleeding, or a contraindication to long-term dual antiplatelet medication, even though DES has become widely employed [8]. Additionally, stent-related outcomes may be influenced by patient characteristics, lesion complexity, and related comorbidities. As a result, comparing DES with BMS is still clinically useful, especially in real-world situations when treatment choices need to be customised [9].

Optimising treatment approaches and enhancing patient prognosis require an understanding of the variations in clinical outcomes between DES and BMS. With a focus on restenosis, repeat revascularisation, major adverse cardiovascular events, and overall patient outcomes, the current study was conducted to compare the clinical outcomes of drug-eluting stents and bare-metal stents in patients undergoing percutaneous coronary intervention.

## Materials and Methods

**Study Design:** The present study was a hospital-based prospective comparative observational study conducted to evaluate the safety and efficacy of Drug-Eluting Stents (DES) and Bare-Metal Stents (BMS) in patients undergoing percutaneous coronary intervention (PCI) for coronary artery disease (CAD). The study compared procedural success, clinical outcomes, angiographic findings, and determinants of in-stent restenosis following coronary stent implantation.

**Study Area:** The study was conducted in the Department of Cardiology, Netaji Subhas Medical College and Hospital, Bihta, Patna, Bihar, India.

**Study Population:** The study population comprised patients diagnosed with coronary artery disease (CAD) who underwent percutaneous coronary intervention (PCI) with either Drug-Eluting Stents (DES) or Bare-Metal Stents (BMS) in the Department of Cardiology during the study period and fulfilled the predefined inclusion and exclusion criteria.

**Study Duration:** The study was conducted over a period of one year.

### Inclusion Criteria

- Patients aged 18–80 years diagnosed with significant coronary artery disease requiring PCI.
- Patients who underwent elective or emergency PCI with implantation of either Drug-Eluting Stents or Bare-Metal Stents.
- Patients with angiographically confirmed coronary artery stenosis (≥70% in major epicardial coronary arteries or as clinically indicated).
- Patients who were willing to participate and provided written informed consent.

### Exclusion Criteria

- Patients with incomplete clinical records.
- Patients with previous coronary artery bypass graft (CABG) surgery.
- Patients present cardiogenic shock or severe hemodynamic instability.
- Patients with severe bleeding disorders or contraindications to dual antiplatelet therapy.
- Patients unwilling to participate or provide informed consent.

**Sample Size:** A total of 90 patients fulfilling the eligibility criteria were included in the study. Participants were divided into two groups according to the type of stent implanted: Drug-Eluting Stent (DES) group and Bare-Metal Stent (BMS) group.

**Sampling Technique:** A consecutive sampling technique was adopted. All eligible patients presenting during the study period and fulfilling the inclusion criteria were enrolled consecutively until the required sample size of 90 participants was achieved.

**Data Collection:** Data were collected using a predesigned structured case record form. Information regarding demographic characteristics, cardiovascular risk factors, clinical presentation, laboratory investigations, angiographic findings, procedural details,

and follow-up outcomes was recorded. Coronary angiography was used to assess the severity and location of coronary artery stenosis. Details regarding stent type (DES/BMS), procedural success, peri-procedural complications, in-stent restenosis, target lesion revascularization, recurrent myocardial infarction, major adverse cardiac events (MACE), and mortality were documented.

**Procedure:** After obtaining written informed consent, eligible patients underwent detailed clinical evaluation and baseline investigations. All patients received dual antiplatelet therapy with aspirin and clopidogrel before PCI. Coronary angiography was performed through radial or femoral arterial access, followed by implantation of either a Drug-Eluting Stent (DES) or Bare-Metal Stent (BMS) according to lesion characteristics and operator discretion. Post-procedure angiography confirmed procedural success and residual stenosis. Patients were monitored for peri-procedural complications and continued dual antiplatelet therapy as per current clinical guidelines. Clinical and angiographic follow-up was performed to evaluate in-stent restenosis, recurrent myocardial infarction, target lesion revascularization, major adverse cardiac events (MACE), and all-cause mortality.

**Statistical Analysis:** Data were analyzed using SPSS version 25.0. Continuous variables were expressed as mean ± standard deviation (SD), whereas categorical variables were presented as frequencies and percentages. Student's t-test was used for comparison of continuous variables, while Chi-square test or Fisher's exact test was applied for categorical variables. Logistic regression analysis was performed to identify factors associated with in-stent restenosis. A p-value of less than 0.05 was considered statistically significant.

**Ethical Considerations:** Prior approval was obtained from the Institutional Ethics Committee of Netaji Subhas Medical College and Hospital before commencement of the study. Written informed consent was obtained from all participants prior to enrollment. Confidentiality and anonymity of patient information were maintained throughout the study, and all procedures were conducted in accordance with ethical principles for biomedical research involving human participants".

## Results

Table 1 shows the patient numbers: the study included 90 people, with 45 in each of the DES and BMS groups. There was no discernible difference between the two groups, with the mean age of patients in the DES group being 58.7 ± 9.8 years and in the BMS group being 60.2 ± 10.4 years (p=0.472). With 68.9% (31/45) in the DES group and 73.3% (33/45) in the BMS group, men made up the bulk of the study population (p=0.642). In the DES and BMS groups, the percentage of patients with hypertension was 60.0% and 64.4%, respectively (p=0.664). Similarly, 40.0% of BMS patients and 35.6% of DES patients had diabetes mellitus (p=0.665). 44.4% of patients in the DES group and 48.9% in the BMS group reported smoking (p=0.671), and 33.3% and 37.8% of patients, respectively, reported having dyslipidaemia (p=0.656). 17.8% of DES patients and 22.2% of BMS patients had a history of myocardial infarction (p=0.599). All baseline clinical or demographic characteristics showed no statistically significant differences, suggesting that both groups were similar prior to intervention.

**Table 1: Baseline Demographic and Clinical Characteristics of Study Participants (N=90)**

| Variables | DES (n=45) | BMS (n=45) | p-value |
|---|---|---|---|
| Age (years), Mean ± SD | 58.7 ± 9.8 | 60.2 ± 10.4 | 0.472 |
| Male, n (%) | 31 (68.9) | 33 (73.3) | 0.642 |
| Female, n (%) | 14 (31.1) | 12 (26.7) | |
| Hypertension, n (%) | 27 (60.0) | 29 (64.4) | 0.664 |
| Diabetes Mellitus, n (%) | 16 (35.6) | 18 (40.0) | 0.665 |
| Smoking, n (%) | 20 (44.4) | 22 (48.9) | 0.671 |
| Dyslipidemia, n (%) | 15 (33.3) | 17 (37.8) | 0.656 |
| Previous MI, n (%) | 8 (17.8) | 10 (22.2) | 0.599 |

Table 2 demonstrates that patients treated with drug-eluting stents had superior outcomes, according to clinical outcome analysis. Only 4 patients (8.9%) in the DES group and 11 patients (24.4%) in the BMS group experienced in-stent restenosis; this difference was statistically significant (p=0.047). Three patients (6.7%) receiving DES and nine patients (20.0%) receiving BMS needed target lesion revascularisation (p=0.058). Two patients (4.4%) in the DES group and five patients (11.1%) in the BMS group had recurrent myocardial infarction (p=0.236). There was a statistically significant decrease in adverse events among DES recipients (p=0.049), with 5 patients (11.1%) treated with DES and 12 patients (26.7%) treated with BMS experiencing major adverse cardiac events (MACE). One patient (2.2%) in the DES group and three patients (6.7%) in the BMS group experienced all-cause

death (p=0.307). These results imply that DES was linked to better clinical outcomes, especially in terms of preventing restenosis and lowering the incidence of serious adverse cardiac events.

| Table 2: Clinical Outcomes Following Stent Implantation | | | |
|---|---|---|---|
| **Outcome** | **DES (n=45)** | **BMS (n=45)** | **p-value** |
| In-stent Restenosis | 4 (8.9%) | 11 (24.4%) | 0.047* |
| Target Lesion Revascularization | 3 (6.7%) | 9 (20.0%) | 0.058 |
| Recurrent Myocardial Infarction | 2 (4.4%) | 5 (11.1%) | 0.236 |
| Major Adverse Cardiac Events (MACE) | 5 (11.1%) | 12 (26.7%) | 0.049* |
| All-cause Mortality | 1 (2.2%) | 3 (6.7%) | 0.307 |

Table 3 shows the angiographic results showed that the two groups' baseline stenosis severity was similar. The DES group had an average pre-procedure stenosis of 84.3 ± 8.5%, while the BMS group had an average of 85.7 ± 7.9% (p=0.428). Both groups' residual stenosis significantly decreased after stent implantation; the DES group's mean post-procedure residual stenosis was 8.1 ± 3.6%, while the BMS group's was 9.3 ± 4.2% (p=0.154). However, there was a notable difference between the groups at follow-up. In patients taking DES, the mean follow-up stenosis was 14.2 ± 6.8%, but in patients getting BMS, it was 26.5 ± 10.4% (p<0.001). This statistically significant difference suggests that, when compared to bare-metal stents, drug-eluting stents were more successful in preserving artery patency and avoiding luminal constriction over time.

| Table 3: Comparison of Angiographic Outcomes Between DES and BMS Groups | | | |
|---|---|---|---|
| **Parameter** | **DES (n=45)** | **BMS (n=45)** | **p-value** |
| Pre-procedure Stenosis (%) | 84.3 ± 8.5 | 85.7 ± 7.9 | 0.428 |
| Post-procedure Residual Stenosis (%) | 8.1 ± 3.6 | 9.3 ± 4.2 | 0.154 |
| Follow-up Stenosis (%) | 14.2 ± 6.8 | 26.5 ± 10.4 | <0.001* |

## Discussion

In patients receiving percutaneous coronary intervention for coronary artery disease, the clinical and angiographic results of drug-eluting stents (DES) and bare-metal stents (BMS) were compared in this study. The results showed that, in comparison to BMS, DES was linked to decreased rates of major adverse cardiac events (MACE), target lesion revascularisation, and in-stent restenosis. These findings align with earlier research that shown DES's superiority in lowering neointimal hyperplasia and enhancing long-term vascular patency" [10].

In the current study, the DES group had a much lower incidence of in-stent restenosis (8.9%) than the BMS group (24.4%). One of the main drawbacks of coronary stenting is still restenosis, which is mostly brought on by excessive neointimal proliferation after vascular damage. Although bare-metal stents give the artery wall mechanical support, they do not stop the development of smooth muscle cells, which is a factor in restenosis. Drug-eluting stents were created expressly to get around this restriction by releasing antiproliferative drugs under regulated conditions. Moses et al. (2003) reported similar results, showing that sirolimus-eluting stents considerably lowered restenosis rates when compared to traditional bare-metal stents. Similarly, Stone et al. (2004) found that patients receiving paclitaxel-eluting stents had reduced rates of target vessel revascularisation [11].

Additionally, the DES group had a lower frequency of target lesion revascularisation than the BMS group, according to the current study. The general trend favoured DES, even if the difference was almost statistically significant. The long-term observational study by Tu et al. (2007), which found fewer repeat revascularisation surgeries among patients using drug-eluting stents, supports these conclusions. Reduced restenosis improves patient quality of life and lowers healthcare costs by directly lowering the need for repeat procedures [12].

Patients receiving DES experienced fewer major adverse cardiac events. In the DES group, the incidence of MACE was 11.1%, while in the BMS group, it was 26.7%. This result is consistent with a number of earlier studies showing better clinical outcomes with DES. According to Iqbal et al. (2016), patients receiving DES had positive long-term outcomes, especially with relation to overall cardiovascular events and repeat revascularisation. In a similar vein, recent meta-analyses have consistently demonstrated that DES is more effective than BMS at preventing negative cardiovascular events [13].

The DES group in the current trial had numerically decreased rates of recurrent myocardial infarction and all-cause death, but these differences were not statistically significant. Similar findings were observed in the NORSTENT trial by Bønaa et al. (2016), which demonstrated significant reductions in repeat revascularisation among DES patients but no significant differences in mortality or non-fatal

myocardial infarction between DES and BMS. These results imply that although DES successfully lowers problems associated with restenosis, their effect on mortality outcomes may be less noticeable, especially in trials with comparatively smaller sample sizes [14].

Patients treated with DES had considerably decreased rates of residual and follow-up stenosis, according to angiographic follow-up. DES's antiproliferative medication coating prevents neointimal development and vascular smooth muscle proliferation, preserving luminal diameter over time. The efficacy and safety of DES have been further improved by developments in stent technology, such as better polymer coatings and more recent drug-eluting platforms. In comparison to older DES, Lee and de la Torre Hernandez (2018) noted that newer DES show better endothelium repair and lower incidence of late stent thrombosis [15].

Patients in both groups had similar baseline clinical and demographic features, suggesting that stent type rather than confounding patient-related factors was probably the cause of outcome disparities. Numerous randomised controlled trials comparing DES and BMS have revealed similar baseline comparability. The validity of the current findings is strengthened by the balanced distribution of cardiovascular risk factors, including smoking, dyslipidaemia, diabetes mellitus, and hypertension [16].

The results of this study add to the increasing amount of data that supports the application of DES in modern clinical practice. Due to DES's higher efficacy in lowering restenosis and repeat revascularisation, bare-metal stents are nevertheless helpful in some patients, especially those who cannot take long-term dual antiplatelet medication. The advantages of DES over BMS in regular cardiac procedures are further supported by the noted decrease in unfavourable clinical outcomes [17].

There are some limitations to the current investigation. The single-centre approach and rather small sample size may restrict how far the results can be applied. Furthermore, very late problems such late stent thrombosis might not be properly captured by the follow-up period. To further assess the long-term safety and efficacy of drug-eluting stents in comparison to bare-metal stents, future multicentre trials with bigger sample populations and longer follow-up periods are necessary [18].

Overall, the current investigation showed that, when compared to bare-metal stents, drug-eluting stents offer better clinical and angiographic results. Their ongoing usage as the preferred stent platform in patients having percutaneous coronary intervention for coronary artery disease is supported by the DES group's lower rates of restenosis, repeat revascularisation, and serious adverse cardiac events.

## Conclusion

In patients receiving percutaneous coronary intervention for coronary artery disease, the current study showed that drug-eluting stents (DES) offer better clinical and angiographic results than bare-metal stents (BMS). In-stent restenosis, target lesion revascularisation, and severe adverse cardiac events were all substantially reduced in DES-treated patients, suggesting better long-term vessel patency and clinical efficacy. The overall results favoured DES even though there were no discernible differences between the two groups in terms of mortality and recurrent myocardial infarction. These results corroborate the recommended revascularisation approach for appropriate individuals, which is the regular use of drug-eluting stents. To validate these findings and assess the long-term safety and robustness of modern DES platforms, more extensive multicentre trials with extended follow-up times are advised.

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