Drug-eluting stents demonstrate better outcomes after one year than bare metal stents

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Use of drug-eluting stents is associated with a lower risk of major cardiovascular events at one year compared to bare metal stents when followed by an individualized course of blood-thinning medication among patients previously thought to be uncertain candidates for drug-eluting stents due to their heightened risk of bleeding or blood clots, according to research presented at the American College of Cardiology's 63rd Annual Scientific Session.

Positive study findings for patients receiving a shorter than currently recommended course of blood thinners may call into question existing guidelines for a more prolonged anti-platelet therapy following placement of drug-eluting stents, which points to the need for a more personalized approach, according to authors.

This multinational, single-blinded trial involved 1,606 patients who were randomly assigned to receive a specific type of drug-eluting stent (Zotarolimus-eluting stent) or a bare metal stent. The purpose of the study was to assess whether implantation of the drug-eluting stent followed by an individualized course of dual anti-platelet therapy – a combination of aspirin and an anti-platelet that thins the blood to prevent clots – would decrease the incidence of 12-month major adverse cardiovascular events compared to implantation with a bare metal stent among patients classified as uncertain candidates for drug-eluting stents. A significantly higher number of patients in the bare metal stent group

had major adverse cardiovascular events at one year, including all-cause death, non-fatal heart attacks or any procedures to re-open the artery.

"Given the assumed risks, we were surprised by the lower rate of heart attack and blood clots among our drug-eluting stent patients," said Marco Valgimigli, M.D., Ph.D., cardiologist and associate professor, Erasmus University Medical Center in the Netherlands, and lead investigator of the study. "For the first time, we have handled a drug-eluting stent as we would a bare metal stent in terms of the duration and intensity of anti-platelet therapy and have still shown the superior safety and efficacy of the drug-eluting stent."

A total of 140 or 17.5 percent of patients with the drug-eluting stent had a major cardiovascular event in the first year compared with 178 or 22.1 percent of patients implanted with the bare metal stent. Patients with the drug-eluting stent also had lower rates of heart attack (2.9 compared to 8.1 percent) and procedures to re-open the artery (5.9 compared to 10.7 percent). This group also had lower rates of blood clots around the stent (2.0 compared to 4.1 percent). The rate of bleeding did not differ between groups.

Patients were enrolled at 20 sites in Italy, Switzerland, Portugal and Hungary. All were undergoing percutaneous coronary intervention with stent implantation. Adult patients who met any one of the three criteria to be uncertain candidates for drug-eluting stents were randomly assigned to receive bare metal or drug-eluting stents. To qualify as "uncertain" candidates for drug-eluting stents, patients in the study had to either have a high risk of blood clots, high risk of bleeding and/or low risk of restenosis – the artery becoming blocked again. Patients at a low risk of restenosis were included because the risk of blood clots associated with drug-eluting stents – along with the assumed risk of bleeding from the prolonged course of blood thinners taken afterward – may, in fact, outweigh benefits of this type of stent for these patients.

The majority of patients (95.4 percent) took some course of dual anti-platelet therapy after stent placement, 96.7 percent with aspirin and clopidogrel and the remaining 3.3 percent with aspirin and either prasugrel or ticagrelor. Duration of therapy was dictated by patients' individual risk factors and spanned from no treatment to six to 12 months, with a median of 32 days. Patients who were not eligible for dual anti-platelet therapy were treated with either aspirin or an anti-platelet alone. This protocol represents a departure from current guidelines that recommend the use of dual anti-platelet therapy for six to 12 months after the placement of a drug-eluting stent.

Bare metal stents are metal mesh tubes inserted into clogged arteries to prop them open after they are widened through angioplasty. Scar tissue grows around the stent and holds it in place, but sometimes an overgrowth of tissue can cause the artery to become blocked. This may require the patient to have additional procedures to re-open the artery.

Drug-eluting stents are coated with medication to help prevent scar tissue from growing and to keep the artery smooth and open. Although these stents reduce restenosis rates, they have also been linked to a higher incidence of blood clots around the stent, leading to the current guidelines on prolonged dual anti-platelet therapy after they are placed.

Authors caution that the results of this study pertain to the Zotarolimus-eluting stent and may not apply to other types of drug-eluting stents. According to Valgimigli, additional research is needed to determine whether the personalized dual anti-platelet therapy tested in this study can be safely implemented in patients using other types of drug-eluting stents. He also suggests that a longer follow-up study be conducted to confirm results of this study over time.

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