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LECTURE ESSENTIALS

Lecture Notes

American College of Cardiology 60th Annual Scientific Session & i2 Summit

One Year Clinical Outcomes from the Pivotal Multicenter RESOLUTE US Study

Sponsor: Medtronic Vascular

Clinical Trial: NCT00726453

Background

Drug-eluting stents (DES) are commonly used to treat coronary artery disease because they reduce in-stent stenosis and the need for repeat revascularization compared with bare-metal stents (BMS). Safety concerns about complications from thrombosis, are initiating further developments in DES.

Summary

To evaluate the clinical effectiveness of the RESOLUTE zotarolimus-eluting stent (R-ZES) in a US population and show noninferiority to historical results of the ENDEAVOR zotarolimus-eluting stent (E-ZES) in rates of clinical restenosis, death, myocardial infarction (MI), and stent thrombosis at 1 year.

Study Design

- Prospective, observational
- n=1402
- Mean age of patients: 64 years
- 68% men
- 33% diabetic
- Mean target vessel diameter: 2.59±0.47 mm
- Dual antiplatelet use: 93%

Primary endpoint

- 12-month target lesion failure (TLF; defined as a composite of cardiac death, MI, and clinically-driven target lesion revascularization [TLR])

Results (Main Cohort)

- At 1 year, TLF occurred in 36 of the 982 patients with complete follow-up, which is a rate of 3.7% versus 6.5% (70/1076) in the E-ZES historical controls (ie, a risk difference of -2.8%; $p<0.001$ for noninferiority)

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- The development of secondary endpoints was also low
  - » TLF 3.7%
  - » TLR 2.0%
  - » MI 1.3%
  - » Cardiac death 0.4%
- The TLF rate in the overall clinical cohort (n=1402) was 4.7%
- The 12-month rate of stent thrombosis was 0.1%, which occurred exclusively in subjects with small-vessel, 2.25-mm stents

Conclusions

RESOLUTE US reported a similar rate of events with the R-ZES next-generation DES compared with earlier E-ZES trials. The low 1-year incidence of in-stent thrombosis and the low need for repeat revascularization that was achieved on very high compliance of dual antiplatelet therapy are reassuring in challenging patients with diabetes mellitus and small-sized vessels. Further follow-up is required to demonstrate long-term efficacy and safety of the R-ZES.

Further Reading

Yeung AC et al. *J Am Coll Cardiol* 2011.

Mauri L et al. *Am Heart J* 2011.