Low and comparable rates of stent thrombosis found with zotarolimus- and sirolimus-eluting stents

27 August 2012

Rates of stent thrombosis at three years were low and comparable between zotarolimus-eluting and sirolimus-eluting stents, according to findings from the PROTECT study described here today at ESC Congress 2012.

Presenting the results, Professor William Wijns from the Cardiovascular Center in Aalst, Belgium, said that the decline in rates of stent thrombosis seen recently and in the PROTECT (Patient Related OuTcomes with Endeavor versus Cypher Stenting) study was probably explained by several factors, including "improvements in patient selection, procedural techniques, and duration of and compliance with dual antiplatelet therapy". Concerns about the safety of drug-eluting stents (DES) had emerged at ESC Congress 2006 when retrospective studies proposed that DES were subject to a higher risk of stent thrombosis (with a trend towards more late stent thrombosis) than bare-metal stents.

The effect of DES on vessel healing, long-term safety, particularly stent thrombosis, and clinical outcomes has been shown to vary according to drug, polymer and characteristics of the stent. The PROTECT study was thus designed to determine prospectively the safety profile of two DES with different antiproliferative properties.

This, said Professor Wijns, was the largest comparative DES study performed as an open-label, randomised trial. It compared the effect zotarolimus-eluting (E-ZES) and sirolimus-eluting (C-SES) stents in a broad group of patients and lesions, including those with stable and acute coronary syndrome and single or multivessel disease, and with a mix of simple and/or complex lesions. The primary outcome of the study was definite or probable stent thrombosis at three years, with a main secondary outcome of mortality and large non-fatal MI.

PROTECT ultimately randomised 8709 patients equally into each study arm and, for the primary endpoint, followed them up to three years. At this point, the rates of definite or probable stent thrombosis did not differ between groups (1.4% for E-ZES and 1.8% for C-SES; HR 0.81, 95% CI 0.58-1.14, p=0•22).

Rates of death and large non-fatal MI were also similar (5.3% vs 6.0%; HR 0.88, 95% CI 0.73-1.05, p=0.16). Dual antiplatelet therapy (DAPT) was used in 96.5% patients at discharge, 87.8% at one year, 36.6% at two years, and 30.0% at three years.

The investigators found a low incidence of definite stent thrombosis in the C-SES arm at one year when DAPT use was over 85%, but a more than three-fold increase in the rate per year when DAPT use decreased to less than 40%. In the E-ZES arm the incidence of definite very late stent thrombosis decreased two-fold after one year, despite decreasing DAPT regimen. This trend, said Professor Wijns, was consistent with the hypothesis that DAPT use may have a different long-term clinical relevance according to the type of stent used.

Follow-up to five years, currently in progress, will determine whether the rates of 'definite' as well as 'definite or probable' stent thrombosis diverge further and translate into differences in clinical safety.

Provided by European Society of Cardiology