Twelve vs 48 months of dual antiplatelet therapy after drug-eluting stent placement

The OPTIDUAL randomized trial

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on behalf of the OPTIDUAL Investigators

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DECLARATION OF INTEREST

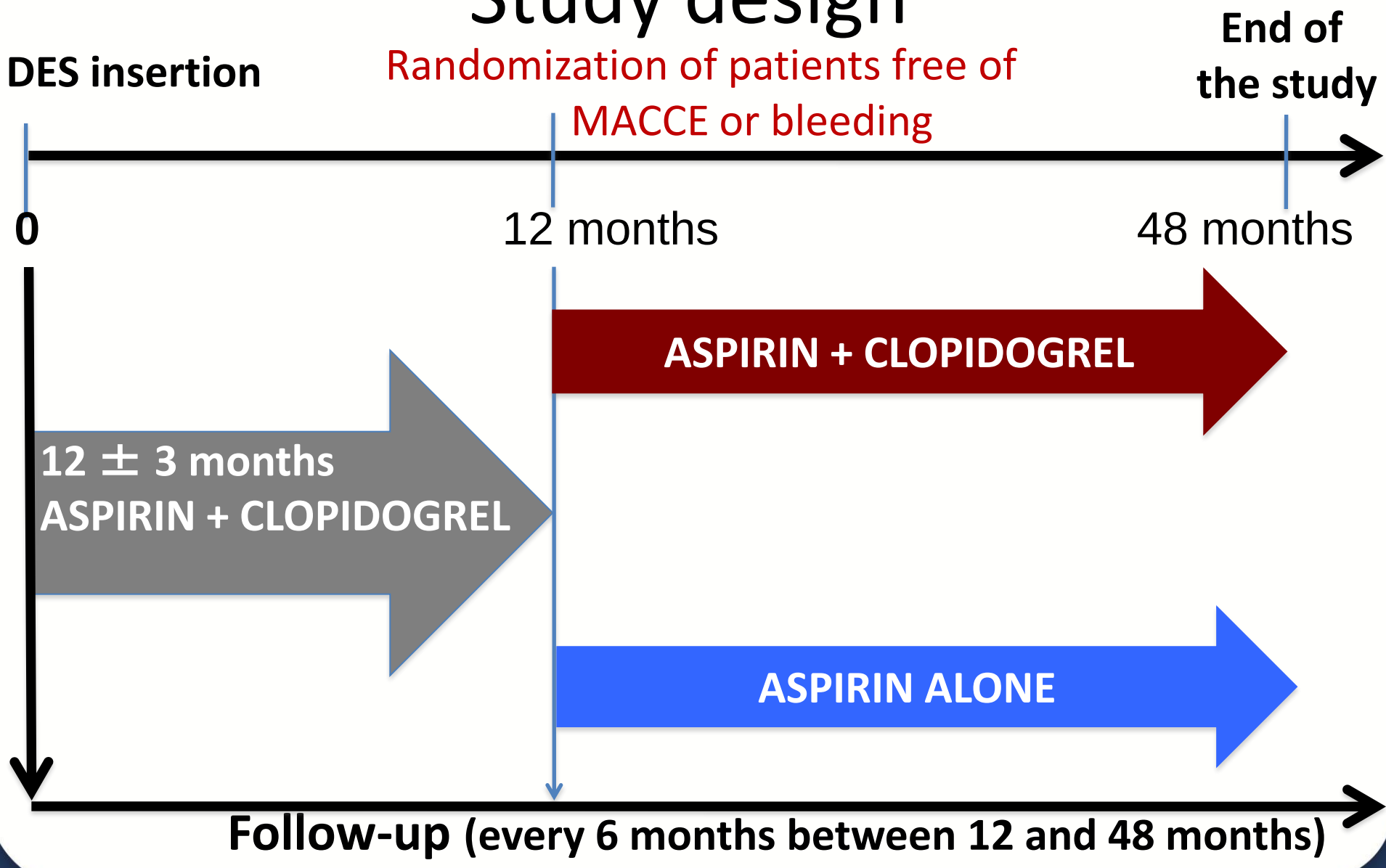
- Research contracts
- Consulting/Royalties/Owner/ Stockholder of a healthcare company

Hypothesis

- On a background of aspirin, **continuing clopidogrel for up to 48 months** would be **superior to stopping clopidogrel at 12 months following drug-eluting stent (DES)** implantation in **reducing net adverse clinical events** (composite of death, MI, stroke or major ISTH bleeding)
  - Randomized, multicentre, open-label study conducted in 58 sites in France (January 2009–January 2013)
  - Funded by the French Ministry of Health. Additional unrestricted research grants from Fédération Française de Cardiologie, Cordis, Boston, Medtronic, Terumo and Biotronik

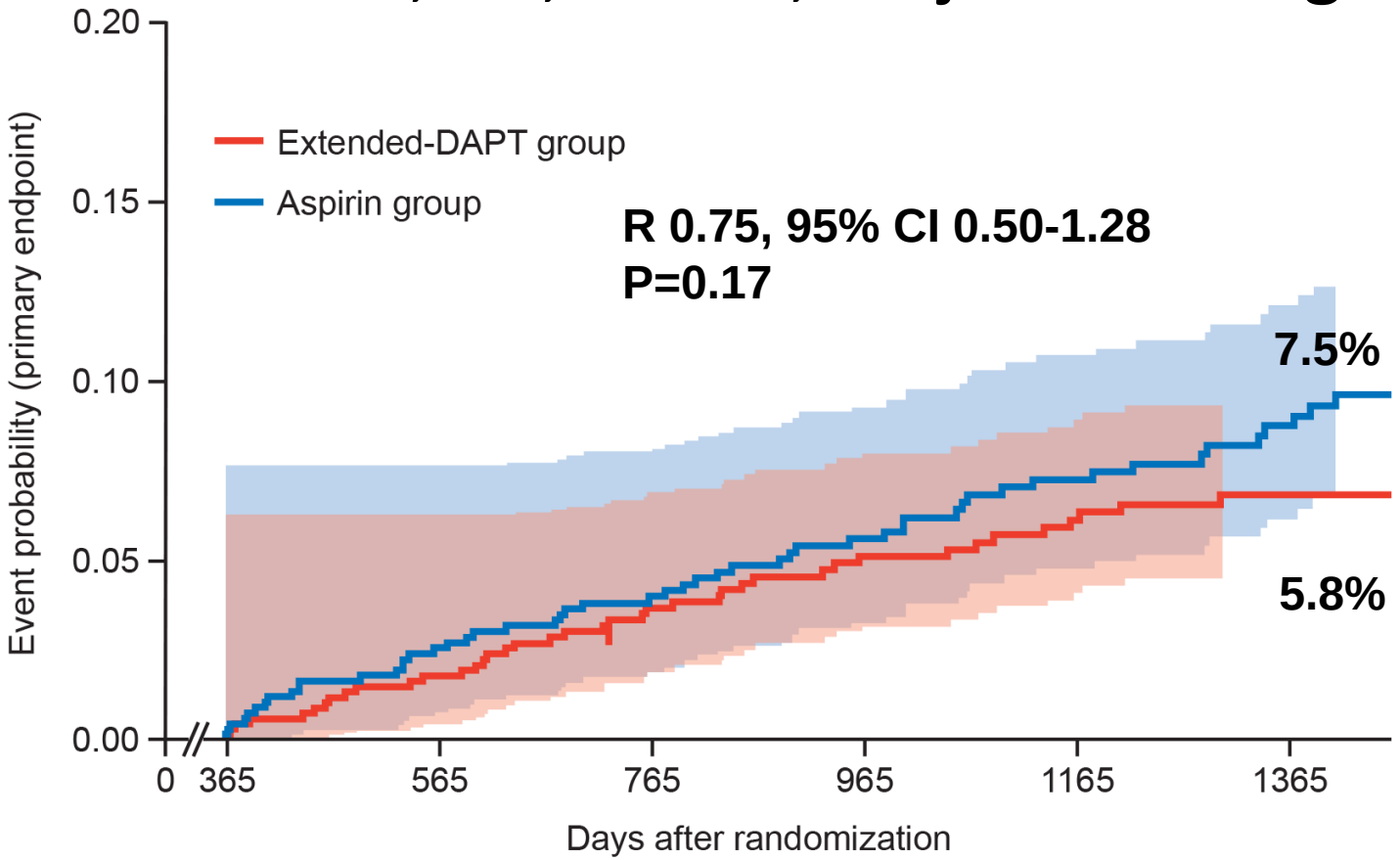
Helft G et al, Trials 2013;14:56

Study design



Primary outcome:

Composite of death, MI, stroke, major bleeding

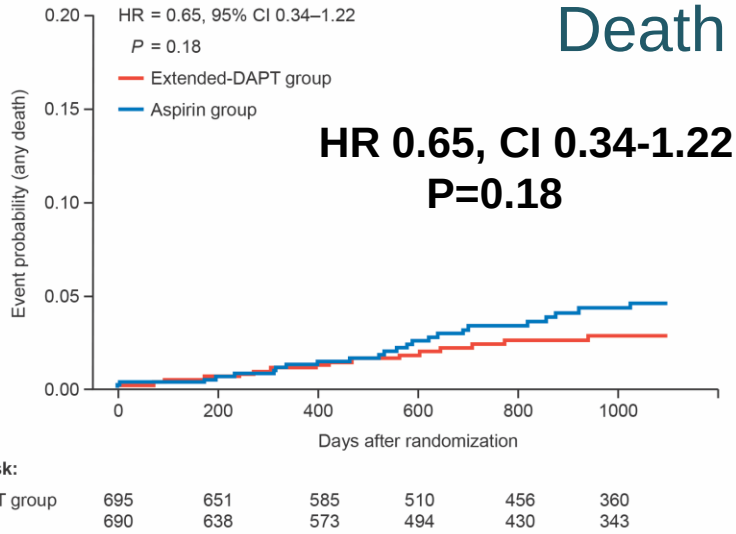


Number at risk:

Extended-DAPT group	695	643	570	493	440	344
Aspirin group	690	626	557	479	415	329

Components of the primary endpoint

Death

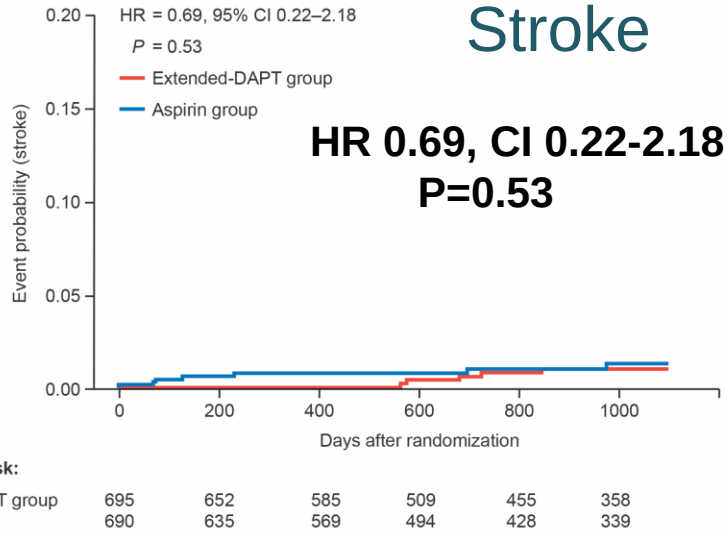


HR 0.65, CI 0.34-1.22
P=0.18

Numbers at risk:

Extended-DAPT group	695	651	585	510	456	360
Aspirin group	690	638	573	494	430	343

Stroke

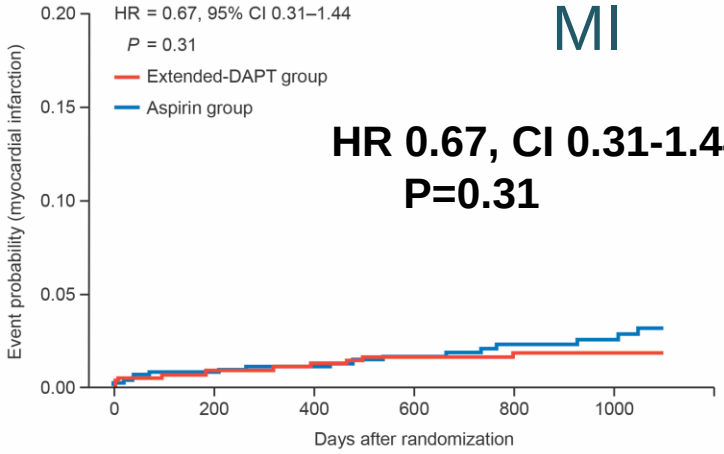


HR 0.69, CI 0.22-2.18
P=0.53

Numbers at risk:

Extended-DAPT group	695	652	585	509	455	358
Aspirin group	690	635	569	494	428	339

MI

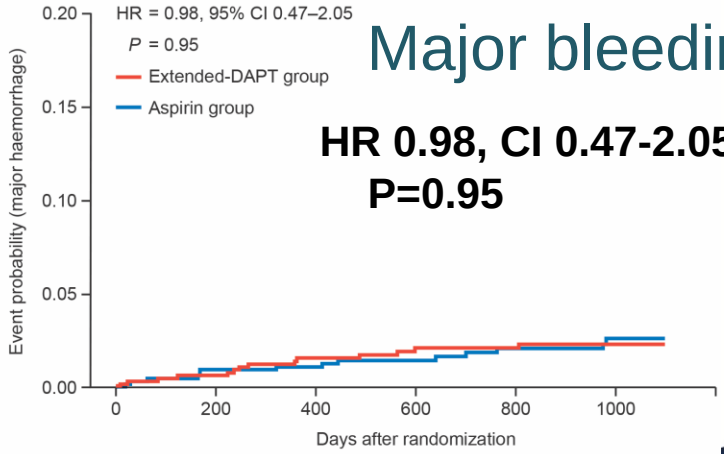


HR 0.67, CI 0.31-1.44
P=0.31

Numbers at risk:

Extended-DAPT group	695	652	585	509	455	358
Aspirin group	690	635	569	494	428	339

Major bleeding

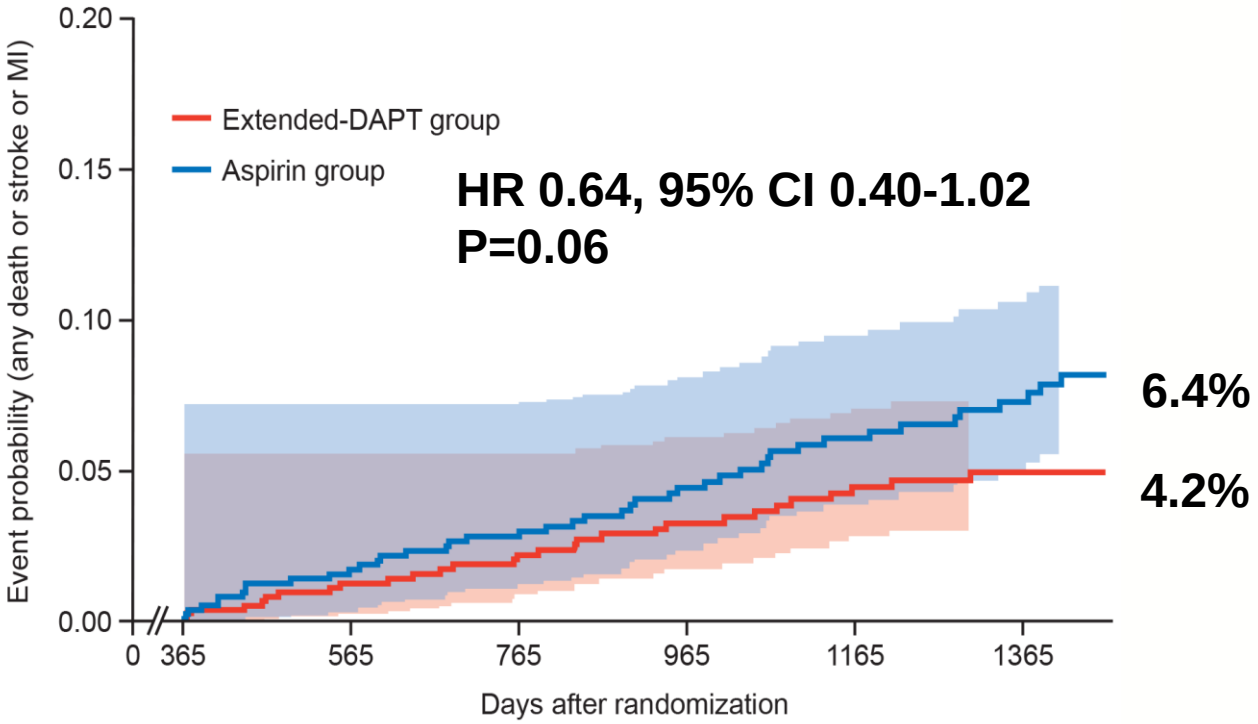


HR 0.98, CI 0.47-2.05
P=0.95

Numbers at risk:

Extended-DAPT group	695	648	576	501	449	354
Aspirin group	690	632	566	491	426	338

Post-hoc analysis of ischaemic outcomes: death, stroke, or MI



Number at risk:

Extended-DAPT group	695	643	570	493	440	344
Aspirin group	690	626	557	479	415	329

Conclusions

- Extending DAPT duration for up to 48 months did not achieve statistical superiority compared with stopping clopidogrel at 12 months with regards to NACE.
- Borderline but non-statistically significant reduction in post-hoc analysis of ischaemic outcomes with extended DAPT.
- No apparent increase in bleeding and all-cause mortality with extended DAPT.