МГМСУ им. А.И. Евдокимова

СНК кафедры кардиологии

Сравнение отдаленных результатов полной реваскуляризации и реваскуляризации только инфаркт-связанной артерии при ИМпST и многососудистом поражении

The CvLPRIT Trial Long-Term Follow-Up

Подготовил: студент 6 курса лечебного факультета
МГМСУ им. А.И. Евдокимова
Наливайко А.П.

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Long-Term Follow-Up of Complete Versus Lesion-Only Revascularization in STEMI and Multivessel Disease

The CvLPRIT Trial

Anthony H. Gershlick, MBBS,[a] Amerjeet S. Banning, BSc (Hons), MBBS,[a] Emma Parker, RCN,[a] Duolao Wang, PhD,[b] Charley A. Budgeon, PhD,[a] Damian J. Kelly, MB ChB, MD,[c] Peter O. Kane, MBBS, MD,[d] Miles Dalby, MBBS, MD,[e] Simon L. Hetherington, MB ChB, MD,[f] Gerry P. McCann, MB ChB, MD,[a] John P. Greenwood, MB ChB, PhD,[g] Nick Curzen, BM (Hons), PhD[h]

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ORIGINAL INVESTIGATIONS

Randomized Trial of Complete Versus Lesion-Only Revascularization in Patients Undergoing Primary Percutaneous Coronary Intervention for STEMI and Multivessel Disease

The CvLPRIT Trial

Anthony H. Gershlick, MBBS,* Jamal Nasir Khan, MB ChB,* Damian J. Kelly, MB ChB, MD,† John P. Greenwood, MB ChB, PhD,†§ Thiagarajah Sasikaran, BSc, PhD,‖ Nick Curzen, BM, PhD,¶ Daniel J. Blackman, MD,§ Miles Dalby, MBBS, MD,# Kathryn L. Fairbrother, BA,** Winston Banya, MSc,†† Duolao Wang, PhD,†† Marcus Flather, MB BS,§§ Simon L. Hetherington, MB ChB, MD,‖‖ Andrew D. Kelion, BM BCh, DM,¶¶ Suneel Talwar, MB BS, MD,## Mark Gunning, MD,*** Roger Hall, MD,§§ Howard Swanton, MB BChir, MD,††† Gerry P. McCann, MB ChB, MD*

ИМпST

+

Многососудистое поражение

Стентирование только инфаркт-связанной артерии

Стентирование инфаркт-связанной артерии и других значимых стенозов

ДИЗАЙН

- Открытое
- Проспективное
- Рандомизированное
- Мультицентровое (7 центров)

Длительность рандомизации пилотного исследования: май 2011 – май 2013, 12-месячное наблюдение завершилось в мае 2014.

Контроль отдаленных результатов: с 12 месяца наблюдений пилотного исследования (май 2012-май2014) до августа 2018

Медиана наблюдения = 5.6 лет

КОНЕЧНЫЕ ТОЧКИ

Первичные: комбинированные основные неблагоприятные сердечно-сосудистые события (MACE)

- Смерть от всех причин
- Повторный ИМ
- Сердечная недостаточность
- Повторная реваскуляризация

Вторичные конечные точки

- Смерть/ИМ
- Отдельные компоненты MACE

Критерии включения

- Предполагаемый или подтвержденный ИМ с подъемом сегмента ST или БЛНПГ на ЭКГ
- < 12 часов с начала появления симптомов
- Первичное ЧКВ по клиническим показаниям
- Письменное информированное согласие
- Многососудистое поражение коронарных артерий при выполнении ангиографии
- Диаметр не инфаркт-связанной артерии > 2 мм с возможностью постановки стента

Критерии исключения

- Противопоказание к первичному ЧКВ
- <18 лет
- Противопоказание для многососудистого ЧКВ согласно решению оперирующего хирурга
- Q-образующий ИМ в анамнезе
- Пациенты с АКШ в анамнезе

Продолжение

- Тромбоз стента в анамнезе
- Кардиогенный шок
- Дефект межжелудочковой перегородки или средняя/тяжелая митральная регургитация
- ХБП С4-С5
- Хроническая тотальная окклюзия не инфаркт-связанной артерии

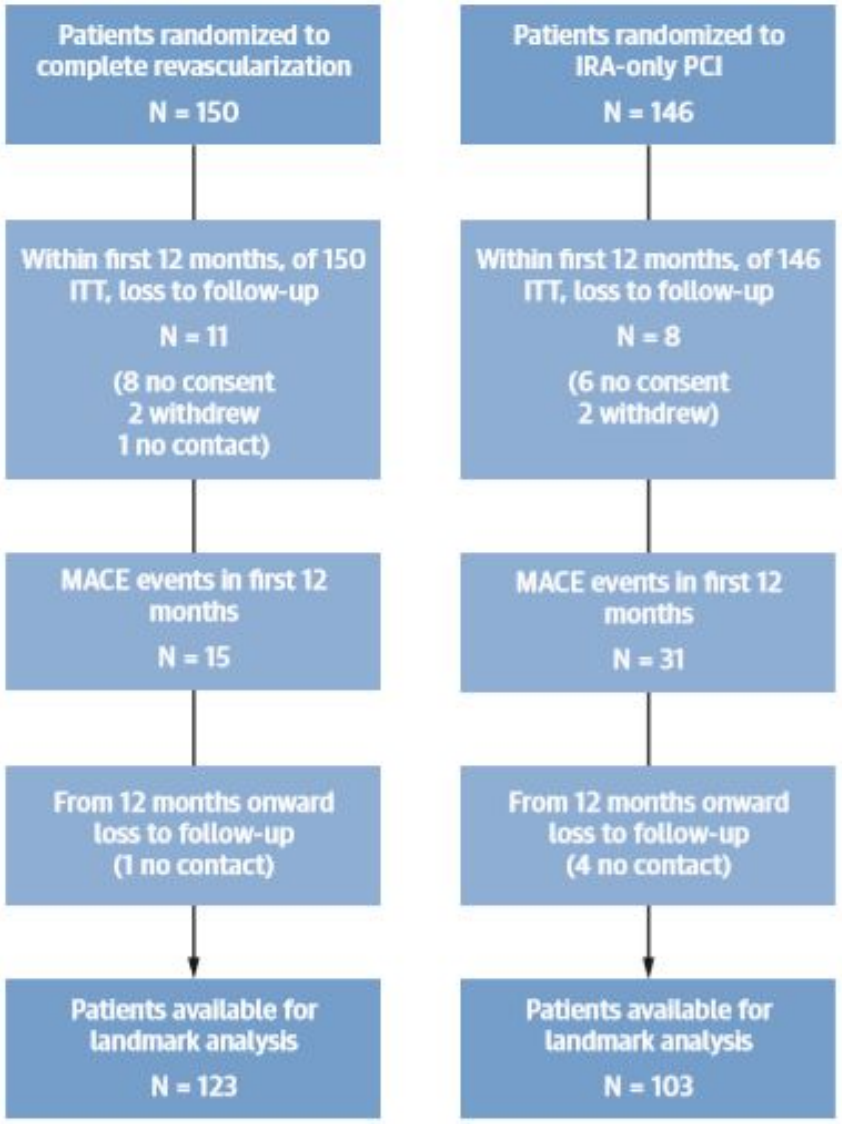
TABLE 1 Demographics and Baseline Clinical Characteristics

	Complete Revascularization (n = 150)	IRA-Only Revascularization (n = 146)	p Value
Age, yrs	64.6 ± 11.2	65.3 ± 11.9	0.57
Male	128 (85.3)	112 (76.7)	0.06
Treated diabetes	19/147 (12.9)	20/140 (14.3)	0.74
Treated hypertension	54/147 (36.6)	51/140 (36.4)	0.96
Treated hypercholesterolemia	41/147 (27.9)	34/140 (24.3)	0.49
Current smoker	50/146 (34.3)	37/138 (26.8)	0.17
Previous MI	7/147 (4.8)	5/140 (3.6)	0.62
Previous PCI	6/147 (4.1)	3/140 (2.1)	0.50
Killip class II/III on admission	10/147 (6.8)	13/139 (9.4)	0.43
GFR <30 ml/min	1/140 (0.7)	1/137 (0.7)	1.00
Anterior MI	54/150 (36.0)	52/146 (35.6)	0.94
IRA site (selected CASS)			
1 Proximal RCA	29 (19.3)	30 (20.5)	
2 Mid RCA	23 (15.3)	24 (16.4)	0.82
11 LMS	0	0	
12 Proximal LAD	29 (19.3)	31 (21.2)	
13 Mid LAD	22 (14.7)	16 (11.0)	
18 Proximal Cx	9 (6.0)	13 (8.9)	
Other	38 (25.3)	32 (21.9)	
N-IRA anatomic site (selected CASS)			
1 Proximal RCA	23 (15.3)	22 (15.1)	
2 Mid RCA	24 (16.0)	23 (15.8)	0.96
11 LMS	1 (0.7)	2 (1.4)	
12 Proximal LAD	27 (18.0)	21 (14.4)	
13 Mid LAD	44 (29.3)	49 (33.6)	
18 Proximal Cx	20 (13.3)	20 (13.7)	
Other	11 (7.3)	9 (6.2)	
N-IRA stenoses >70%	131 (87.3)	118 (80.8)	0.12
2-Vessel disease	119 (79.3)	110 (75.3)	0.41
3-Vessel disease	31 (20.7)	36 (24.7)	
Symptom to balloon time, min	182 (115-282)	159 (119-265)	0.41
Maximum HS-TnT elevation	985 (629-1,625)	1073 (509-1,824)	0.96
EF (by CMR), %	45.8 ± 9.8 (n = 100)	45.1 ± 9.5 (n = 103)	0.57
Balloon pump	2 (1)	1 (0.6)	1.00
Radial approach	112/146 (76.7)	102/140 (72.9)	0.45

Values are mean ± SD, n (%), n/N (%), or median (interquartile range).

CASS = Coronary Artery Scoring System; CMR = cardiac magnetic resonance; Cx = circumflex; EF = ejection fraction; GFR = glomerular filtration rate; HS-TnT = high-sensitivity troponin T; IQR = interquartile range; IRA = infarct-related artery; LAD = left anterior descending; LMS = left main stem; MI = myocardial infarction; N-IRA = noninfarct-related artery; PCI = percutaneous coronary intervention; RCA = right coronary artery.

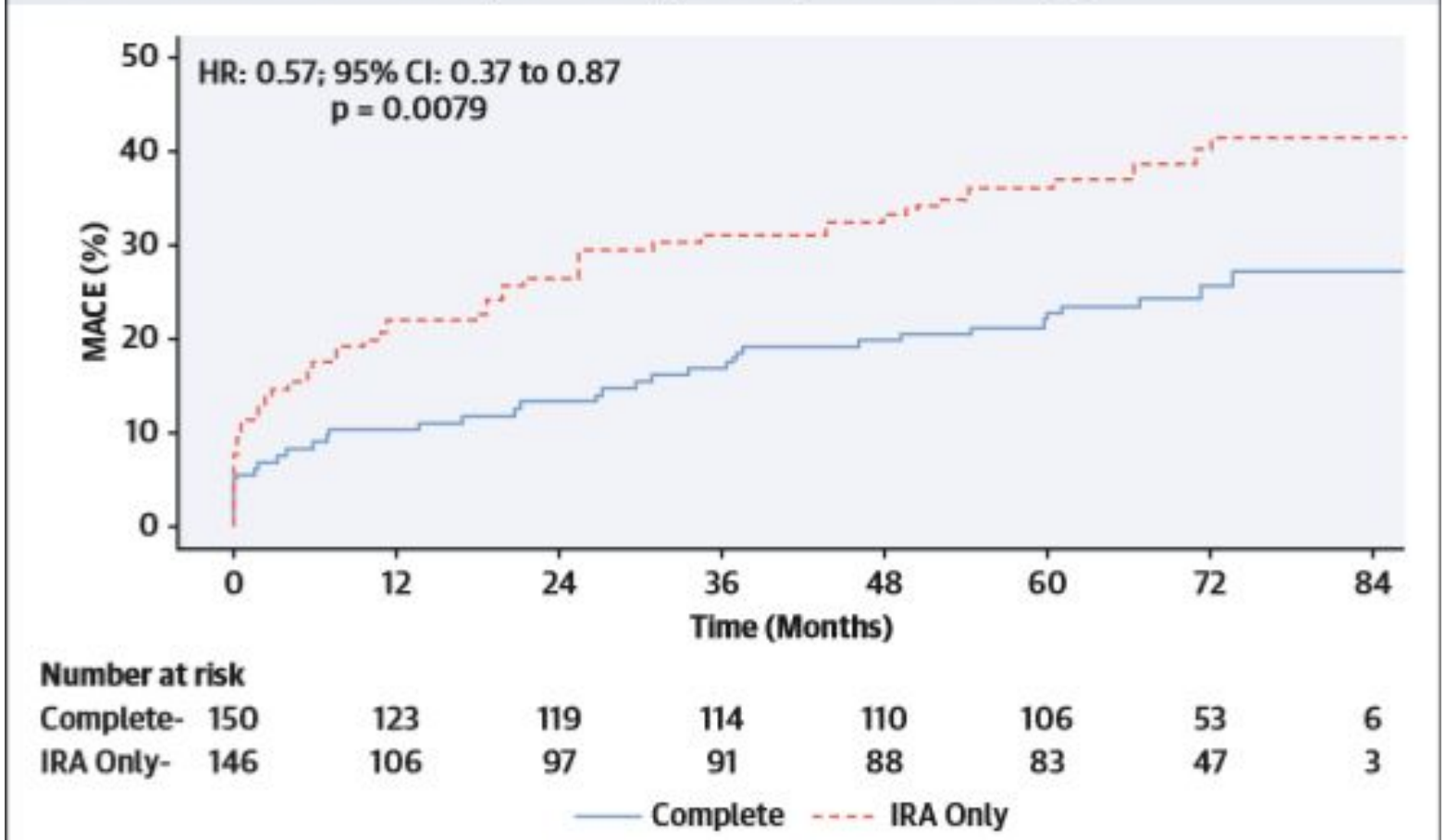
FIGURE 1 Flow Diagram for Long-Term Follow-Up and Landmark Analyses of CvLPRIT



Flow diagram illustrating the longer-term follow-up of patients randomized to complete revascularization or IRA-only PCI, and the number of patients in each group available for landmark analysis beyond 12 months of initial randomization. CvLPRIT = Complete versus Lesion-only Primary PCI Trial; IRA = infarct-related artery; ITT = intention to treat; MACE = major adverse cardiovascular events; PCI = percutaneous coronary intervention.

Анализ отдаленных результатов комплексной первичной конечной точки

FIGURE 2 MACE for Randomization to Long-Term Follow-Up (First Event, Intention-to-Treat Analysis)



Kaplan-Meier curves indicating composite MACE (all-cause death, myocardial infarction, heart failure, and ischemia-driven revascularization) in the complete revascularization **(blue line)** and IRA-only **(red line)** groups, from randomization until end of longer-term follow-up. There is a significant reduction in MACE with the complete revascularization group compared with IRA-only PCI group (HR: 0.57; 95% CI: 0.37 to 0.87; p = 0.0079, log-rank test). CI = confidence interval; HR = hazard ratio; other abbreviations as in Figure 1.

The CvLPRIT Trial Long-Term Follow-Up

Отдельные компоненты первичной конечной точки (MACE)

TABLE 1 Individual Components of MACE: Randomization to End of Long-Term Follow-Up

	Complete (n = 150)	IRA-Only (n = 146)	HR (95% CI)	p Value
Total MACE	36 (24.0)	55 (37.7)	0.57 (0.37–0.87)	0.0079
Death (all-cause)	9 (6.0)	15 (10.3)	0.51 (0.22–1.16)	0.1001
Recurrent MI	6 (4.0)	12 (8.2)	0.43 (0.16–1.15)	0.0837
Heart failure	4 (2.7)	9 (6.2)	0.42 (0.13–1.37)	0.1383
Ischemia-driven revascularization	17 (11.3)	19 (13.0)	0.76 (0.40–1.49)	0.4447
Death/MI	15 (10.0)	27 (18.5)	0.47 (0.25–0.89)	0.0175

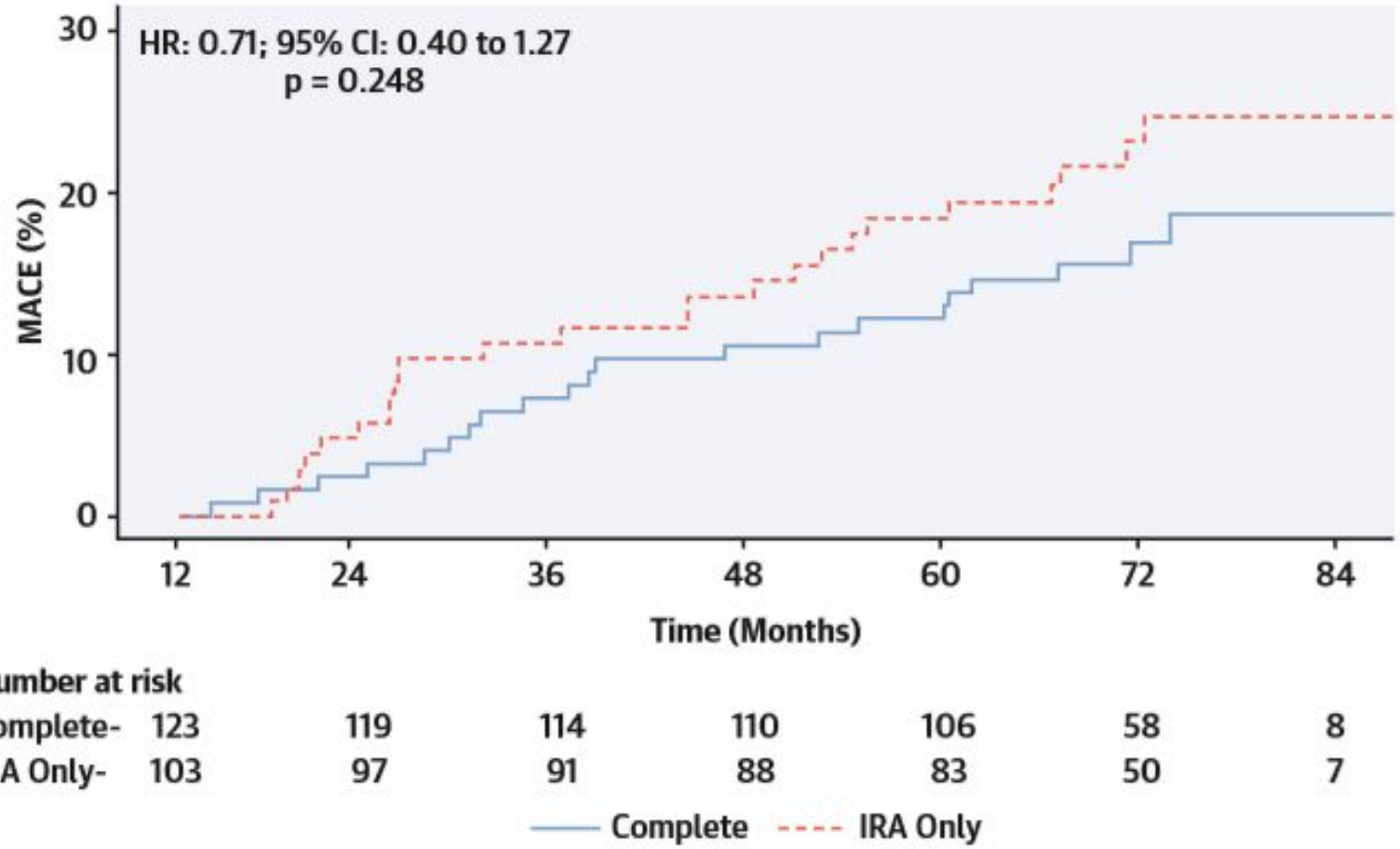
Values are n (%) unless otherwise indicated.

CI = confidence interval; HR = hazard ratio; IRA = infarct-related artery; MACE = major adverse cardiovascular events; MI = myocardial infarction.

The CvLPRIT Trial Long-Term Follow-Up

Анализ результатов с 12 месяца до конца наблюдения

FIGURE 3 Landmark Analysis in Patients From 12 Months to Follow-Up (Intention-to-Treat Analysis)



Kaplan-Meier curves indicating composite MACE (all-cause death, myocardial infarction, heart failure, and ischemia-driven revascularization) in the complete revascularization **(blue line)** and IRA-only **(red dotted line)** groups, from 12 months post-randomization until end of longer-term follow-up. There is no significant difference in MACE rate within the complete revascularization group compared with IRA-only PCI group (HR: 0.71; 95% CI: 0.40 to 1.27; p = 0.248, log-rank test), indicating sustained initial reduction in MACE with complete revascularization over the longer-term follow-up period. Abbreviations as in Figures 1 and 2.

The CvLPRIT Trial Long-Term Follow-Up

TABLE 2 Components of MACE in Landmark Analysis: From 12 Months to End of Follow-Up

	Complete (n = 123)	IRA-Only (n = 103)	HR (95% CI)	p Value
Total MACE	21 (17.1)	24 (23.3)	0.71 (0.40–1.27)	0.248
Death (all-cause)	7 (5.7)	9 (8.7)	0.63 (0.23–1.68)	0.3478
Recurrent MI	4 (3.3)	8 (7.8)	0.41 (0.12–1.36)	0.1333
Heart failure	0 (0.0)	0 (0.0)	NA	NA
Ischemia-driven revascularization	10 (8.1)	7 (6.8)	1.12 (0.44–3.04)	0.7694
Death/MI	11 (8.9)	17 (16.5)	0.53 (0.25–1.12)	0.0905

Values are n (%) unless otherwise indicated. Twenty-four individuals were excluded, as they withdrew consent at 12 months (12 from each treatment group; 8 IRA and 11 complete from initial trial; additional 4 IRA and 1 complete who did not consent beyond 12 months). p from log-rank test.

NA = not applicable; other abbreviations as in Table 1.

TABLE 3 Ischemia-Driven Revascularization Beyond 12 Months in All Patients Surviving Beyond 12 Months

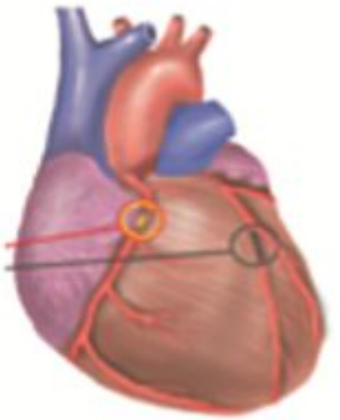
	Complete Revascularization (n = 148)	IRA-Only PCI (n = 140)	p Value
TVR	6 (4.1)	3 (2.1)	0.346
Non-TVR	7 (4.7)	11 (7.9)	0.279
Total IDR	13 (8.8)	14 (10.0)	0.736

Values are n (%). For IRA-only group, TVR refers to revascularization required in the culprit-only artery. For complete revascularization group, TVR refers to revascularization required in any vessel that was treated with PCI during index admission.

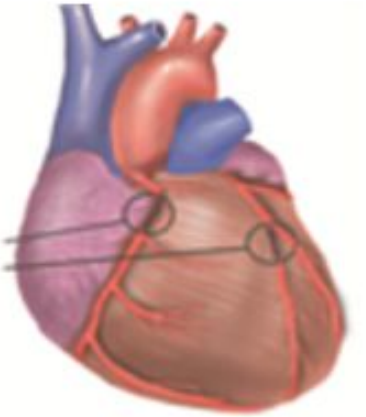
IDR = ischemia-driven revascularization; IRA = infarct-related artery; PCI = percutaneous coronary intervention; TVR = target-vessel revascularization.

FIGURE 4 Revascularization During Follow-Up According to Randomization Group and Artery Treated (IRA or N-IRA) During 2 Periods of Follow-Up (Randomization Until 12 Months and 12 Months Until Last Follow-Up)

Lesion only
Revascularization
Treat IRA only
Leave N-IRA stenoses



Complete
Revascularization
Treat IRA AND
N-IRA stenoses



IRA only treatment	X	√	Complete revascularization	√	√
	N-IRA 255	IRA 146		N-IRA 251	IRA 150
IDR Rand – 12 mo	11	1	IDR Rand – 12 mo	5	2
IDR 12 mo follow-up	11	3	IDR 12 mo follow-up	7	6
TOTAL	22	4	TOTAL	12	8

The table shows the number of lesions in the IRA and N-IRA and the number of lesions treated. IDR = ischemia-driven revascularization; IRA = infarct-related artery; N-IRA = noninfarct-related artery; Rand = randomized.

TABLE 4 Subsequent Events During Long-Term Follow-Up in Those Patients With a Nonfatal Event in the First 12 Months After Randomization (First Event Only Per Patient)

	Complete Revascularization (n = 13)	IRA-Only PCI (n = 25)
Death	2 (15.4)	5 (20.0)
Myocardial infarction	1 (7.7)	1 (4.0)
Ischemia-driven revascularization	0 (0.0)	2 (8.0)
Heart failure	0 (0.0)	0 (0.0)
MACE events from 12 months until end of follow-up	3 (23.1)	8 (32.0)

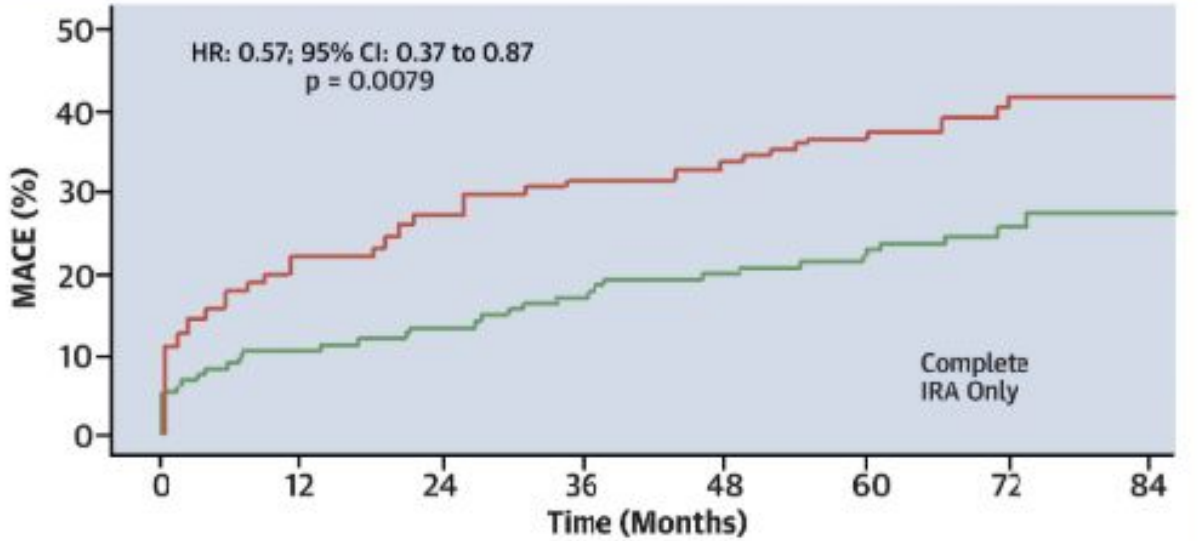
Values are n (%).

Abbreviations as in Tables 1 and 3.

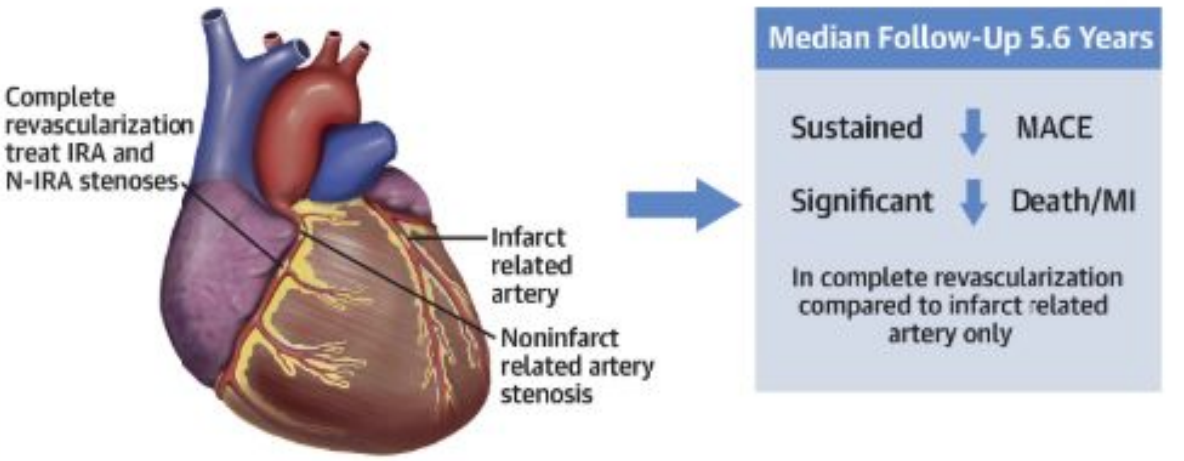
Выводы

- Статистически значимая разница в комбинированной конечной точке между сравниваемыми группами наблюдается не только в течение 12 месяцев, но и в отдаленном периоде (медиана 5.6 лет)
- Хотя компоненты первичной конечной точки (MACE) не показали значимую разницу в отдельности, но их комбинация была статистически значимо ниже в группе полной реваскуляризации
- Частота вторичной конечной точки (смерть/ИМ) была также значимо ниже в группе полной реваскуляризации

CENTRAL ILLUSTRATION: Longer-Term Follow-Up of Complete Versus Infarct-Related-Artery-Only Revascularization in Patients Presenting With ST-Segment Elevation Myocardial Infarction and Multivessel Disease



Complete	150	123	119	114	110	106	53	6
IRA Only	146	106	97	91	88	83	47	3



Gershlick, A.H. et al. J Am Coll Cardiol. 2019;74(25):3083–94.

Заключение

Результаты данного исследования показали безопасность и эффективность полной реваскуляризации у пациентов с ИМпST и многососудистым поражением в долгосрочной перспективе

СПАСИБО ЗА ВНИМАНИЕ!