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Complete versus incomplete revascularization in patients with a non-ST-elevation myocardial infarction: Analysis from the e-ULTIMASTER registry

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ABSTRACT

Background: Incomplete revascularization (ICR) has been associated with a worse prognosis after a percutaneous coronary intervention (PCI). In NSTEMI patients with multivessel disease (MVD) however, the benefit of a complete revascularization (CR) remains unclear.

Methods: Patients presenting with an NSTEMI and MVD were selected from the global e-ULTIMASTER registry and grouped according to completeness of revascularization at index hospitalization discharge. The primary endpoint was the patient oriented composite endpoint (POCE) defined as all death, any myocardial infarction, and any revascularization at 1 year. Target lesion failure (TLF) was defined as the composite of cardiac death, target vessel related myocardial infarction and clinically driven target lesion revascularization. Inverse propensity score weighting (IPSW) was performed to harmonize the patient's baseline characteristics between the groups.

Results: CR was achieved in 1800 patients (47.0 %) and ICR in 2032 patients (53.0 %). The incidence of POCE at 1 year was lower in the CR group compared to the ICR group: 7.0 % vs. 12.9 %, $p < 0.0001$. Similarly for TLF at 1 year: 3.6 % vs. 5.5 %, $p < 0.01$. After IPSW, the incidence of POCE was 7.7 % vs. 12.0 %, $p < 0.0001$, due to a lower all-cause mortality: 2.7 % vs. 4.2 %, $p = 0.02$ and less revascularizations: 4.9 % vs. 7.9 %, $p < 0.001$. The incidence of TLF was no longer statistically significant: CR 3.9 % vs. IR 5.0 %, $p = 0.10$.

Conclusions: Patients with a NSTEMI and multi vessel disease undergoing a percutaneous coronary revascularization with a complete revascularization during index hospitalization have better 1-year clinical outcomes. Randomized studies are warranted to confirm these results.

1. Introduction

Of those patients who present with an acute myocardial infarction, up to two-thirds presenting with a non-ST-elevation (NSTEMI) and nearly one-half of the patients with an ST-elevation (STEMI) [1,2] have significant stenosis in more than one vessel [3,4]. Patients with multivessel coronary artery disease (MVD) may undergo revascularization with either coronary artery bypass graft (CABG) surgery or percutaneous coronary interventions (PCI). In the acute setting of a myocardial infarction, a PCI can be quickly organized, and the culprit lesion can be treated, restoring coronary flow without any substantial delay. The next steps in the revascularization strategy depend on the presence of lesions in vessels other than the infarct related artery, with the

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Abbreviations

CABG	Coronary artery bypass grafting
CI	Confidence interval
CD-TLR	Clinically driven target lesion revascularization
CD-TVR	Clinically driven target vessel revascularization
CR	Complete revascularization
HR	Hazard ratio
ICR	Incomplete revascularization
IPSW	Inverse propensity score weighting
MI	Myocardial infarction
MVD	Multi vessel disease
NSTEMI	Non-ST-elevation myocardial infarction
PCI	Percutaneous coronary intervention
POCE	Patient oriented composite endpoint
SD	Standard deviation
TLF	Target lesion failure
TVF	Target vessel failure
TVR	Target vessel revascularization

option to treat these lesions during the index procedure or in a later phase. The severity of the coronary artery disease, the patient's co-morbidities, the myocardium at risk, and the likelihood of an incomplete revascularization with either PCI or CABG determine the modality of revascularization [5]. CABG results in a more complete revascularization [6,7], but the advantage should be weighted against the higher risk of a non-elective cardiac surgical procedure in patients with a (recent) myocardial infarction [8].

Concerning PCI, the recent 2023 ESC Guidelines for the management of acute coronary syndromes concluded a Class I, level A recommendation to achieve a CR either during the index procedure or within 45 days for stable STEMI patients with MVD [9]. This recommendation is based upon sound evidence about the benefits of CR generated in randomized, controlled trials [10]. Conversily, for NSTEMI patients, there was a lower class (IIa) recommendation to consider CR preferably during index hospitalization. The level of evidence was C indicating consensus of opinion of the experts, small studies, retrospective studies, or registries. No data from dedicated randomized, controlled trials is available for the impact of CR vs. ICR in NSTEMI patients. Pending the availability of data from randomized controlled trials, the present analysis sought to evaluate whether CR in patients undergoing a PCI in the context of an NSTEMI and MVD offers a benefit compared to ICR. We aimed this sub-analysis from the large international e-ULTIMASTER registry.

2. Methods

Patients with an NSTEMI and MVD enrolled in the global e-ULTIMASTER registry [11] were grouped based on whether CR or ICR was achieved at index hospitalization discharge, including outcomes of eventual staged procedures performed during the index hospitalization. Method for assessing the criticality of non-culprit lesions, i.e., anatomically or functionally, the decision to perform a staged procedure and the timing hereof were at operator's discretion. Completeness of revascularization was assessed by the operator at the end of each procedure and documented in the electronic data capture system. MVD was defined as the presence of a lesion requiring intervention in ≥ 2 coronary arteries.

The e-ULTIMASTER registry (clinicaltrial.gov: NCT02188355) is a global observational registry that enrolled 37,198 patients with minimal inclusion - and exclusion criteria to evaluate the Ultimaster stent in an all-comer patient population with an indication for a percutaneous coronary intervention. Sites in Europe, Asia, Africa, the Middle East, South America, and Mexico participated. The Ultimaster stent is a thin-strut (80 μm) cobalt-chromium sirolimus eluting stent. It features a bioresorbable polymer coating (poly-D,L-lactic acid polycaprolactone) that is fully metabolized through dl-lactide and caprolactone into carbon dioxide and water in 3–4 months. The coating is applied on the abluminal side of the struts only and a bare metal stent remains after resorption of the coating.

The primary endpoint for this post-hoc subgroup analysis patient oriented composite endpoint (POCE) was defined as all death, any myocardial infarction, and any revascularization at 1 year. Target lesion failure (TLF) was defined as the composite of cardiac death, target vessel related myocardial infarction (TV-MI) and clinically driven target lesion revascularization (CD-TLR). The Target vessel failure was defined as cardiac death, TV-MI and any clinically indicated target vessel revascularization. For MI, the extended historical MI definition that primarily uses creatine kinase myocardial band (MB), or if not available troponin, as cardiac biomarker criterion was applied (see Supplement for definitions). All primary endpoints related events as well as stent thrombosis were adjudicated by an independent clinical events committee. The study was approved by the participating sites' ethical committees and all patients provided written informed consent.

Follow-up was performed 3 months and 1-year post index procedure. The patient was contacted by telephone or by a visit to the outpatient clinic. Relevant information on adverse events, i.e., death, MI, re-PCI, coronary artery bypass grafting (CABG), bleeding, vascular complication, stent thrombosis or other were collected.

2.1. Statistical analysis

NSTEMI patients with CR were compared to patients with ICR at index hospitalization discharge. Continuous variables are presented as the mean ± standard deviation (SD) and compared using the Student's *t*-test. Categorial variables are presented as frequencies (percentages) and compared using the chi-square test or Fischer's exact test, as appropriate. One-year event rates were calculated based on the number of patients with available follow-up data, i.e., either a cardiac event up to 1 year or a performed follow-up visit at 1 year. Time to event graphs were constructed by the Kaplan-Meir method. Hazard ratios (HR) and 95 % confidence intervals (CI) were calculated with Cox hazards regression analysis. An inverse propensity score weighted (IPSW) analysis was performed to address differences in baseline patient and lesion characteristics, including the following 23 variables listed in increasing order of standardized difference before IPSW matching: left main index target vessel, balloon post-dilatation at the index procedure, hypercholesterolemia, thrombus aspiration performed, ostial lesion index target vessel, in-stent restenotic lesion, bifurcation index target lesion, severe or moderate calcification index target lesion, intracoronary imaging at index procedure, current smoker, male gender, balloon pre-dilation at the index procedure, age, diabetes mellitus, family history of heart disease, previous PCI, CTO lesion at index procedure, previous CABG, renal impairment, radial access, hypertension, previous myocardial infarction and the number of identified lesions (Table S1 and Fig. S1). Analyses were performed with SAS software, version 9.4 (SAS Institute Inc., Cary, NC, USA.)

3. Results

3.1. Completeness of revascularization at discharge

There were 4353 patients presenting with an NSTEMI who had MVD. After excluding 209 patients with missing information on the completeness of the revascularization, the revascularization at the index procedure was considered complete in 1716 patients (41.4 %) and incomplete in 2428 patients (58.6 %). Of the 396 patients who underwent a staged procedure during the index hospitalization, a CR was achieved in 84 patients. In total CR was achieved in 1800 patients (47.0 %) and ICR in 2032 patients (53.0 %) during index hospitalization. See Fig. 1 for a detailed patient disposition.

The mean age in the CR group was lower compared to the NCR group, along with a lower prevalence of diabetes mellitus, hypertension, peripheral artery disease and renal impairment (see Table 1 for patient and procedural characteristics). They had less often a myocardial infarction, a PCI or a CABG in their medical history. More lesions were treated and on average more stents were implanted in the CR group.

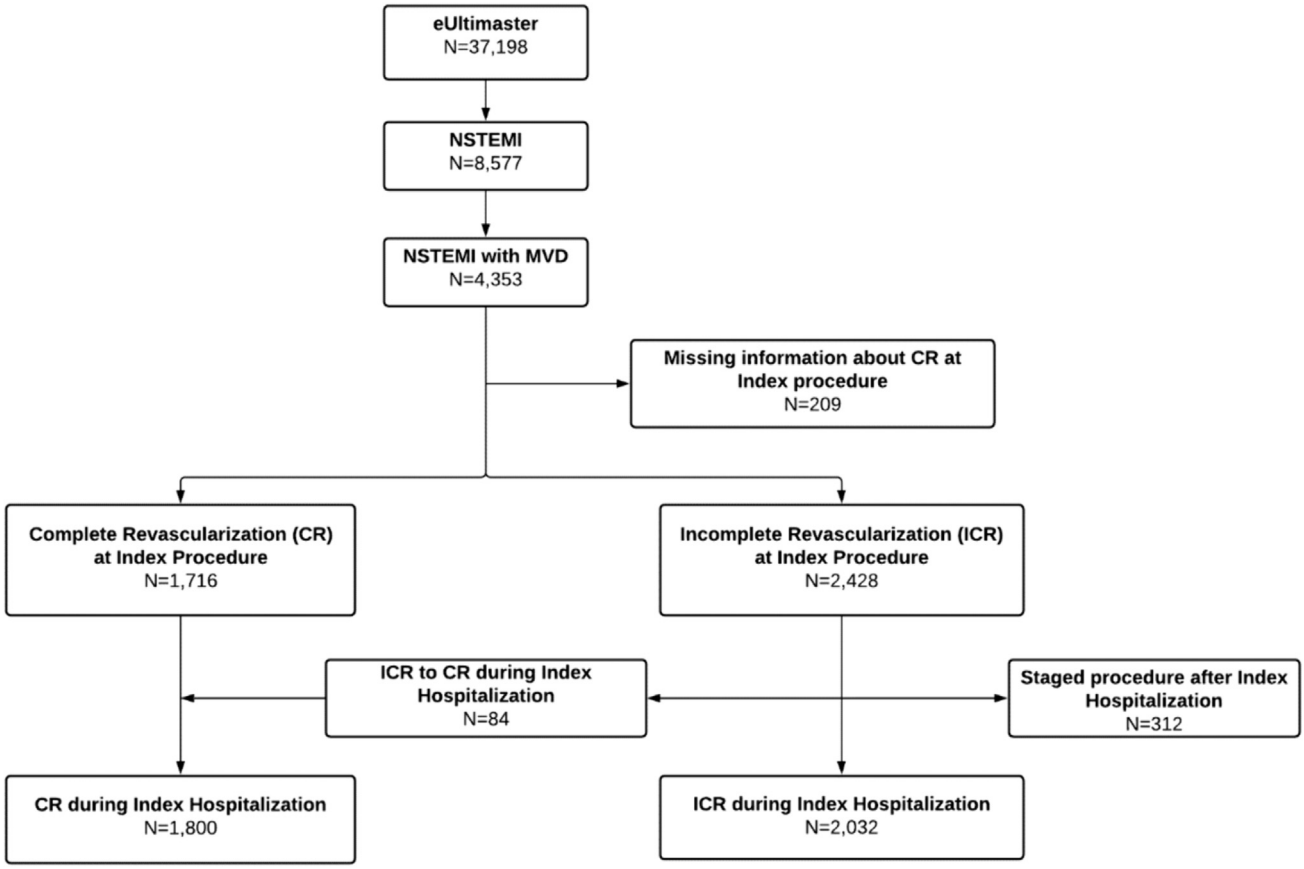

Fig. 1. Patient disposition.

Follow-up at 1 year was available for 1712 patients (95.1 %) and 1949 patients (95.9 %) for the CR and ICR groups, respectively. The incidence of POCE was lower in the CR group with 7.0 % vs. 12.9 % in the ICR group, $p < 0.0001$. For TLF and TVF, the rates were also lower after a CR: TLF 3.6 % vs. 5.5 %, $p < 0.01$ and TVF 4.3 % vs. 6.3 %, $p = 0.01$. Similar for the composite of cardiac death and MI, there were fewer events after CR (2.6 % vs. 4.8 %, $p < 0.001$). The number of any revascularizations was lower after CR (4.5 % vs. 8.3 %, $p < 0.0001$) because of due tofewer non-TVRs in the CR group compared to the IR group (2.5 % vs. 6.0 %, $p < 0.0001$). A small number of revascularizations were performed within 45 days (0.7 % vs. 1.3 %, $p = 0.04$). See Table 2 for other event rates.

After IPSW, the incidence of POCE at 1 year was 7.7 % for the CR group vs. 12.0 % for the ICR group, $p < 0.0001$. For TLF and TVF, the rates were no longer statistically significantly different with respectively 3.9 % vs. 5.0 %, $p = 0.10$ and 4.8 % vs. 5.5 %, $p = 0.30$. The incidence of the composite of death and myocardial infarction was lower for patients with a CR: 2.9 % vs. 4.2 %, $p = 0.03$. There were also fewer non-TVRs if CR was achieved at discharge: 2.7 % vs. 5.7 %, $p < 0.0001$. See Fig. 2.

The 1-year hazards for POCE (HR 0.67; 95 % CI 0.55 to 0.81; $p < 0.0001$) and any revascularization (HR 0.68; 95 % CI 0.53 to 0.87; $p < 0.01$) were lower after CR. There was a trend for a lower HR for the composite of cardiac death and myocardial infarction with a HR of 0.72, 95 % CI 0.51 to 1.01, $p = 0.05$. TLF were similar for both groups: hazard ratio (HR) 0.82; 95 % confidence interval (CI) 0.61 to 1.10, $p = 0.18$) (Fig. 3).

4. Discussion

This study aimed to investigate the effect of completeness of revascularization on 1 year outcomes in patients presenting with an NSTEMI with MVD. Completeness of revascularization was physician's assessed at index hospitalization discharge. After adjustment for differences in baseline characteristics, there were lower rates for POCE, all cause death, non-TVR and the composite endpoint cardiac death/myocardial infarction after a CR. Hence, our study results reinforce the importance of CR in NSTEMI patients with MVD.

The better clinical outcomes and lower event rates at 1-year follow-up in those patients who achieved CR on index admission in the context of NSTEMI and MVD are consistent with previously published observational studies. In the SCAAR registry [12], which included 11,150 NSTE-ACS patients, the HR for the composite of death, MI or repeat revascularization at 1 year was two times higher in patients with ICR than CR in the adjusted analysis (HR 2.02–95 % CI: 1.83 to 2.23; $p < 0.0001$).

Nevertheless, the impact of CR on long-term mortality has yet to be definitively established in NSTEMI patients. A previous registry conducted by Iqbal et al. [13], showed no benefit of CR at 3-year follow-up of NSTE-ACS patients with MVD after an adjusted analysis (HR 0.63, 95 % CI: 0.30–1.34, $p = 0.233$).

This study distinguishes itself from some recent studies in which both STEMI as NSTEMI patients were included. The FIRE trial investigators found that physiology-guided complete revascularization resulted in a lower clinical event rate at 1 year than patients who received culprit-lesion only PCI in patients ≥75 years of age [14]. In the FRAME-AMI study, a strategy of selective PCI using FFR-guided decision-making was superior to a strategy of routine PCI based on angiographic diameter stenosis for the treatment of non-infarct-related artery lesions regarding the risk of a clinical event over a median follow-up of 3.5 years [15]. Both studies showed no interaction between the initial clinical presentation and the primary endpoint. Pending confirmatory study conducted solely in NSTEMI patients, the results should be considered for all AMI patients.

In the current study, the cohort of patients undergoing CR exhibited a greater proportion of chronic total occlusions, indicating a higher degree of complexity associated with the revascularization procedure. Interestingly, these findings contrast to the observations made by Waldo SW et al. [16] from a retrospective registry, revealing that chronic total occlusions were a significant anatomical obstacle impeding CR. This was

Table 1
Baseline patient and procedural characteristics for NSTEMI patients with multi-vessel disease patients with a complete and incomplete hospitalization at index hospitalization discharge.

Variable	Complete Revascularization	No Complete Revascularization	*P*-value
	N = 1800	*N* = 2032	
Age (mean ± SD)	65.1 ± 12.0 (1800)	66.4 ± 11.2 (2032)	<0.01
Male gender	77.3 (1392/1800)	74.4 (1511/2032)	0.03
Diabetes mellitus	29.5 (528/1791)	33.1 (666/2013)	0.02
IDDM	6.5 (117/1791)	8.1 (165/2032)	0.06
NIDDM	22.9 (411/1791)	24.6 (500/2032)	0.23
Current smoker	27.1 (452/1669)	23.8 (458/1926)	0.02
Hypercholesterolemia	61.1 (981/1606)	62.6 (1173/1875)	0.37
Hypertension	65.7 (1112/1693)	74.4 (1425/1916)	<0.0001
Previous myocardial infarction	19.3 (330/1711)	30.2 (588/1945)	<0.0001
Previous PCI	19.8 (342/1732)	24.3 (478/1970)	<0.001
Previous CABG	6.5 (113/1737)	9.5 (185/1958)	<0.001
Peripheral artery disease	6.5 (111/1697)	10.1 (195/1928)	<0.001
Renal impairment	8.9 (159/1784)	13.3 (267/2003)	<0.0001
Index procedure			
Femoral access	18.5 (333/1800)	13.3 (271/2032)	<0.0001
Radial access	79.9 (1439/1800)	85.0 (1727/2032)	<0.0001
Femoral and radial access	1.4 (25/1800)	1.2 (25/2032)	0.67
Intra-coronary imaging (IVUS/OCT)	3.0 (54/1800)	2.1 (42/2032)	0.07
Target vessel			
Left main	5.1 (91/1800)	5.0 (101/2032)	0.90
Right coronary artery	45.3 (815/1800)	31.7 (645/2032)	<0.0001
Left anterior descendant	58.6 (1054/1800)	45.8 (931/2032)	<0.0001
Left circumflex	53.1 (956/1800)	36.4 (740/2032)	<0.0001
Arterial or venous bypass graft	2.1 (37/1800)	2.6 (53/2032)	0.26
Chronic total occlusion	4.3 (77/1800)	2.5 (50/2032)	<0.01
Bifurcation	15.1 (271/1800)	12.8 (260/2032)	0.04
Calcification (severe/moderate)	24.2 (435/1800)	22.2 (452/2032)	0.16
Number of lesions identified (mean ± SD)	2.5 ± 1.0 (1800)	3.0 ± 1.2 (2032)	<0.0001
Number of lesions treated (mean ± SD)	1.9 ± 0.8 (1799)	1.4 ± 0.6 (2032)	<0.0001
Number of successfully implanted stent (mean ± SD)	2.2 ± 1.1 (1799)	1.6 ± 0.9 (2032)	<0.0001
Total length successfully implanted stent (mean ± SD)	38.7 ± 24.0 (1793)	31.7 ± 19.6 (2027)	<0.0001

compounded by challenging culprit lesions and the persistence of non-dominant small vessel disease. The improved CR rate in our registry underscores the current advocacy for a more proactive approach to achieve CR by percutaneous treatment [5,17], driven mainly by the rapid progress in intracoronary diagnostic imaging [18–20], advancements in devices designed for plaque modification and management of complex coronary lesions [21–23], and optimized drug therapy.

Prior conveyed data suggests that in NSTEMI, the interrelation between CR and the decrease in mortality differs from the patterns observed in the context of STEMI and even in stable CAD [24,25]. Contemporary research has underscored that the nature of ischemia in CAD does not necessarily equate to the acute physiological instability inherent to NSTEMI. Therefore, from a pathophysiological perspective, myocardial infarction, defined as an acute coronary syndrome that implies a greater or lesser degree of instability in terms of the underlying CAD, causes myocardial damage with a generalized inflammatory response and subsequent ischemia-reperfusion damage. However, as a result of the ISCHEMIA study [26], the term "ischemia" is not always linked with physiological instability. The ISCHEMIA trial demonstrated that patients with stable CAD and moderate or severe ischemia did not show a prognostic benefit when reperfusion therapy (percutaneous or surgical) was performed instead of initiating and maintaining optimal medical treatment. Hence, these results cannot be extended to situations of pathophysiological instability, such as acute coronary syndromes, or to the type of revascularization performed (complete vs incomplete, or surgical vs percutaneous).

Table 2
Cardiac event rates at 1 year for the crude and the adjusted analysis NSTEMI patients with multi-vessel disease with a complete and incomplete revascularization at index hospitalization discharge.

Cardiac event rate at 1 year	Crude analysis			Adjusted analysis		
	Complete Revascularization	No Complete Revasc.	*P*-values	Complete Revascularization	No Complete Revasc.	*P*-values
	N = 1712	*N* = 1949		N = 1712	N = 1949	
POCE	7.0 (120)	12.9 (252)	<0.0001	7.7 (131)	12.0 (234)	<0.0001
Target lesion failure	3.6 (61)	5.5 (108)	<0.01	3.9 (67)	5.0 (98)	0.10
Target vessel failure	4.3 (74)	6.3 (122)	0.01	4.8 (82)	5.5 (108)	0.30
Cardiac death or MI	2.6 (45)	4.8 (94)	<0.001	2.9 (49)	4.2 (82)	0.03
All cause death	2.5 (43)	4.7 (91)	<0.001	2.7 (47)	4.2 (82)	0.02
Cardiac death	1.5 (25)	2.9 (57)	<0.01	1.6 (28)	2.4 (47)	0.09
Any MI	1.4 (24)	2.3 (45)	0.04	1.6 (27)	2.1 (42)	0.19
Target vessel MI	1.00 (17)	1.5 (29)	0.18	1.1 (19)	1.5 (29)	0.33
Any revascularization	4.5 (77)	8.3 (162)	<0.0001	4.9 (84)	7.9 (153)	<0.001
Non-TVR	2.5 (43)	6.0 (117)	<0.0001	2.7 (47)	5.7 (110)	<0.0001
CD-TVR	2.8 (48)	3.2 (63)	0.45	3.1 (53)	3.0 (59)	0.87
CD-TLR	2.0 (35)	2.4 (46)	0.52	2.2 (38)	2.3 (46)	0.81
Stent thrombosis (definite/probable)	0.9 (15)	0.9 (17)	0.99	0.9 (16)	0.8 (16)	0.81

POCE: patient oriented composite endpoint (all death, any myocardial infarction, and any revascularization); Target lesion failure: cardiac death, target vessel myocardial infarction and clinically driven target lesion revascularization; MI: myocardial infarction; TVR: target vessel revascularization; TLR: target lesion revascularization.

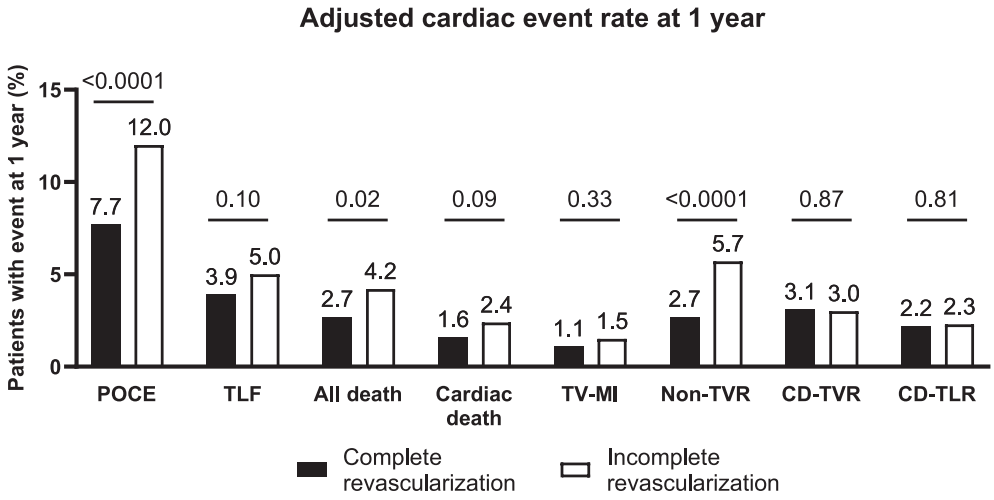

Fig. 2. Cardiac event rate at 1 year after inverse-weighted propensity score adjustment. POCE: patient oriented composite endpoint; TLF: target lesion failure; TV-MI: target vessel myocardial infarction; non-TVR: non target vessel revascularization; CD-TVR: clinically driven target vessel revascularization; CD-TLR: clinically driven target lesion revascularization.

The present study is a subgroup analysis of the observational e-ULTIMASTER study with its inherent limitations, and the results should be interpreted in the context of several limitations. Firstly, the protocol lacked anatomical and/or functional definitions of what constitutes a significant lesion and when a revascularization can be considered complete. Secondly, revascularization completeness was operator assessed and not further validated by an independent core laboratory. Thirdly, completeness of revascularization was assessed at index hospital discharge. Planned staged revascularizations performed thereafter were not considered. Fourthly, the propensity score-adjusted analysis included a selection of the measured baseline patient- and lesion characteristics. However, by design, undocumented variables that could potentially affect patient outcomes were not incorporated into the model. Finally, the follow-up of 1-year is relatively short considering the favorable life expectancy after an NSTEMI. The lack of consistency and

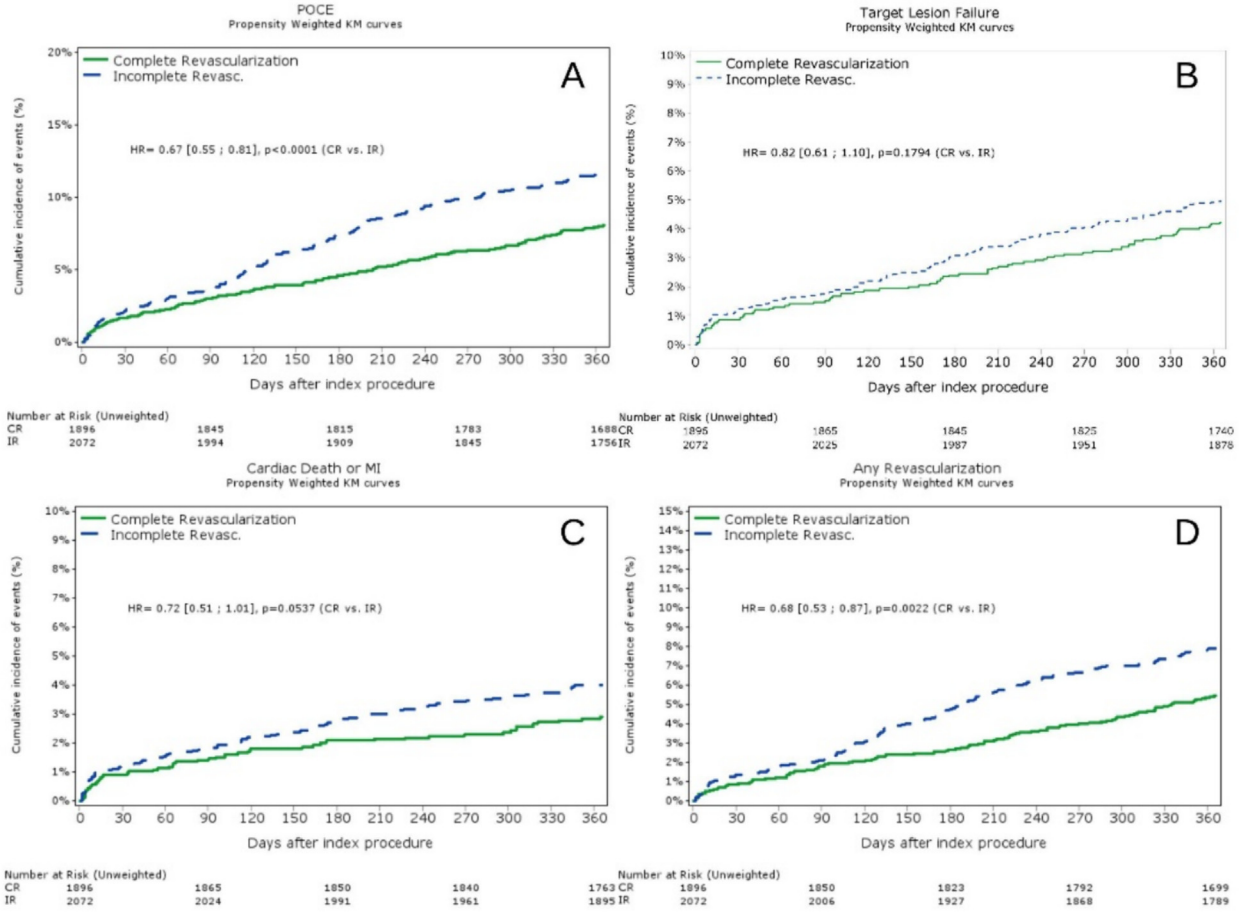

Fig. 3. Kaplan-Meir cumulative incidence of events curves after inverse-weighted propensity score adjustment. A: patient oriented composite outcome (POCE); B: target lesion failure; C: composite of cardiac death and myocardial infarction; D: any revascularization.

independent validation of the accuracy by which patients were stratified among the two study groups and the potential investigator's bias to assess the revascularization completeness, introduces potential random and non-random errors that could not be accounted for in the analysis. However, the large number of patients enrolled in the e-ULTIMASTER study allowed this subgroup analysis to be performed and reflects real-world practice.

In conclusion, the outcomes from this subgroup analysis indicate that patients with a NSTEMI and MVD who undergo CR experience improved clinical outcomes at the one-year follow-up in contrast to those who received ICR. Further evaluations through randomized clinical trials are required to confirm these results and to evaluate its long-term benefits.

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Credit authorship contribution statement

Victor A. Jiménez Díaz: Writing – original draft, Data curation. **Helen Routledge:** Writing – review & editing, Data curation. **Fazila-Tun-Nesa Malik:** Writing – review & editing, Data curation. **David Hildick-Smith:** Writing – review & editing, Data curation. **Antoine Guédès:** Writing – review & editing, Data curation. **Pascual Baello:** Writing – review & editing, Data curation. **Shoichi Kuramitsu:** Writing – review & editing, Data curation. **Rajiv Das:** Writing – review & editing. **Willem Dewilde:** Writing – review & editing, Data curation. **Javier Fernandez Portales:** Writing – review & editing, Conceptualization. **Michael Angioi:** Writing – review & editing, Conceptualization. **Pieter C. Smits:** Writing – review & editing, Data curation. **Andrés Iñiguez Romo:** Writing – review & editing, Conceptualization.

Data availability

The data underlying this article are available in the article.

Declaration of competing interest

None of the authors reported a conflict of interest related to this manuscript.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.carrev.2024.07.011.

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