No Differences Found Between Drug-Eluting Stents in Everyday Clinical Practice

Galloe AM, Thusen L, Kelbaek H, et al. Comparison of paclitaxel- and sirolimus-eluting stents in everyday clinical practice: the SORT OUT II randomized trial. JAMA 2008;299:409–16.

Study Overview

Objective. To compare sirolimus-eluting and paclitaxel-eluting stents for prevention of major adverse cardiac events.

Design. Randomized, blinded trial.

Setting and participants. 2098 men and women treated with percutaneous coronary intervention (PCI) were randomized to receive either sirolimus-eluting (n = 1065) or paclitaxel-eluting (n = 1033) stents. Patients were enrolled from 5 university hospitals in Denmark from August 2004 to January 2006. Indications for PCI included ST-segment elevation myocardial infarction (STEMI), non-STEMI or unstable angina, and stable angina.

Main outcome measures. The primary outcome was a composite endpoint of major adverse cardiac events, including cardiac death, myocardial infarction (MI), target lesion revascularization, and target vessel revascularization. Secondary endpoints were individual components of the composite endpoint, all-cause mortality, and stent thrombosis.

Main results. There was no significant difference in major adverse cardiac events between the sirolimus-eluting and paclitaxel-eluting stent groups (9.3% vs. 11.2%, respectively; hazard ratio, 0.83 [95% confidence interval, 0.63–1.08]; P = 0.16). None of the secondary endpoints were found to be significant. Stent thrombosis rates did not differ significantly between the 2 groups (2.5% for sirolimus-eluting vs. 2.9% for paclitaxel-eluting stents; hazard ratio, 0.87 [95% confidence interval, 0.52–1.46]; P = 0.6).

Conclusion. No significant differences in clinical outcomes were found between patients receiving sirolimus-eluting and paclitaxel-eluting stents.

Commentary

There continues to be controversy regarding the safety and efficacy of the 2 commercially available drug-eluting stents: the sirolimus-eluting Cypher (Cordis/Johnson & Johnson, Miami Lakes, FL) and the paclitaxel-eluting Taxus (Boston Scientific Corp, Natick, MA). A recent meta-analysis of 16 randomized head-to-head trials showed that the sirolimus-eluting stent was superior to the paclitaxel-eluting stent with regards to target lesion revascularization and stent thrombosis [1]. Other studies [2,3] have shown equivalent rates of target lesion revascularization between the 2 stents. Adding to the literature surrounding this controversy, Galloe et al attempt to evaluate the effects of these stents in everyday practice by using clinically driven repeat angiography (eg, angina pectoris, acute MI) rather than mandatory repeat angiography, as previous studies have done. The authors conclude that there was no significant difference in clinical outcomes between patients receiving sirolimus-eluting or paclitaxel-eluting stents.

There are a number of limitations in this study that should be considered. The authors acknowledge that the study power was insufficient to detect a difference in outcomes. Although the original design had appropriate study power, the actual event rate (10.2% vs. 20% expected) and the absolute difference between the rates in the 2 treatment groups (1.9% vs. 5% expected) were lower than expected. As a consequence, the study's power to detect a difference in outcomes fell to 28.7%, well below the calculated 80% power target. With the decrease in power, the probability of a type II error (ie, concluding that no difference exists when, in fact, a difference does exist) increases and may explain the nonsignificant findings.

An editorial that accompanied this study [4] alluded to another limitation—that less than one third (27.7%) of potentially eligible patients were randomized. This suggests the possibility of selection bias and thus may decrease the generalizability of the study. Also, the rates of stent thrombosis between sirolimus-eluting stents (2.5%) and paclitaxel-eluting stents (2.9%) were higher than expected and may highlight a need to decrease this risk by increasing adherence to dual antiplatelet (aspirin and clopidogrel) therapy.

Applications for Clinical Practice

Although the authors concluded that there were no differences in clinical outcomes between patients receiving sirolimus-eluting and paclitaxel-eluting stents, the study was underpowered to detect a significant difference. The negative results of this trial may be due to a type II error;

therefore, further study is required to clarify if there is a true difference between these 2 stents.

—Review by Robert L. Huang, MD, MPH

References

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