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LECTURE ESSENTIALS

Lecture Notes

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

# The Randomized Comparison of 6-Month Versus 12-Month Duration of Dual Antiplatelet Therapy After Implantation of DES: From Comparison of EES Versus SES for Coronary Revascularization (EXCELLENT) Trial

**Sponsor:** Seoul National University Hospital

**Clinical Trial #:** NCT00698607

### Background

The Randomized Comparison of 6-Month vs 12-Month Duration of Dual Antiplatelet Therapy (DAT) after Implantation of Drug-Eluting Stent (DES): From Comparison of Everolimus- versus Sirolimus-Eluting Stents for Coronary Revascularization (EXCELLENT) Trial was designed to test the hypothesis that 6 months of DAT after DES is as safe and effective as the current guideline recommendations of at least 12 months.

### Study Design

- Randomized; 2x2 factorial design
- Open-label
- Prospective
- Noninferiority

### Primary Endpoint

- The incidence of target vessel failure (TVF) at 12 months, defined as a composite of cardiac death, myocardial infarction (MI), or target vessel revascularization (TVR)

### Secondary Endpoints

- Components of the primary outcome, stroke, stent thrombosis, TIMI major bleeding, and a composite safety endpoint

### Subject Characteristics

- n=1443
- Mean age 63 years
- One-third women
- About 40% diabetic
- >99% on aspirin and clopidogrel; >80% on statins; >50% on beta blockers; about 33% on ACE inhibitors



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### Outcomes

- The primary endpoint of TVF at 12 months did not differ significantly between the 2 groups (4.7% for 6-month therapy vs 4.4% for the 12-month group; risk difference +0.3%; 97.5% CI, +3.6%; p=0.43 for superiority; p=0.0031 for noninferiority)
- However, there was a statistically significant association (p<0.001) between the presence of diabetes and less favorable results with 6 months of DAT (HR, 3.15; p=0.005)
- Nondiabetics had better outcomes, with 6 months of DAT (HR, 0.42; p=0.022). There was no evidence of interaction according to stent type
- No significant differences were noted in the 6- and 12-month primary safety composite (3.1% versus 3.4%; p=0.76), major bleeding (0.6% versus 0.7%; p=0.42) or the secondary endpoint of stent thrombosis (0.4% versus 0.8%; p=0.33)

### Conclusions

Though the data are limited due to the low power of the trial and the low event rate, the findings suggest that treatment with a thienopyridine (in addition to aspirin) may be discontinued at 6 months for nondiabetic patients; before making any changes in clinical practice, more data are needed from larger, appropriately powered trials that assesses hard clinical endpoints.

### Further Reading

http://clinicaltrials.gov/ct2/show/NCT00698607?term=NCT00698607&rank=1