

Results of RIBS IV trial reported

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A new clinical trial comparing the use of everolimus-eluting stents (EES) and drug-eluting balloons (DEB) in treating in-stent restenosis (ISR) from drug-eluting stents found that EES provided superior late angiographic results and better late clinical outcomes.

Findings were reported today at the 26th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine.

Treatment of [patients](#) with ISR remains a challenge, especially in patients presenting with drug-eluting stent (DES) ISR. In this setting, DEB appear to be as effective as first generation DES. However, the relative value of DEB compared to new generation DES with DES-ISR remains unknown.

RIBS IV was a multicenter [prospective randomized trial](#) that compared the efficacy of DEB with that of EES in patients with DES-ISR. The primary endpoint was minimal lumen diameter (MLD) at late angiographic follow up. Secondary endpoints including diameter stenosis, angiographic late lumen loss, and binary restenosis were also analyzed at nine months.

A total of 309 patients with DES-ISR were randomized to receive either EES (n=155) or DEB (n=154). Late angiographic follow up was obtained in 90 percent of eligible patients. At nine months, the EES

group reported a larger in-segment MLD than the DEB group (2.03 vs. 1.80, respectively; $p=0.004$). After one year, the EES group also reported higher rates of freedom from target lesion revascularization (96 percent vs. 87 percent, $p=0.008$) and freedom from major adverse coronary events, including cardiac death, myocardial infarction, and target vessel revascularization (90 percent vs. 82 percent, $p=0.044$).

"In patients with DES-ISR, our study found that EES provides superior late angiographic results and better late clinical outcomes compared to DEB," said lead investigator Fernando Alfonso, MD, PhD. Dr. Alfonso is the Head of the Cardiac Department at the Hospital Universitario de La Princesa in Madrid, Spain. "Treatment of DES-ISR remains challenging and associated with poorer clinical and angiographic results than treatment of bare metal stent ISR. Further studies with more patients and longer follow-up are warranted in this adverse setting."

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