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Long-term safety and performance of the BioMime Morph sirolimus-eluting coronary stent system for very long coronary lesions in real-world settings

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Abstract

Background: Long stents reduce the risk for in-stent restenosis associated with percutaneous coronary interventions in long, tapered coronary lesions.

Aims: The Morph India study investigated the long-term safety and clinical performance of the BioMime Morph sirolimus-eluting stent (SES), a tapered stent used for treating long coronary lesions.

Methods: This is a prospective, multicentre, single-arm, real-world, post-marketing surveillance study conducted among patients with long coronary lesions (length >26 mm to ≤56 mm, reference vessel diameter 2.25-3.50 mm) implanted with the BioMime Morph SES. The primary endpoint was freedom from target lesion failure (TLF). The incidence of target vessel failure (TVF) - defined as a composite of cardiac death related to the target vessel, target vessel myocardial infarction (TVMI), and ischaemia-driven target vessel revascularisation (ID-TVR) - was the secondary endpoint. An angiographic follow-up was conducted at 9 months, and subjects were followed up for 3 years.

Results: Out of 448 enrolled patients, 420 patients completed the 3-year follow-up. The rate of freedom from TLF was 99.31% at 12 months and 98.80% at 3 years. In 3 years, there were 4 events each of TVMI, TVR (including ID-TVR) and ischaemia-driven target lesion revascularisation (all 0.95%). Quantitative coronary angiography analysis at a mean of 9.2 months revealed in-segment late lumen loss (LLL) of 0.29±0.23 mm and in-device LLL of 0.35±0.11 mm. The in-device minimal lumen diameter improved from 0.63±0.42 mm at preprocedure to 2.13±0.37 mm ($p<0.001$) at 9.2 months.

Conclusions: The 3-year safety and clinical outcomes of BioMime Morph SES for treating long coronary lesions were satisfactory. Further long-term comparative studies are necessary to validate these results.

Figures

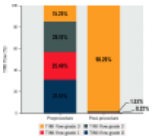

Figure 1. Changes in TIMI flow after...

Central illustration. Morph India study: BioMime Morph...

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