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# Final results from the CENTURY II trial: 5-year clinical outcomes after bioresorbable versus durable polymer drug eluting stent implantation

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# Potential conflicts of interest

**Saito S:**

- ❑ **I have the following potential conflicts of interest to report**
  - Consultant: Terumo

# CENTURY II
## Why this study?

The **aim of the CENTURY II trial** was to establish long-term safety and efficacy of a sirolimus-eluting stent with **bioresorbable polymer coating, Ultimaster (BP-SES),** by comparing it with **permanent, biocompatible, polymer-coated, Xience** everolimus-eluting stent (**PP-EES**).

### Inclusion criteria

- Age ≥ 18 years (≥20 years Japan)
- Suitable for treatment with DES
- RVD matching stents 2.5-4.0 mm
- Diameter stenosis >50%
- Eligible for DAPT

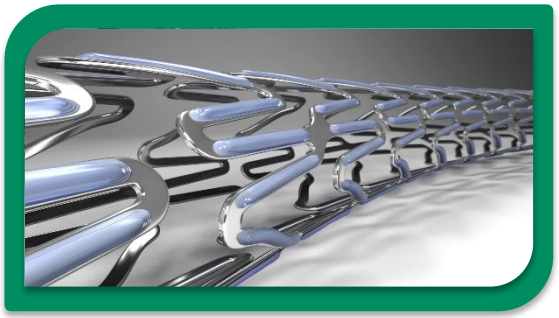
### Exclusion criteria - general

- EF<25%
- Renal failure
- Cardiogenic shock
- Planned staged procedure

### Additional exclusion criteria - Japan

- AMI < 48h
- Target lesion located in left-main trunk
- Ostial lesions
- Lesion in venous or arterial graft
- Previous (<1month) PCI with stenting
- Previous stenting in target lesion

# CENTURYII – Study devices
# What did we study?



| | Ultimaster BP-SES | Xience PP-EES |
|---|---|---|
| **Platform** | Thin-strut (80µm) Co-Cr<br>Open cell design | Thin-strut (81µm) Co-Cr |
| **Drug Carrier** | PDLLA-PCL copolymer<br>resorbed within 3-4 months | PVDF-HFP non-erodable<br>fluorinated copolymer |
| **Coating** | Abluminal gradient<br>coating technology  | Circumferential<br>coating  |
| **Drug** | sirolimus<br>70 µg/cm² | everolimus<br>100 µg/cm² |

# CENTURY II – Study design
## How was the study executed?

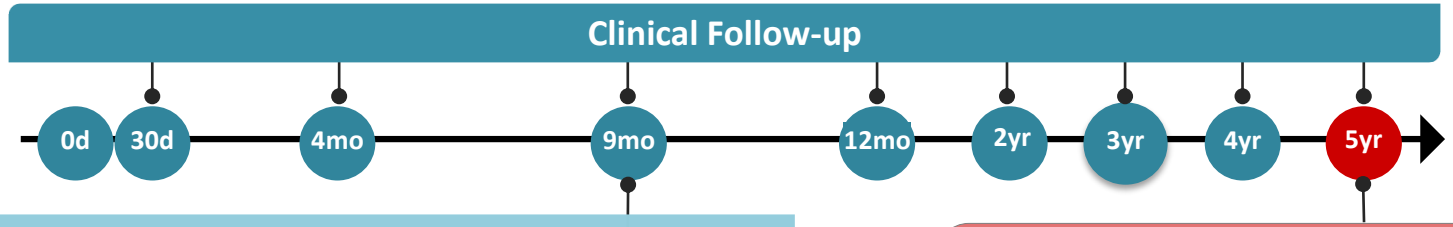
**Total population (per-protocol analysis)**
**N=1101 pts**

**Randomization**
**(1:1)**
**Principal investigators:**
**William Wijns**
**Shigeru Saito**

**Ultimaster**
**N=551 pts**

**Xience**
**N=550 pts**

Single blind, non-inferiority multi-center study
58 global study sites in Europe, Japan and Korea



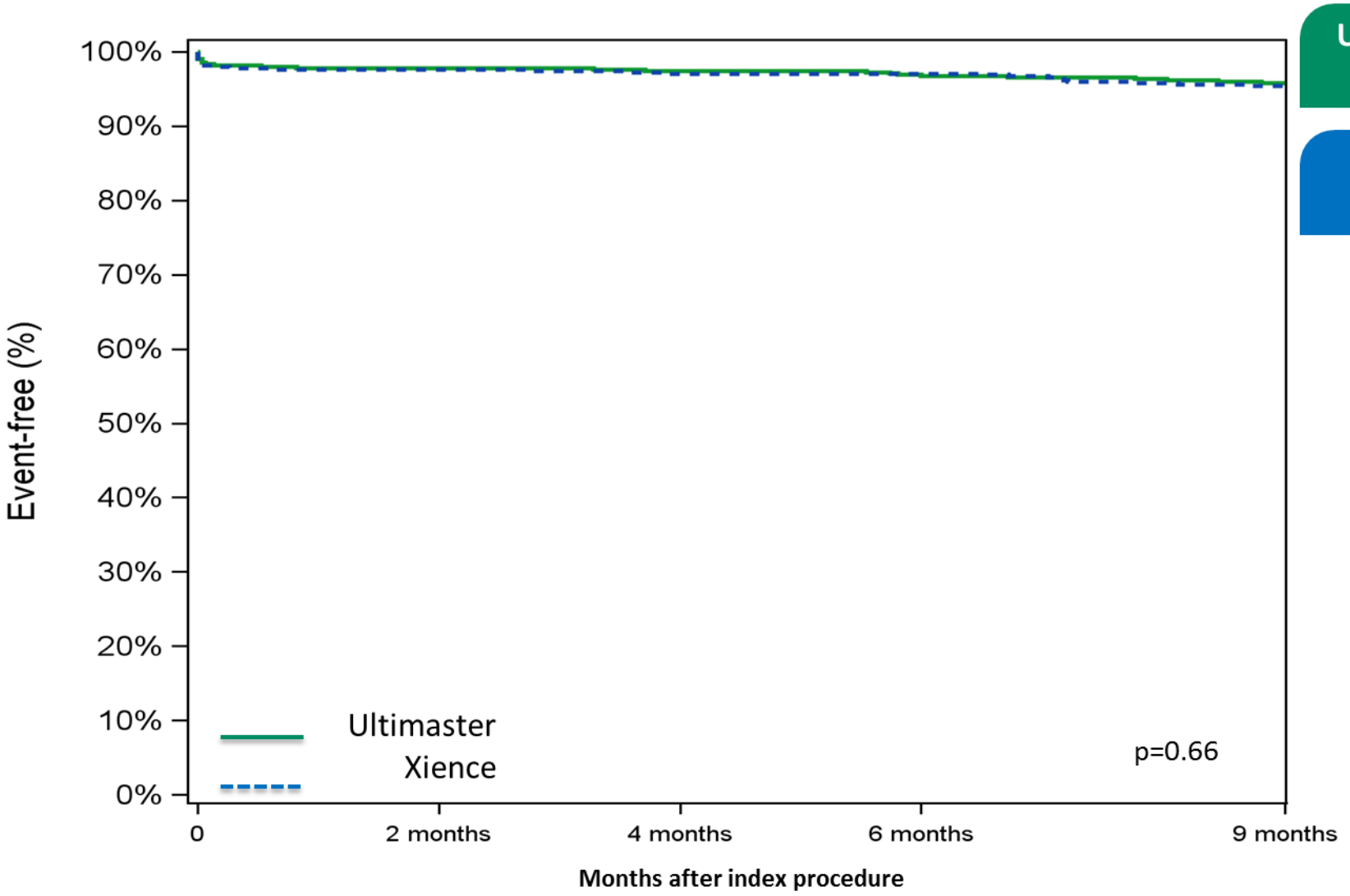

**Primary endpoint – Freedom from target lesion failure (TLF) at 9 months**

**Non-inferiority of the primary endpoint** at 9 months was met: **Freedom from TLF**: Ultimaster vs. Xience 95.6% vs. 95.1%; $p_{non\text{-}inferiority}$ <0.0001

**5 years FU**
**(95.9%)**

*All data were monitored by independent data monitoring committee and adverse events were adjudicated by an independent clinical event committee*

# CENTURY II
## Primary endpoint 9-month TLF-free rate




**TLF**: target lesion failure defined as cardiac death, target vessel myocardial infarction and target lesion revascularization

# CENTURY II
## Baseline patient characteristics

| | Ultimaster N=551 pts | Xience N=550 pts | P |
|---|---|---|---|
| Age, years (mean±SD) | 65.2±10.5 | 65.5±10.6 | 0.61 |
| Gender – male, % | 78.6 | 82.4 | 0.11 |
| DM, % | 31.9 | 30.9 | 0.71 |
| IDDM, % | 16.5 | 14.7 | 0.65 |
| Hypertension, % | 73.3 | 67.8 | 0.05 |
| Current Smoker, % | 22.2 | 23.9 | 0.50 |
| Previous smoker, % | 46.7 | 42.0 | 0.12 |
| Previous MI, % | 28.3 | 27.6 | 0.80 |
| Previous PCI, % | 37.2 | 35.0 | 0.45 |
| Previous CABG, % | 4.5 | 3.7 | 0.46 |
| Peripheral vascular disease, % | 9.6 | 6.6 | 0.06 |
| High risk ACS, % | 22.5 | 24.7 | 0.39 |

ACS= acute coronary syndrome, CABG= coronary artery bypass graft, DM= diabetes mellitus, IDDM= insulin-dependent DM, MI= myocardial infarction, PCI= percutaneous coronary intervention,

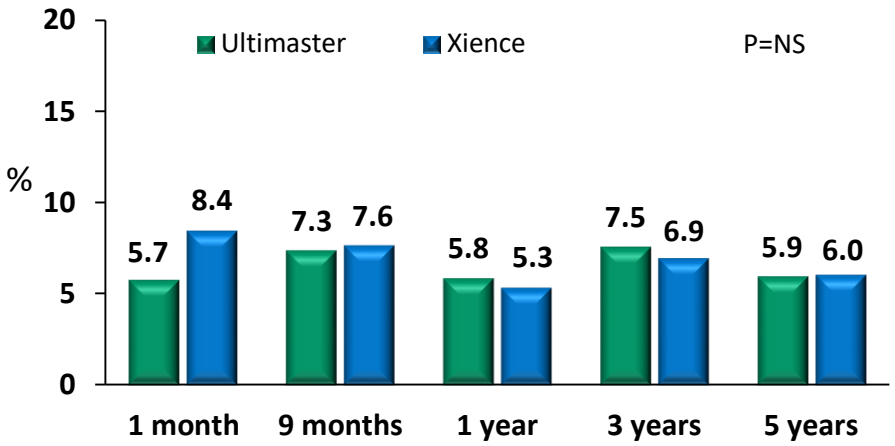
# CENTURY II

## Baseline lesion and procedure characteristics

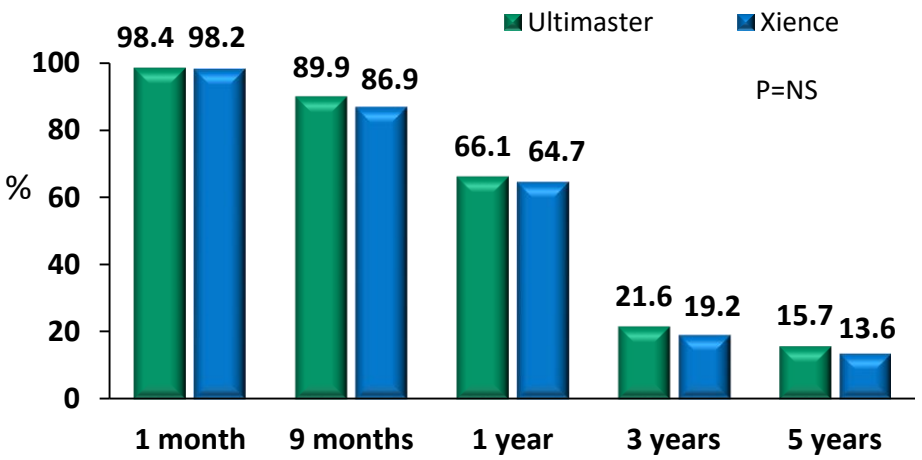
| | Ultimaster N=551 pts $N_{lesions}$=711 | Xience N=550 pts $N_{lesions}$=716 | P |
|---|---|---|---|
| Multi-vessel disease, % | 39.6 | 41.3 | 0.56 |
| Lesions detected, n | 2.0±1.3 | 2.0±1.3 | 0.67 |
| Lesions treated,n | 1.3±0.6 | 1.3±0.6 | 0.62 |
| Bifurcation/lesion, % | 13.8 | 14.4 | 0.74 |
| Ostial/lesion, % | 6.0 | 8.4 | 0.08 |
| Moderate/severe calcification, % | 21.5 | 17.7 | 0.70 |
| Access site, %<br>Radial<br>Femoral | <br>71.7<br>26.7 | <br>73.1<br>25.6 | 0.55 |
| N° of stents implanted/pt | 1.5±0.8 | 1.6±0.9 | 0.94 |
| Total implanted stent length/pt | 29.5±17.0 | 29.6±18.1 | 0.66 |
| Delivery success, % | 99.1 | 99.5 | 0.23 |
| Procedure success/pt, % | 98.0 | 98.2 | 0.83 |

# 5-year angina status – DAPT - bleeding rate

## Angina complaints during follow-up, %

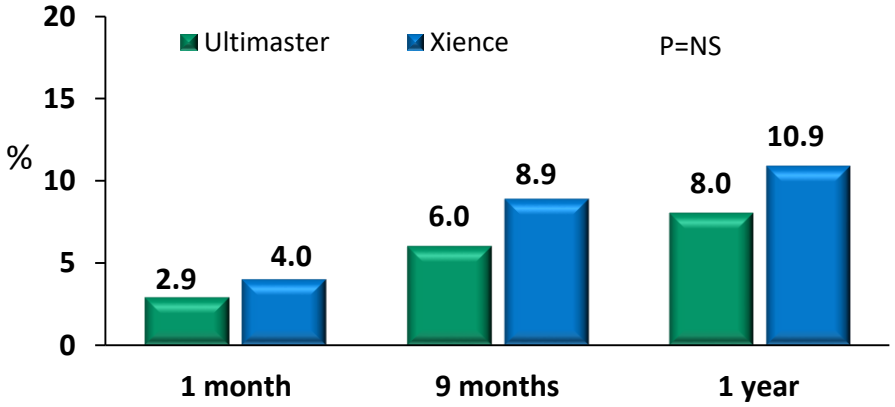



## Dual antiplatelet therapy (DAPT), %

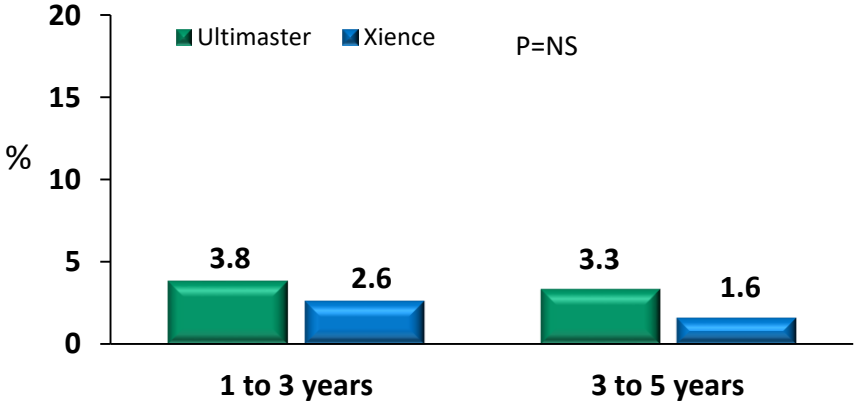



## Bleeding rates

### Bleeding rates – cumulative up to 1 year

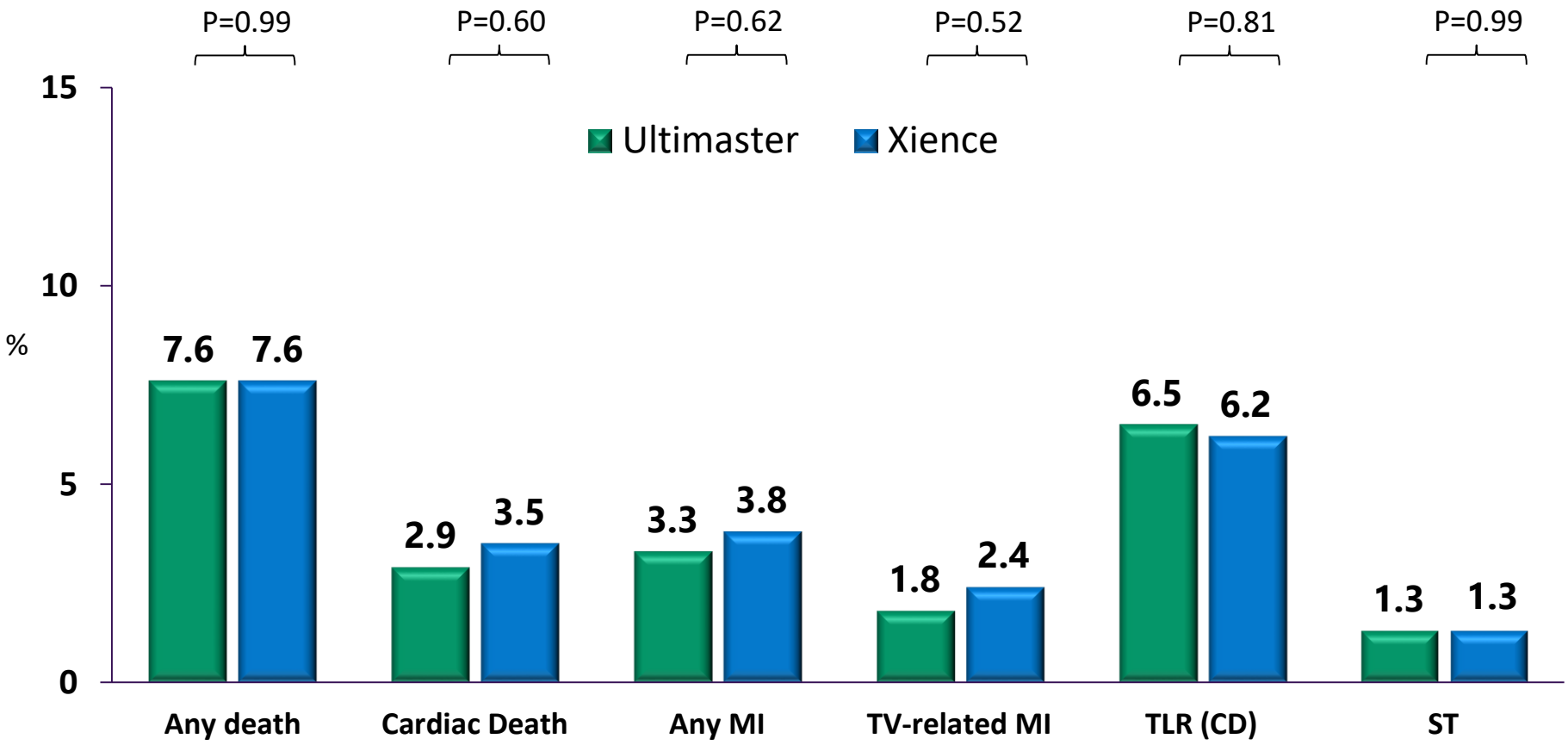



### Bleeding rates – 1 to 5 years



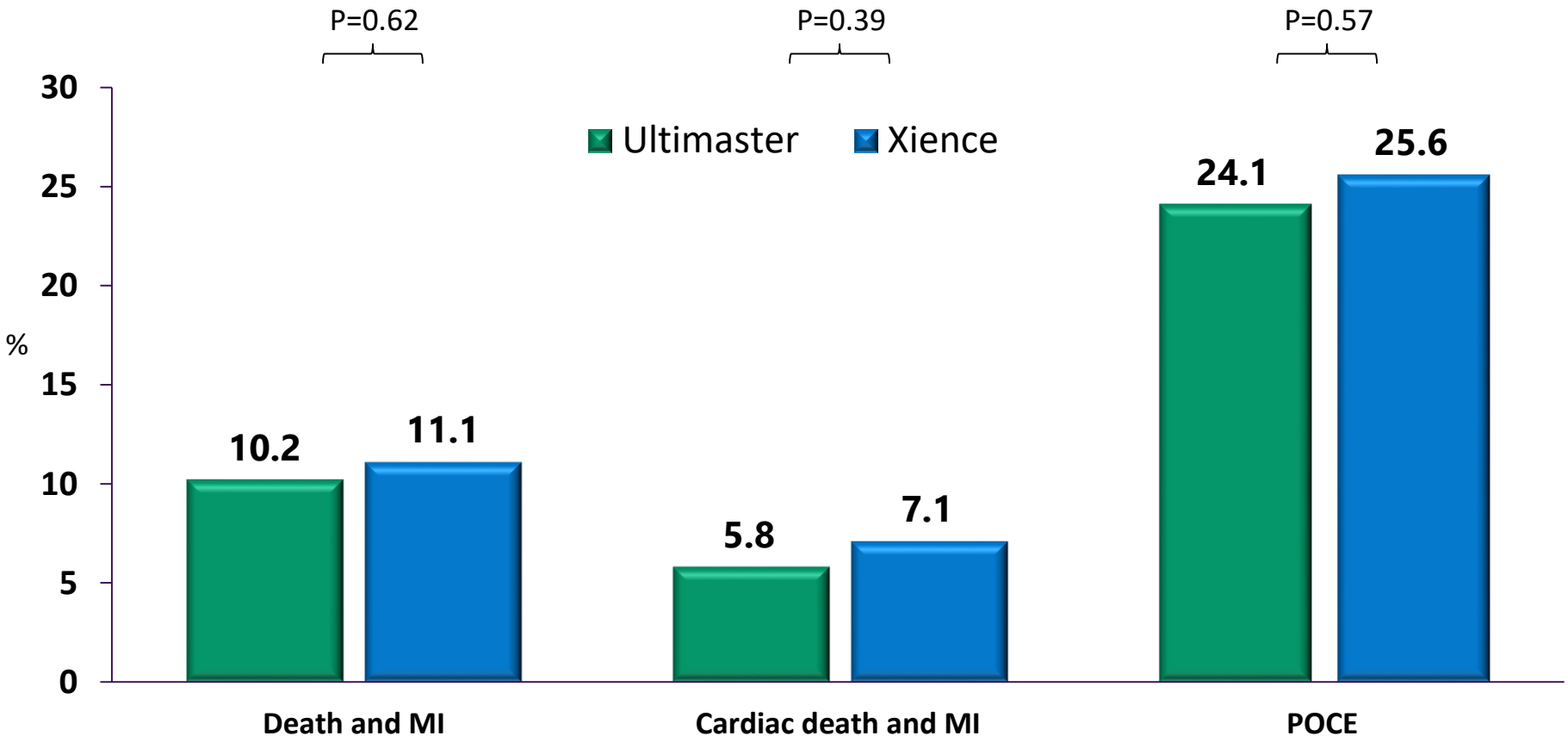

NS: not significant (P>0.05)

# What are the essential results? 5-year clinical outcomes



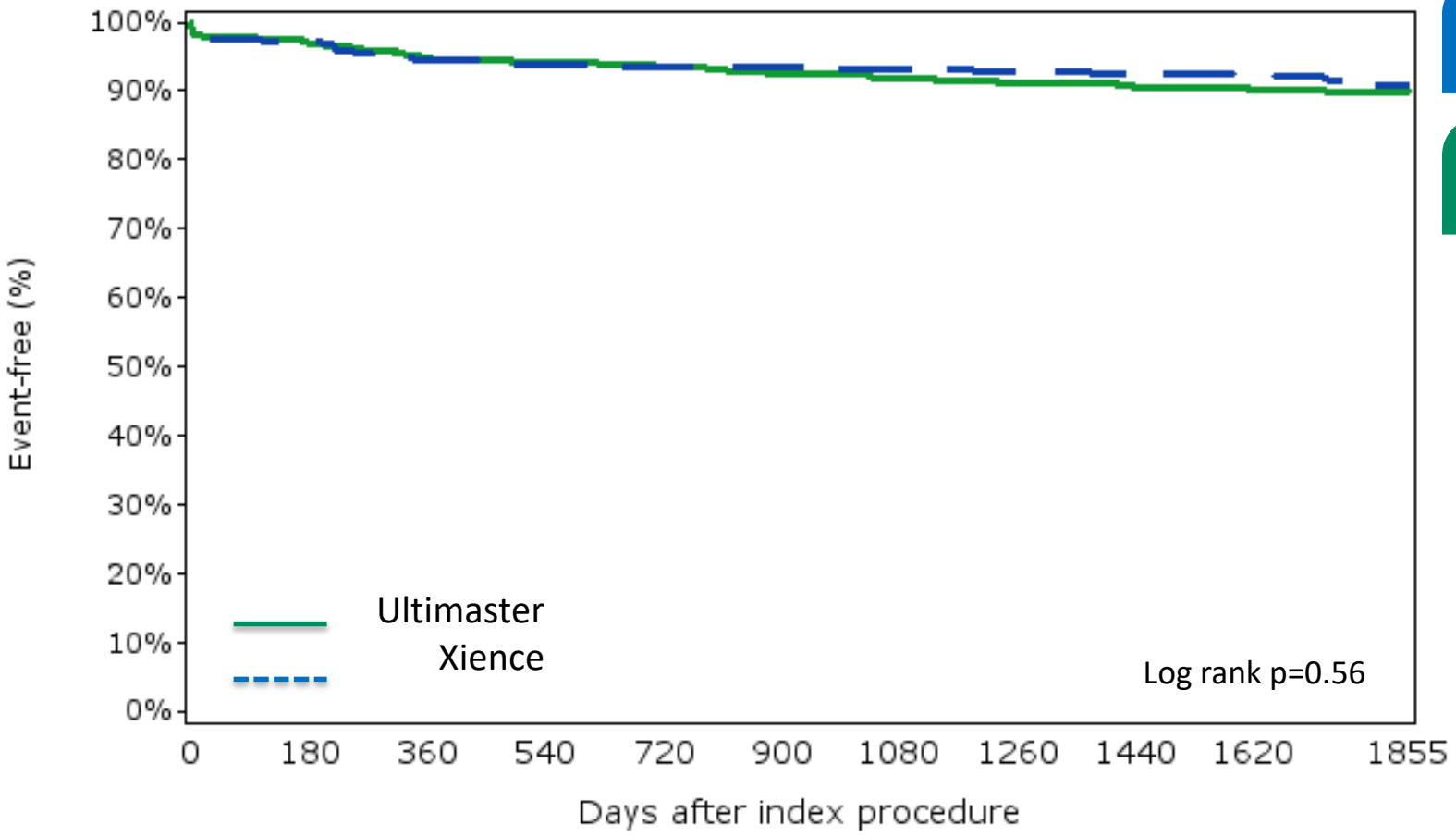

**TV-related MI**: target vessel-related myocardial infarction; **CD**: clinically driven; **TLR**: target lesion revascularization; **ST**: definite + probable stent thrombosis

# What are the essential results? 5-year clinical outcomes




**POCE**: patient-oriented composite endpoint of any death, any MI and any revascularization

# CENTURY II
## 5-year TLF-free rate




**Xience**
**91.1%**

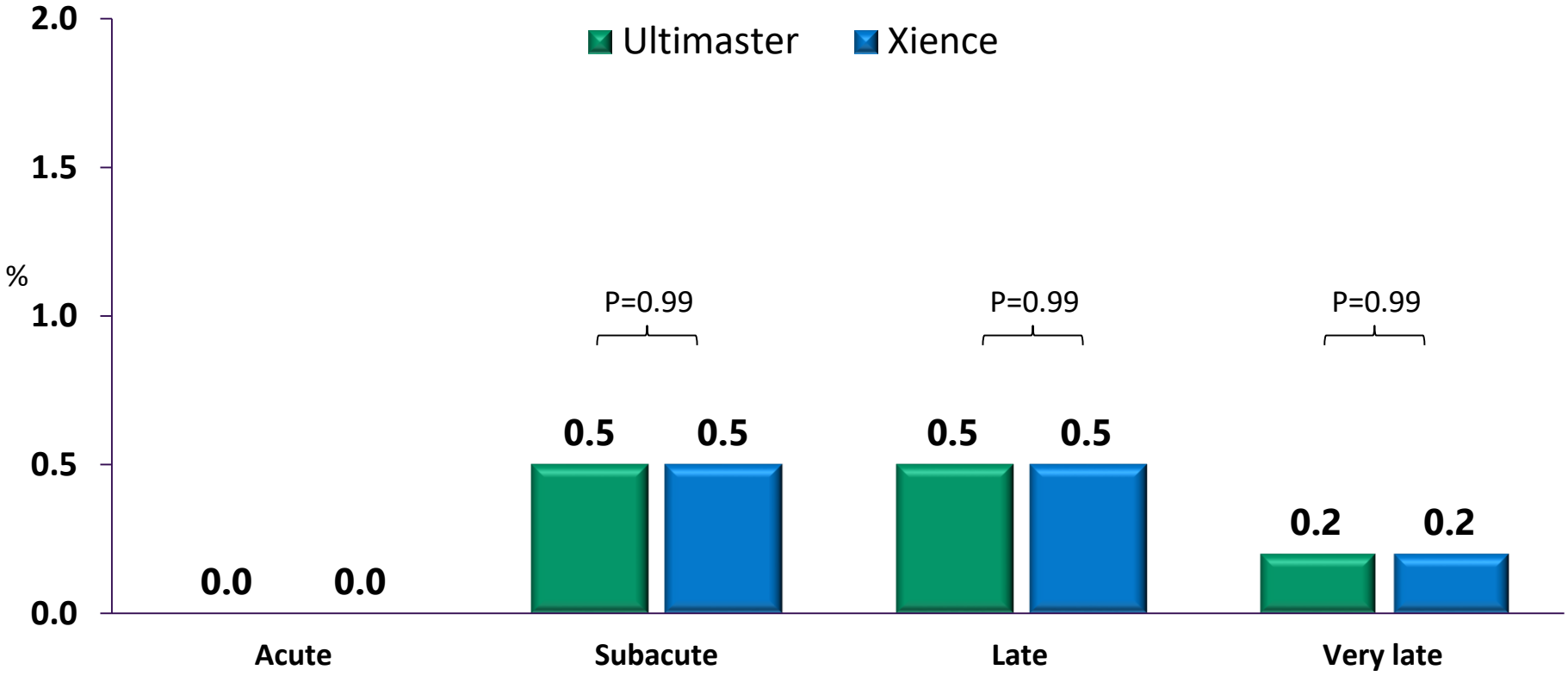
**Ultimaster**
**90.0%**

Number at Risk

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| BP-SES | 551 | 533 | 520 | 516 | 509 | 501 | 495 | 489 | 483 | 477 | 471 |
| PP-EES | 550 | 534 | 515 | 510 | 505 | 501 | 498 | 492 | 490 | 486 | 477 |

**TLF**: target lesion failure defined as cardiac death, target vessel myocardial infarction and target lesion revascularization

# CENTURY II
## Stent thrombosis rate during follow-up



# Why is this important?

- Comparable clinical outcomes of sirolimus-eluting (Ultimaster) stent with bioresorable polymer coating versus everolimus-eluting (Xience) stent with durable polymer coating are maintained up to five years.
- Particularly remarkable was the low rate of very late stent thrombosis (0.2%) in both arms.
- These data supports the long term **safe use and good performance** of the Ultimaster DES.

# The essentials to remember

**Why?**

Establish long-term safety and efficacy of a sirolimus-eluting stent with bioresorbable polymer.

**What?**

Ultimaster DES with bioresorable polymer coating was compared with Xience DES with permanent, biocompatible polymer coating.

**How?**

CENTURY II is a large scale, prospective, multicentre, randomized, single blind, controlled, non-inferiority trial.

**What are the results?**

Comparable clinical outcomes of Ultimaster DES versus Xience DES are maintained up to five years, with particularly low rates of very late stent thrombosis.

**Why is this important?**

Longest available clinical data regarding efficacy and safety following Ultimaster implantation, supporting its safe use in routine clinical PCI practice.

Final summary slide