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Contemporary bifurcation treatment practice: what we can learn from a large global registry

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on behalf of e-ULTIMASTER Investigators

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Study Background

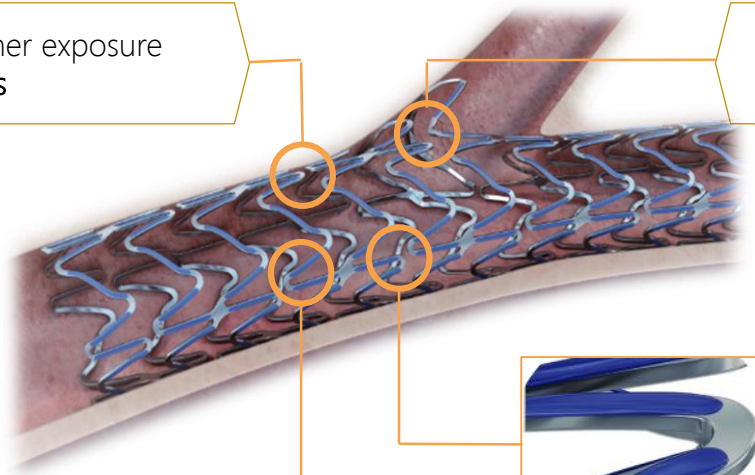
- In bifurcation PCI, understanding the interaction between devices and vessels is crucial in order to achieve higher chance of technical success as well as improve long-term outcomes .
- A large worldwide registry that enrolled more than 3300 patients with a bifurcation lesion provides a good opportunity to explore the real-world bifurcation treatment practice.

Study device

Key features of Ultimaster DES

Short-term PDLLA-PCL polymer exposure within 3–4 months

Open cell, 2-link design eases side branch access



No drug coating on parts of the stent that experience the most physical stress

Gradient coating maintains polymer integrity when overexpanded[2]

Good overexpansion capacity[1]
An independently initiated study showed expansion of up to 5.8 mm with Ultimaster™

1. Ng J et al. Int J Cardiol 2016;221:171–9; 2. Saito N et al. Medical Devices: Evidence and Research 2016:9;33-43.

Study design

e-Ultimaster registry
4 continents, 50 countries, 376 sites

Study enrolment completed, follow-up ongoing
> 37,000 patients enrolled

Interim analysis
1-year follow-up or death
n=25,990 patients

Patient treated in bifurcation
n=3,372

CLINICAL FOLLOW-UP

An independent Clinical Event Committee reviewed and adjudicated all endpoint-related serious adverse events

Baseline characteristics

Patient characteristics	All bifurcation n=3372
Mean age, year	**65.8±11.1**
Male patients, %	**77.0**
Hypertension, %	**64.9**
Diabetes, %	**27.3**
Hypercholesterolemia, %	**58.8**
Current smoker, %	**21.0**
Renal impairment, %	**9.1**
Previous PCI, %	**29.6**
Present with ACS, %	**48.1**

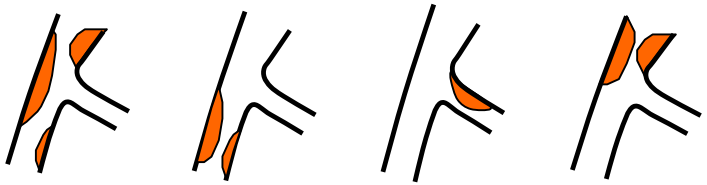
Lesion/procedure characteristics	All bifurcation n=3372
Radial access, %	**81.4**
Num of lesions identified, %	**2.0±1.1**
Num of stents/pt, n	**1.7±1.0**
Total stent length/pt, mm	**37.3±24.3**
Imaging used (IVUS+OFDI), %	**13.8**
Direct stenting, % per lesion	**29.3**
Post dilatation, % per lesion	**55.2**
Left main bifurcation, %	**8.9**
Both main and side branch treated, %	**50.7**
Both main and side branch stented, %	**22.4**

MEDINA classification & bifurcation techniques

True bifurcation

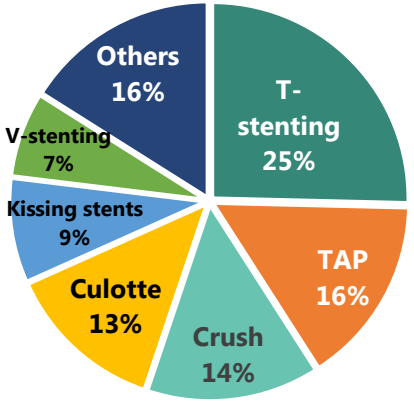
Medina classification	1,1,1	1,0,1	0,1,1
Percentage, %	36.3	8.3	8.1

Other bifurcation



Medina classification	1,1,0	0,1,0	0,0,1	1,0,0
Percentage, %	26.4	9.6	3.8	8.6

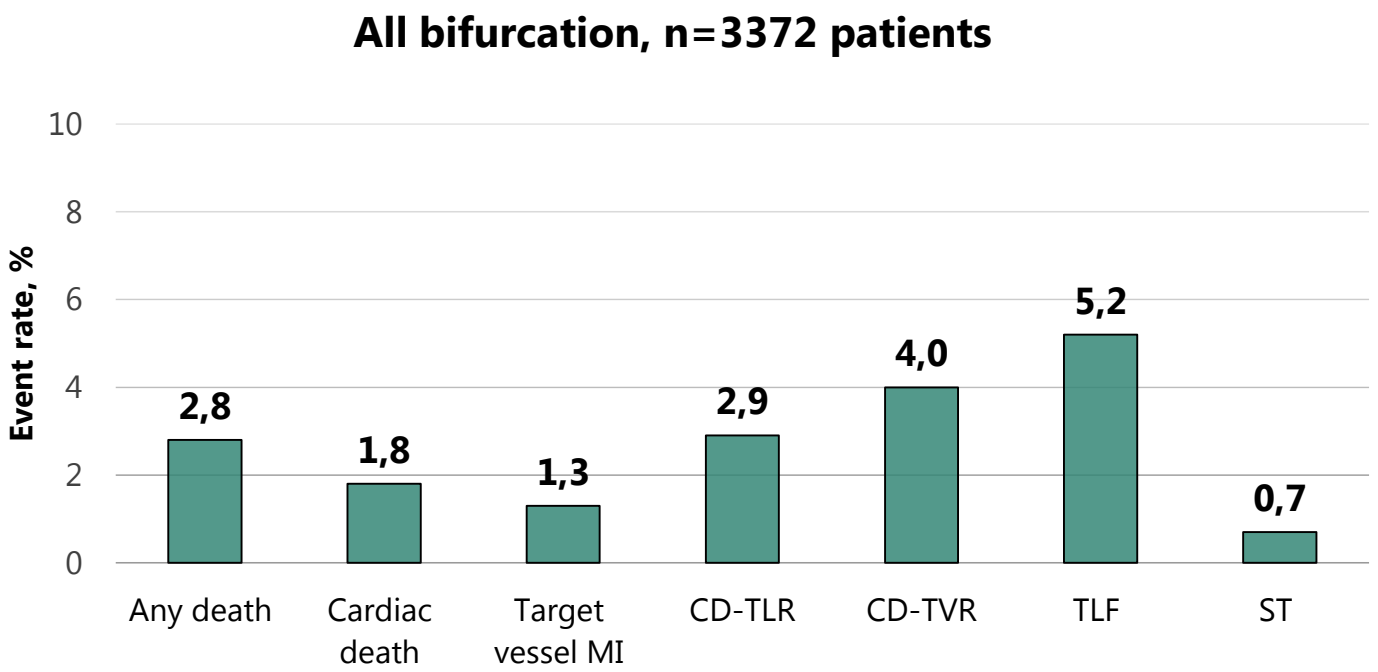
Two stents techniques



Kissing balloon: 36.9%

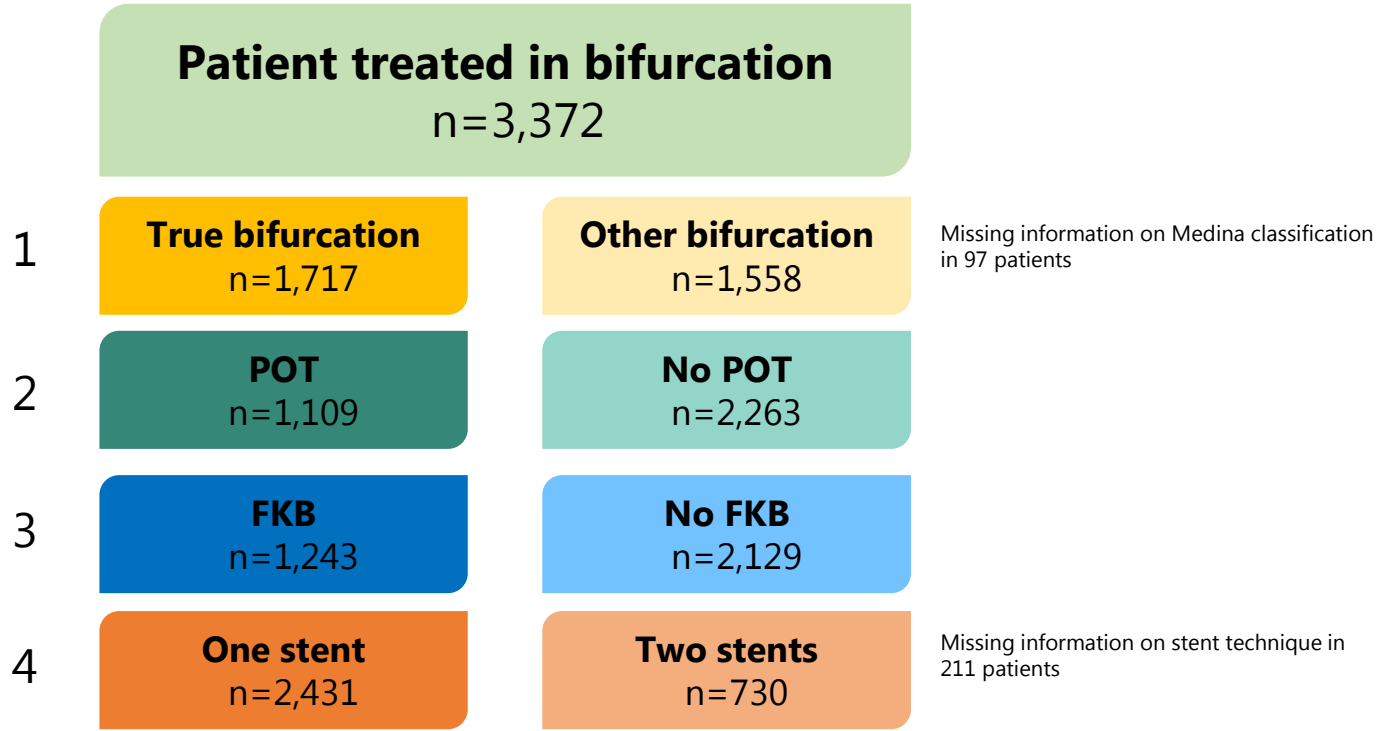
POT: 32.9%

1 year clinical outcomes



CD-TLR: clinically driven target lesion revascularization; **CD-TVR**: clinically driven target vessel revascularization; **MI**: myocardial infarction; **ST:** definite/probable stent thrombosis; **TLF**: target lesion failure (cardiac death, target vessel MI or CD-TLR)

Propensity matched analysis

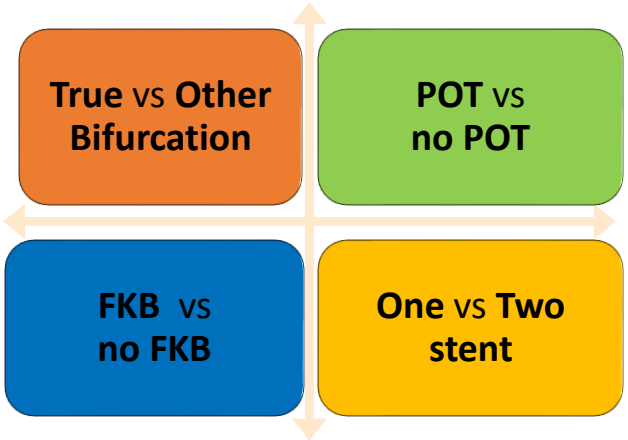


Propensity matched analysis: adjusted for baseline patients' and lesions' characteristics

FKB: final kissing balloon
POT: proximal optimization technique

Propensity matched analysis

Bifurcation treatment techniques

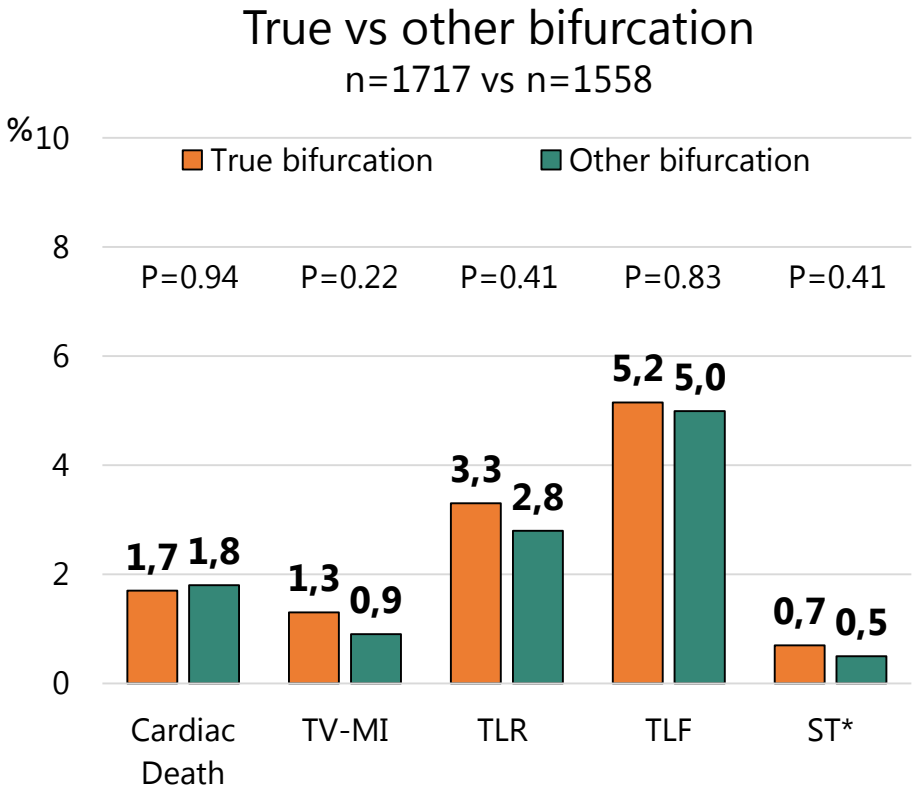


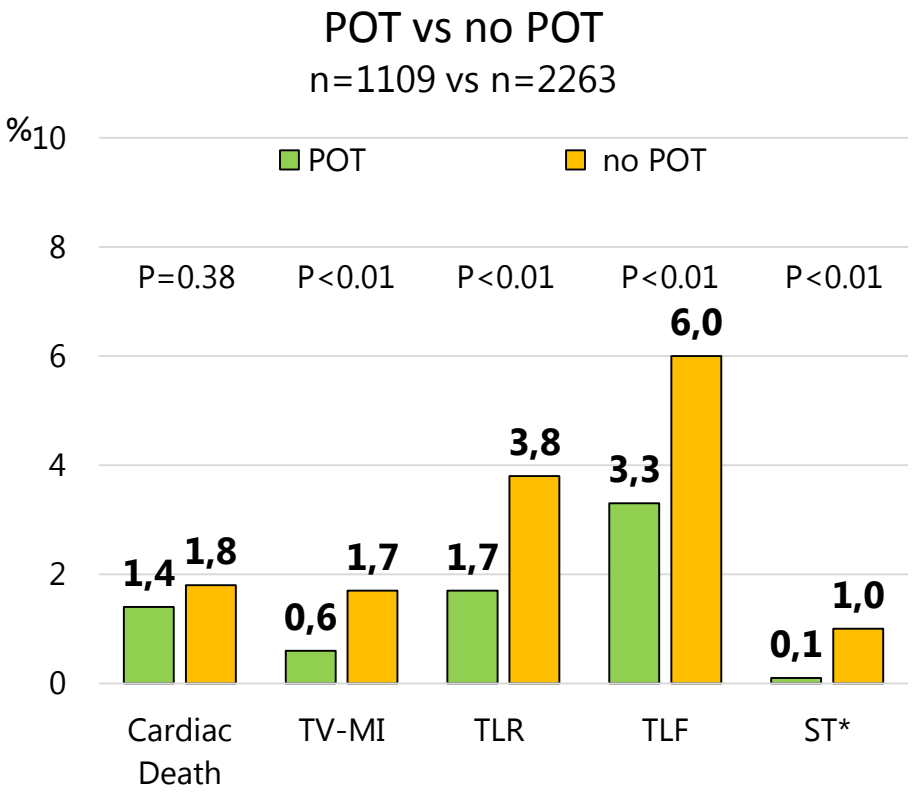
FKB: final kissing balloon
POT: proximal optimization technique

Propensity matched analysis: adjusted for baseline patients' and lesions' characteristics, and in addition adjusted for the following:

- ❑ **True vs non true:** POT vs no POT, 1 vs 2 stent, kissing versus no kissing
- ❑ **POT vs no POT:** true vs non true bifurcation, 1 vs 2 stent technique, Kissing vs no Kissing
- ❑ **FKB vs no FKB:** True vs non true bifurcation, 1 vs 2 stent technique; POT versus no POT
- ❑ **1 vs 2 stent:** True vs non true bifurcation; POT vs no POT; kissing versus no kissing

1-year clinical outcomes
Propensity matched analysis

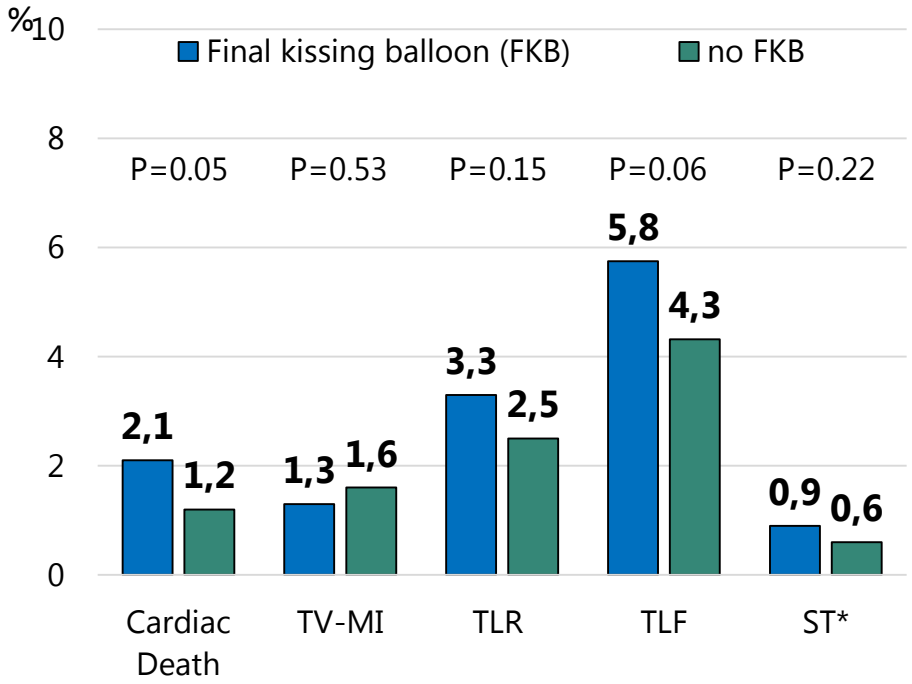




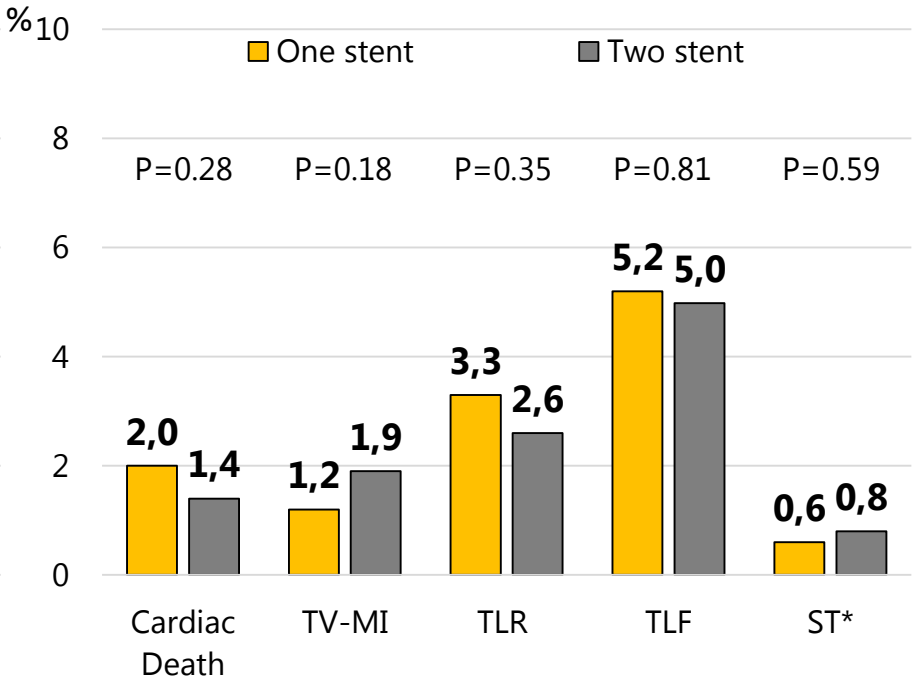
POT: proximal optimization technique **ST**: definite/probable stent thrombosis; **TLR**: target lesion revascularization; **TLF**: target lesion failure (cardiac death, target vessel MI or clinically driven TLR); **TV-MI**: target vessel myocardial infarction;

1-year clinical outcomes
Propensity matched analysis

Kissing balloon vs no kissing balloon
n=1243 vs n=2129



One vs two-stent technique
n=2431 vs n=730



ST: definite/probable stent thrombosis; **TLR**: target lesion revascularization; **TLF**: target lesion failure (cardiac death, target vessel MI or clinically driven TLR); **TV-MI**: target vessel myocardial infarction;

Conclusions

In this large prospective sub-study of >3300 patients treated with Ultimaster DES on, at least, one bifurcation lesion:

- Clinical outcome evaluation of the global bifurcation was good with a 5.2% 1-y TLF rate with no difference between XX1 and XX0 Medina lesions
- After propensity matching, at one year, there was
  - No difference between 1 or 2-stent techniques
  - No benefit of final kissing balloon
  - A strong benefit of POT technique