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Research Brief

# Twelve-months clinical outcomes of biodegradable polymer-coated sirolimus-eluting coronary stent in real-world patients: A single-center experience.

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ABSTRACT

This study was designed to evaluate the safety and performance of Metafor™ SES in real-world patients with coronary artery disease. This was retrospective, single-centre, post-marketing, observational study. The primary endpoint was the occurrence of major adverse cardiac event (MACE). A total of 141 patients (187 lesions) were treated with the study device. The average stent length and diameter was 24.75 ± 9.50 mm and 2.93 ± 0.38 mm, respectively. The cumulative incidence of MACE was 1.42%. No incidence of stent thrombosis was observed at 12-months follow-up. This retrospective study demonstrated favourable safety and performance of Metafor™ SES.


## 1. Introduction

The biodegradable polymer coated drug-eluting stents (BPDES) are designed to overcome late and very late stent thrombosis (ST) and atherosclerosis associated with the earlier generation stents.[1] The clinical safety and effectiveness of BPDES over bare-metal stents (BMS) and first-generation drug-eluting stents has been proved in numerous clinical trials.[2–4]

Metafor™ sirolimus-eluting stent (SES) (Meril Life Sciences Pvt. Ltd., India) is a CE-approved sirolimus-eluting biodegradable polymer-coated cobalt-chromium coronary stent system. The safety and efficacy of the Metafor SES have been confirmed among all-comers populations of south India.[5] This retrospective, observational study was designed to evaluate the safety and performance of Metafor SES in real-world populations having a wide spectrum of coronary artery disease (CAD).

## 2. Methods

### 2.1. Study design and patient population

This was a retrospective, single-centre, post-marketing, observational study, including patients who were treated with the study device between January 2016 and February 2017 in India. All the patients who were treated with at least one Metafor SES for native coronary artery lesions were included in the study irrespective of clinical presentation, number of treated vessels or number, type and length of treated lesions. However, the patients were excluded if any of the lesions were treated by other techniques such as balloon angioplasty, atherectomy or if any additional stent(s) other than DES were implanted during the index procedure.

### 2.2. Description of the study device

The Metafor SES is a sirolimus-eluting stent built on CE-approved NexGen™, with a unique cell design comprising of an intelligent mix of opened and closed cells. The stent exhibits ultra-

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thin strut thickness (65 μm). The stent is coated with biodegradable and biocompatible polymers namely poly-L-lactic acid (PLLA) and poly (lactic-co-glycolic acid) (PLGA) which contains a low dose of sirolimus (1.25 μg/mm$^2$). The biodegradable polymers elute drug over a period of 30–40 days and eventually degrade.

### 2.3. Endpoints of the study and definitions

The primary endpoint of the study was the occurrence of a major adverse cardiac event (MACE) and ST at 12-months. MACE was defined as a composite of cardiac death, MI and target vessel revascularization (TLR). ST was defined according to the Academic Research Consortium.[6]

### 2.4. Statistical analysis

The categorical data were presented as counts (percentages) and continuous variables were presented as mean ± standard deviation (SD). Data were processed using the Statistical Package for Social Sciences, version 20 (SPSS, Chicago, IL, USA).

## 3. Results

A total of 141 patients were included in the study; the mean age was 54.01 ± 12.69 years, and 105 (74.5%) were male. Among these included patients, 56.7% had hypertension, and 40.4% were diabetic and 17.7% were a smoker. The baseline clinical characteristics of all the enrolled patients are shown in Table 1. A total of 187 lesions were treated with the study device (1.35 study stent per patient). Among them, 81 (43.3%) lesions were located in the left descending artery (LAD). The average stent length and diameter was 24.75 ± 9.50 mm and 2.93 ± 0.38 mm, respectively. Other baseline lesions and procedural characteristics are demonstrated in Table 2.

As represented in Table 3, the cumulative incidence of MACE was 2 (1.42%) (due to sudden death) at 12-months clinical follow-up. Additionally, none of the patients experienced ST.

**Table 1**
Demographic and baseline clinical characteristics of the study population.

| Baseline and demographics characteristics | n = 141 |
|---|---|
| **Age (Mean ± SD), years** | 54.01 ± 12.69 |
| **Gender** | |
| Male | 105 (74.5) |
| Female | 36 (25.5) |
| **Medical history** | |
| Hypertension | 80 (56.7) |
| Diabetes mellitus | 57 (40.4) |
| Smokers | 25 (17.7) |
| Alcoholic | 10 (7.1) |
| Previous percutaneous coronary intervention | 1 (0.7) |
| Angina | 3 (2.1) |
| Other illness | 7 (5.0) |
| Family history of coronary artery disease | 3 (2.1) |
| **Disease vessel** | |
| Single vessel | 43 (30.5) |
| Double vessel | 60 (42.6) |
| Triple vessel | 38 (27.0) |
| **Clinical presentation** | |
| Stable angina | 16 (11.3) |
| Unstable angina | 34 (24.1) |
| ST-elevation myocardial infarction | 74 (52.5) |
| Non ST-elevation myocardial infarction | 11 (7.8) |
| Asymptomatic/silent ischemia | 6 (4.3) |

**Table 2**
Lesion and procedural characteristics.

| Lesion characteristic | N = 187 |
|---|---|
| Total number of lesions | 294 |
| Total number of lesions treated with study stent | 187 |
| Lesion per patient | 1.33 |
| Study stent per patient | 1.35 |
| **Lesion location (CASS code)** | |
| Right coronary artery | 60 (32.1) |
| Left descending artery | 81 (43.3) |
| Left circumflex | 21 (11.2) |
| Ramus | 4 (2.1) |
| Diagonal | 6 (3.2) |
| Obtuse marginal | 9 (4.8) |
| Other | 6 (3.2) |
| **Lesion class, n (%)** | |
| A | 40 (21.4) |
| B1 | 103 (55.1) |
| B2 | 24 (12.8) |
| C | 20 (10.7) |
| Average stent length (Mean ± SD), mm | 24.75 ± 9.50 |
| Average stent diameter (Mean ± SD), mm | 2.93 ± 0.38 |
| Occlusion (Mean ± SD), % | 87.78 ± 11.78 |

**Table 3**
Cumulative major adverse cardiac events at 12-month clinical follow-up.

| Events, (%) | (n = 141) |
|---|---|
| All-cause death | 5 (3.55) |
| Cardiac death | 2 (1.42) |
| Non-cardiac death | 3 (2.13) |
| Myocardial infarction | 0 (0.00) |
| Target lesion revascularization | 0 (0.00) |
| Stent thrombosis | 0 (0.00) |
| **Major adverse cardiac events** | 2 (1.42) |

## 4. Discussion

This retrospective, observational, single-centre study demonstrates the safety and performance of Metafor SES in a real-world Indian population as evident by a low incidence of MACE (1.42%) and ST (0%) at 12-months of clinical follow-up. Whether to implement these results to daily practice or not is a topic of controversy, hence, the real-world studies in the unselected and complex population under similar risk factors as in daily practice are important.

The ultra-thin (65 μm) cobalt-chromium stent platform with a hybrid cell design of Metafor SES showed increased performance by optimizing the deliverability and flexibility of the device. The hybrid cell structure of the stent minimizes the edge injury that was the case with conventional DES.[7]

The 12-months clinical outcomes from the current study are consistent with other retrospective real-world studies evaluating the safety and performance of the study device, Metafor SES, under similar conditions. Kasturi et al assessed the safety and performance of the study device in 251 consecutive patients (295 lesions) including a considerable number of patients having STEMI (46.6%). In this study, the incidence of MACE and ST was 1.6% and 0.4% at 12-month follow-up, respectively.[5] In the long term follow-up (3.6 ± 0.6 years) of Metafor SES in a real-world retrospective study by Rao et al reported a MACE rate of 1.6% (attributed by 2 incidences of TLR) in 127 patients (169 lesions). Low rate of MACE obtained on long term follow-up is noteworthy despite of complex patient population.[8]

The results of the current real-world retrospective study are comparable with other sirolimus-eluting BPDES. The clinical outcomes of an ultrathin (60 μm) biodegradable polymer-coated

Supraflex stent in the FLEX Registry showed 3.7% of MACE, attributed by 1.6% of MI, 0.7% of TLR and 1.1% of ST at 12months of follow-up.[9] The Manipal-S Registry evaluating safety and efficacy of Supralimus sirolimus-eluting BPDES showed similar rates of TLR (1.7%), MI (0%) and possible ST (0.9%) at 12-months follow-up.[10] Moreover, the clinical outcomes of Metafor SES in the current real-world study are better than the previous long-term follow-up trials of durable DES, which underlines the effectiveness of BPDES in reducing the clinical events and increasing the effectiveness.[11,12]

### 4.1. Study limitations

Single-arm, non-randomized, retrospective study design that did not include a comparator group is the major limitation of the current study. Other limitations include the small sample size of the study and the lack of long-term follow-up data. Further, the lack of quantitative coronary angiography (QCA), intravascular ultrasound (IVUS), fractional flow reserve (FFR) and optical coherence tomography (OCT) is also the limitation of the study.

## 5. Conclusion

The retrospective real-world analysis at 12-months follow-up demonstrated the satisfactory clinical performance of Metafor SES in real-world patients with native CAD as evident by the low rate of MACE and absence of ST.

## Financial disclosure

None declared.

## Declaration of competing interest

All authors have none to declare.

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