

**Final results from an all-comer worldwide
registry on percutaneous coronary intervention
with bioresorbable polymer sirolimus-eluting
stent and impact of geographical differences**

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Potential conflicts of interest

Speaker's name : Marco Roffi

I have the following potential conflicts of interest to declare:

Institutional research grants from Terumo, Boston Scientific, Medtronic, Biotronik, GE Healthcare





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Why this study?

- Safety and efficacy of the bioresorbable polymer sirolimus-eluting stent Ultimaster have been documented in RCT.
- The **eUltimaster Registry** was initiated to evaluate stent performance in an all-comer PCI population.
- Its worldwide design offers a unique opportunity to assess geographical differences in PCI practice.





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What did we study? How was the study executed

Study Device: Ultimaster DES

| | |
|---|---|
| Platform | Cobalt chromium |
| Strut thickness | 80 µm |
| Drug carrier | Poly (DL-lactic-acid)-poly caprolactone |
| Coating | Abluminal coating technology |
| Drug | Sirolimus |
| Polymer degradation and drug release time | 3-4 months |

Primary endpoint

Target lesion failure (TLF) : composite of cardiac death, target-vessel myocardial infarction (TV-MI) and clinically-driven target lesion revascularization (CD-TLR) at 1 year

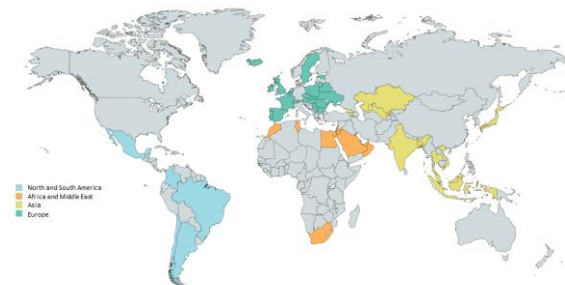
Event adjudication

All components of the primary endpoint adjudicated by an independent Clinical Event Committee

Global all-comers study

Total patients: 37,198

- Europe: 25,736 (69%)
- Asia: 6,614 (18%)
- Africa/ Middle East: 2,438 (7%)
- S America/ Mexico: 2,410 (6%)



Follow-up

Follow-up at 1 year: 95.1%

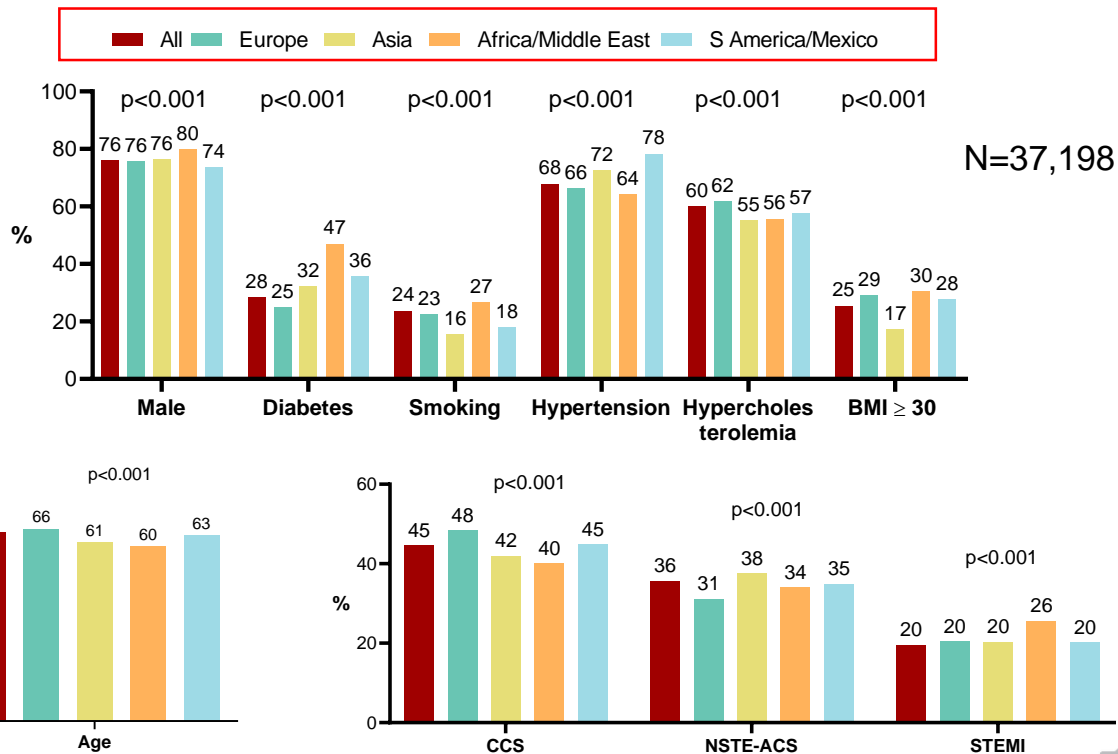
Statistical analysis

Stepwise logistic regression for primary endpoint for total population

Patient baseline characteristics



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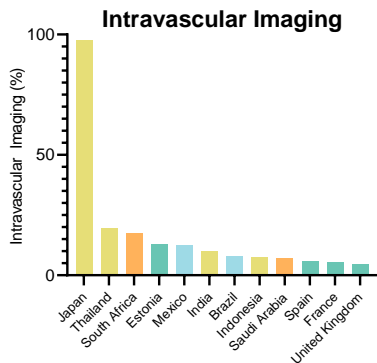
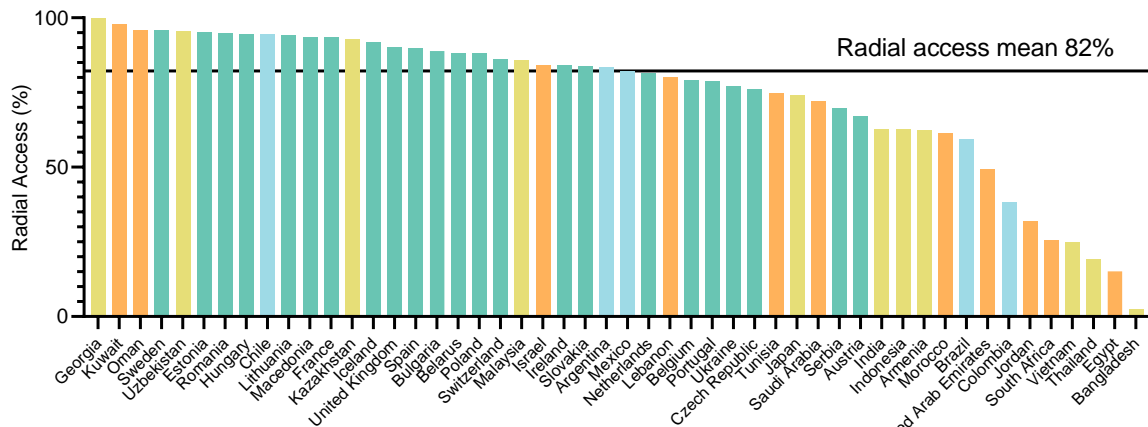


CCS= chronic coronary syndrome; NSTE-ACS = non-ST-elevation acute coronary syndromes; STEMI = ST-elevation myocardial infarction

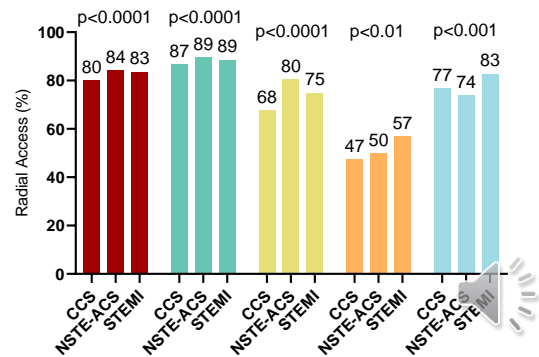


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Worldwide implementation of radial access and intravascular imaging

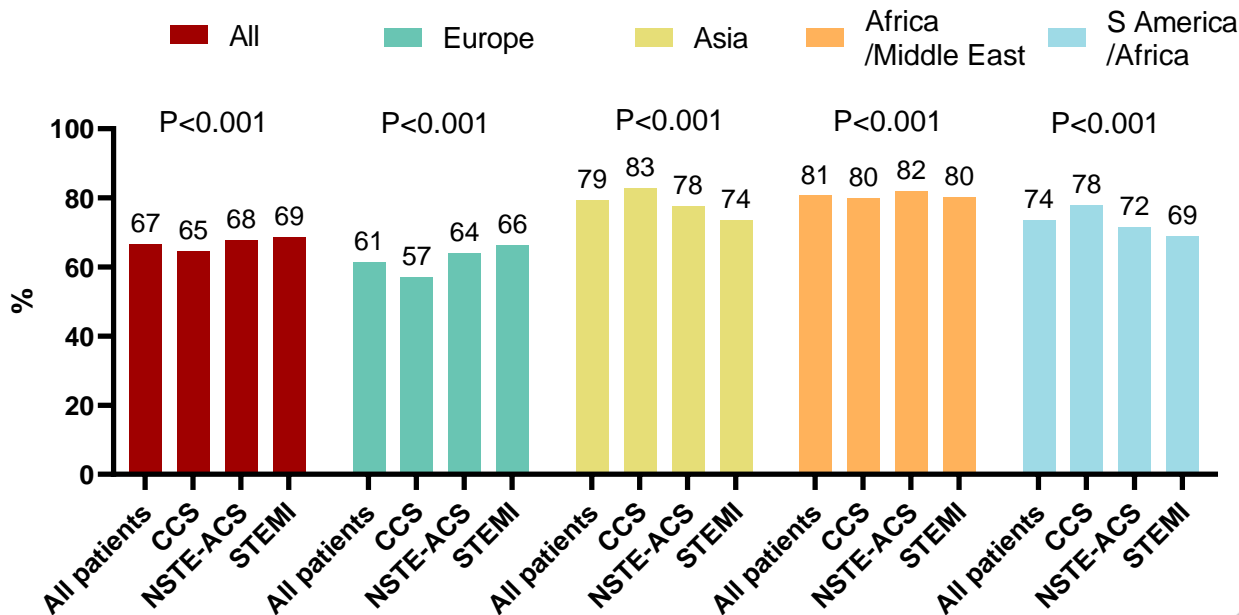


Europe Asia Africa/Middle East S America/Mexico





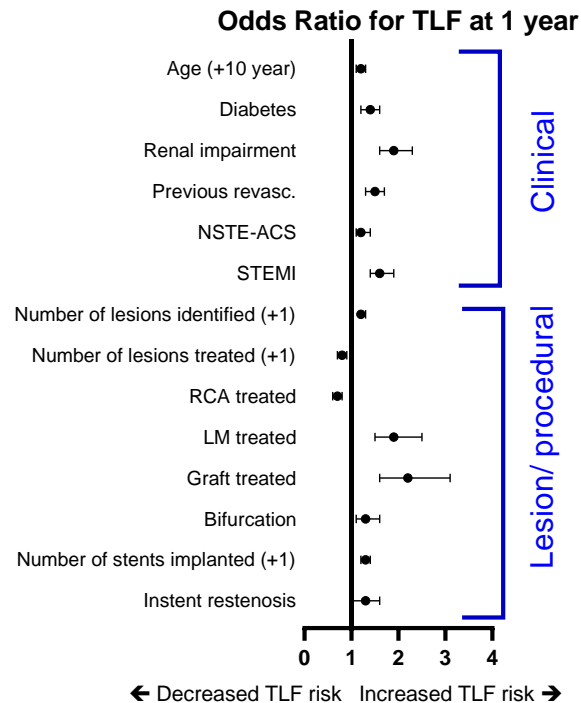
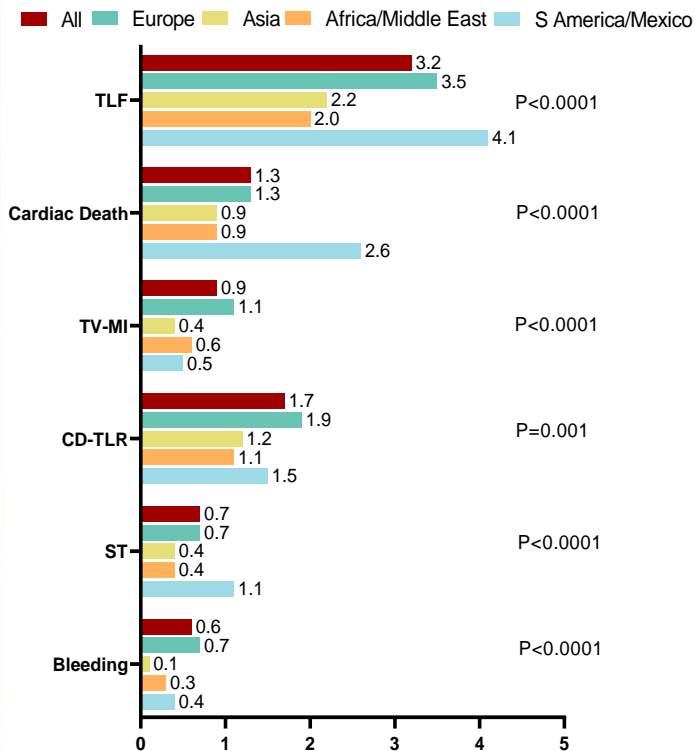
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Patient outcomes at 1 year



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Target lesion failure (TLF) : cardiac death, target-vessel myocardial infarction (TV-MI) and clinically-driven target lesion revascularization (CD-TLR),
 ST: stent thrombosis (def/prob); Bleeding: BARC 3-5



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Why is this important?

- The eUltimaster registry enrolled over 37,000 all-comer patients undergoing contemporary PCI (45% CCS, 55% ACS) .
- Ultimaster DES showed an excellent performance at 1 year with a TLF rate <5% in all continents and stent thrombosis rate <1%.
- Independent clinical predictors of TLF included age, diabetes, renal impairment, previous revascularization and ACS.
- With respect to PCI practice worldwide
 - Major difference in the prevalence of diabetes (23% in Europe, 47% in Africa and Middle East).
 - Radial access widely embraced (>80%), though with major differences worldwide (88% in Europe and 50% in Africa/Middle East).
 - Intravascular imaging was rarely used, with the exception of Japan.
 - At 1 year, only approximately 2/3 of the ACS patients were on DAPT and the difference in DAPT rates between CCS and ACS was < 5%.





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The essentials to remember

- **Why?** Real life data on newer generation DES needed.
- **What?** eUltimaster registry was a large-scale PCI study worldwide.
- **How?** All-comers population, prospective registry, independent clinical event committee adjudicated all events related to the primary endpoint.
- **What are the results?**
 - Ultimaster DES showed excellent efficacy and safety profile at 1 y.
 - Performance was reproducible across the globe.
 - This registry allows for a unique insight in worldwide practice of PCI.
- **Why is this important?**
 - PCI is one of the most widely performed invasive treatment in medicine.
 - This study shows that PCI using latest generation DES conveys remarkable results that can be replicated worldwide.



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