Biolimus-Eluting Stents With Biodegradable Polymer Versus Bare Metal Stents in Acute Myocardial Infarction: the COMFORTABLE AMI Trial

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Potential conflicts of interest

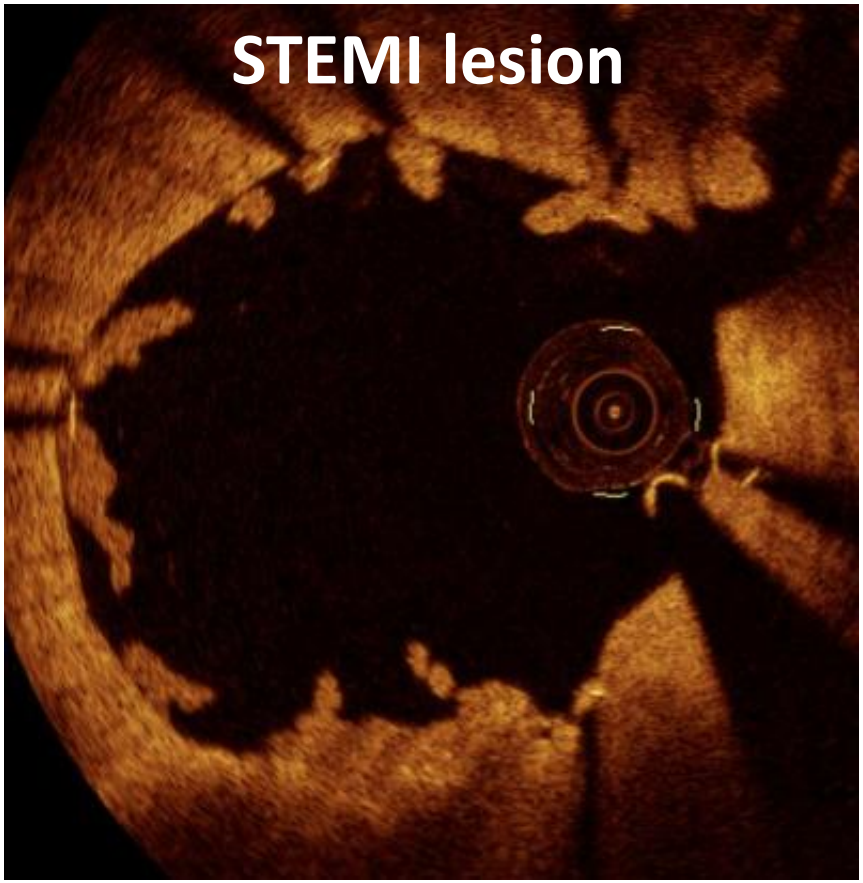
Speaker's name: Lorenz Räber

☐ **I have the following** potential conflicts of interest to report:

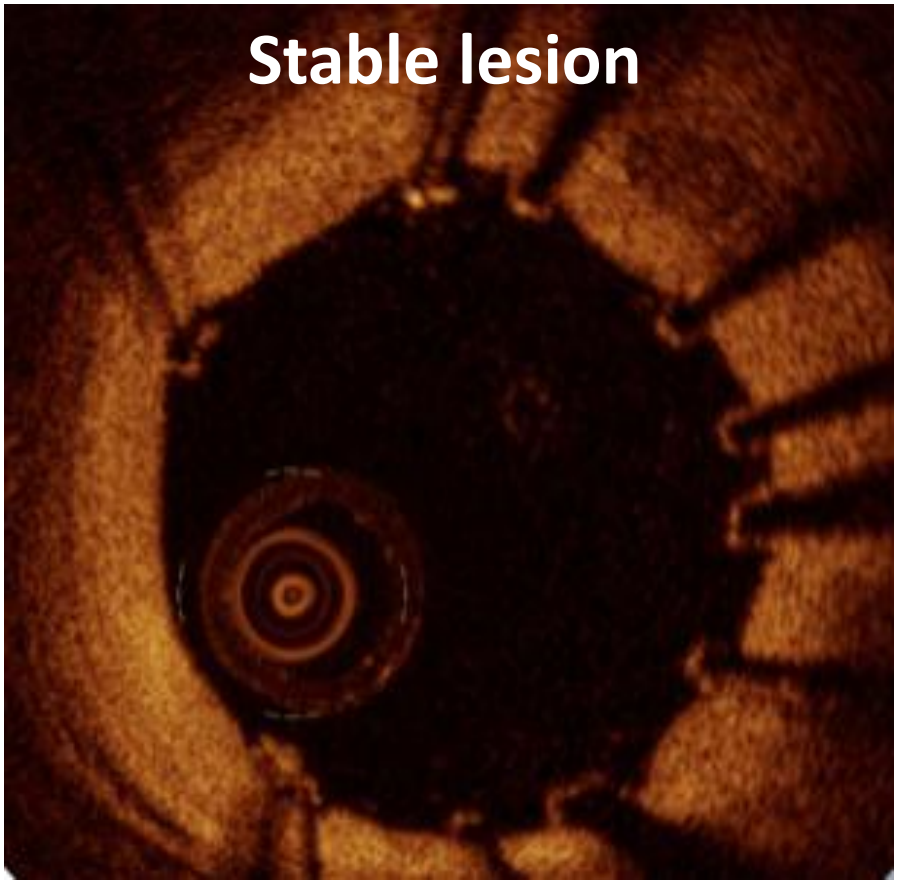
- ☐ Research contracts
- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☒ **I do not have any potential conflict of interest**

COMFORTABLE AMI – BACKGROUND I



-Necrotic core, lipid pool
-High thrombus load



-Fibrous tissue
-Thrombus absent

COMFORTABLE AMI – BACKGROUND I

1. Use of DES remains controversial in STEMI

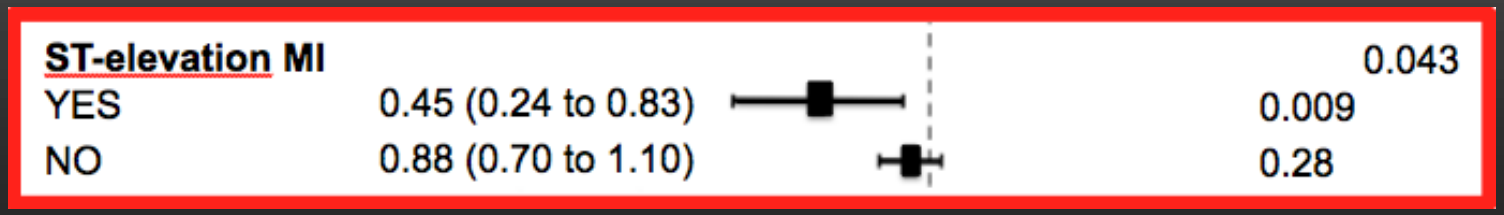
• Vessel healing of culprit lesions in AMI patients delayed following implantation of early generation DES (Virmani et al. Circulation 2010)

•Two-fold increased risk of very late stent thrombosis and myocardial infarction following implantation of early generation DES
(Kalesan B, *EHJ 2012;* De Luca et al, Arch Int. *Med. 2012*)

2. LEADERS data

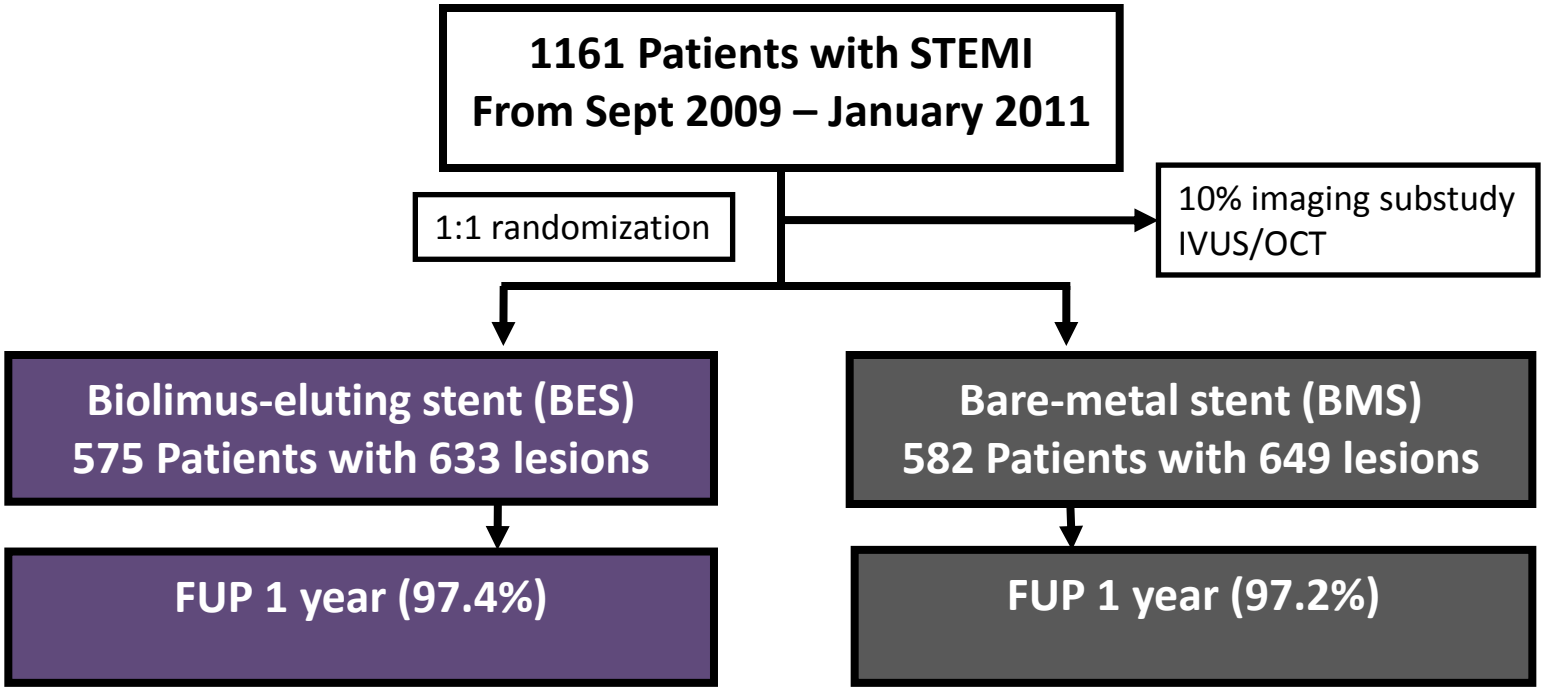
•Biodegradable Polymer BES (BioMatrix™) has shown non-inferiority @1 year and superiority @4 years

•A stratified analysis suggested a particular benefit of BES in STEMI patients

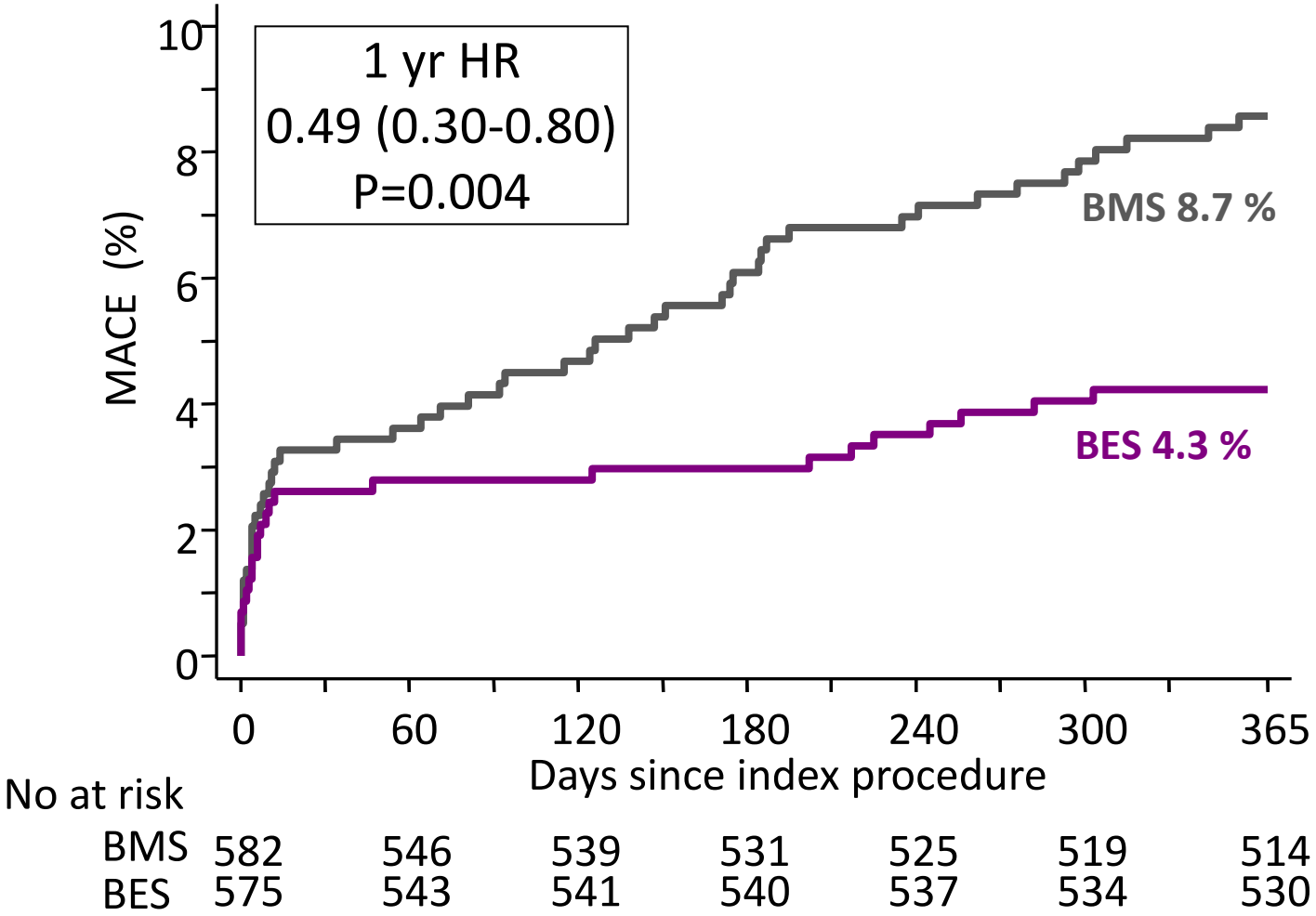


Hypothesis, Design, Study Flow

- **Hypothesis**: Biodegradable polymer BES (BioMatrix™) is superior to a BMS of identical design (Gazelle™)
- **Design**: Randomized, assessor blinded, international trial conducted at 11 sites in Europe and Israel
- **Eligibility**: Inclusion criteria were broad in order to reflect routine clinical practice

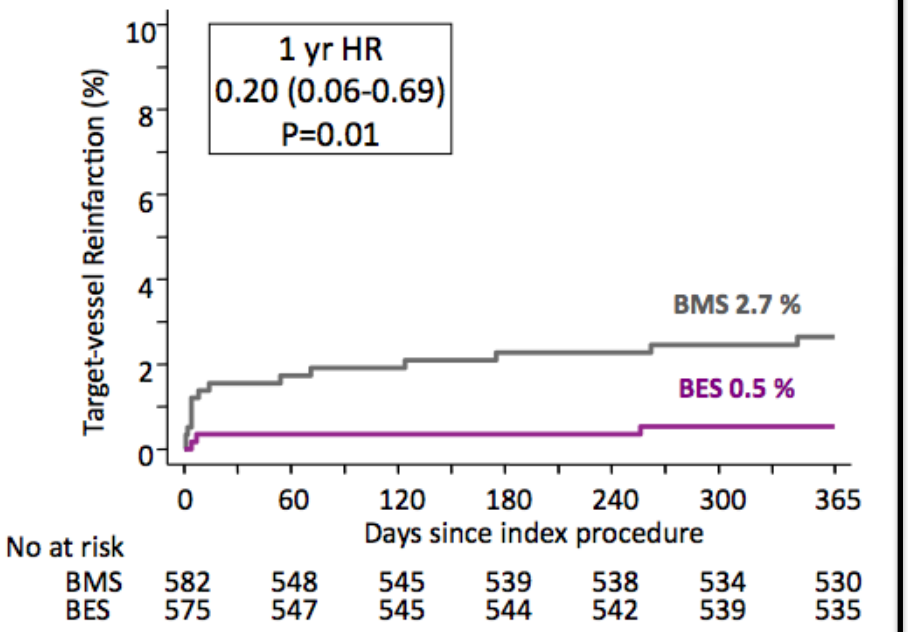


Primary Endpoint – MACE @ 1 Year

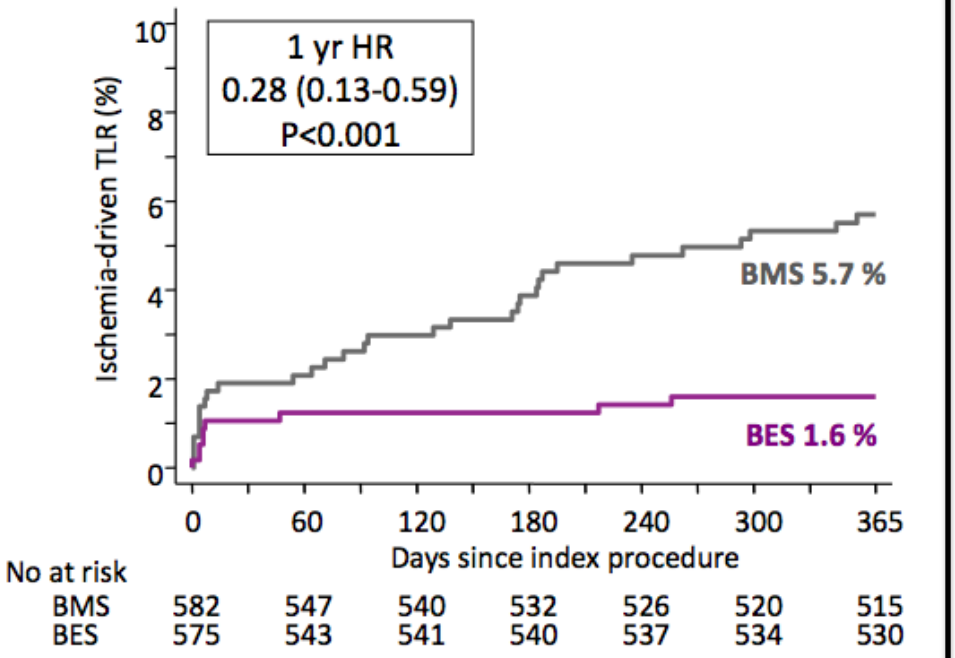


Clinical outcomes were adjudicated by an independent and blinded CEC

2nd Endpoint – TV-Reinfarction



2nd Endpoint – ID-TLR



Patients on any DAPT at 1 year
BES 90.0% vs. BMS 88.1%, p=0.30

Summary – Take home message

- First RCT investigating biodegradable polymer stent platformin STEMI patients.

- Biodegradable polymer BES (BioMatrix™) are superior to BMS in reducing major adverse cardiac events among STEMI patients at one year with a NNT of 24.

- The difference in favour of biodegradable polymer BES is driven by both, a lower risk of TV-reinfarction and TLR.

- Efficacy advantages of biodegradable polymer BES over BMS were substantial (RRR 72%).

- Safety advantage of a DES over a BMS has not been observed in previous RCTs comparing DES and BMS among STEMI patients.