

PCI Strategy in AMI with MVD

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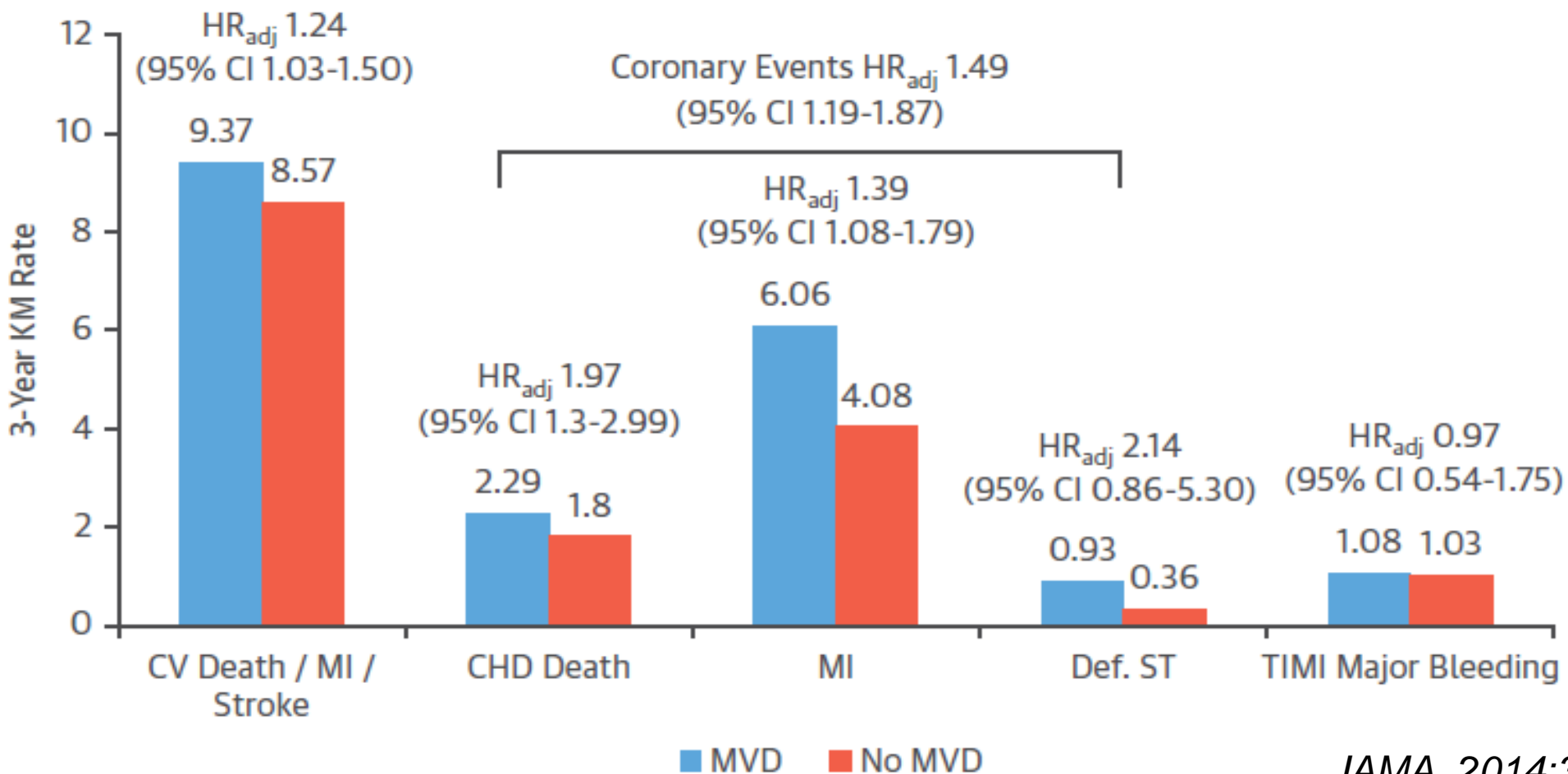
Boston Scientific

Medtronic

Abbott

Prognosis of AMI Patients with MVD

Approximately 50% of AMI patients, Poor Clinical Outcomes



STEMI with MVD: Major RCTS

Culprit Only vs. Complete Revascularization Trials in STEMI

TABLE 1 Is Complete/NCL Revascularization Beneficial?

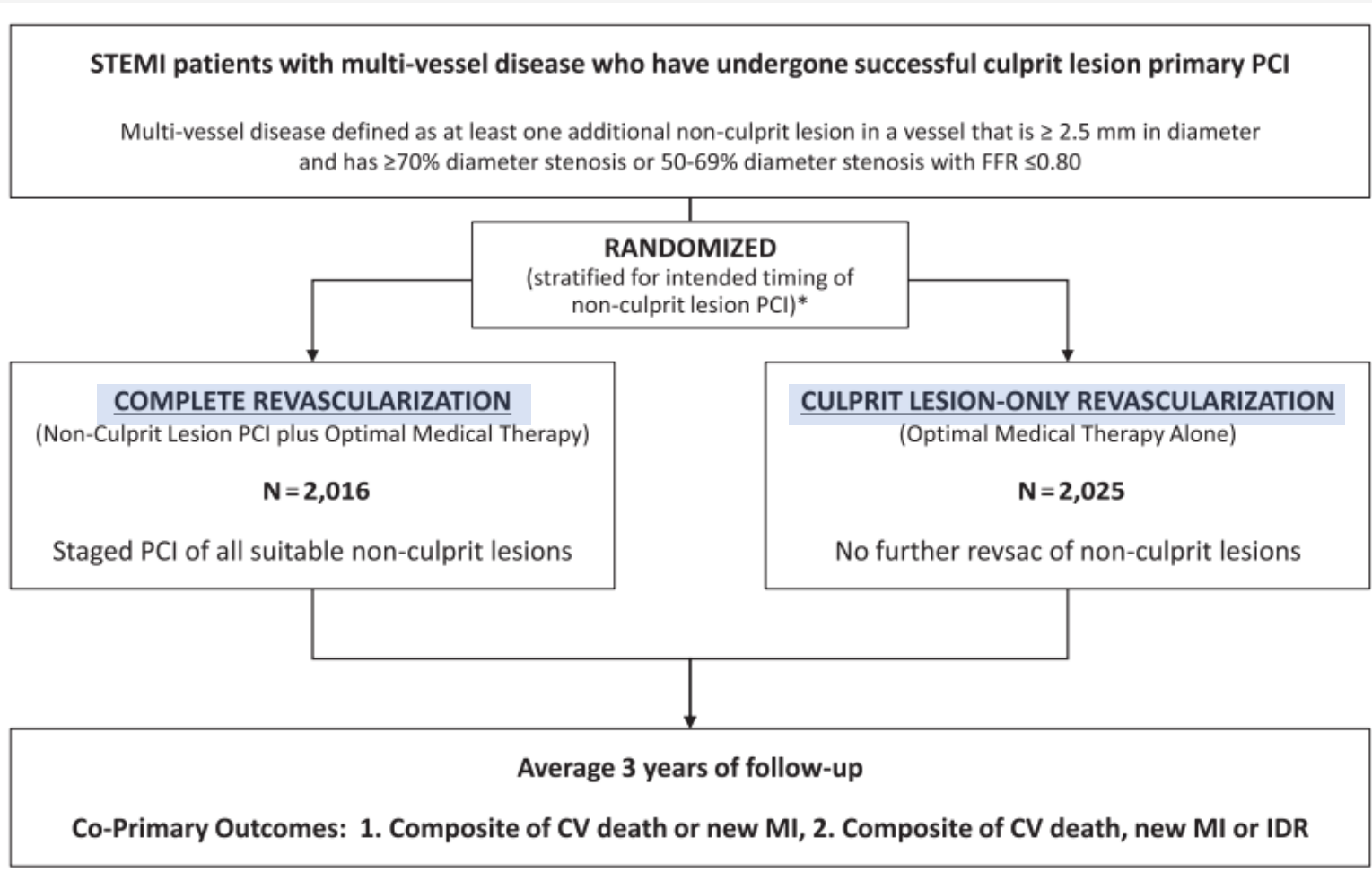
Study (Ref. #)	Inclusion Period	Intervention	Control	Primary Outcome	Results
PRAMI (3)	2008–2013	Index procedure PCI of NCLs with angiographic diameter stenosis >50% (n = 234)	No further PCI (n = 231)	Composite of death from cardiac causes, nonfatal MI, or refractory angina	Mean follow-up 23 months. Outcome 9% with complete revascularization and 23% without NCL revascularization (HR: 0.35; 95% CI: 0.21–0.58).
CvLPRIT (4)	2011–2013	Index procedure or index admission PCI of NCLs with angiographic diameter stenosis >70% in one view or >50% in 2 views (n = 138)	No further PCI (n = 139)	Composite of all-cause mortality, recurrent MI, heart failure, and ischemia-driven revascularization by PCI or CABG	Median follow-up 364 days. Outcome 10.0% with complete revascularization and 21.2% without NCL revascularization (HR: 0.45; 95% CI: 0.24–0.84).
DANAMI-3-PRIMULTI (5)	2011–2014	Index admission (not index procedure) PCI of NCLs with angiographic diameter stenosis >50% (n = 314)	No further PCI (n = 313)	Composite of all-cause mortality, reinfarction, or ischemia-driven revascularization	Median follow-up 27 months. Outcome 13% with complete revascularization and 22% without NCL revascularization (HR: 0.56; 95% CI: 0.38–0.83).
COMPARE-ACUTE (6)	2011–2015	Index admission (not index procedure) PCI of NCLs with angiographic diameter stenosis >50% and FFR ≤ 0.80 (n = 295)	No further PCI (n = 294)	Composite of all-cause mortality, reinfarction, or ischemia-driven revascularization, and cerebrovascular events	1-year follow-up. Outcome 7.8% with complete revascularization and 20.5% without NCL revascularization (HR: 0.35; 95% CI: 0.22–0.55).
COMPLETE (7)	2013–2017	Index admission (not index procedure) or staged PCI of NCLs with angiographic diameter stenosis >70% or angiographic diameter stenosis >50% and FFR ≤ 0.80 (n = 2,025)	No further PCI (n = 2,025)	1. Composite of cardiovascular death and myocardial infarction 2. Composite of cardiovascular death, myocardial infarction, ischemia-driven revascularization	Median follow-up 3 yrs. Outcome 1: 7.8% with complete revascularization and 10.5% without NCL revascularization (HR: 0.51; 95% CI: 0.43–0.61). Outcome 2: 9.9% with complete revascularization and 16.7% without NCL revascularization (HR: 0.51; 95% CI: 0.43–0.61).

Reduced Repeated Revascularization

Reduced Cardiac Death/MI



COMPLETE Trial



COMPLETE TRIAL

**Angiography Guided
(DS $\geq 70\%$)**

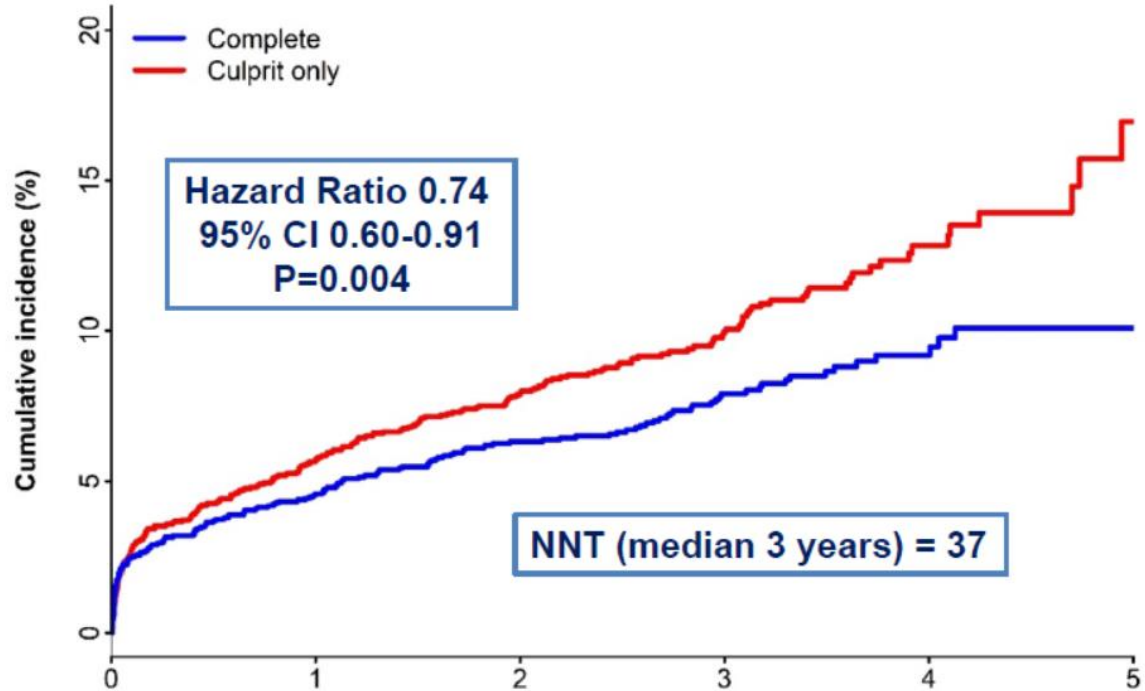
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**Physiology Guided
(DS 50-69%)**

Complete Revasc

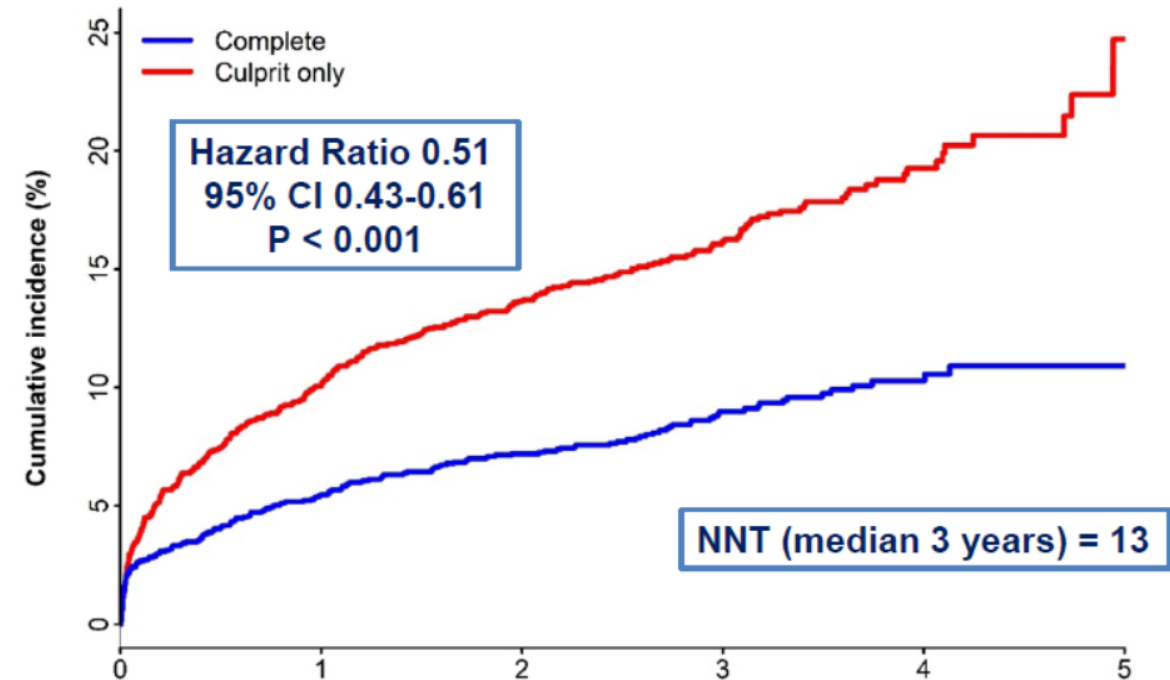
COMPLETE Trial: Main Result

First Co-Primary Outcome: CV Death or New MI



No. at Risk		Years of Follow-up					
	0	1	2	3	4	5	
Complete	2016	1904	1677	938	337	70	
Culprit only	2025	1897	1666	933	310	59	

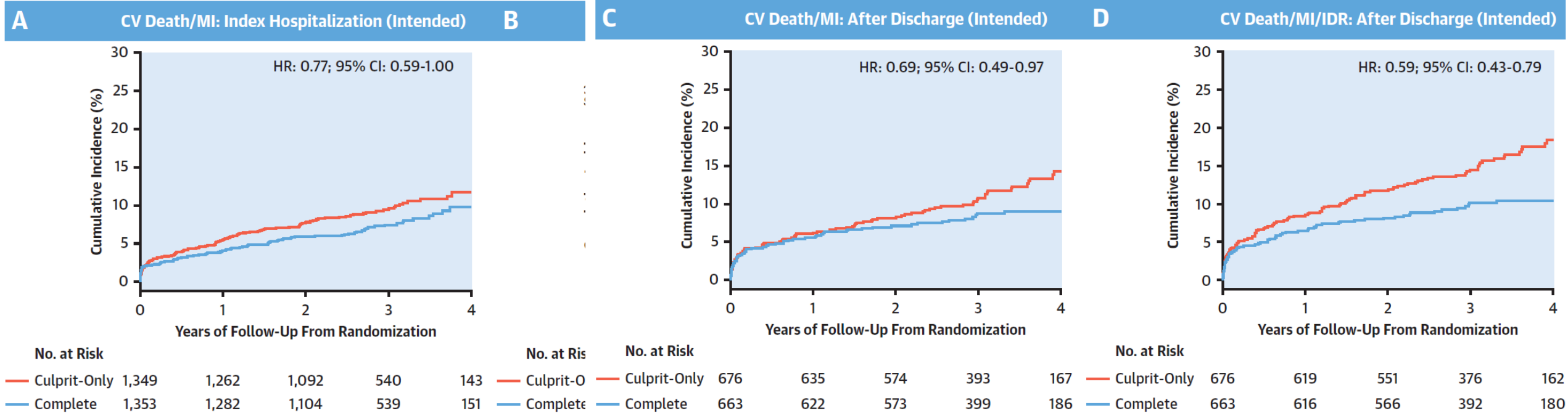
2nd Co-Primary Outcome: CV Death, New MI, or IDR



No. at Risk		Years of Follow-up					
	0	1	2	3	4	5	
Complete	2016	1886	1659	925	329	66	
Culprit only	2025	1808	1559	865	294	57	

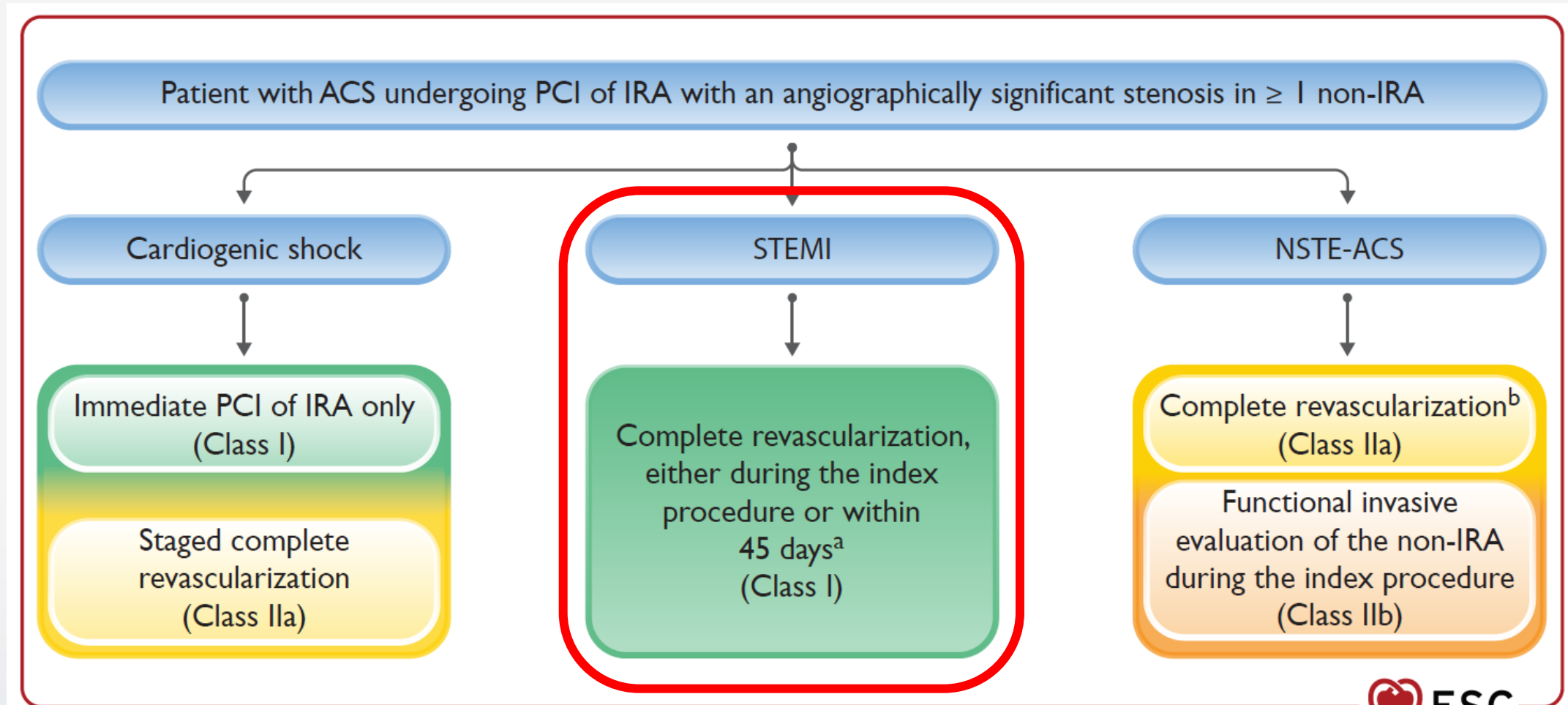
COMPLETE Trial: Time to Treat NCL

Benefit of Complete Revascularization over Culprit-Lesion only PCI was Consistent among Timing of Nonculprit-Lesion Intervention.



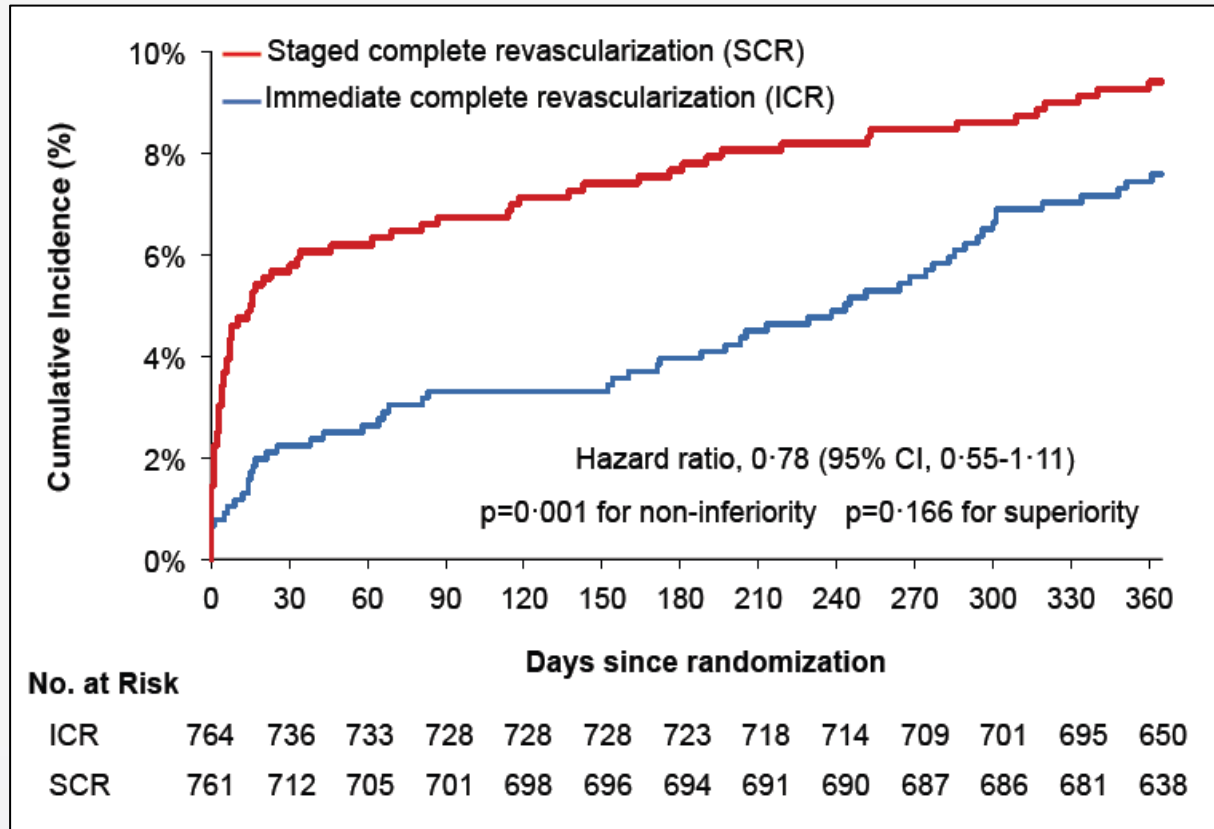
STEMI with MVD: Current Guidelines

Recent Revascularization Guideline

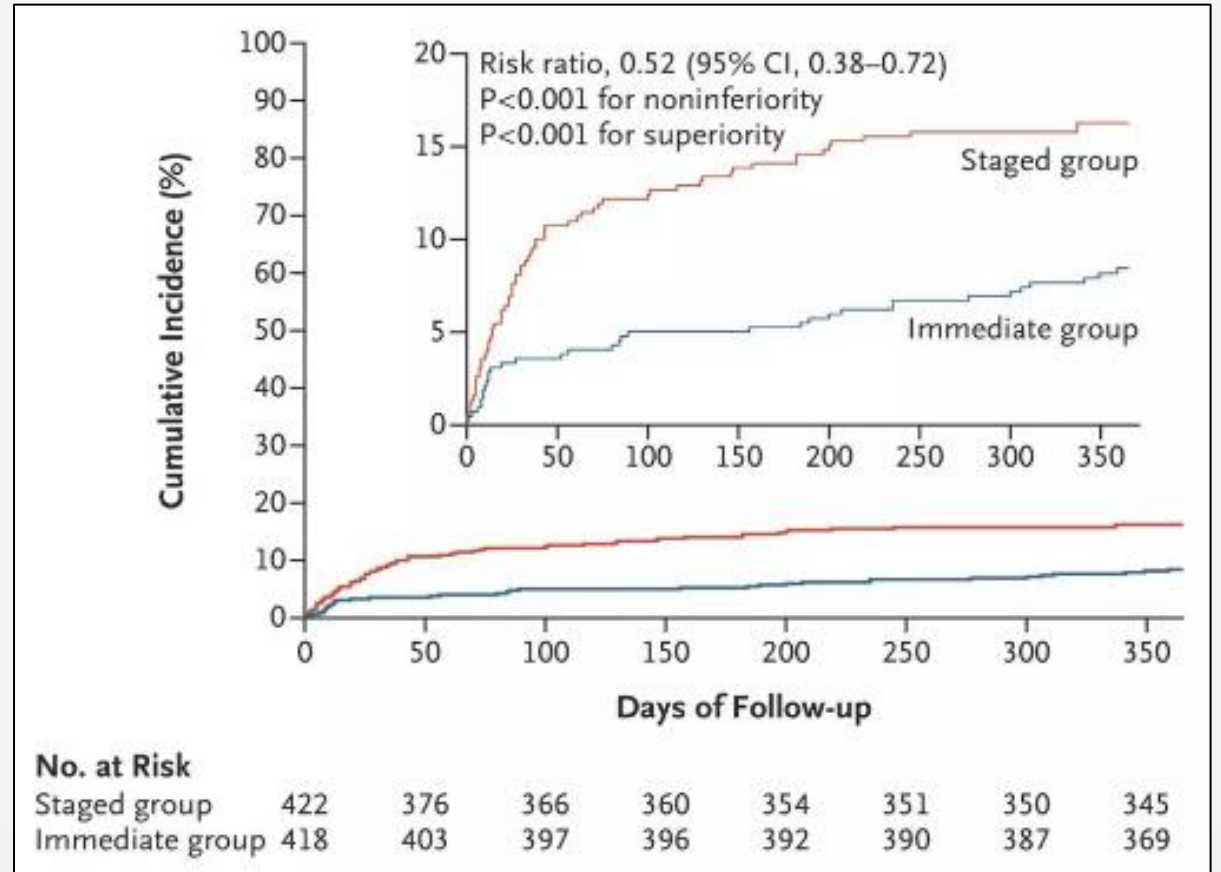


Recent Major RCTs

Non-inferior results with Immediate CR compared with Staged CR



All-cause mortality, MI, any unplanned IDR, or CVEs

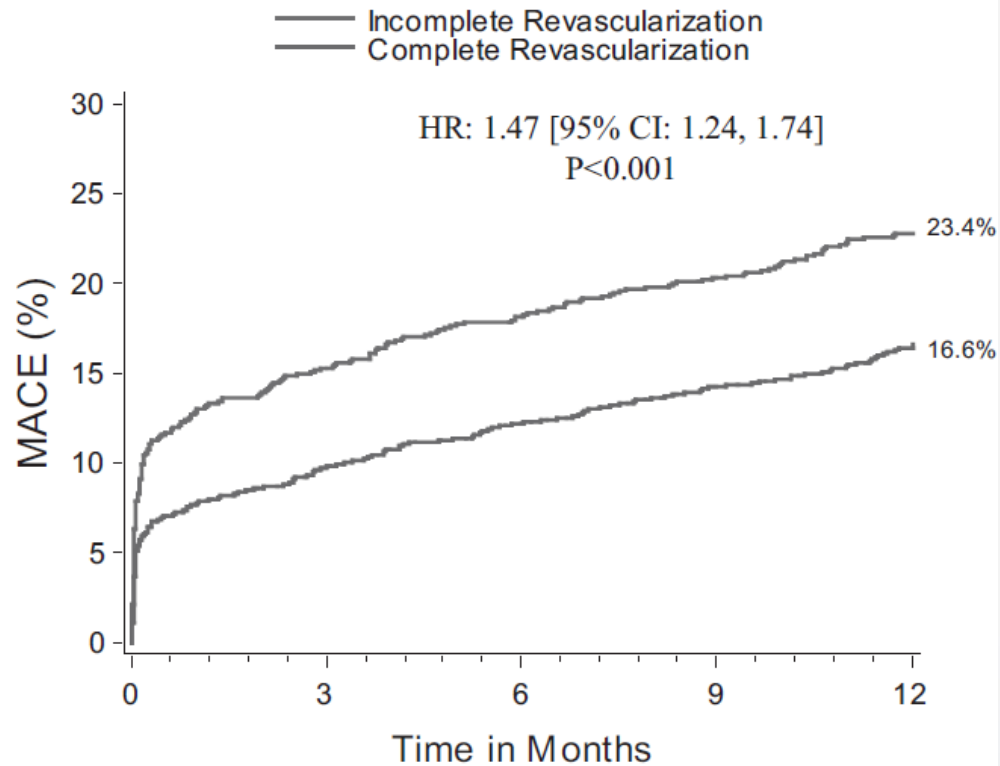


Death from any cause, nonfatal MI, stroke, unplanned IDR, or hospitalization for HF

Impact of Incomplete Revascularization

ICR was strongly associated with Poor Clinical Outcomes

A



Number at risk:

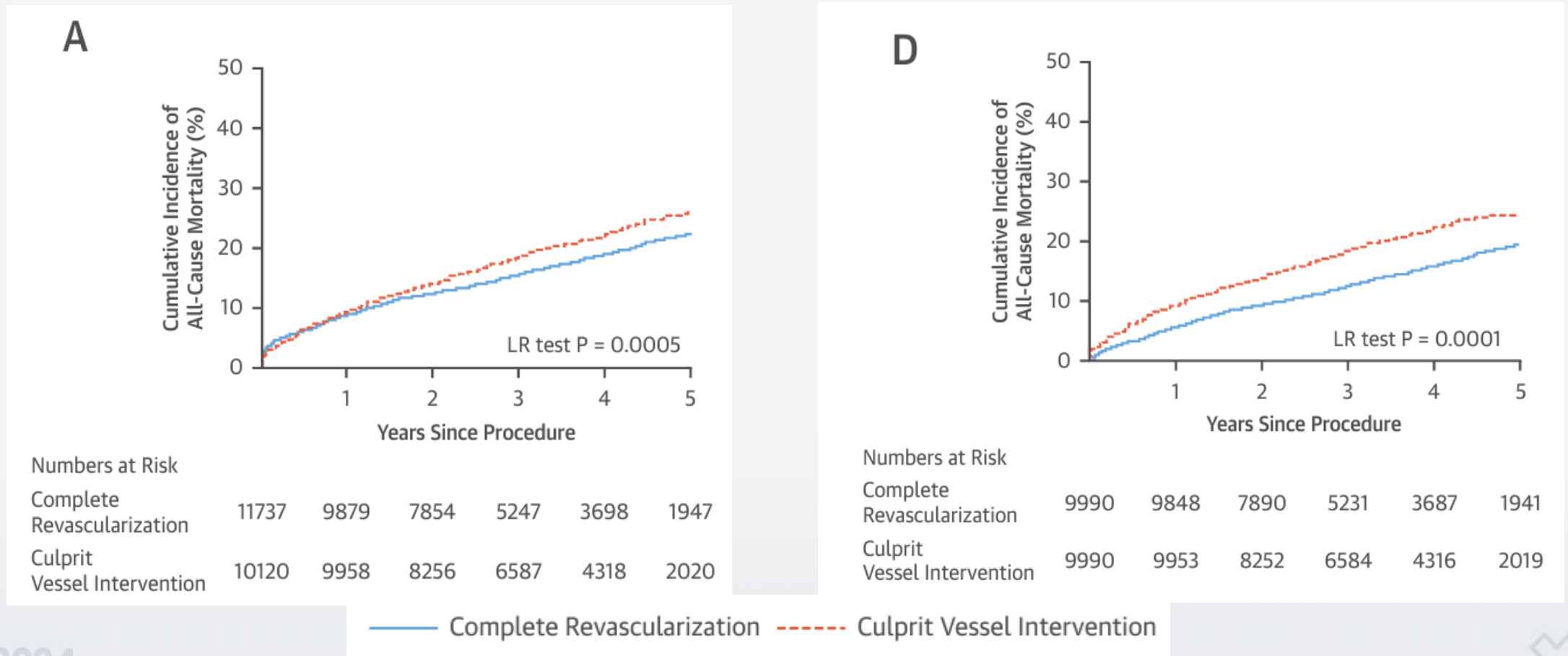
ICR	1103	901	870	844	521
CR	1851	1622	1574	1530	893

Table 4. Independent Predictors of 1-Year Major Adverse Cardiovascular Events

Variable	HR (95% CI)	P
ICR (DS \geq 50%)	1.36 (1.12–1.64)	0.002
Insulin-treated diabetes mellitus	1.34 (1.01–1.79)	0.046
Hyperlipidemia	1.23 (1.00–1.51)	0.049
Previous PCI	1.31 (1.08–1.60)	0.007
Renal insufficiency	1.61 (1.29–2.01)	<0.0001
No. of lesions treated by PCI	1.21 (1.11–1.32)	<0.0001
Triple-vessel CAD	1.21 (1.00–1.46)	0.053
Baseline WBC count	1.03 (1.00–1.06)	0.04

NSTEMI with MVD: Observational Study

Complete Revascularization showed better Long Term Clinical Outcomes compared with Culprit-Lesion only PCI



NSTEMI with MVD: Meta-Analysis

Complete Revascularization showed better Long Term Clinical Outcomes compared with Culprit-Lesion only PCI

MACE

2.1.2 >2 years

Correia 2018	28	71	70	131	7.3%	0.57 [0.32, 1.02]
Lee 2011	35	179	61	187	9.0%	0.50 [0.31, 0.81]
Onuma 2013	159	611	106	379	12.9%	0.91 [0.68, 1.21]
Shishehbor 2007	168	479	274	761	14.0%	0.96 [0.76, 1.22]
Subtotal (95% CI)		1340		1458	43.2%	0.76 [0.57, 1.02]

Total events

390

511

Heterogeneity: $\text{Tau}^2 = 0.05$; $\text{Chi}^2 = 7.61$, $\text{df} = 3$ ($P = 0.05$); $I^2 = 61\%$

Test for overall effect: $Z = 1.82$ ($P = 0.07$)

Total (95% CI)	3890	6236	100.0%	0.76 [0.61, 0.93]
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Total events

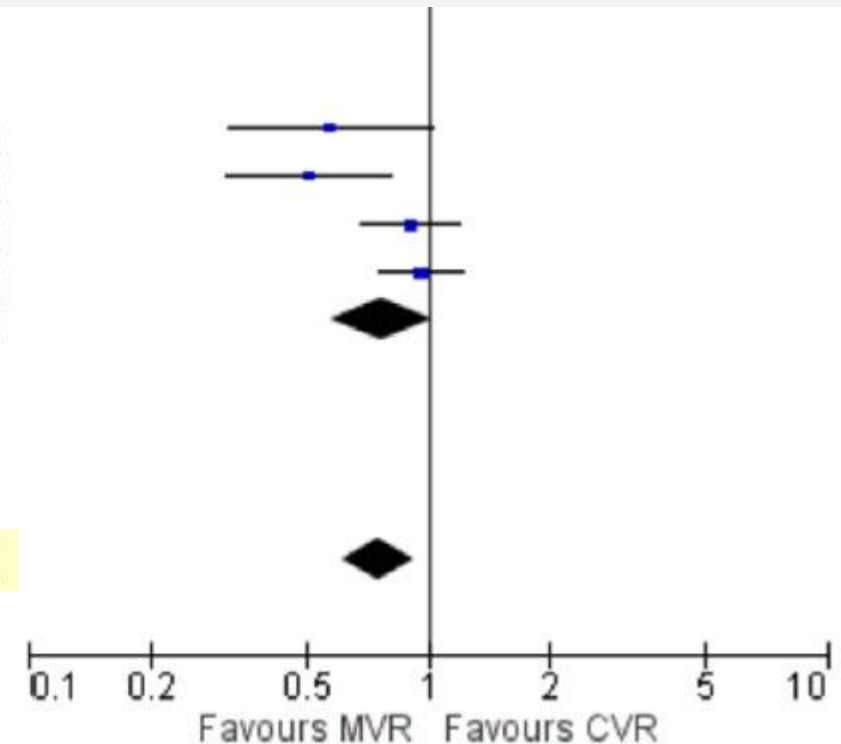
728

1367

Heterogeneity: $\text{Tau}^2 = 0.07$; $\text{Chi}^2 = 27.68$, $\text{df} = 9$ ($P = 0.001$); $I^2 = 67\%$

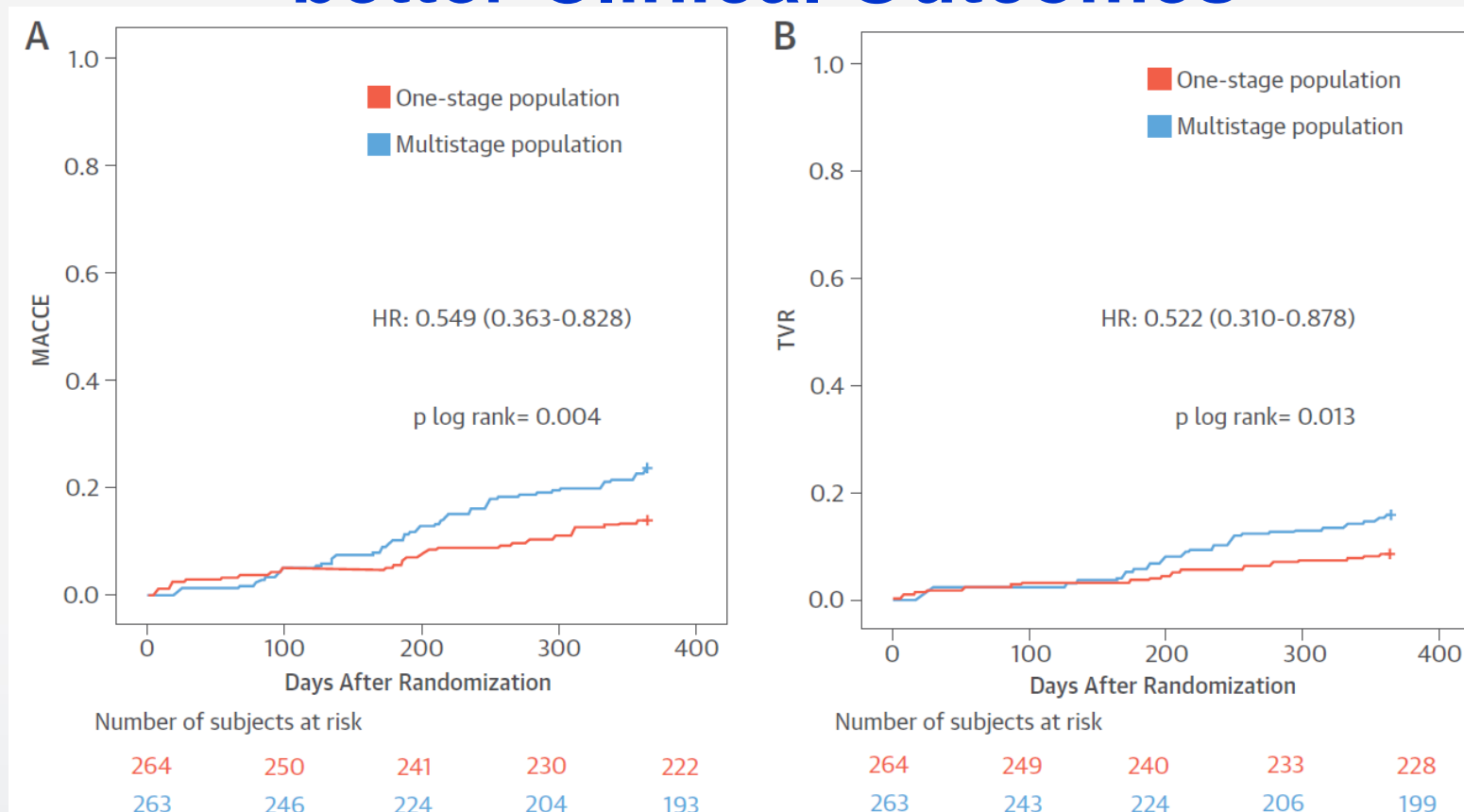
Test for overall effect: $Z = 2.61$ ($P = 0.009$)

Test for subgroup differences: $\text{Chi}^2 = 0.00$, $\text{df} = 1$ ($P = 0.96$), $I^2 = 0\%$



SMILE Trial (NSTEMI with MVD)

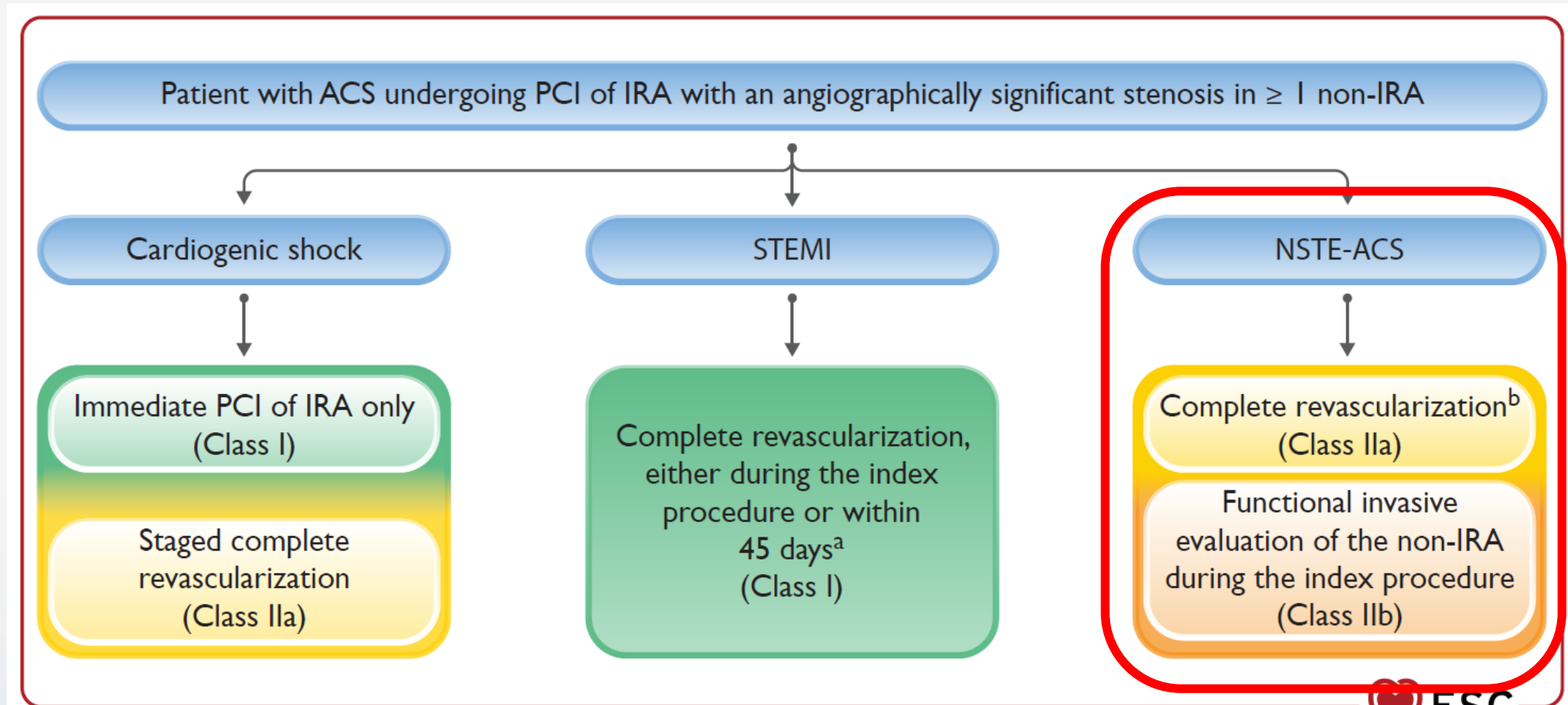
Complete One-stage Coronary Revascularization showed better Clinical Outcomes



MACCE: cardiac death, death, reinfarction, rehospitalization for UA, repeat coronary revascularization (target vessel revascularization), and stroke at 1 year

NSTEMI with MVD: Current Guidelines

Recent Revascularization Guideline



Treatment of MVD in AMI (STEMI)

How to Plan Revascularization Strategies

- **Timing: Immediate vs. Staged PCI for NIRA**
- **Evaluation of NIRA**

Treatment of MVD in STEMI

Evaluation of NIRA

- **Angiography Guided**
- **Physiology Guided**
- **Imaging Guided**
- **Patient Risk Guided**

OPTION-STEMI study

OPTimal **TI**ming of Fractional Flow Reserve-Guided Complete Revascularizati**ON** for Non-infarct Related Artery in **ST**-Segment **E**levation **M**ycocardial **I**nfarction with Multivessel Disease

Protocol Overview (NCT04626882)

994 Patients with STEMI and MVD
Non-IRA with at least 2.5 mm diameter and 50% diameter stenosis by visual estimation

Primary PCI for IRA

1:1 Randomization

Immediate Complete Revascularization

In-hospital Staged Complete Revascularization

For IRA lesions with stenosis $\geq 70\%$ by visual estimation without FFR. FFR evaluation with 50–69% stenosis

Primary endpoint at 12-month follow-up
Composite of all-cause death, non-fatal myocardial infarction, or all unplanned revascularization

Secondary Endpoint: all-cause death, cardiac death, non-cardiac death, non-fatal MI, hospitalization for UA, HF, major bleeding, stroke, CIN, ST during 1-year

- In hospital staged PCI
- FFR-guided NIRA (50-69% intermediate) PCI
- Periprocedural MI inclusion?

OPTION-NSTEMI (NCT04968808)

676 Patients with NSTEMI and MVD
Non-inferiority Trial

Successful PCI for IRA

Randomization

**Immediate Complete
Revascularization (n=338)**

**Staged in-hospital Complete
Revascularization (n=338)**

Cons of an immediate MV PCI in STEMI

Vasoconstriction in the acute phase



Unnecessary implantation of stents that are smaller than needed?

Significance of non-culprit lesions



No role for physiological indices (e.g., FFR) during the acute phase

Suboptimal antiplatelet inhibition



↑ risk of stent thrombosis, especially in high-risk lesions and multiple stents

Early revascularisation or early intensive care treatment?



Is delayed intensive care counterbalanced by the benefits of early complete revascularisation?

Conclusion

- **Complete revascularization (CR)** is recommended.
- **Timing:** Immediate CR is not inferior or comparable to staged CR.
- Evaluation of NIRA is to be determined.
- **OPTION-STEMI** will find the outcome of in-hospital staged PCI and FFR-guided NIRA PCI.
- Complex lesions in NIRA could be recanalized in the staged PCI.