Сеченовский Университет

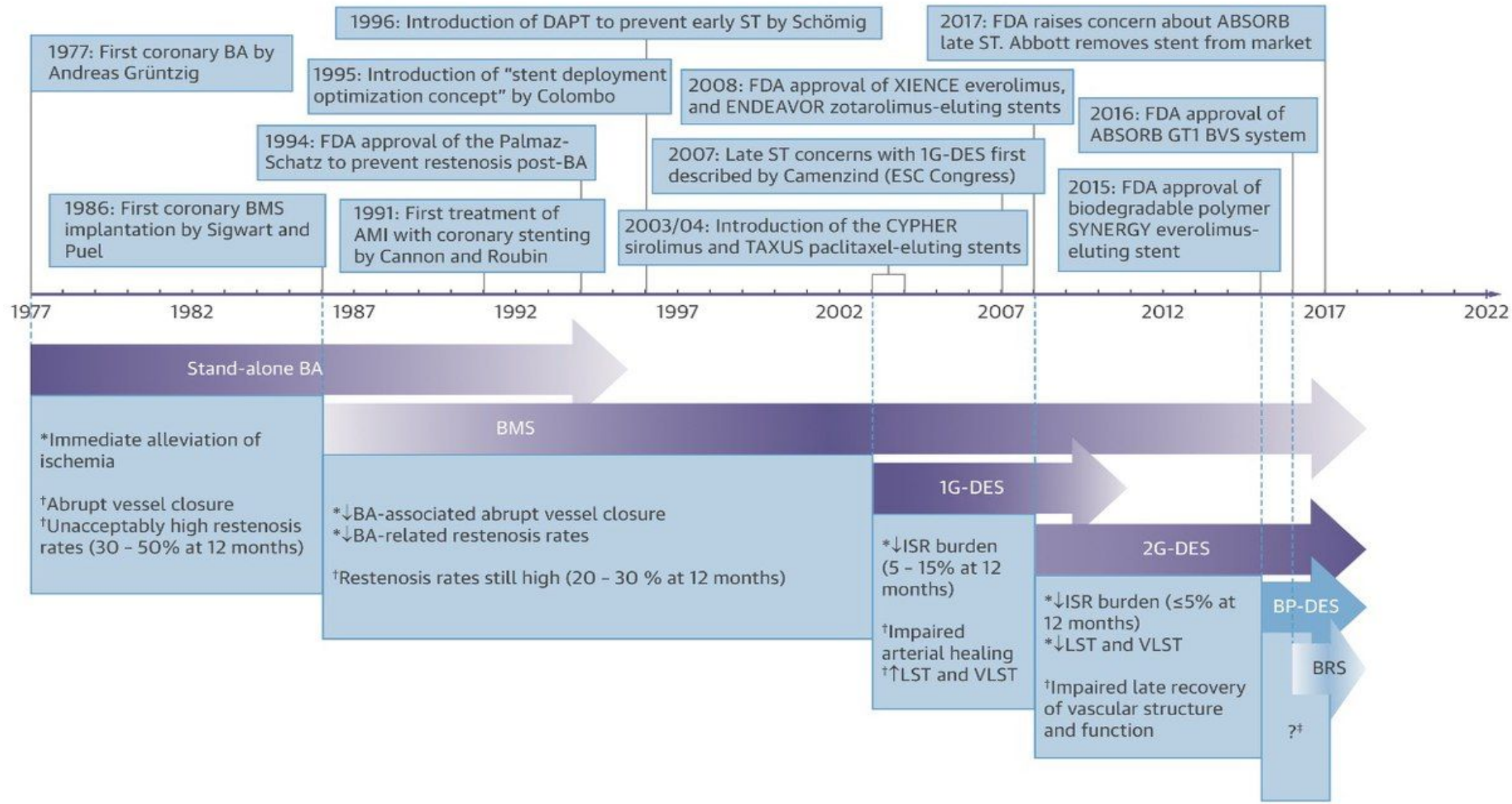
Кафедра интервенционной кардиоангиологии

Чрескожные коронарные вмешательства при ХИБС

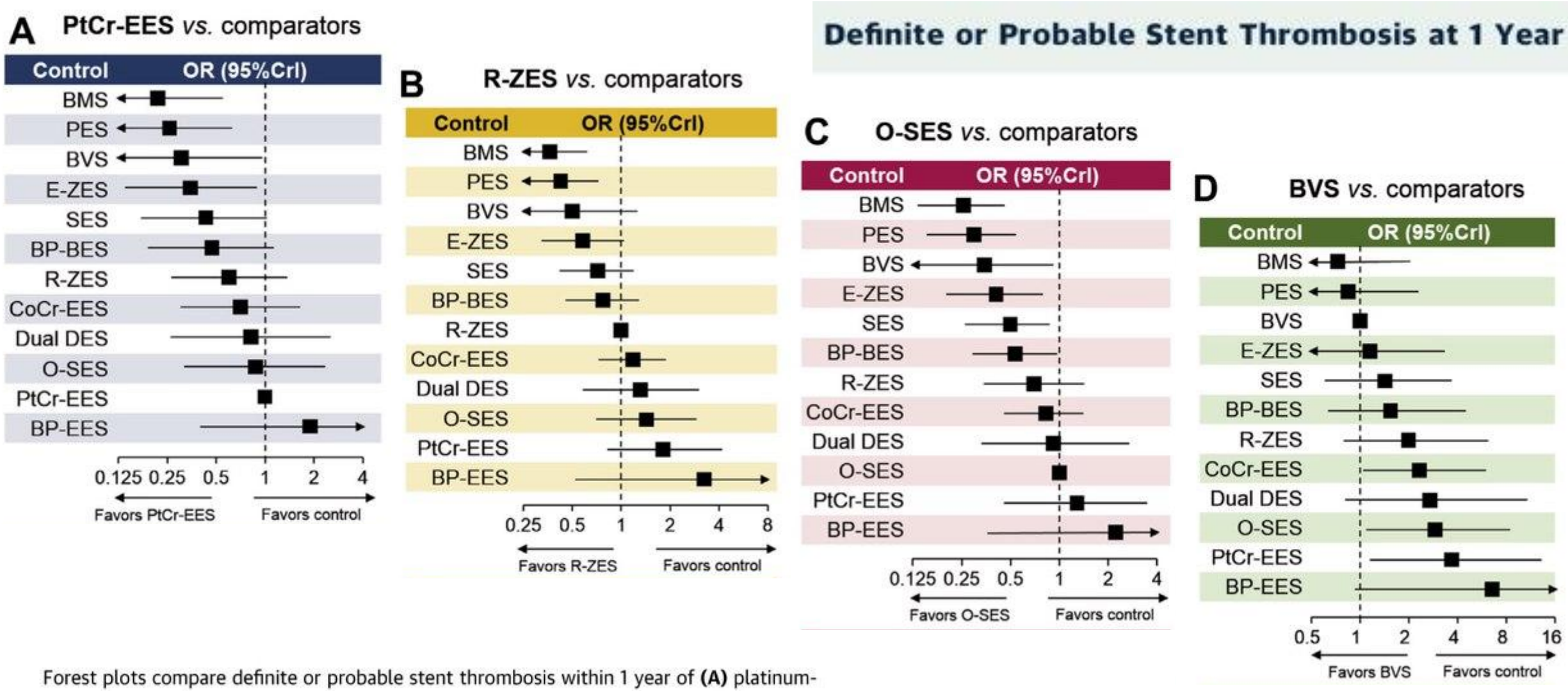
Глушко Ярослав

5 курс, лечебный факультет

Milestones in the Evolution of PCI Over the First 40 Years



*Strength of the procedure. †Weakness of the procedure. ‡A definitive role in PCI is not yet established. The **intensity of the color and length of the arrows** correlate with interventional procedure utilization. 1G-DES = first-generation drug-eluting stent; 2G-DES = second-generation drug-eluting stent; AMI = acute myocardial infarction; BA = balloon angioplasty; BMS = bare-metal stent; BP-DES = biodegradable polymer-based drug-eluting stents; BRS = bioresorbable scaffold; DAPT = dual-antiplatelet therapy; ESC = European Society of Cardiology; FDA = Food and Drug Administration; ISR = in-stent restenosis; LST = late stent thrombosis; PCI = percutaneous coronary intervention; ST = stent thrombosis; VLST = very late stent thrombosis.



Forest plots compare definite or probable stent thrombosis within 1 year of **(A)** platinum-chromium everolimus-eluting stent(s) (Pt-EES), **(B)** Resolute zotarolimus-eluting stent(s) (R-ZES), **(C)** hybrid sirolimus-eluting stent(s) (O-SES), and **(D)** bioresorbable vascular scaffolds (BVS) versus comparators. The **squares** and **horizontal lines** indicate pairwise odds ratios (OR) and their 95% credible intervals (CrI) estimated with a multiple-treatment meta-analysis. Other abbreviations as in Figure 2.

Поражение ствола ЛКА

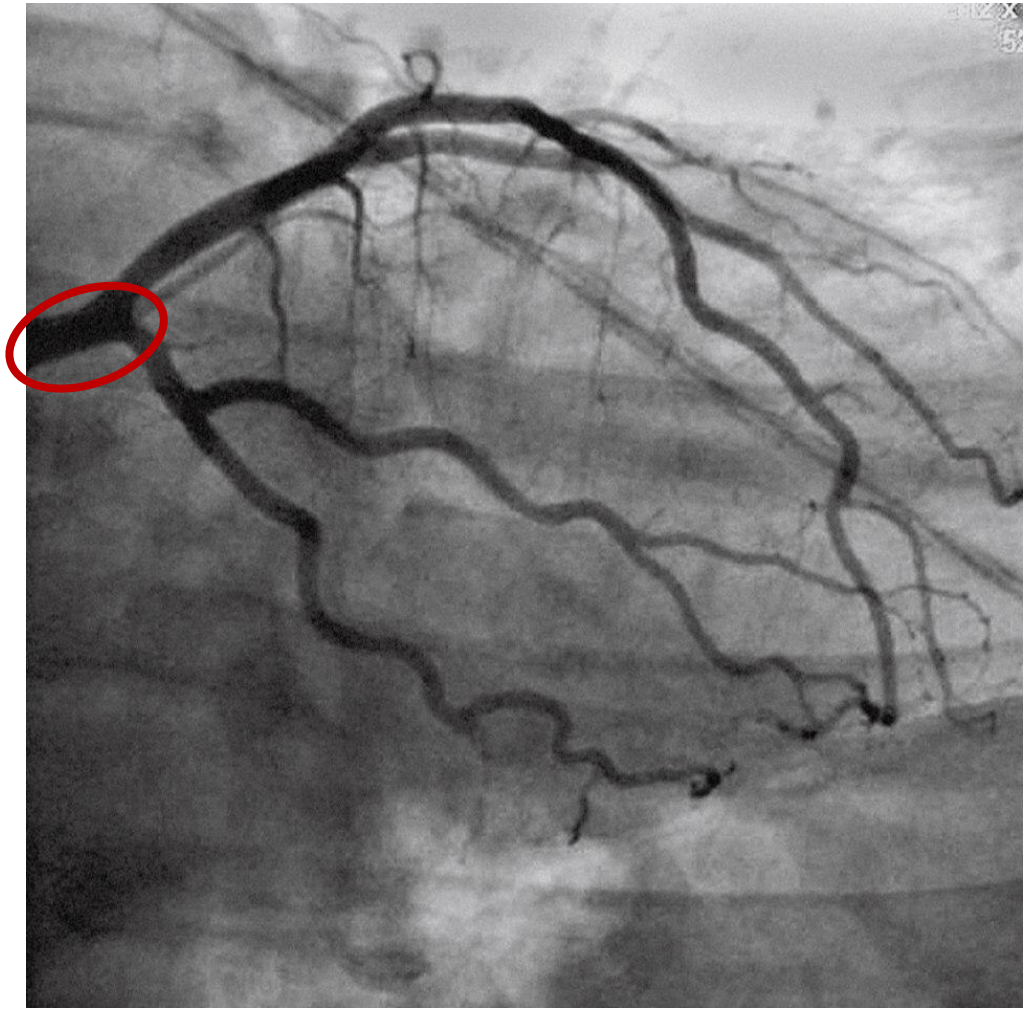


Table. Main Characteristics of the Included Trials

Source	No. of Patients Randomized, PCI vs CABG	Centers, No.	Region	Enrollment Period	Design	Primary End Point	Follow-up, y[a]	Registration[b]
LMCA stenosis								
SYNTAX (LMCA cohort)[26,28-30]	357 vs 348	85	The Netherlands, United States, Germany, United Kingdom, France, Italy, Sweden, Belgium, Hungary, Poland, Austria, Denmark, Latvia, Finland, Spain, Portugal	March 2005-April 2007	Noninferiority	All-cause death, myocardial infarction, stroke, or repeat revascularization	5	NCT00114972
PRECOMBAT[21]	300 vs 300	13	South Korea	April 2004-August 2009	Noninferiority	All-cause death, myocardial infarction, stroke, or ischemia-driven target-vessel revascularization	5	NCT00422968
EXCEL[7]	948 vs 957	126	United States, United Kingdom, Canada, France, Italy, Germany, Spain, the Netherlands, Hungary, Switzerland, Poland, Latvia, Portugal, Argentina, Brazil, Australia, South Korea	September 2010-March 2014	Noninferiority	All-cause death, myocardial infarction, or stroke[c]	3	NCT01205776
NOBLE[8]	598 vs 603	36	United Kingdom, Sweden, Denmark, Latvia, Estonia, Finland, Germany	December 2008-January 2015	Noninferiority	All-cause death, nonprocedural myocardial infarction, stroke, or repeat revascularization	5	NCT01496651

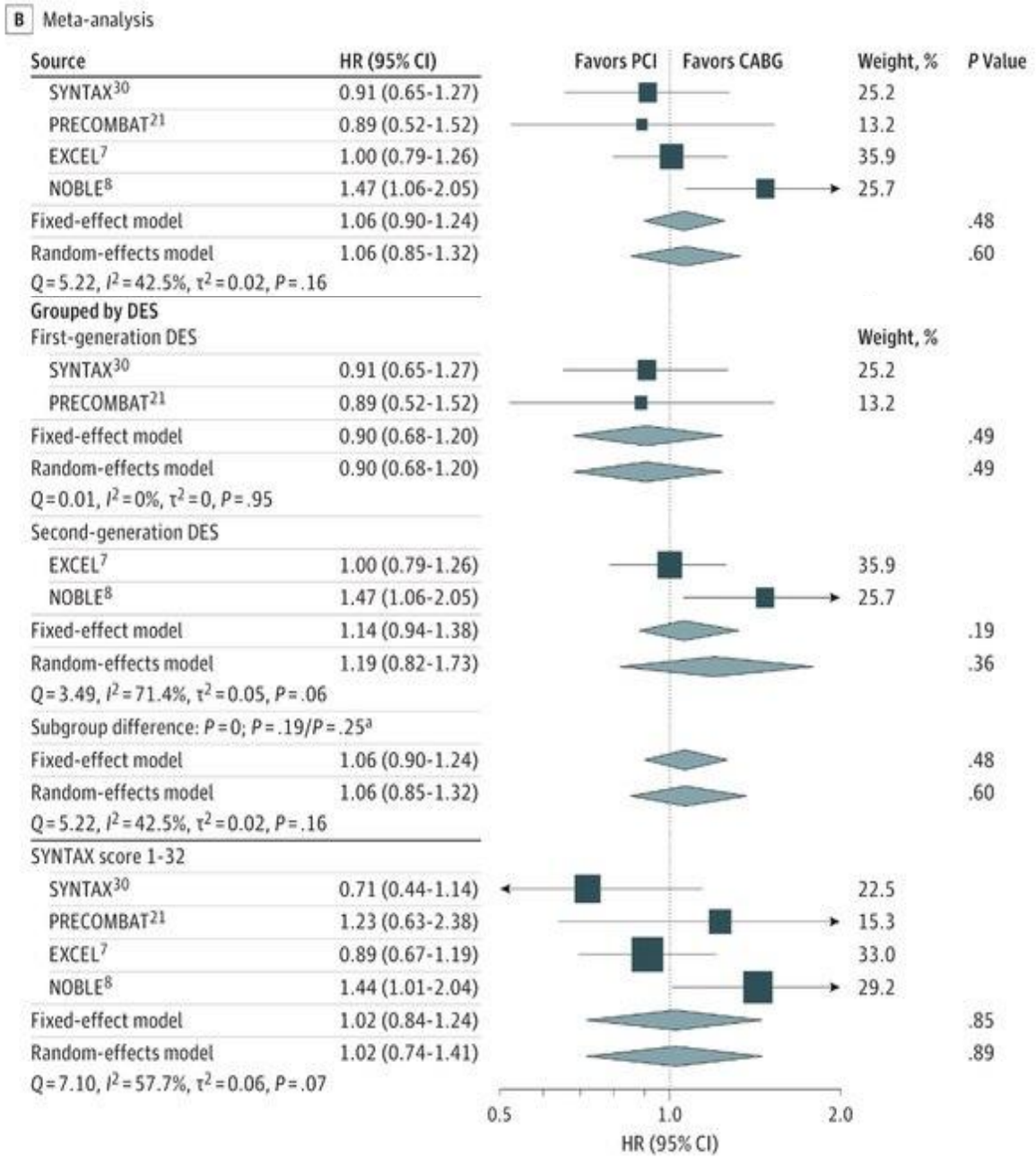
Abbreviations: CABG, coronary artery bypass grafting; EXCEL, Evaluation of Xience vs Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization; LMCA, left main coronary artery; NOBLE, Nordic-Baltic-British Left Main Revascularisation; PCI, percutaneous coronary intervention; PRECOMBAT, Bypass Surgery vs Angioplasty Using Sirolimus-Eluting Stent in Patients With Left Main Coronary Artery Disease; SYNTAX, Synergy Between PCI With Taxus and Cardiac Surgery.

[a] Longest follow-up at Kaplan-Meier analysis.

[b] Registration numbers in http://www.clinicaltrials.gov database.

[c] In the EXCEL trial,[7] the composite of all-cause death, myocardial infarction, stroke, or repeat revascularization was defined as a secondary end point.

Primary End Point of Major Adverse Cardiac and Cerebrovascular Events



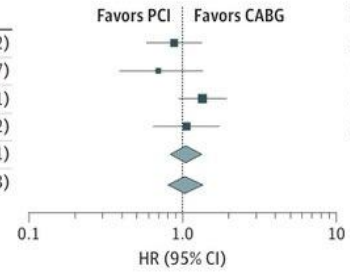
A, In Kaplan-Meier analysis, cumulative incidence across the 5 years of follow-up did not show significant difference between techniques. B, In meta-analyses, patients with coronary artery disease (CAD) involving left main coronary artery, percutaneous coronary intervention (PCI) vs coronary artery bypass grafting (CABG) had comparable risk of a composite of all-cause death, myocardial infarction, or stroke. In influence analysis, the Nordic-Baltic-British Left Main Revascularisation (NOBLE) trial[8] introduced heterogeneity. In drug-eluting stent (DES) generation, results were not significantly influenced when trials were grouped according to drug-eluting stent generation. In anatomic complexity, results also were not significantly influenced after including only patients with low to intermediate CAD complexity. EXCEL indicates Evaluation of Xience vs Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization (Xience; Abbott Vascular); HR, hazard ratio; PRECOMBAT, Bypass Surgery vs Angioplasty Using Sirolimus-Eluting Stent in Patients With Left Main Coronary Artery Disease; and SYNTAX, Synergy Between PCI With Taxus and Cardiac Surgery (Taxus; Boston Scientific).

[a] Testing for interaction by using values of fixed-effect and random-effects models, respectively.

Secondary End Points of All-Cause Death, Cardiac Death, Myocardial Infarction, and Stroke

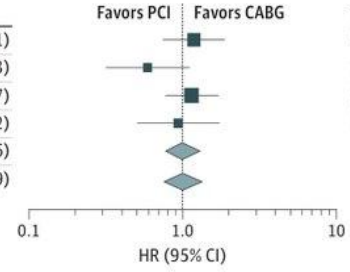
A All-cause death

	HR (95% CI)	Weight, %	*P* Value
SYNTAX[30]	0.88 (0.58-1.32)	28.4	
PRECOMBAT[21]	0.73 (0.39-1.37)	14.0	
EXCEL[7]	1.34 (0.94-1.91)	34.9	
NOBLE[8]	1.07 (0.67-1.72)	22.7	
Fixed-effect model	1.05 (0.85-1.31)		.65
Random-effects model	1.04 (0.81-1.33)		.77
$Q = 3.83$, $I^2 = 21.6\%$, $\tau^2 = 0.01$, $P = .28$			



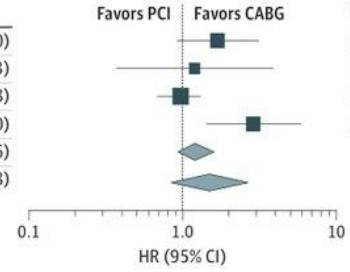
B Cardiac death

	HR (95% CI)	Weight, %	*P* Value
SYNTAX[30]	1.23 (0.71-2.11)	28.4	
PRECOMBAT[21]	0.54 (0.26-1.13)	17.5	
EXCEL[7]	1.18 (0.74-1.87)	36.2	
NOBLE[8]	0.93 (0.45-1.92)	17.9	
Fixed-effect model	1.02 (0.76-1.36)		.91
Random-effects model	1.00 (0.72-1.39)		.99
$Q = 3.78$, $I^2 = 20.6\%$, $\tau^2 = 0.02$, $P = .29$			



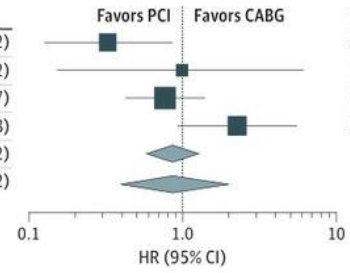
C Myocardial infarction

	HR (95% CI)	Weight, %	*P* Value
SYNTAX[30]	1.67 (0.91-3.10)	26.7	
PRECOMBAT[21]	1.20 (0.37-3.93)	14.2	
EXCEL[7]	0.93 (0.67-1.28)	35.1	
NOBLE[8]	2.88 (1.40-5.90)	24.0	
Fixed-effect model	1.21 (0.93-1.56)		.15
Random-effects model	1.48 (0.85-2.58)		.17
$Q = 9.20$, $I^2 = 67.4\%$, $\tau^2 = 0.2$, $P = .03$			



D Stroke

	HR (95% CI)	Weight, %	*P* Value
SYNTAX[30]	0.33 (0.12-0.92)	25.2	
PRECOMBAT[21]	0.99 (0.14-7.02)	12.0	
EXCEL[7]	0.77 (0.43-1.37)	34.9	
NOBLE[8]	2.25 (0.93-5.48)	27.9	
Fixed-effect model	0.86 (0.56-1.32)		.49
Random-effects model	0.87 (0.39-1.92)		.72
$Q = 8.04$, $I^2 = 62.7\%$, $\tau^2 = 0.39$, $P = .045$			



A, In Kaplan-Meier analysis, cumulative incidence across the 5 years of follow-up did not show significant difference between techniques. B, In meta-analyses, patients with coronary artery disease (CAD) involving left main coronary artery, percutaneous coronary intervention (PCI) vs coronary artery bypass grafting (CABG) had comparable risk of a composite of all-cause death, myocardial infarction, or stroke. In influence analysis, the Nordic-Baltic-British Left Main Revascularisation (NOBLE) trial[8] introduced heterogeneity. In drug-eluting stent (DES) generation, results were not significantly influenced when trials were grouped according to drug-eluting stent generation. In anatomic complexity, results also were not significantly influenced after including only patients with low to intermediate CAD complexity. EXCEL indicates Evaluation of Xience vs Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization (Xience; Abbott Vascular); HR, hazard ratio; PRECOMBAT, Bypass Surgery vs Angioplasty Using Sirolimus-Eluting Stent in Patients With Left Main Coronary Artery Disease; and SYNTAX, Synergy Between PCI With Taxus and Cardiac Surgery (Taxus; Boston Scientific).

[a] Testing for interaction by using values of fixed-effect and random-effects models, respectively.

PRECOMBAT

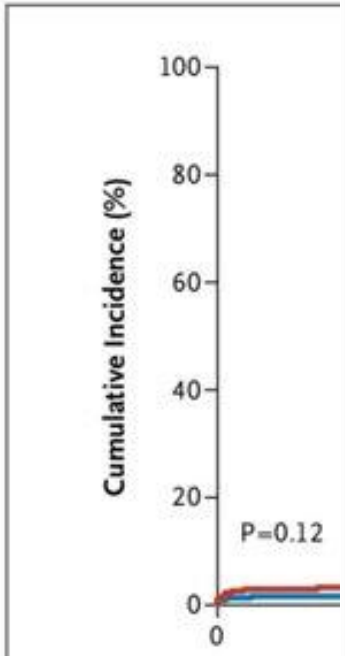


Figure 1. Cumulative In
Cardiac or Cerebrovasc

The 2-year event rates
mates and were compa
the same data on an er
notes coronary-artery b
vention.

Subgroup	PCI	CABG	Hazard Ratio (95% CI)	P Value	P Value for Interaction
	no./total no. (%)				
Overall	36/300 (12.2)	24/300 (8.1)	1.50 (0.90–2.52)	0.12	
Age					0.44
≥65 yr	15/129 (11.9)	14/149 (9.7)	1.87 (0.88–3.97)	0.10	
<65 yr	21/171 (12.5)	10/151 (6.7)	1.24 (0.60–2.56)	0.57	
Sex					0.59
Male	26/228 (11.7)	16/231 (7.0)	1.65 (0.88–3.07)	0.12	
Female	10/72 (13.9)	8/69 (11.7)	1.22 (0.48–3.08)	0.68	
Left main coronary artery stenosis					0.63
>70%	15/140 (10.8)	14/159 (9.0)	1.19 (0.57–2.47)	0.64	
50–70%	21/160 (13.6)	10/141 (7.1)	1.90 (0.89–4.03)	0.10	
Coronary artery disease distribution					0.14
Left main only	1/27 (3.8)	3/34 (8.8)	0.39 (0.04–3.72)	0.41	
Left main with single-vessel disease	2/50 (4.1)	3/53 (5.8)	0.70 (0.11–4.16)	0.69	
Left main with double-vessel disease	13/101 (13.0)	11/90 (12.2)	1.04 (0.47–2.32)	0.93	
Left main with triple-vessel disease	20/122 (16.8)	7/123 (5.8)	3.05 (1.29–7.21)	0.01	
Bifurcation involvement					0.83
Yes	23/200 (11.8)	13/183 (7.3)	1.62 (0.82–3.20)	0.16	
No	13/99 (13.2)	10/111 (9.1)	1.46 (0.64–3.32)	0.37	
Right coronary artery involvement					0.27
Yes	3/149 (15.8)	13/159 (8.3)	1.95 (0.99–3.84)	0.05	
No	13/151 (8.7)	11/141 (7.9)	1.07 (0.48–2.40)	0.86	
Acute coronary syndrome					0.44
Yes	21/140 (15.1)	19/163 (11.7)	1.34 (0.70–2.55)	0.38	
No	15/160 (9.6)	5/137 (3.9)	2.07 (0.85–5.02)	0.11	
Diabetes					0.92
Yes	16/102 (16.3)	10/90 (11.1)	1.43 (0.65–3.16)	0.37	
No	20/198 (10.2)	14/210 (6.8)	1.51 (0.76–2.99)	0.24	
SYNTAX score					0.80
>29	14/89 (15.9)	10/91 (11.1)	1.60 (0.73–3.54)	0.24	
>19 to ≤29	14/105 (13.9)	5/93 (5.7)	2.32 (0.82–6.57)	0.11	
≤19	8/95 (8.5)	5/85 (5.9)	1.38 (0.40–4.21)	0.57	

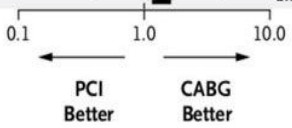
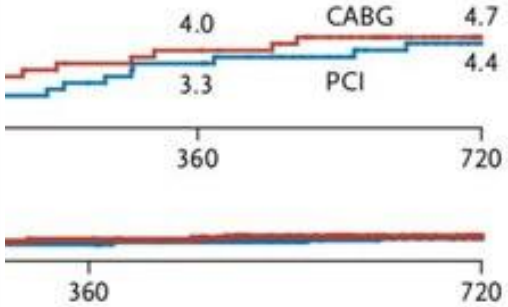


Figure 3. Subgroup Analyses of the Primary End Point at 2 Years.

Hazard ratios, with 95% confidence intervals, are shown for the primary end point of major adverse cardiac or cerebrovascular events (a composite of death from any cause, myocardial infarction, stroke, or ischemia-driven target-vessel revascularization) at 2 years, according to subgroups of patients randomly assigned to the percutaneous coronary intervention (PCI) group or the coronary-artery bypass grafting (CABG) group. The percentages shown are Kaplan–Meier estimates from the intention-to-treat analysis. The P value for interaction represents the likelihood of interaction between the variable and the relative treatment effect. The SYNTAX score ranges from 0 to 83, with higher scores indicating more complex disease.



ince Randomization

288 256
284 248

ath from Any Cause, Myocardial
Groups.
d with the use of Kaplan–Meier esti-
se of the log-rank test. The inset shows
and on a condensed x axis. CABG de-
and PCI percutaneous coronary inter-

EXCEL

Table 2. **Primary and Hierarchical Se**

End Point	io	P Value for Superiority
Primary end point		
Death, stroke, or myocardial infarctio		—
Secondary end points		
Death, stroke, or myocardial infarctio		—
Death, stroke, myocardial infarction, revascularization at 3 yr		—
Death, stroke, or myocardial infarctio	26)	0.98

* Event rates were based on Kaplan–M
† The value represents the upper 97.5
‡ The value represents the upper 95.0
§ The test for superiority with respect

Subgroup	95% CI)	P Value for Interaction
All patients	1.00 (0.79–1.26)	
Age (median		0.07
<67 yr	0.78 (0.55–1.11)	
≥67 yr	1.22 (0.89–1.69)	
Sex		0.06
Male	0.87 (0.66–1.14)	
Female	1.48 (0.93–2.41)	
Diabetes me		0.77
Yes	1.04 (0.70–1.55)	
No	0.97 (0.72–1.30)	
Chronic kidn		0.36
eGFR ≤60	1.24 (0.75–2.07)	
eGFR >60	0.95 (0.72–1.25)	
Left ventricul		0.99
<50%	0.98 (0.52–1.83)	
≥50%	0.98 (0.75–1.27)	
Geographic l		0.14
North Am	1.22 (0.82–1.82)	
Europe	0.95 (0.69–1.29)	
Other	0.37 (0.08–1.20)	
Non–left ma (core lal		0.78
0	0.99 (0.54–1.79)	
1	0.72 (0.46–1.12)	
2	1.44 (0.96–2.21)	
3	0.87 (0.50–1.48)	
Left main bif ≥50% (		0.82
Yes	0.98 (0.75–1.27)	
No	1.05 (0.59–1.87)	
SYNTAX sco		0.70
≤22	0.95 (0.70–1.31)	
23–32	1.05 (0.73–1.51)	
SYNTAX sco		0.49
≤22	0.71 (0.44–1.13)	
23–32	1.02 (0.71–1.47)	
≥33	1.15 (0.71–1.87)	

5.0

Figure 2. **Su**

Data are sho ... d on Kaplan–Meier estimates in time-to-first ... for interaction represents the likelihood of ... ckcroft–Gault equation. The Synergy betw ... ssment of the coronary vascula-ture, with hi

Table 3. (Continued.)

Variable	PCI (N=948)		CABG (N=957)		Hazard Ratio (95% CI)	P Value
	Events	Event Rate†	Events	Event Rate†		
	no.	%	*no.*	%		
Periprocedural	36	3.8	57	6.0	0.63 (0.42–0.96)	0.03
Spontaneous	37	4.3	23	2.7	1.60 (0.95–2.70)	0.07
STEMI	12	1.3	26	2.8	0.46 (0.23–0.91)	0.02
Non-STEMI	62	7.0	54	5.9	1.15 (0.80–1.65)	0.46
Q-wave	11	1.2	15	1.6	0.73 (0.34–1.59)	0.43
Non–Q-wave	61	6.8	60	6.5	1.01 (0.71–1.45)	0.95
Death, stroke, myocardial infarction, or ischemia-driven revascularization	208	23.1	174	19.1	1.18 (0.97–1.45)	0.10
Revascularization						
Ischemia-driven revascularization	112	12.6	66	7.5	1.72 (1.27–2.33)	<0.001
PCI	92	10.3	59	6.8	1.57 (1.13–2.18)	0.006
CABG	30	3.5	7	0.8	4.29 (1.88–9.77)	<0.001
Ischemia-driven target-vessel revascularization	97	10.9	63	7.2	1.55 (1.13–2.13)	0.006
Ischemia-driven target-lesion revascularization	84	9.5	60	6.9	1.40 (1.00–1.95)	0.05
Ischemia-driven non–target-lesion revascularization	28	3.2	5	0.6	5.64 (2.18–14.61)	<0.001
Ischemia-driven non–target-vessel revascularization	21	2.5	6	0.7	3.50 (1.41–8.67)	0.004
All revascularization	114	12.9	67	7.6	1.72 (1.27–2.33)	<0.001
Stent thrombosis, definite or probable‡	12	1.3	0	0	—	<0.001
Definite	6	0.7	0	0	—	0.01
Probable	6	0.7	0	0	—	0.01
Early, 0 to 30 days	7	0.7	0	0	—	0.008
Late, 30 days to 1 yr	1	0.1	0	0	—	0.32
Very late, 1 to 3 yr	4	0.5	0	0	—	0.05
Graft occlusion, symptomatic	0	0	48	5.4	—	<0.001
Definite stent thrombosis or symptomatic graft occlusion‡	6	0.7	48	5.4	0.12 (0.05–0.28)	<0.001

* Results have not been adjusted for multiple testing. Rates of stroke and myocardial infarction are nonhierarchical (i.e., fatal and nonfatal events were included). TIMI denotes Thrombolysis in Myocardial Infarction.
† Event rates were based on Kaplan–Meier estimates in time-to-first-event analyses.
‡ Definite stent thrombosis and probable stent thrombosis were defined according to the Academic Research Consortium criteria.[14]
§ Bleeding Academic Research Consortium (BARC) type 2–5 is bleeding that requires medical attention, and type 3–5 is severe or fatal bleeding.

Поражение ПНА

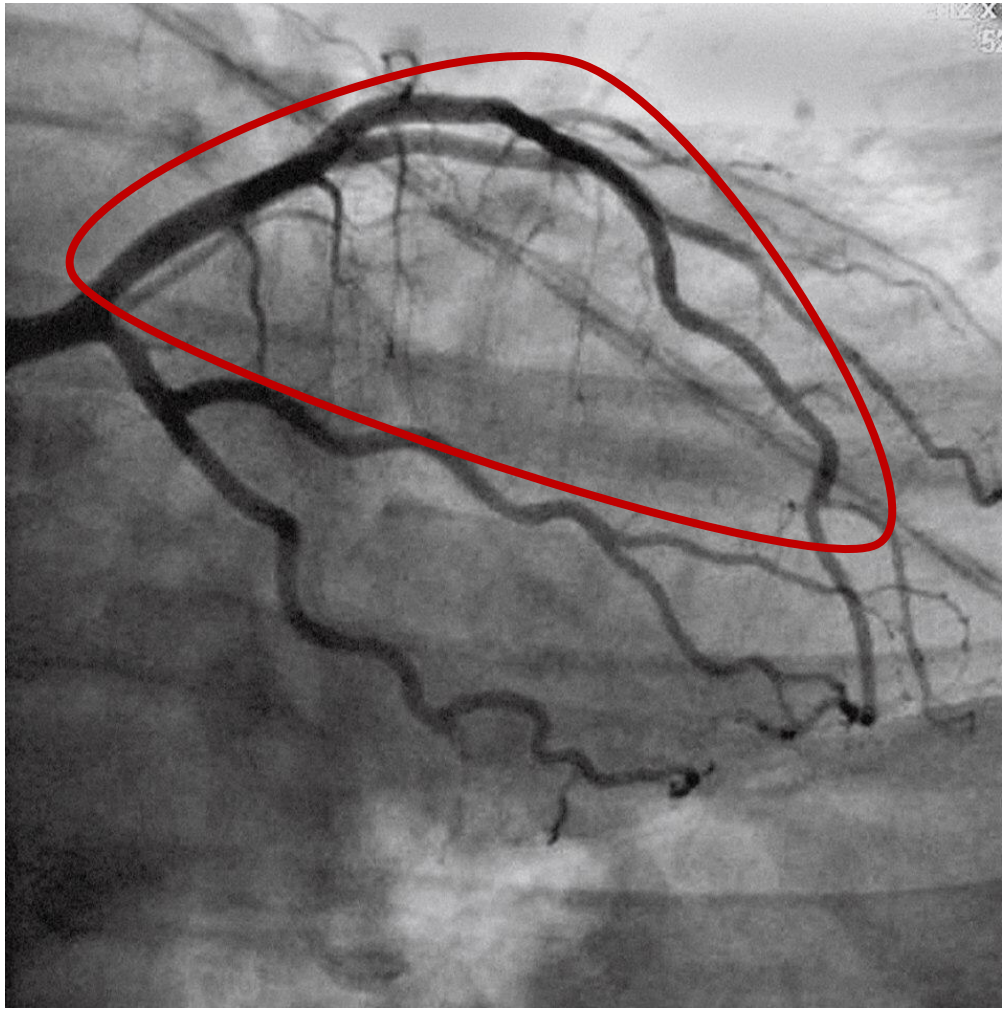
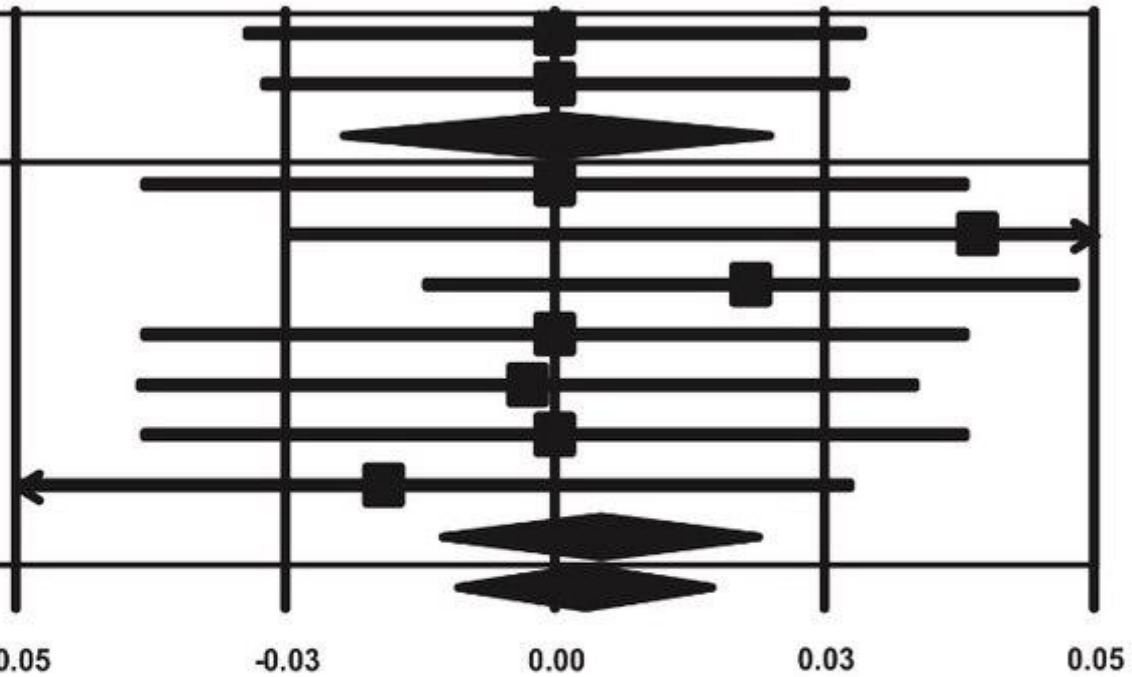


Table 3. Procedural Outcomes

Trial	Intervention	Procedural All-Cause Mortality, %*	Procedural Nonfatal MI, %*	Other Short-Term Complications*		
				Stroke, %	PCI Reintervention, %	Surgical Reintervention, %
AMIST (14)	PCI	0	0	NR	NR	NR
	CABG	0	0	NR	NR	2.0
Groningen (15)	PCI	0	9.8	2.0	NR	0.0
	CABG	3.9	2.0	0.0	NR	2.0
Lausanne (3)	PCI	0	2.9	NR	NR	NR
	CABG	0	1.5	NR	NR	NR
Leipzig (5)	PCI	0	1.8	0.0	1.8	NR
	CABG	1.8	3.6	0.9	NR	2.7
MASS-I (1)	PCI	0	2.8	0.0	NR	NR
	CABG	0	1.4	0.0	NR	NR
Poland (16)	PCI	0	2.0	NR	6.0	NR
	CABG	0	0	NR	0.0	NR
Seoul-Hong (17)	PCI	1.7	3.3	0.0	1.7	NR
	CABG	1.4	2.9	1.4	1.4	NR
Seoul-Kim (18)	PCI	0	4	NR	2.0	2.0
	CABG	0	2	NR	2.0	0.0
SIMA (19)	PCI	1.6	4.8	1.6	NR	NR
	CABG	0	3.3	NR	NR	NR

Procedural Survival in Balloon Angioplasty or Stent Trials Versus CABG

Study name	Statistics for each study				Survival / Total	
	Risk difference	Lower limit	Upper limit	p-Value	PCI	CABG
Lausanne	0.000	-0.029	0.029	1.000	68 / 68	66 / 66
MASS	0.000	-0.027	0.027	1.000	72 / 72	70 / 70
Summary for Balloon Trials	0.000	-0.020	0.020	1.000	140 / 140	136 / 136
AMIST	0.000	-0.038	0.038	1.000	50 / 50	50 / 50
Groningen	0.039	-0.025	0.103	0.229	51 / 51	49 / 51
Leipzig	0.018	-0.012	0.048	0.239	110 / 110	108 / 110
Poland	0.000	-0.038	0.038	1.000	50 / 50	50 / 50
Seoul-Hong	-0.003	-0.039	0.034	0.891	117 / 119	69 / 70
Seoul-Kim	0.000	-0.038	0.038	1.000	50 / 50	50 / 50
SIMA	-0.016	-0.059	0.028	0.474	62 / 63	60 / 60
Summary for Stent Trials	0.004	-0.011	0.019	0.585	490 / 493	436 / 441
Summary for All SVD Trials	0.003	-0.009	0.014	0.661	630 / 633	572 / 577

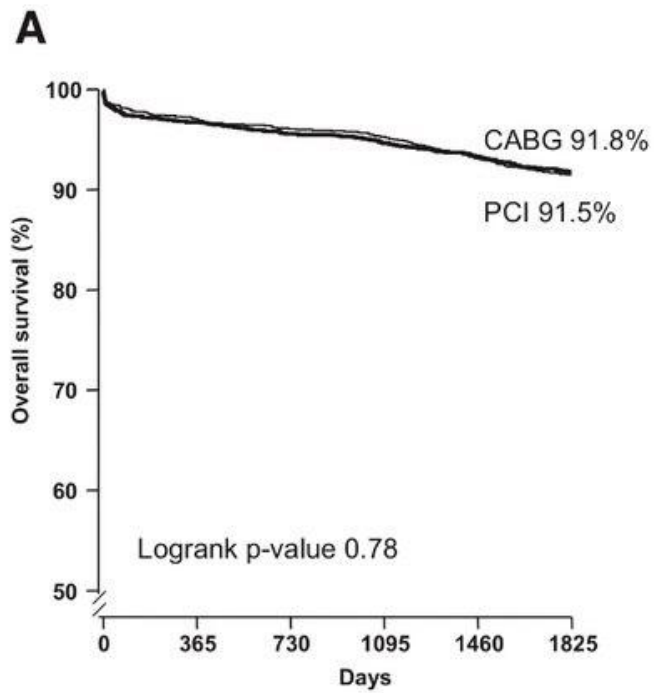


Heterogeneity Statistics:
Balloon trials: Q=0.0, p=1.0; I^2=0.0.
Stent trials: Q=3.1, p=0.8; I^2=0.0.
All SVD trials: Q=3.2, p=0.9; I^2=0.0.

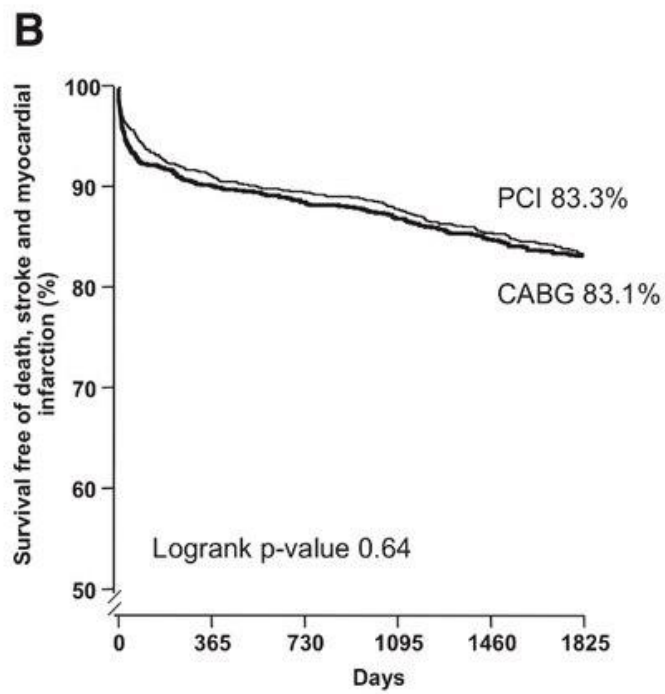
Многососудистое поражение

Event Rates at 5 Years	Crude Event Rates, %			Kaplan–Meier Estimates, %			
Variables	PCI (n=1518 Patients)	CABG (n=1533 Patients)	*P*	PCI (n=1518 Patients)	CABG (n=1533 Patients)	HR (95% CI)*	*P*
Death	8.5 (129/1518)	8.2 (125/1533)	0.74	8.5	8.2	0.95 (0.73–1.23)	0.69
Stroke	2.5 (38/1518)	2.9 (45/1533)	0.51	3.1	3.6	1.16 (0.73–1.83)	0.54
MI	6.6 (100/1518)	6.1 (94/1533)	0.66	7.3	7.6	0.91 (0.68–1.23)	0.54
Repeat revascularization	25.0 (379/1518)	6.3 (96/1533)	<0.001	29.0	7.9	0.23 (0.18–0.29)	<0.001
Repeat PCI	18.3 (278/1518)	5.4 (83/1533)	<0.001	21.5	6.9	0.29 (0.22–0.37)	<0.001
Repeat CABG	9.1 (138/1518)	1.2 (18/1533)	<0.001	10.4	1.5	0.12 (0.07–0.21)	<0.001
Death, stroke, or MI	14.2 (215/1518)	14.6 (224/1533)	0.76	16.7	16.9	1.04 (0.86–1.27)	0.69
Death, MI, or repeat revascularization	32.5 (494/1518)	17.5 (268/1533)	<0.001	37.1	20.4	0.50 (0.43–0.58)	<0.001
Death, stroke, MI, or repeat revascularization	34.2 (519/1518)	19.6 (301/1533)	<0.001	39.2	23.0	0.53 (0.45–0.61)	<0.001

*Adjusted for between-trial outcomes and the following predetermined clinical characteristics: age, gender, diabetes, dyslipidemia, hypertension, prior MI, number of diseased vessels, left ventricular ejection fraction, and peripheral vascular disease.



Group	0	365	730	1095	1460	1825
PCI	1518	1472	1456	1440	1406	1347
CABG	1533	1479	1457	1439	1412	1349



Group	0	365	730	1095	1460	1825
PCI	1518	1381	913	896	872	846
CABG	1533	1377	908	891	868	845

Kaplan–Meier event-free survival analysis of death (A); death, stroke, or MI (B)

Заключение

- ЧКВ vs АКШ у пациентов со стенозом ЛКА: группы показали сходные результаты у пациентов с SYNTAX scores ≤32.
- ЧКВ vs АКШ у пациентов с изолированным стенозом ПНА: выживаемость пациентов с изолированным стенозом ПНА в обеих группах одинакова.
- ЧКВ vs АКШ у пациентов с многососудистым поражением: ЧКВ не уступает АКШ у пациентов с многососудистым поражением и SYNTAX scores ≤22.