



Показания к проведению ЧКВ и АКШ согласно современным рекомендациям

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Herzzentrum Leipzig

Circulation

ACC/AHA/SCAI CLINICAL PRACTICE GUIDELINE

2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

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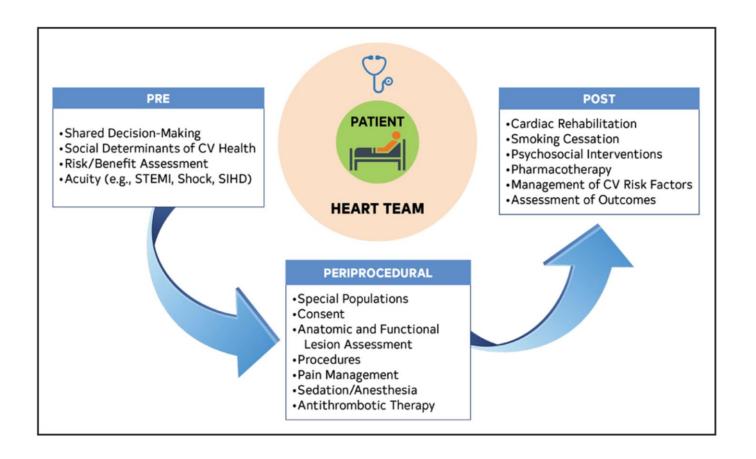
AIM: The guideline for coronary artery revascularization replaces the 2011 coronary artery bypass graft surgery and the 2011 and 2015 percutaneous coronary intervention guidelines, providing a patient-centric approach to guide clinicians in the treatment of patients with significant coronary artery disease undergoing coronary revascularization as well as the supporting documentation to encourage their use.

METHODS: A comprehensive literature search was conducted from May 2019 to September 2019, encompassing studies, reviews, and other evidence conducted on human subjects that were published in English from PubMed, EMBASE, the Cochrane Collaboration, CINHL Complete, and other relevant databases. Additional relevant studies, published through May 2021, were also considered.

STRUCTURE: Coronary artery disease remains a leading cause of morbidity and mortality globally. Coronary revascularization is an important therapeutic option when managing patients with coronary artery disease. The 2021 coronary artery revascularization guideline provides recommendations based on contemporary evidence for the treatment of these patients. The recommendations present an evidence-based approach to managing patients with coronary artery disease who are being considered for coronary revascularization, with the intent to improve quality of care and align with patients' interests.

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Key Words: AHA Scientific Statements ■ percutaneous coronary intervention ■ angioplasty ■ coronary artery bypass graft surgery
■ myocardial infarction ■ cardiac surgery, stent(s) ■ angiogram by angioplasty ■ percutaneous withsulmiac oronary angioplasty
■ coronary atheroscienosis ■ saphenous veni graft ■ internal mammary artery graft ■ internal thoracic artery graft ■ arterial graft
■ post-bypass ■ non-ST-segment-elevated myocardial infarction ■ veni graft lesions ■ myocardial revascularization
■ multivessel PCI = left ventricular divsfunction
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[&]quot;Writing committee members are required to recuse themselves from voting on sections to which their specific relationships with industry may apply; see Appendix 1



Three-vessel Disease (3VD) Cohort

Multivessel CAD		
2 b	B-R	5. In patients with SIHD, normal ejection fraction, significant stenosis in 3 major coronary arteries (with or without proximal LAD), and anatomy suitable for CABG, CABG may be reasonable to improve survival. ^{10,13-15}
2 b	B-R	6. In patients with SIHD, normal ejection fraction, significant stenosis in 3 major coronary arteries (with or without proximal LAD), and anatomy suitable for PCI, the usefulness of PCI to improve survival is uncertain. ¹⁴⁻²⁴

Syntax 10 years FU

Percutaneous coronary intervention versus coronary artery bypass grafting in patients with three-vessel or left main coronary artery disease: 10-year follow-up of the multicentre randomised controlled SYNTAX trial





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Background The Synergy between PCI with Taxus and Cardiac Surgery (SYNTAX) trial was a non-inferiority trial that compared percutaneous coronary intervention (PCI) using first-generation paclitaxel-eluting stents with coronary artery bypass grafting (CABG) in patients with de-novo three-vessel and left main coronary artery disease, and reported results up to 5 years. We now report 10-year all-cause death results.

Methods The SYNTAX Extended Survival (SYNTAXES) study is an investigator-driven extension of follow-up of a multicentre, randomised controlled trial done in 85 hospitals across 18 North American and European countries. Patients with de-novo three-vessel and left main coronary artery disease were randomly assigned (1:1) to the PCI group or CABG group. Patients with a history of PCI or CABG, acute myocardial infarction, or an indication for concomitant cardiac surgery were excluded. The primary endpoint of the SYNTAXES study was 10-year all-cause death, which was assessed according to the intention-to-treat principle. Prespecified subgroup analyses were performed according to the presence or absence of left main coronary artery disease and diabetes, and according to coronary complexity defined by core laboratory SYNTAX score tertiles. This study is registered with ClinicalTrials.gov, NCT03417050.

Findings From March, 2005, to April, 2007, 1800 patients were randomly assigned to the PCI (n=903) or CABG (n=897) group. Vital status information at 10 years was complete for 841 (93%) patients in the PCI group and 848 (95%) patients in the CABG group. At 10 years, 244 (27%) patients had died after PCI and 211 (24%) after CABG (hazard ratio 1.17 [95% CI 0.97-1.41], p=0.092). Among patients with three-vessel disease, 151 (28%) of 546 had died after PCI versus 113 (21%) of 549 after CABG (hazard ratio 1.41 [95% CI 1.10-1.80]), and among patients with left main coronary artery disease, 93 (26%) of 357 had died after PCI versus 98 (28%) of 348 after CABG (0.90 [0.68-1.20], pietraction =0.019). There was no treatment-by-subgroup interaction with diabetes (pietraction=0.66) and no linear trend across SYNTAX score tertiles (p, =0.30).

Interpretation At 10 years, no significant difference existed in all-cause death between PCI using first-generation paclitaxel-eluting stents and CABG. However, CABG provided a significant survival benefit in patients with three-vessel disease, but not in patients with left main coronary artery disease,

September 2, 2019 http://dx.doi.org/10.1016/ 50140-6736(19)31997-X

See Online/Comment http://dx.doi.org/10.1016/ 50140-6736(19)32040-9 *Investigators are listed in the

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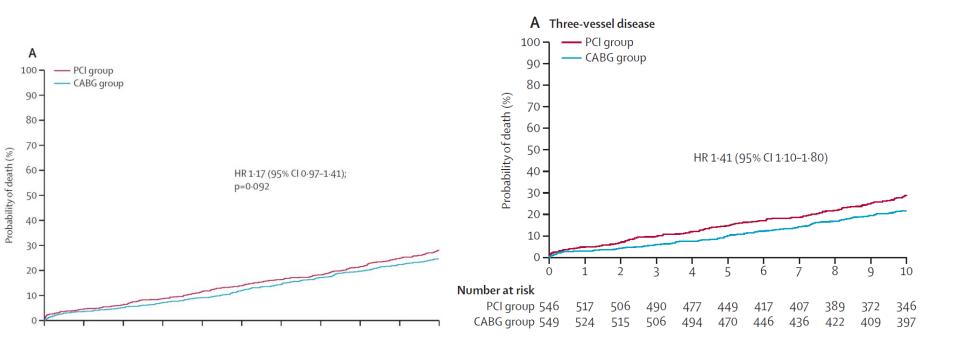
CABG vs PCI

N = 1800

903 PCI 897 ACBG

10 years Follow up

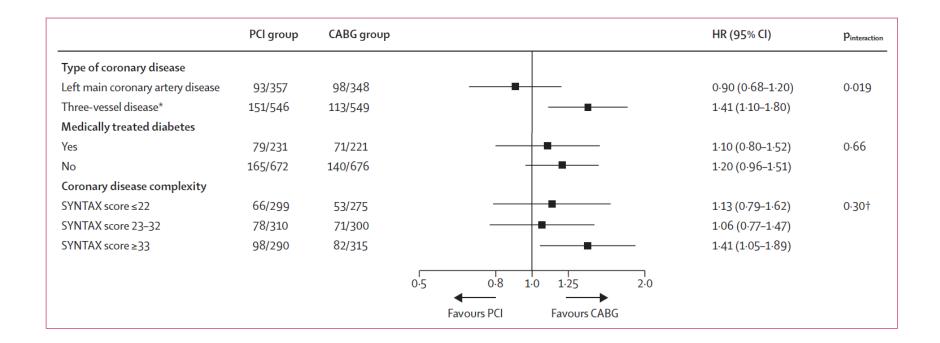
Syntax 10 years FU



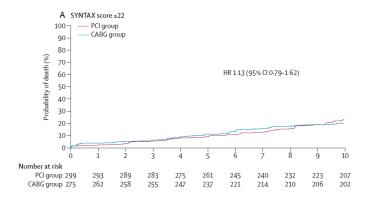
Recommendations for Patients With Complex Disease Referenced studies that support the recommendations are summarized in Online Data Supplement 13.

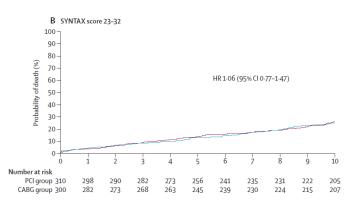
COR	LOE	Recommendations
1	B-R	 In patients who require revascularization for significant left main CAD with high-complexity CAD, it is recommended to choose CABG over PCI to improve survival.^{1,2}
2 a	B-R	 In patients who require revascularization for multivessel CAD with complex or diffuse CAD (eg, SYNTAX score >33), it is reasonable to choose CABG over PCI to confer a survival advantage.²⁻⁵

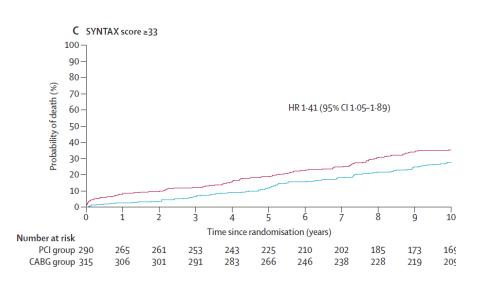
Syntax 10 years FU



Syntax 10 years FU







Пациенты с 3-х сосудистым поражением

- 1. Пациентам с тяжелым трехсосудистым поражением коронарных артерий (Syntax SCORE > 33) показана операция АКШ
- 2. При невозможности выполнить АКШ показано проведение ЧКВ
- 3. При 3-х сосудистом поражении и стенозах ствола левой коронарной артерии показано АКШ
- 4. АКШ и ЧКВ положительно влиляют на выживаемость при 3-х сосудитом поражении

Left Main Disease (LMD) – стоволовое поражение левой коронарной артерии

Left main CAD		
1	B-R	 In patients with SIHD and significant left main stenosis, CABG is recommended to improve survival.⁹⁻¹²
2 a	B-NR	4. In selected patients with SIHD and significant left main stenosis for whom PCI can provide equivalent revascularization to that possible with CABG, PCI is reasonable to improve survival.9

PRECOMBAT 10 years FU

Circulation

ORIGINAL RESEARCH ARTICLE



Ten-Year Outcomes After Drug-Eluting Stents Versus Coronary Artery Bypass Grafting for Left Main Coronary Disease

Extended Follow-Up of the PRECOMBAT Trial

Editorial, see p 1447

BACKGROUND: Long-term comparative outcomes after percutaneous coronary intervention (PCI) with drug-eluting stents and coronary-artery bypass grafting (CABG) for left main coronary artery disease are highly debated.

METHODS: In the PRECOMBAT trial (Premier of Randomized Comparison of Bypass Surgery versus Angioplasty Using Sirolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease), patients with unprotected left main coronary artery disease were randomly assigned to undergo PCI with sirolimus-eluting stents (n=300) or CABG (n=300) in 13 hospitals in Korea from April 2004 to August 2009. The follow-up was extended to at least 10 years for all patients (median, 11.3 years). The primary outcome was the incidence of major adverse cardiac or cerebrovascular events (composite of death from any cause, myocardial infarction, stroke, or ischemia-driven target-vessel revascularization).

RESULTS: At 10 years, a primary outcome event occurred in 29.8% of the PCI group and in 24.7% of the CABG group (hazard ratio [HR] with PCI vs CABG, 1.25 [95% Cl, 0.93–1.69]). The 10-year incidence of the composite of death, myocardial infarction, or stroke (18.2% vs 17.5%; HR 1.00 [95% Cl, 0.70–1.44]) and all-cause mortality (14.5% vs 13.8%; HR 1.13 [95% Cl, 0.75–1.70]) were not significantly different between the PCI and CABG groups. Ischemia-driven target-vessel revascularization was more frequent after PCI than after CABG (16.1% vs 8.0%; HR 1.98 [95% Cl, 1.21–3.21).

CONCLUSIONS: Ten-year follow-up of the PREC OMBAT trial of patients with left main coronary artery disease randomized to PCI or CABG did not demonstrate significant difference in the incidence of major adverse cardiac or cerebrovascular events. Because the study was underpowered, the results should be considered hypothesis-generating, highlighting the need for further research.

Duk-Woo Park, MD* Jung-Min Ahn, MD* Hanbit Park, MD Sung-Cheol Yun, PhD Do-Yoon Kang, MD Pil Hyung Lee, MD Young-Hak Kim, MD Do-Sun Lim, MD Seung-Woon Rha, MD Gyung-Min Park, MD Hyeon-Cheol Gwon, MD Hyo-Soo Kim, MD In-Ho Chae, MD Yangsoo Jang, MD Myung-Ho Jeong, MD Seung-Jea Tahk, MD Ki Bae Seung, MD Seung-Jung Park®, MD On behalf of the PRECOMBAT Investigators

*Drs D.-W. Park and Ahn contributed

Key Words: coronary artery bypass grafting ■ coronary artery disease ■ drug-eluting stents ■ outcome assessment ■ percutaneous coronary intervention ■ survival

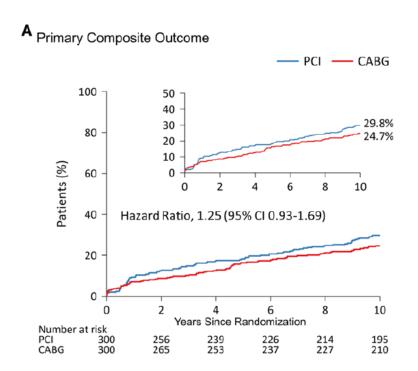
CABG vs PCI patients with left main coronary disease

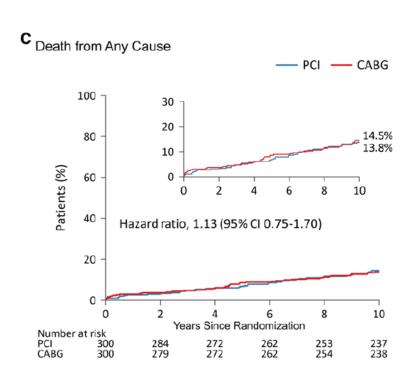
n = 600

300 PCI 300 ACBG

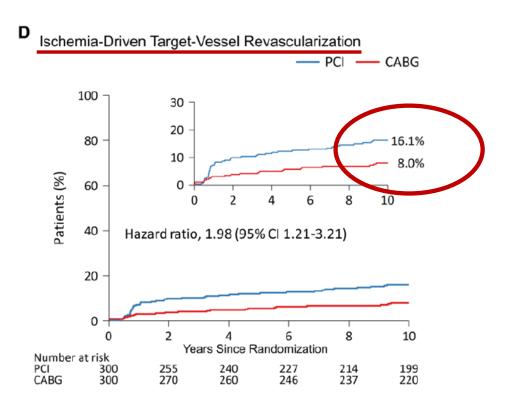
5 years Follow up

PRECOMBAT 10 years FU

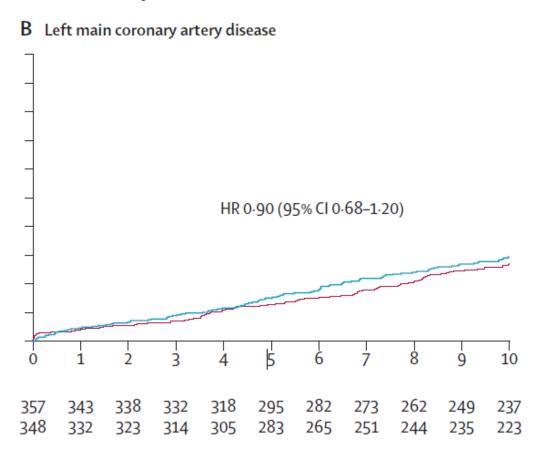




PRECOMBAT 10 years FU



Syntax 10 years FU - mortality



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NEIM.org.

2020, at NEJM.org. N Engl J Med 2019:381:1820-30.

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*A complete list of investigators, institu-

tions, and research organizations partici-

the Supplementary Appendix, available at

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ECXEL 5 years FU

Five-Year Outcomes after PCI or CABG for Left Main Coronary Disease

G.W. Stone, A.P. Kappetein, J.F. Sabik, S.J. Pocock, M.-C. Morice, J. Puskas, D.E. Kandzari, D. Karmpaliotis, W.M. Brown III, N.I. Lembo, A. Banning, B. Merkely, F. Horkay, P.W. Boonstra, A.I. van Boven, I. Ungi, G. Bogáts, S. Mansour, N. Noiseux, M. Sabaté, J. Pomar, M. Hickey, A. Gershlick, P.E. Buszman, A. Bochenek, E. Schampaert, P. Pagé, R. Modolo, J. Gregson, C.A. Simonton, R. Mehran, I. Kosmidou, P. Généreux, A. Crowley, O. Dressler, and P.W. Serruys, for the EXCEL Trial Investigators*

ABSTRACT

The authors' full names, academic de- Long-term outcomes after percutaneous coronary intervention (PCI) with contemporary drug-eluting stents, as compared with coronary-artery bypass grafting (CABG), in patients with left main coronary artery disease are not clearly estab-Foundation, 1700 Broadway, 8th Fl., New lished.

We randomly assigned 1905 patients with left main coronary artery disease of low pating in the EXCEL trial is provided in or intermediate anatomical complexity (according to assessment at the participating centers) to undergo either PCI with fluoropolymer-based cobalt-chromium everolimus-eluting stents (PCI group, 948 patients) or CABG (CABG group, 957 patients). The primary outcome was a composite of death, stroke, or myocardial infarction.

At 5 years, a primary outcome event had occurred in 22.0% of the patients in the PCI group and in 19.2% of the patients in the CABG group (difference, 2.8 percentage points; 95% confidence interval [CI], -0.9 to 6.5; P=0.13). Death from any cause occurred more frequently in the PCI group than in the CABG group (in 13.0% vs. 9.9%; difference, 3.1 percentage points; 95% CI, 0.2 to 6.1). In the PCI and CABG groups, the incidences of definite cardiovascular death (5.0% and 4.5%, respectively: difference, 0.5 percentage points; 95% CI, -1.4 to 2.5) and myocardial infarction (10.6% and 9.1%; difference, 1.4 percentage points; 95% CI, -1.3 to 4.2) were not significantly different. All cerebrovascular events were less frequent after PCI than after CAEG (3.3% vs. 5.2%; difference, -1.9 percentage points; 95% CI, -3.8 to 0), although the incidence of stroke was not significantly different between the two groups (2.9% and 3.7%; difference, -0.8 percentage points; 95% CI, -2.4 to 0.9). Ischemia-driven revascularization was more frequent after PCI than after CABG (16.9% vs. 10.0%; difference, 6.9 percentage points; 95% CI, 3.7 to 10.0).

In patients with left main coronary artery disease of low or intermediate anatomical complexity, there was no significant difference between PCI and CABG with respect to the rate of the composite outcome of death, stroke, or myocardial infarction at 5 years. (Funded by Abbott Vascular; EXCEL Clinical Trials.gov number, NCT01205776.)

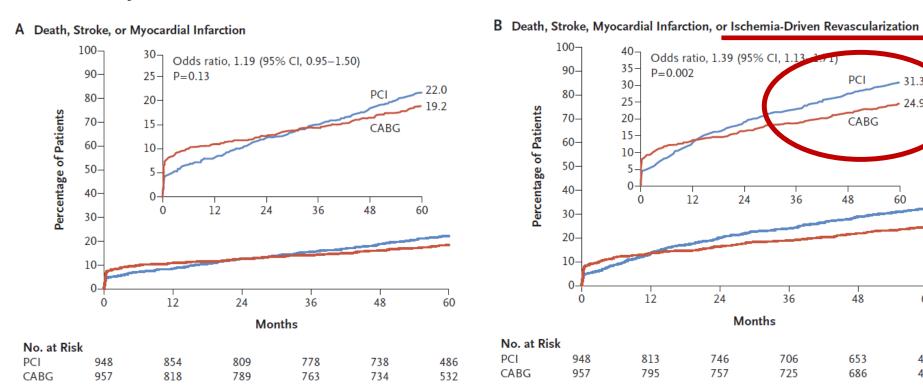
CABG vs PCI patients with left main coronary disease

n = 1905

948 PCI **957 ACBG**

5 years Follow up

ECXEL 5 years FU

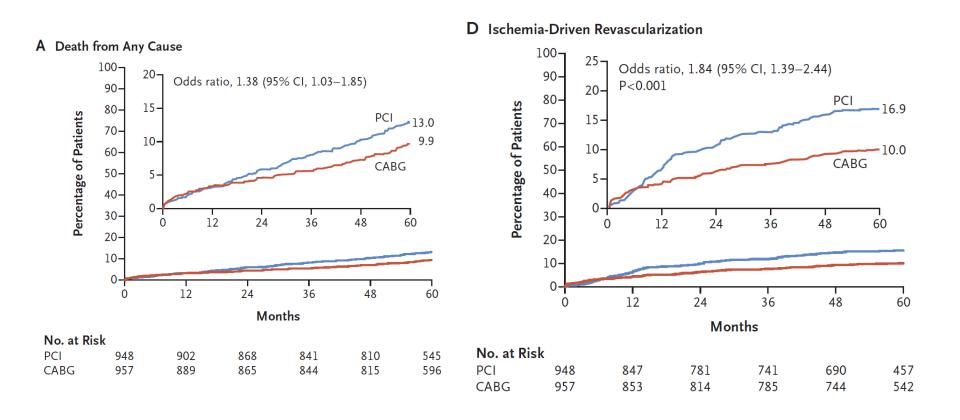


24.9

CABG

Months

ECXEL 5 years FU



PRECOMBAT 10 years FU

Journal of the American Heart Association

ORIGINAL RESEARCH

Ten-year Outcomes After Drug-Eluting Stents or Bypass Surgery for Left Main Coronary Disease in Patients With and Without Diabetes Mellitus: The PRECOMBAT Extended Follow-Up Study

Yeong Jin Jeong , MD*; Jung-Min Ahn , MD*; Junho Hyun , MD; Junghoon Lee , MD; Ju Hyeon Kim, MD; Yujin Yang, MD; Kyungjin Choe, MD; Hanbit Park, MD; Do-Yoon Kang, MD; Pil Hyung Lee, MD; Soo-Jin Kang, MD; Seung-Whan Lee , MD; Young-Hak Kim, MD; Cheol Whan Lee, MD; Seong-Wook Park, MD; Seung-Jung Park , MD; Dik-Woo Park , MD, PhD

BACKGROUND: Several trials reported differential outcomes after percutaneous coronary intervention with drug-eluting stents (DES) and coronary-artery bypass grafting (CABG) for multivessel coronary disease according to the presence of diabetes mellitus (DM). However, it is not well recognized how DM status affects very-long-term (10-year) outcomes after DES and CABG for left main coronary artery disease.

METHODS AND RESULTS: In the PRECOMBAT (Premier of Randomized Comparison of Bypass Surgery versus Angioplasty using Strolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease) trial, patients with LMCA were randomly assigned to undergo PCI with sirolimus-eluting stents (n=300) or CABG (n=300). The primary outcome was the incidence of major adverse cardiac or cerebrovascular events (MACCE; a composite of death from any cause, myocardial infarction, stroke, or ischemia-criven target-vessel revascularization). Outcomes were examined in patients with (n=192) and without (n=408) medically treated diabetes. The follow-up was extended to at least 10 years for all patients (median, 11.3 years). The 10-year rates of MACCE were not significantly different between DES and CABG in patients with DM (36.3% versus 22.9%, respectively; Ha, 1.15; 95% CI, 0.79–1.67; P=0.48) (P-for-interaction=0.48). There were no significant between-group differences in composite of death, MI, or stroke, and all-cause mortality, regardless of DM status. TVR rates were consistently higher after DES than CABG.

CONCLUSIONS: In this 10-year extended follow-up of PRECOMBAT, we found no significant difference between DES and CABG with respect to the incidences of MACCE, serious composite outcome, and all-cause mortality in patients with and without DM with LMCA disease. However, owing to the limited number of patients and no adjustment for multiple testing, overall findings should be considered hypothesis-generating, highlighting the need for further research.

REGISTRATION: URL: https://www.clinicaltrials.gov; Unique identifier: NCT03871127 and NCT00422968.

Key Words: coronary artery bypass grafting ■ drug-eluting stents ■ left main coronary artery disease ■ percutaneous coronary intervention

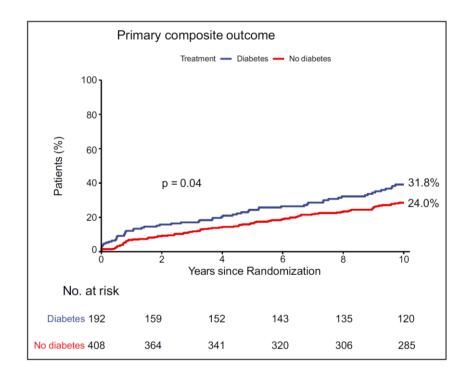
CABG vs PCI in left main Patient with diabetes

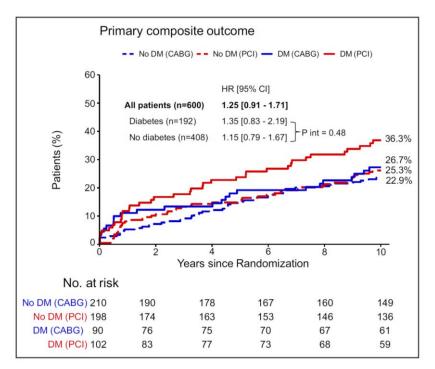
N = 600

300 PCI 300 CBG

10 years Follow up

PRECOMBAT 10 years FU





Пациенты с поражением стовола левой коронарной артерии

- 1. Пациентам с поражением ствола левой коронарной артерии показано АКШ
- 2. ЧКВ приводит к улучшению выживаемости по сравнению с медикаментозной терапией, при не тяжелых поражениях ствола левой коронарной артерии.
- 3. В отдаленные сроки у пациентов с ЧКВ по сравнению с АКШ наблюдается достоверно чаще возвратная ишемия требующая вмешательства

Three-vessel Disease cohort with diabetes

8.2. Patients With Diabetes

Recommendations for Patients With Diabetes
Referenced studies that support the recommendations are
summarized in Online Data Supplement 14.

COR	LOE	Recommendations
1	Α	 In patients with diabetes and multivessel CAD with the involvement of the LAD, who are appropriate candidates for CABG, CABG (with a LIMA to the LAD) is recommended in pref- erence to PCI to reduce mortality and repeat revascularizations.¹⁻⁸
2a	B-NR	2. In patients with diabetes who have multivessel CAD amenable to PCI and an indication for revascularization and are poor candidates for surgery, PCI can be useful to reduce long-term ischemic outcomes. ^{9,10}
2b	B-R	3. In patients with diabetes who have left main stenosis and low- or intermediate-complexity CAD in the rest of the coronary anatomy, PCI may be considered an alternative to CABG to reduce major adverse cardiovascular outcomes. ^{5,11}

Syntax 5 years FU

Treatment of complex coronary artery disease in patients with diabetes: 5-year results comparing outcomes of bypass surgery and percutaneous coronary intervention in the SYNTAX trial[†]

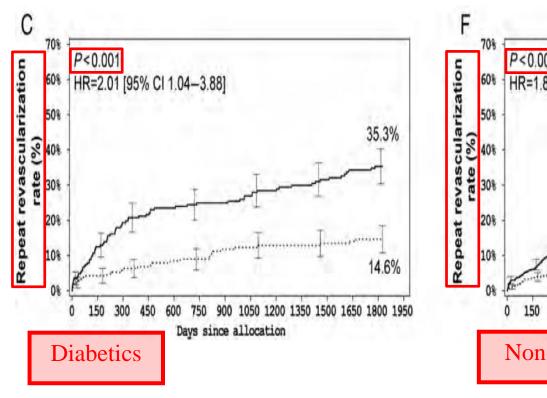
Arie Pieter Kappetein^{a,*}, Stuart J. Head^a, Marie-Claude Morice^b, Adrian P. Banning^c, Patrick W. Serruys^d, Friedrich-Wilhelm Mohr^e, Keith D. Dawkins^f and Michael J. Mack^g on behalf of the SYNTAX Investigators

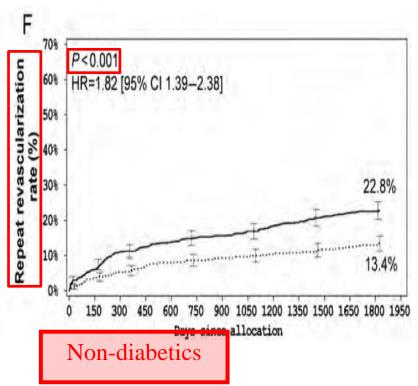
OBJECTIVES: This prespecified subgroup analysis examined the effect of diabetes on left main coronary disease (LM) and/or three-vessel disease (3VD) in patients treated with percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) in the SYNTAX trial.

METHODS: Patients (n = 1800) with LM and/or 3VD were randomized to receive either PCI with TAXUS Express paclitaxel-eluting stents or CABG. Five-year outcomes in subgroups with (n = 452) or without (n = 1348) diabetes were examined: major adverse cardiac or cerebrovascular events (MACCE), the composite safety end-point of all-cause death/stroke/myocardial infarction (MI) and individual MACCE components death, stroke, MI and repeat revascularization. Event rates were estimated with Kaplan–Meier analyses.

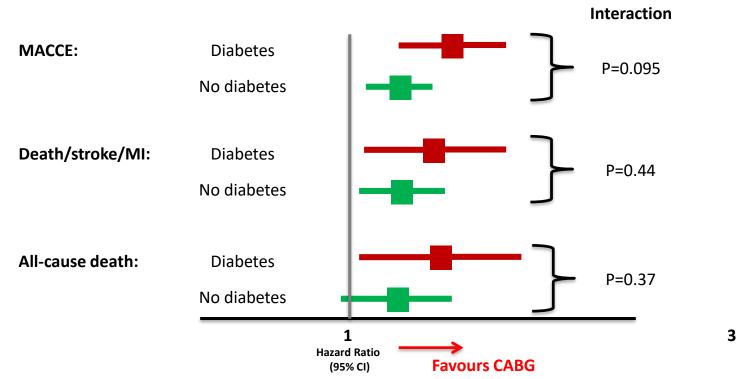
CONCLUSIONS: In both diabetic and non-diabetic patients, <u>PCI</u> resulted in higher rates of MACCE and repeat revascularization at <u>5 years</u>. Although PCI is a potential treatment option in patients with less-complex lesions, <u>CABG</u> should be the revascularization option of choice for patients with more-complex anatomic disease, especially with concurrent diabetes.

Syntax 5 years FU





Syntax 5 years FU – 3 VDS



0.3

Head SJ & Davierwala PM et al. Eur Heart J 2014; online

FREEDOM 7 years FU

Long-Term Survival Following Multivessel Revascularization in Patients With Diabetes



The FREEDOM Follow-On Study

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ABSTRACT

BACKGROUND The FREEDOM (Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease) trial demonstrated that for patients with diabetes mellitus (DM) and multivessel coronary disease (MVD), coronary artery bypass grafting (CABG) is superior to percutaneous coronary intervention with drug-eluting stents (PCI-DES) in reducing the rate of major adverse cardiovascular and cerebrovascular events after a median follow-up of 3.8 years. It is not known, however, whether CABG confers a survival benefit after an extended follow-up period.

OBJECTIVES The purpose of this study was to evaluate the long-term survival of DM patients with MVD undergoing coronary revascularization in the FREEDOM trial.

METHODS The FREEDOM trial randomized 1,900 patients with DM and MVD to undergo either PCI with sirolimuseluting or paclitaxel-eluting stents or CABG on a background of optimal medical therapy. After completion of the trial, enrolling centers and patients were invited to participate in the FREEDOM Follow-On study. Survival was evaluated using Kaplan-Meier analysis, and Cox proportional hazards models were used for subgroup and multivariate analyses.

RESULTS A total of 25 centers (of 140 original centers) agreed to participate in the FREEDOM Follow-On study and contributed a total of 943 patients (49.6% of the original cohort) with a median follow-up of 7.5 years (range 0 to 13.2 years). Of the 1,900 patients, there were 314 deaths during the entire follow-up period (204 deaths in the original trial and 110 deaths in the FREEDOM Follow-On). The all-cause mortality rate was significantly higher in the PCI-DES group than in the CABG group (24.3% [159 deaths] vs. 18.3% [112 deaths]; hazard ratio: 1.36; 95% confidence interval: 1.07 to 1.74; p = 0.01). Of the 943 patients with extended follow-up, the all-cause mortality rate was 23.7% (99 deaths) in the PCI-DES group and 18.7% (72 deaths) in the CABG group (hazard ratio: 1.32: 95% confidence interval: 0.97 to 1.78; p = 0.076).

CONCLUSIONS In patients with DM and MVD, coronary revascularization with CABG leads to lower all-cause mortality than with PCI-DES in long-term follow-up. (Comparison of Two Treatments for Multivessel Coronary Artery Disease in Individuals With Diabetes [FREEDOM]; NCTO0086450) (J Am Coll Cardiol 2019;73:629-38) © 2019 Published by Elsevier on behalf of the American College of Cardiology Foundation.

CABG vs PCI multivessel Patient und diabetes

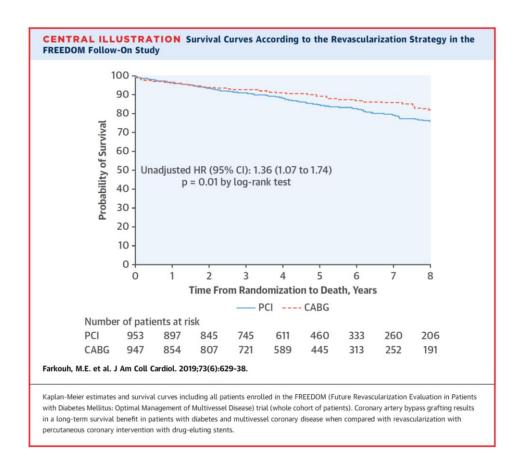
N = 600

478 PCI

456 CBG

7 years Follow up

FREEDOM 7 years FU



Пациенты с сахарным дибетом и 3-х сосудистым поражением коронарных артерий

- 1. Решения о реваскуляризации у пациентов с сахарным диабетом и многососудистым поражением коронарных артерий должно приниматься «сердечной командой».
- 2. Пациентам с сахарным диабетом и трехсосудистым поражением рекомендуется провести АКШ; ЧКВ может быть рассмотрено при невозможности выполнить операцию.

10.1. Radial and Femoral Approaches for PCI

Recommendations for Radial and Femoral Approaches for PCI Referenced studies that support the recommendations are summarized in Online Data Supplement 23.

COR	LOE	Recommendations
1	A	1. In patients with ACS undergoing PCI, a radial approach is indicated in preference to a femoral approach to reduce the risk of death, vascular complications, or bleeding. ¹⁻⁴
1	A	2. In patients with SIHD undergoing PCI, the radial approach is recommended to reduce access site bleeding and vascular complications. ⁴⁻⁷

Summary

- ЧКВ и АКШ альтернативные методы лечения ИБС
- При выполнении <u>АКШ</u> отдаленная выживаемость достоверно лучше у пациентов:
 - с тяжелыми трехсосудистым поражением коронарных артерий
 - с тяжелыми трехсосудистым поражением коронарных артерий и сахарным диабетом
- При ЧКВ ствола левой коронарной артерии достовено чаще в отдаленные сроки
 - возвратная стенокардия
 - повторные вмешательства

Vielen Dank!