EuroPCR 2021

Flash Report

e-Ultimaster
Complete versus incomplete revascularization in NSTEMI patients

"Our findings suggest that a physician-directed complete revascularisation strategy with the Ultimaster stent results in optimised clinical outcomes in this all-comers NSTEMI population" (1

Pieter C. Smits, MD
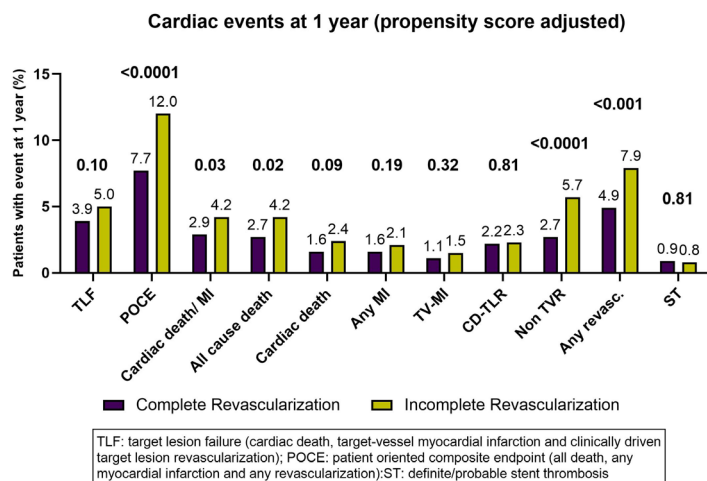Maasstad Ziekenhuis,
Rotterdam, Netherlands

Objective

To Study the impact of completeness of revascularization on the one-year clinical outcomes in MVD-NSTEMI patients treated within the e-Ultimaster registry
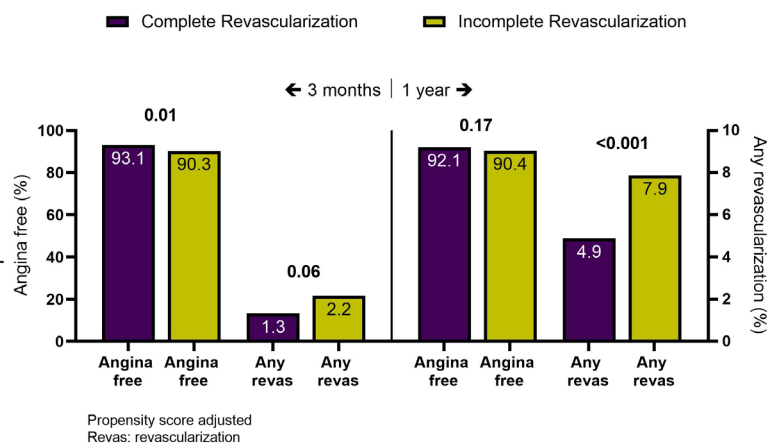
The large e-Ultimaster registry (37,198 patients) enabled to perform a subgroup analysis of patients with CR versus incomplete revascularization (IR).

Result

Cardiac event at 1 year

Cardiac events at 1 year (propensity score adjusted)

	Complete Revascularization	Incomplete Revascularization	p-value
TLF	3.9	5.0	0.10
POCE	7.7	12.0	<0.0001
Cardiac death/ MI	2.9	4.2	0.03
All cause death	2.7	4.2	0.02
Cardiac death	1.6	2.4	0.09
Any MI	1.6	2.1	0.19
TV-MI	1.1	1.5	0.32
CD-TLR	2.2	2.3	0.81
Non TVR	2.7	5.7	<0.0001
Any revasc.	4.9	7.9	<0.001
ST	0.9	0.8	0.81

TLF: target lesion failure (cardiac death, target-vessel myocardial infarction and clinically driven target lesion revascularization); POCE: patient oriented composite endpoint (all death, any myocardial infarction and any revascularization):ST: definite/probable stent thrombosis

Angina status and Revascularization rate at 3 months and 1 year

← 3 months | 1 year →

	Angina free	Any revas	Angina free	Any revas
Complete Revascularization	93.1	1.3	92.1	4.9
Incomplete Revascularization	90.3	2.2	90.4	7.9
p-value	0.01	0.06	0.17	<0.001

Propensity score adjusted
Revas: revascularization

Are you interested in NSTEMI result ?

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TERUMO INTERVENTIONAL SYSTEMS

1) Complete versus incomplete revascularization in NSTEMI patients presented at Euro PCR 2021

e-Ultimaster

First machine learning derived risk score for target lesion failure one year after DES implantation

"We show the feasibility of adopting machine learning approaches in developing a risk prediction model for 1-year TLF, with superior performance than traditional statistic approaches" (2

MAMAS A. MAMAS, MD
Keele University, Staffordshire,
United Kingdom

Objective

To see whether it was feasible to develop a TLF Risk tool using ML and whether this outperforms traditional approaches

Data from the worldwide e-ULTIMASTER registry were used to develop a **machine learning-based model** to predict TLF up to one year, using 90 patient and procedure variables
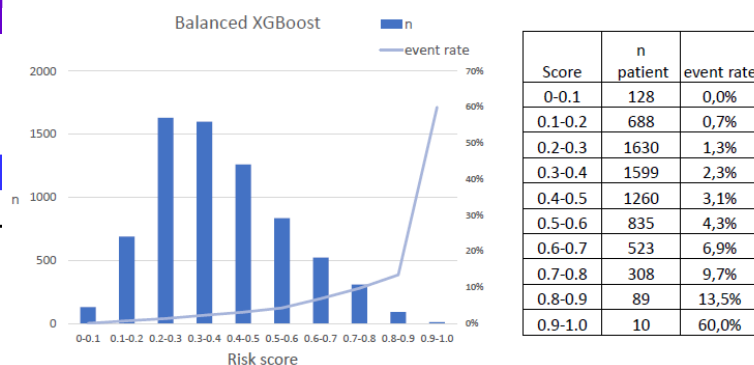
Result

Prediction model evaluation
(test / validation data)

Model	AUC	AUC_lower	AUC_upper	Sensitivity	Specificity
Conventional logistic regression*	**0.683**	**0.648**	**0.719**	**0.73**	**0.572**
Regularized logistic regression	0.709	0.674	0.744	0.643	0.699
Decision tree	0.658	0.621	0.694	0.656	0.596
XGBoost	0.704	0.67	0.738	0.562	0.741
Balanced XGBoost	**0.716**	**0.682**	**0.75**	**0.71**	**0.601**
RuleFit	0.712	0.677	0.746	0.536	0.774

*Conventional logistic regression: This model adopted the variables which are significant based on stepwise method after p-value of the variables are confirmed < 0.1 based on univariate odds ratio. Sensitivity and Specificity are chosen based on Youden-index

AUC in Conventional logistic regression model decreased at validation set. This means the model had the issue called "overfitting", which happen when the model is excessively complex (even after stepwise selection). Machine learning models were less sensitive on this issue

Population distribution according to risk score and observed event rates in test / validation cohort

Balanced XGBoost

Score	n patient	event rate
0-0.1	128	0,0%
0.1-0.2	688	0,7%
0.2-0.3	1630	1,3%
0.3-0.4	1599	2,3%
0.4-0.5	1260	3,1%
0.5-0.6	835	4,3%
0.6-0.7	523	6,9%
0.7-0.8	308	9,7%
0.8-0.9	89	13,5%
0.9-1.0	10	60,0%

Are you interested in Machine Learning by using e-Ultimaster data ?

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TERUMO INTERVENTIONAL SYSTEMS

2) First machine learning derived risk score for target lesion failure one year after DES implantation presented at Euro PCR 2021

CENTURY JSV
Five-year clinical outcomes after coronary stenting of small vessels in Japanese population using 2.25 mm diameter Sirolimus-eluting stent with bioresorbable polymer

"We could certify safety and effectiveness after 2.25mm Ultimaster bioresorbable-polymer sirolimus-eluting stent implantation for 5 years follow-up"
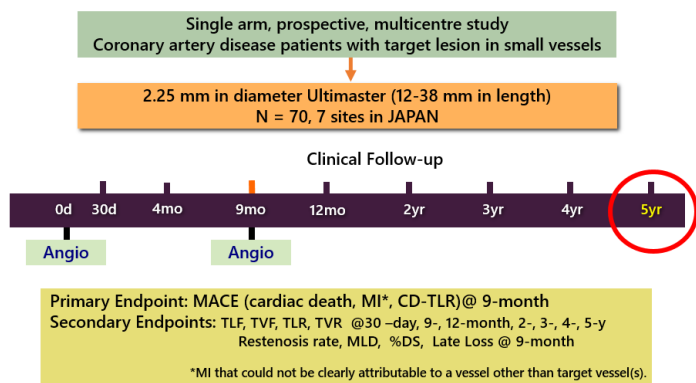
(3

Koki Shishido, MD
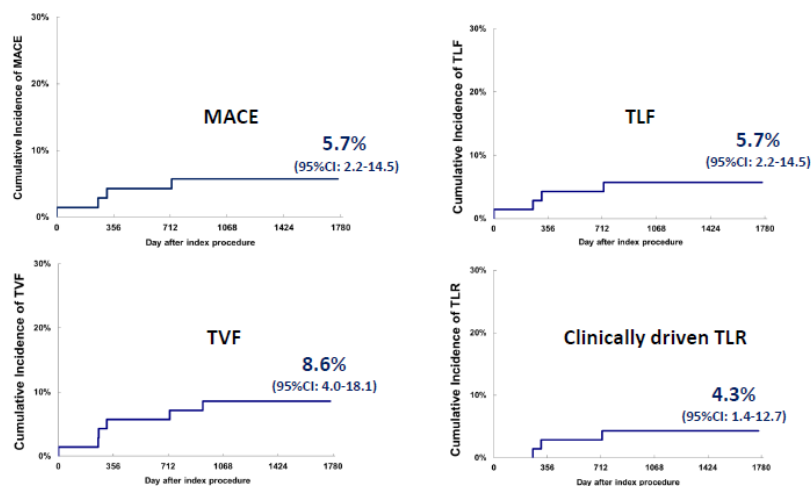Shonan Kamakura General Hospital, Kanagawa, Japan

Objective

To evaluate the safety and effectiveness of the 2.25-mm diameter Ultimaster sirolimus-eluting stent in the treatment of Japanese patients with CAD for long-term follow-up

Study Design

Single arm, prospective, multicentre study
Coronary artery disease patients with target lesion in small vessels

2.25 mm in diameter Ultimaster (12-38 mm in length)
N = 70, 7 sites in JAPAN

Clinical Follow-up

0d 30d 4mo 9mo 12mo 2yr 3yr 4yr 5yr

Angio   Angio

Primary Endpoint: MACE (cardiac death, MI*, CD-TLR)@ 9-month
Secondary Endpoints: TLF, TVF, TLR, TVR @30 –day, 9-, 12-month, 2-, 3-, 4-, 5-y
Restenosis rate, MLD, %DS, Late Loss @ 9-month

*MI that could not be clearly attributable to a vessel other than target vessel(s).

5-Year Results

MACE **5.7%** (95%CI: 2.2-14.5)

TLF **5.7%** (95%CI: 2.2-14.5)

TVF **8.6%** (95%CI: 4.0-18.1)

Clinically driven TLR **4.3%** (95%CI: 1.4-12.7)

NO Stent thrombosis throughout 5 years

No incidence of stent thrombosis throughout 5 years in patients using Ultimaster 2.25mm stent.

Are you interested in the result of Ultimaster in small vessel lesion?

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3) Five-year clinical outcomes after coronary stenting of small vessels in Japanese population using 2.25 mm diameter Sirolimus-eluting stent with bioresorbable polymer– CENTURY JSV study – presented at Euro PCR 2021

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