Third-generation DES
and antithrombotic therapy

The CONFORTABLE AMI Randomized Trial

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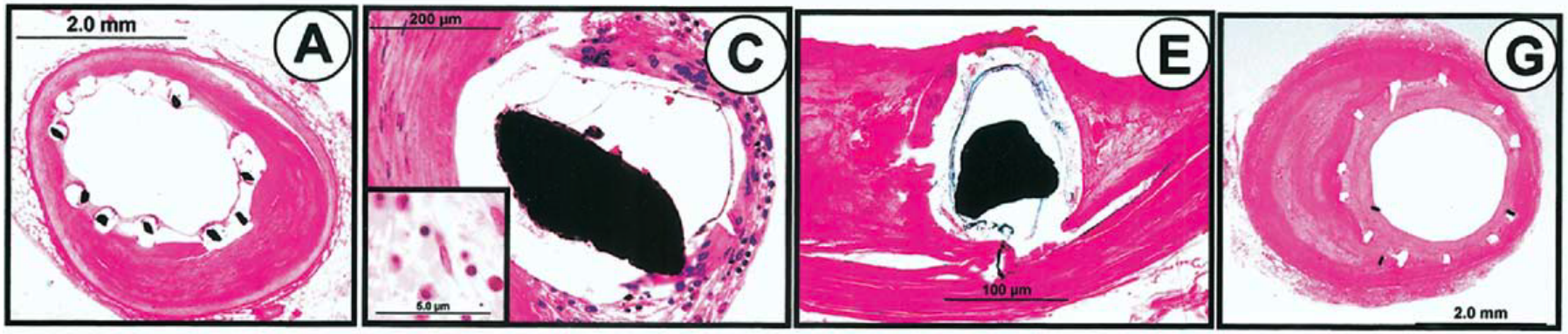
- No conflict of interest



« Human pathologic analysis clearly indicate that healing is delayed by DES in the setting of plaque rupture vs. stable angina and that an increased risk of late thrombotic events should be expected in this setting »

Dr VIRMANI, 2009

Acute myocardial infarction is a predictor of thrombotic stent complications (high thrombus burden, inflammation…)

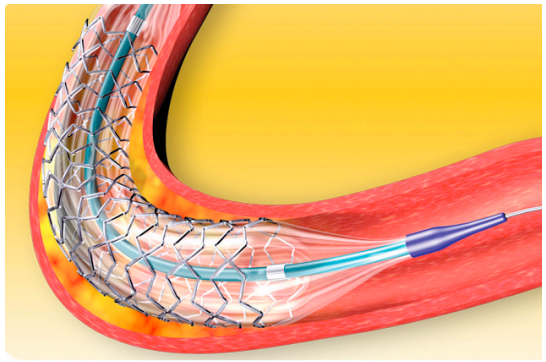
First-generation DES are associated with an increased risk of very late (> 1year) stent thrombosis vs. BMS

Very late stent thrombosis is related to delayed arterial healing owing to ongoing chronic inflammation

The persistence of durable polymer coatings after completion of the drug release has been implicated in this chronic inflammatory response

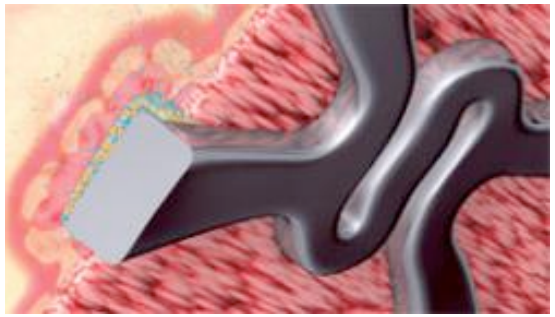
Potential adventage of newer DES coated with permanent polymers with improved biocompatibility or biodegradable polymers

Biolimus-eluding stent



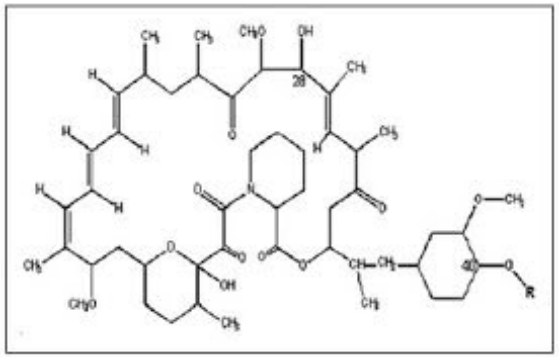
Stainless steel metallic stent platform

- **strut thickness:120 µm**



Polylactic acid biodegradable polymer

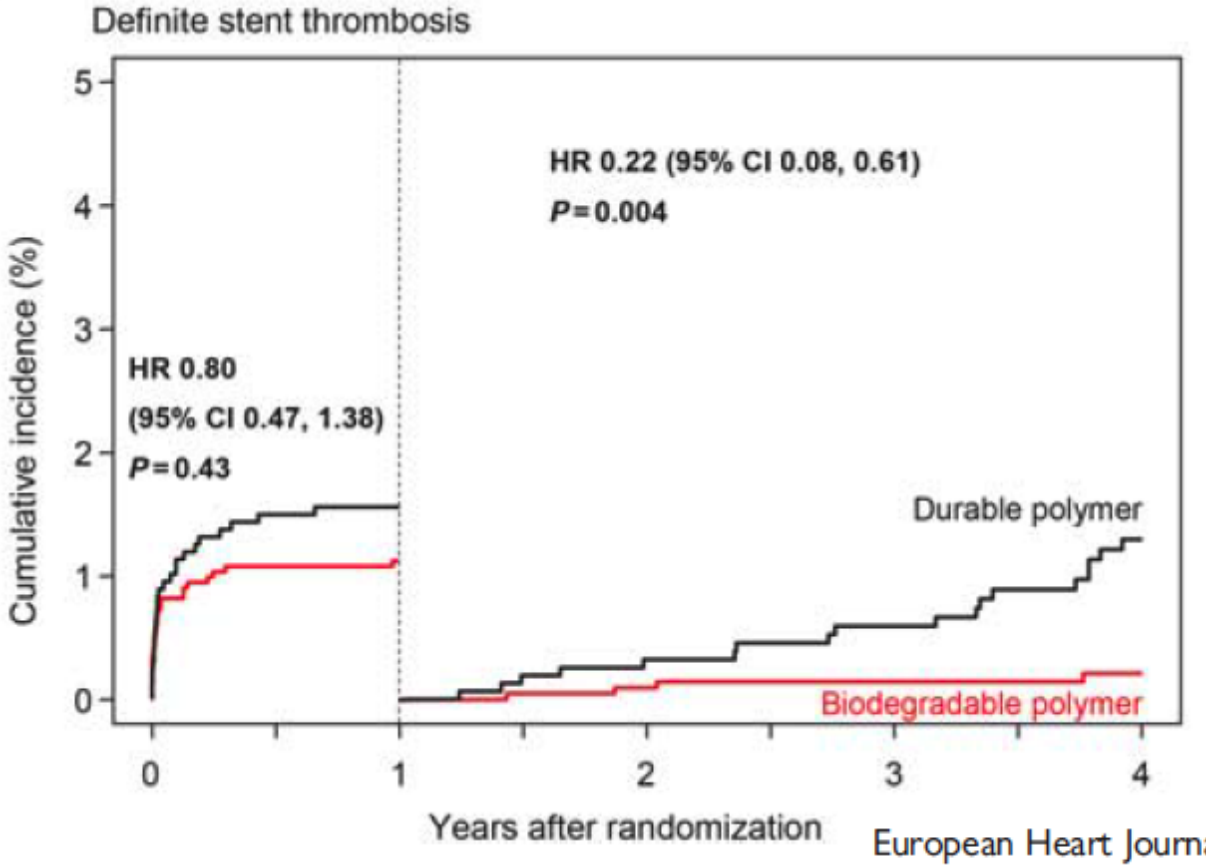
- **disappears over 6 to 9 months**



Biolimus

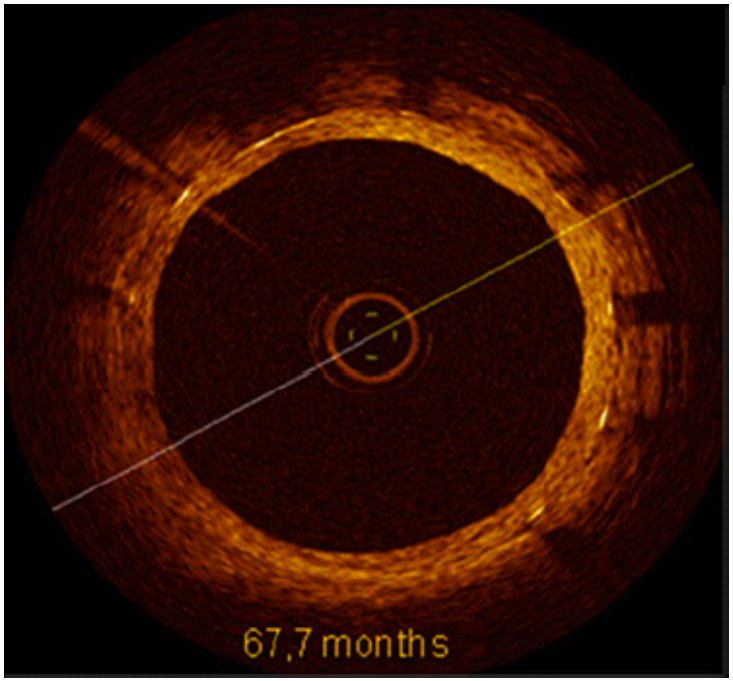
- **highly lipophilic sirolimus analogue**
- **anti-proliferative and anti-inflammatory**
- **98% of the drug has diffused at 1 month**

Biodegradable polymer drug-eluting stents reduce the risk of stent thrombosis at 4 years in patients undergoing percutaneous coronary intervention: a pooled analysis of individual patient data from the ISAR-TEST 3, ISAR-TEST 4, and LEADERS randomized trials

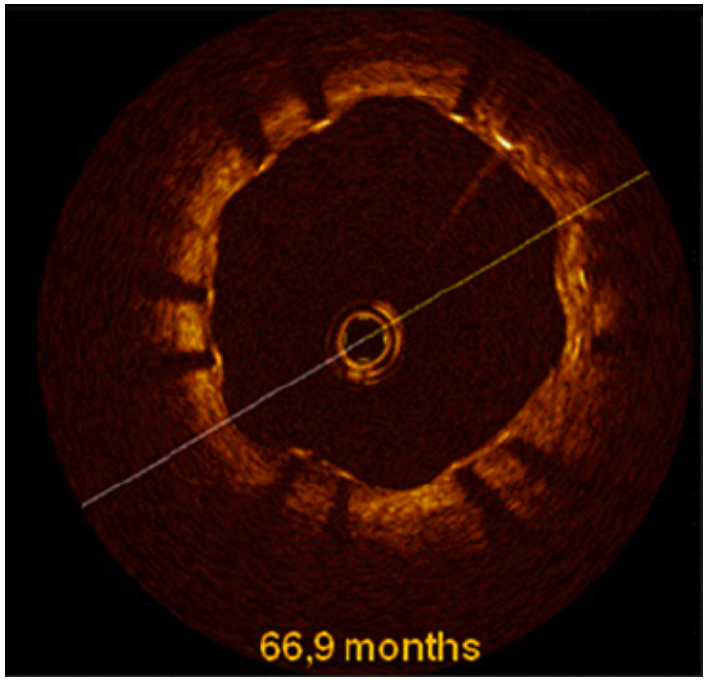


European Heart Journal (2012) **33**, 1214–1222

Very long-term follow-up of strut apposition and tissue coverage with Biolimus A9 stents analyzed by optical coherence tomography



BMS

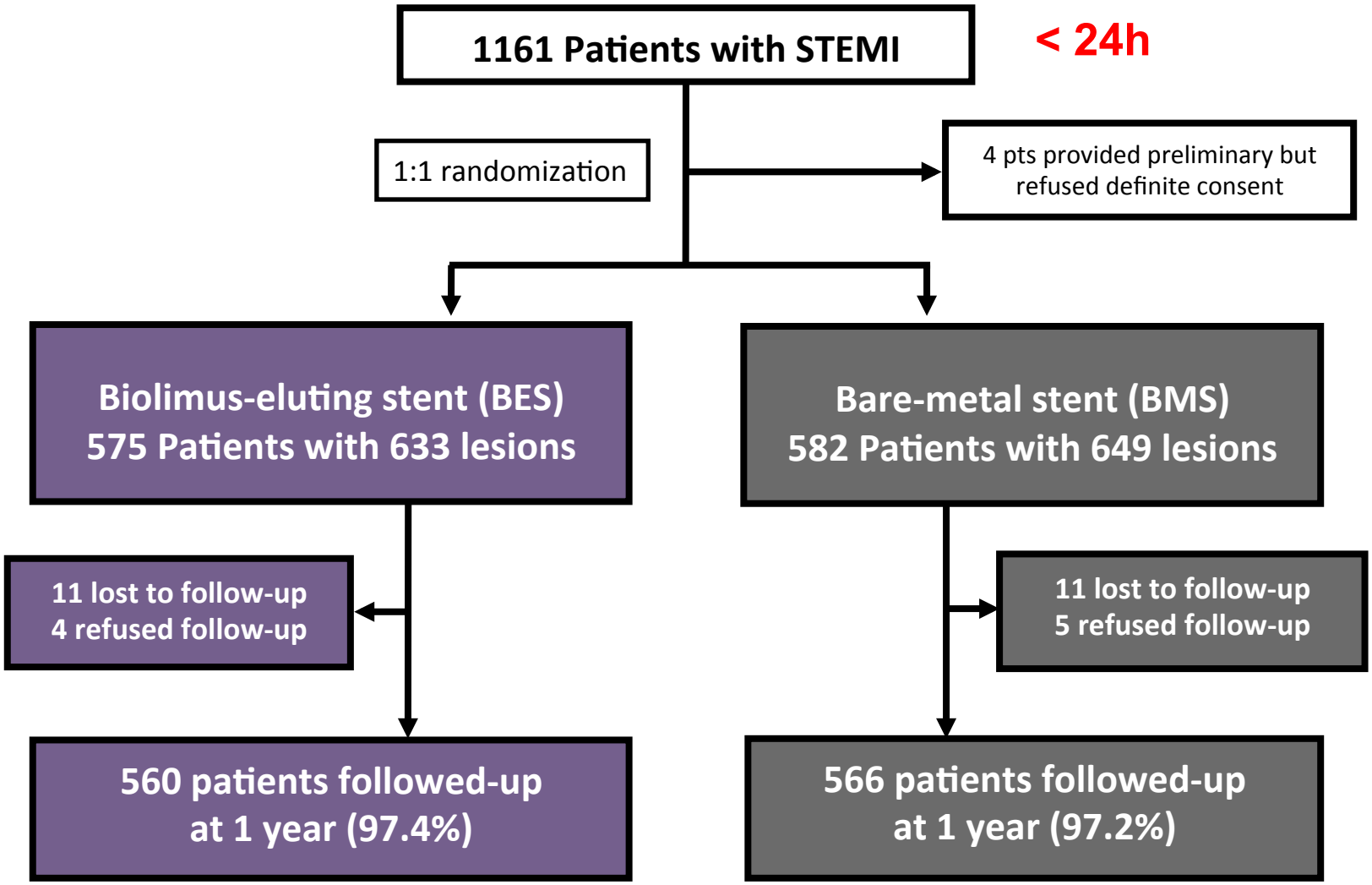


BES

Int J Cardiovasc Imaging 2013

COMFORTABLE AMI Trial

Räber. L. et al., JAMA 2012; 308:777-787.



Thrombus aspiration was recommended before stent implantation in all patients when technically feasible

Predilation of the culpit lesion was left to the discretion of the operator

Acetylsalicylic acid ≥ 250 mg before the procedure

Prasugrel : loading dose of 60 mg followed up with a daily dose of 10 mg

Clopidogrel (if prasugrel not available or contraindicated) : loading dose of 600 mg, followed up with a dose of 75 mg twice daily for 7 days, followed up with a maitenance dose of 75 mg once daily

Dual antiplatelet therapy was prescribed for at least 1 year

The use of **Gp IIb/IIIa antagonists** was left to the discression of the operator

Baseline medications and clinical, angiographic and procedural characteristics were similar in both groups (BES vs. BMS)

Mean age: 60.7 vs. 60.4 y; **Male sex:** 80.5 vs. 78.2 %

Time of ischemia: 232 vs. 236 min

Baseline TIMI flow 0 or 1: 69.6 vs. 65.6 %

Post PCI TIMI flow 3: 95.5 vs. 94.6 %

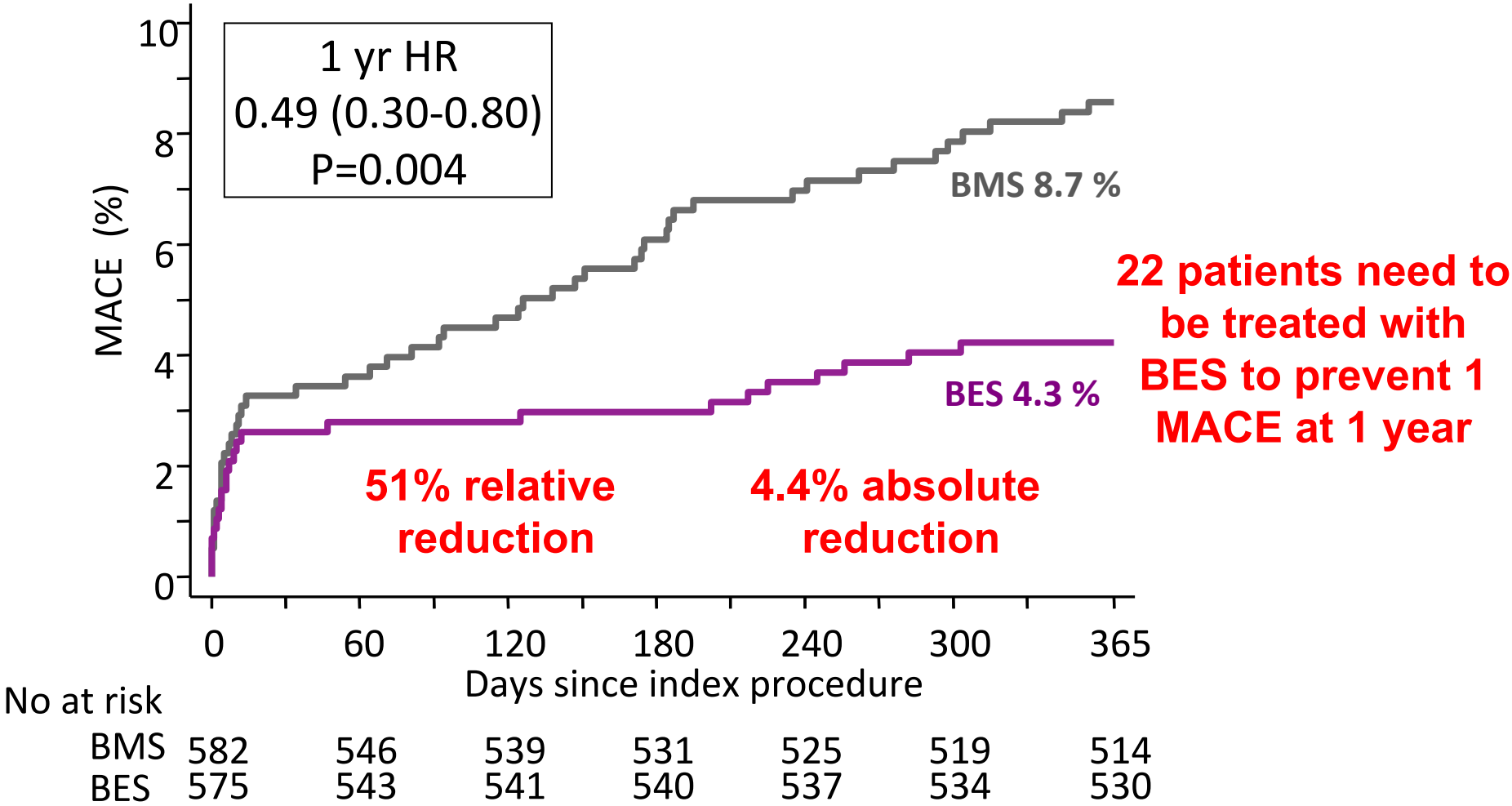
SYNTAX MI score: 15.1 vs. 14.8

Thrombus aspiration: 60.9 vs. 64.4 %

Gp IIb/IIIa antagonist: 48 vs. 45.7 %

Prasugrel at discharge: 43.1 vs. 42.9 %

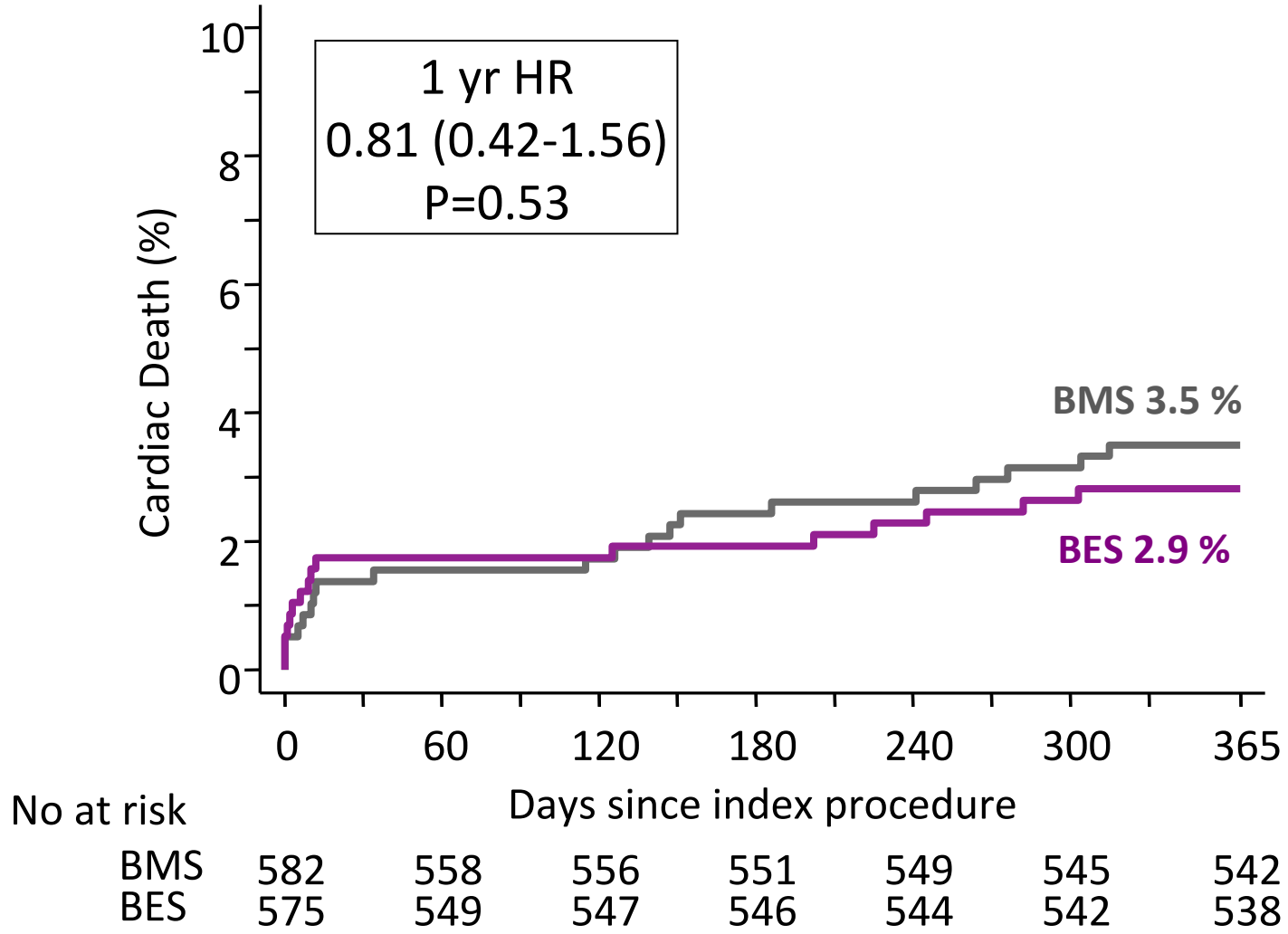
Primary Endpoint – MACE @ 1 Year



MACE = Cardiac death, TV-MI, ci-TLR – Clinical outcomes were adjudicated by an independent and blinded CEC

Räber. L. et al., JAMA 2012; 308:777-787.

2nd Endpoint – Cardiac Death



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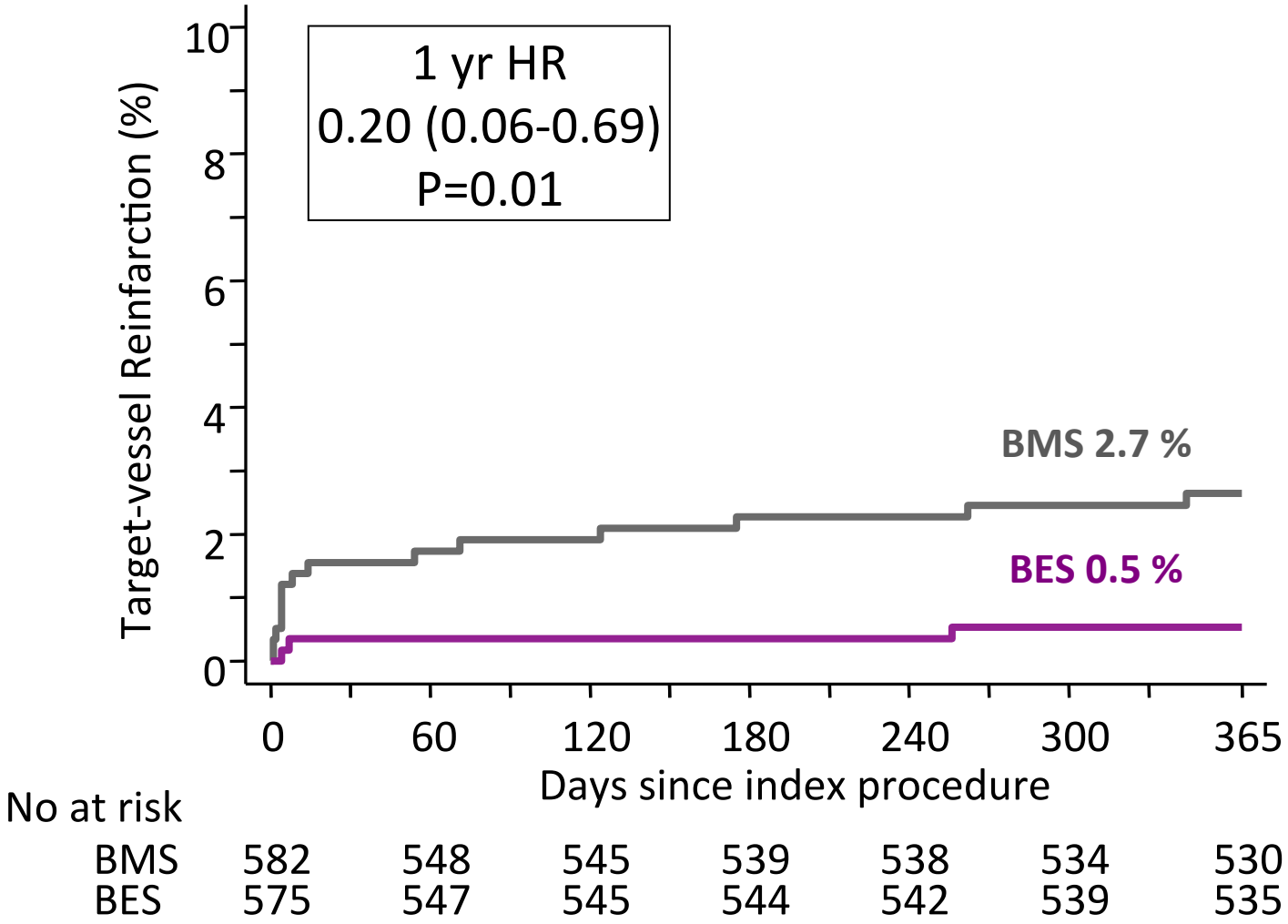
2nd Endpoint – TV-Reinfarction



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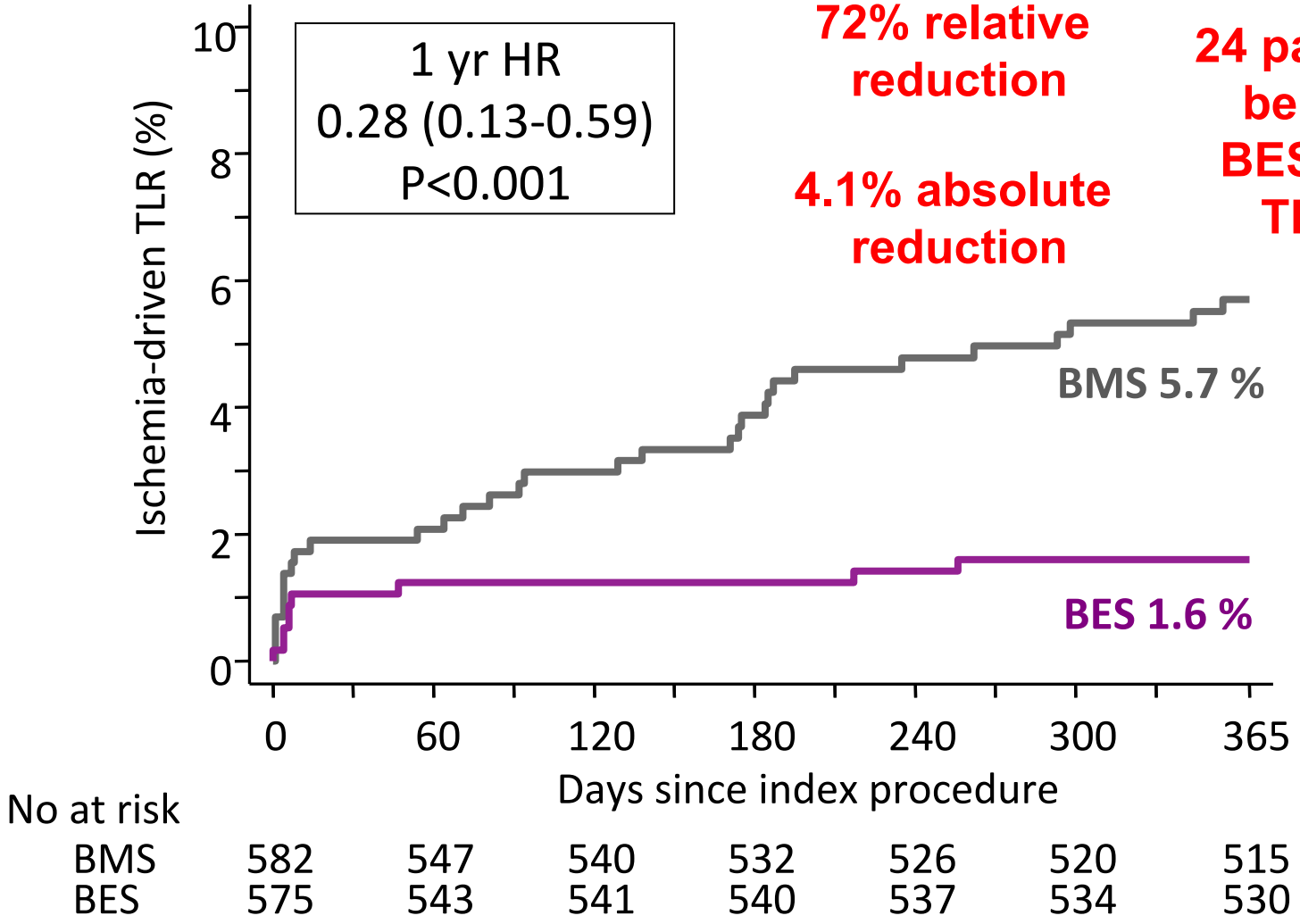
2nd Endpoints – ID-TLR



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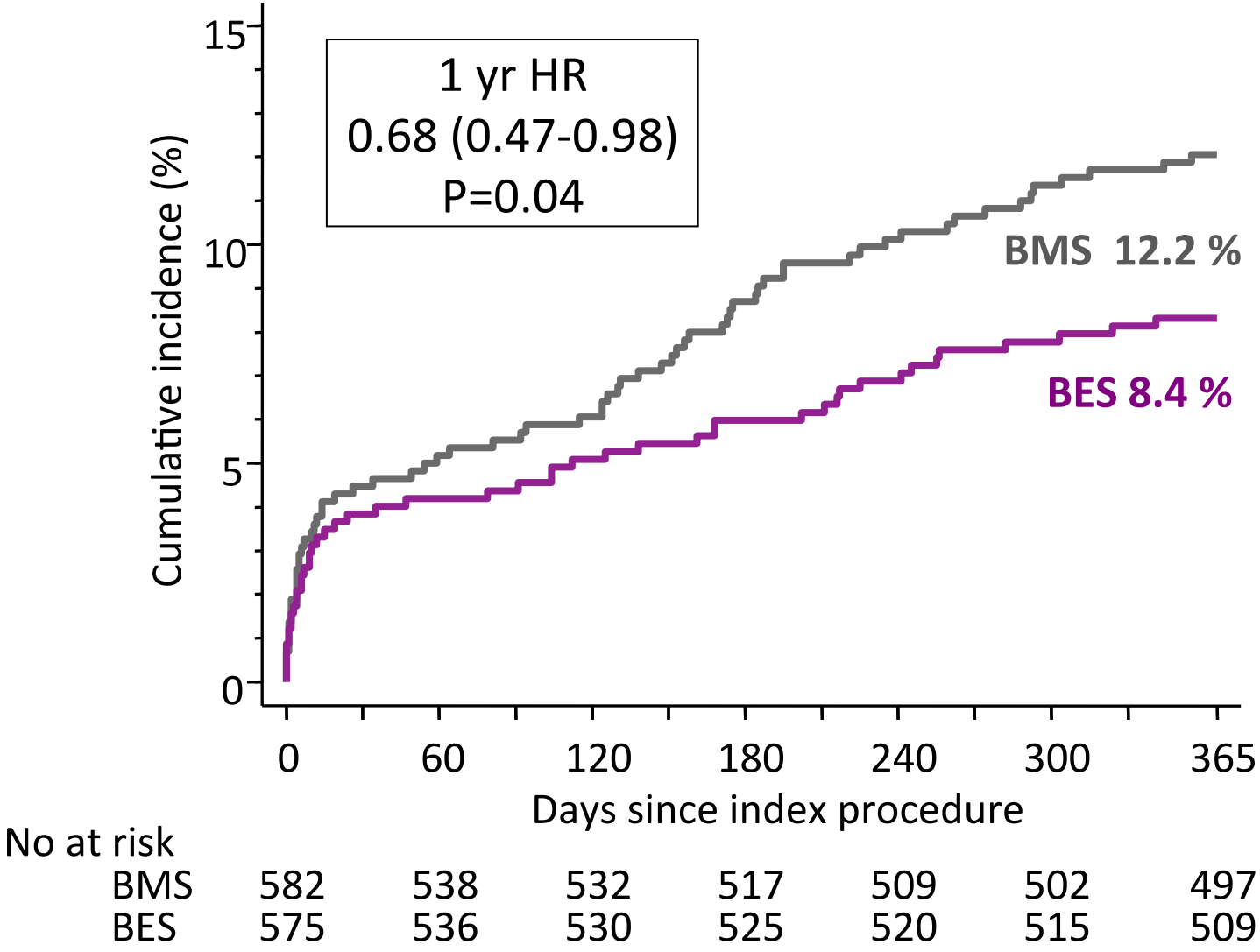
Patient oriented 2nd EP
(death, reinfarction, any revascularization)



No at risk

BMS	582	538	532	517	509	502	497
BES	575	536	530	525	520	515	509

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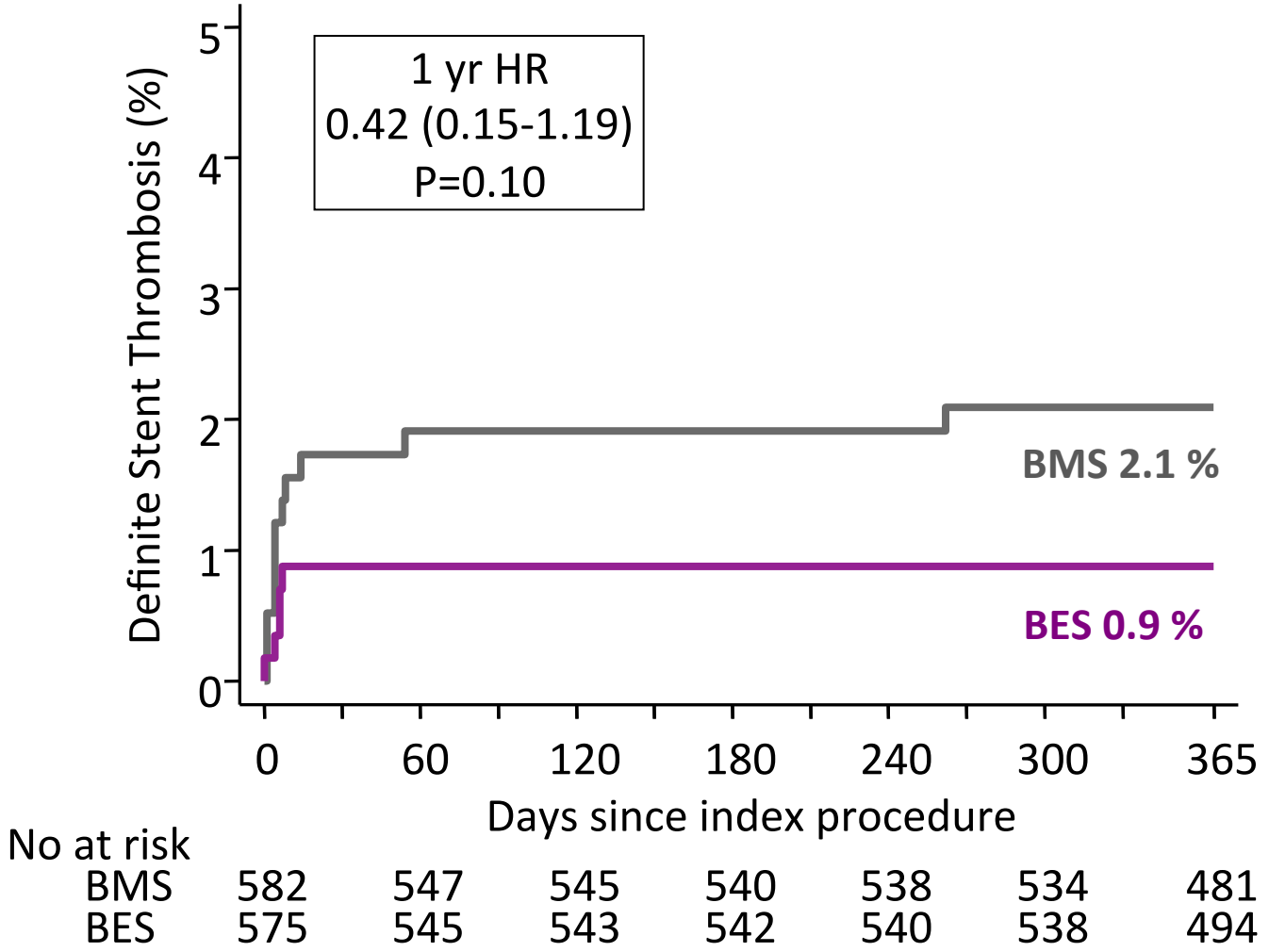
ARC Definite Stent Thrombosis



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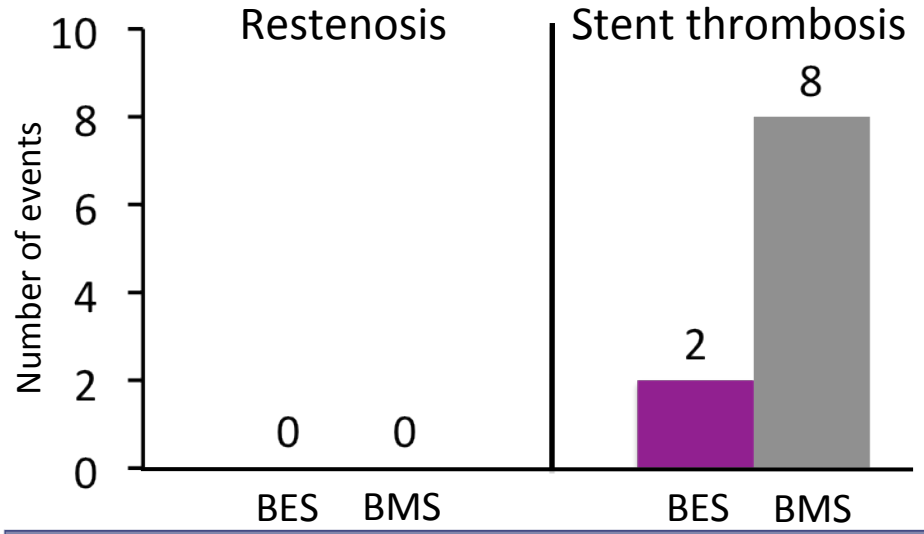
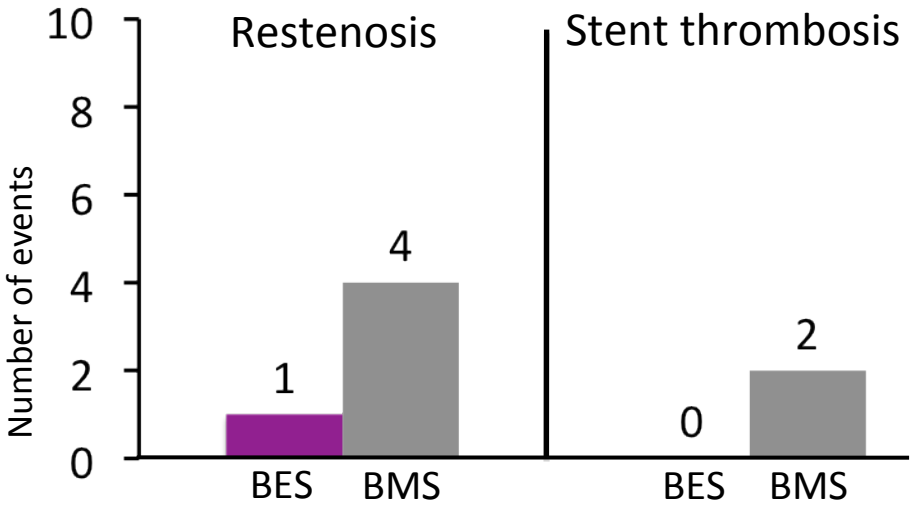
Target vessel MI up to 30 days



Target vessel MI between 30 days and 1 year



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Limitations of the study

Prasugrel was administred in 40% of patients and may have contributed to the low overall event rates in this study

The BMS used in the control group does not have prior records on its performance in the study population

The trial was not powered to address individual components of the composite primary endpoint

The study does not address very late events beyond 1 year

Conclusion

The use of BES with a biodegradable polymer is more effective and safe among patients with STEMI undergoing PCI at 1 year compared to BMS

Long-term results from the COMFORTABLE AMI trial are needed to confirm that BES reduces very late stent thrombosis in AMI patients