Asia-Pacific Hotlines at TCT 2015: a prospective randomised trial of paclitaxel-eluting vs. everolimus-eluting stents in diabetic patients with coronary artery disease (TUXEDO)

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What was your rationale for this study and what was known before?

The choice of a drug-eluting stent in diabetics has been the subject of debate for a decade. Based on a large meta-analysis, paclitaxel-eluting stents have traditionally been given an equivalent status to everolimus-eluting stents (possibly even favoured over them) in insulin-dependent diabetics. This position was challenged on the basis of a patient-based meta-analysis. In the absence of an adequately powered study, a definitive answer was not possible.

What is unique about this study in your country?

This Indian study is the largest international study to compare a paclitaxel-eluting stent (PES) versus an everolimus-eluting stent (EES) in a diabetic population[1]. In total, 1,830 patients with diabetes mellitus were included using a non-inferiority trial design. They received either a PES (TAXUS Element™; Boston Scientific, Marlborough, MA, USA) or an EES (XIENCE PRIME; Abbott Vascular, Santa Clara, CA, USA). The primary endpoint was target vessel failure defined as a composite of cardiac death, target vessel myocardial infarction, or ischaemia-driven target vessel revascularisation at one-year follow-up.

Did you experience any unexpected challenges?

Because of changes to the rules concerning clinical trials in India and slow recruitment due to regulatory issues, recruitment of cases was challenging.

How does the conclusion apply to your daily practice?

PES did not meet the non-inferiority criteria of target vessel failure against everolimus-eluting stents at one year (5.6% vs. 2.9%; relative risk=1.89; 95% CI: 1.20-2.99; pNI=0.38 for non-inferiority at 4% margin; treatment difference 95% CI: 0.78-4.48). There was a significantly higher one-year rate of target vessel failure (p=0.005), myocardial infarction (3.2% vs. 1.2%, p=0.004), stent thrombosis (2.1% vs. 0.4%, p=0.002), target vessel revascularisation (3.4% vs. 1.2%; p=0.002) and target lesion revascularisation (3.4% vs. 1.2%; p=0.002) in the PES group compared to the EES group.

In this trial, the largest conducted in a diabetic population undergoing percutaneous coronary intervention, PES failed to meet non-inferiority compared with EES and resulted in higher rates of target vessel failure, myocardial infarction, stent thrombosis, and target vessel revascularisation at one year. The study has resulted in a marked increase in the use of EES, even in diabetic patients.

Conflict of interest statement

U. Kaul reports grant support from Boston Scientific and other support from Abbott Vascular during the conduct of the study; grant support and personal fees from Boston Scientific, and personal fees from Abbott Vascular and Medtronic outside the submitted work.

Reference

1. Kaul U, Bangalore S, Seth A, Arambam P, Abhaychand RK, Patel TM, Banker D, Abhyankar A, Mullasari AS, Shah S, Jain R, Kumar PR, Bahuleyan CG; TUXEDO–India Investigators. Paclitaxel-Eluting versus Everolimus-Eluting Coronary Stents in Diabetes. *N Engl J Med.* 2015;373:1709-19.

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