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Estudio SYNTAX II o Como Podemos Reducir el Creciente Gap entre PCI y CABG en Lesiones de MVD y LMCS

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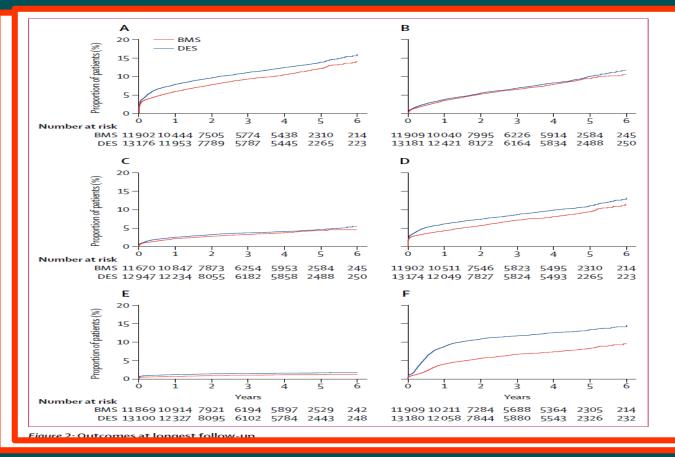
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My Disclosures

Alfredo E Rodriguez DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

However, I published the 1st RCT between POBA and CABG in MVD (ERACI trial; JACC,1993), therefore, my comments about PCI and CABG are related to 30 years journey.





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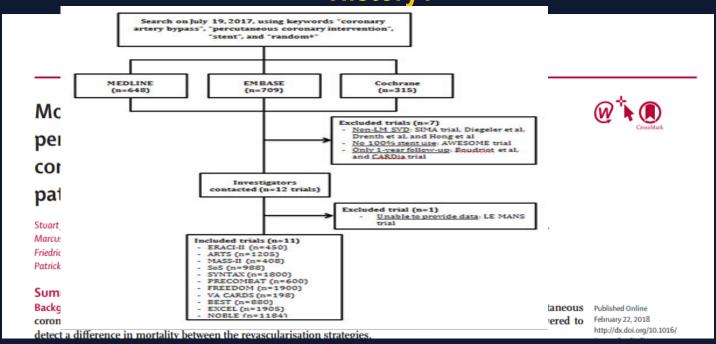
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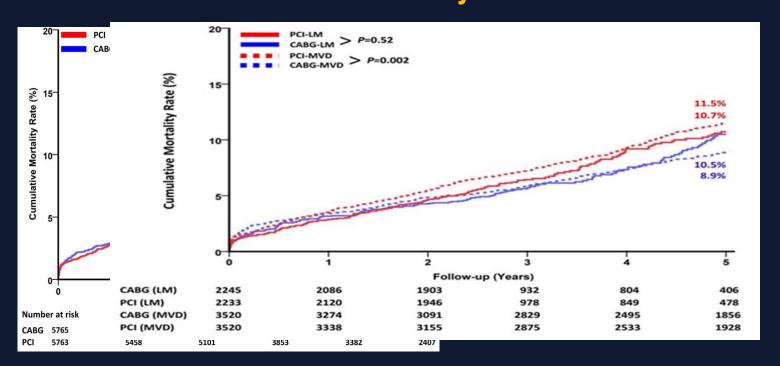
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Mortality Benefit with CABG over PCI with Stents : End of the History?

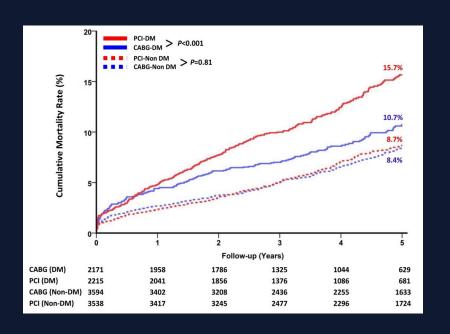


The Lancet., Published online February 22, 2018 http://dx.doi.org/10.1016/S0140-6736(18)30423-9

CIT 2014 Mortality Benefit with CABG over PCI with Stents: End of the History?

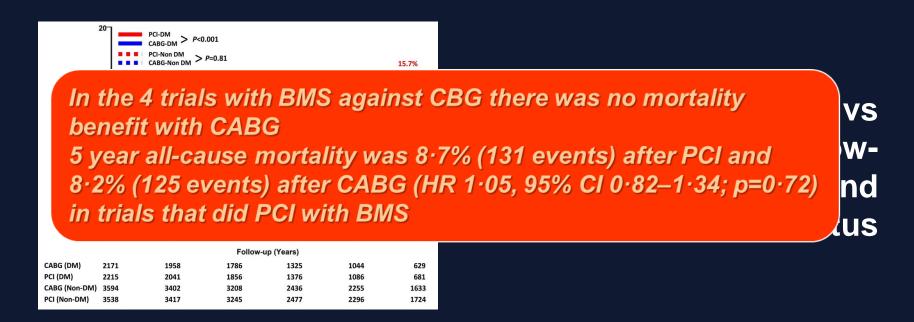


Mortality Benefit with CABG over PCI with Stents: End of the History?



Mortality after CABG vs PCI during 5-year followup of patients with and without diabetes mellitus

Mortality Benefit with CABG over PCI with Stents: End of the History?

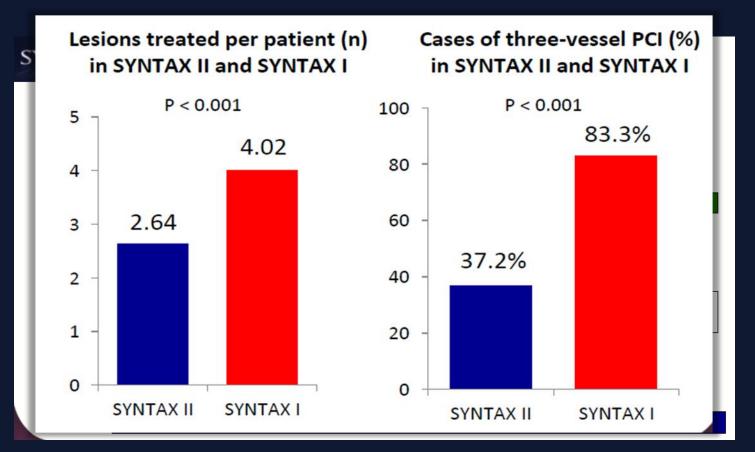


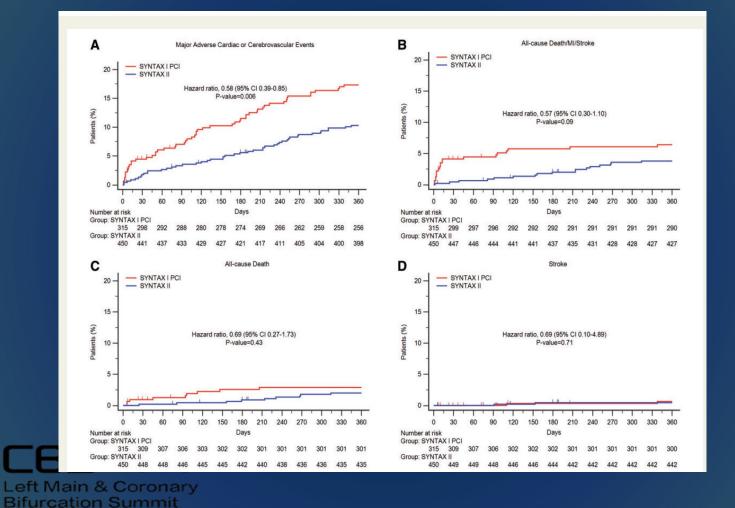
Interventional cardiology

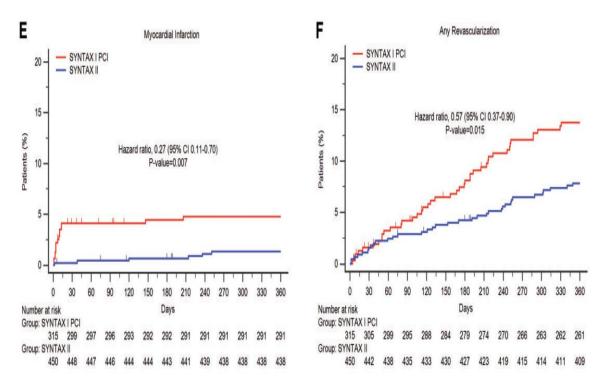
Clinical outcomes of state-of-the-art percutaneous coronary revascularization in patients with de novo three vessel disease: 1-year results of the SYNTAX II study

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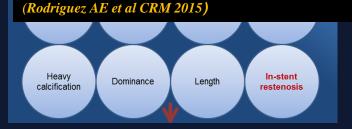




Modifying angiographic syntax score according to PCI strategy: lessons learnt from ERACI IV Study

In addition, excluding all intermediate lesions and severe stenosis in vessels
<2mm, the number of diseased vessels also changed, with the new scoring
13.4% had 1 vessel CAD, 59.8% 2 vessel CAD and 26.8% 3 vessel CAD

osis (≥ 70%) with)

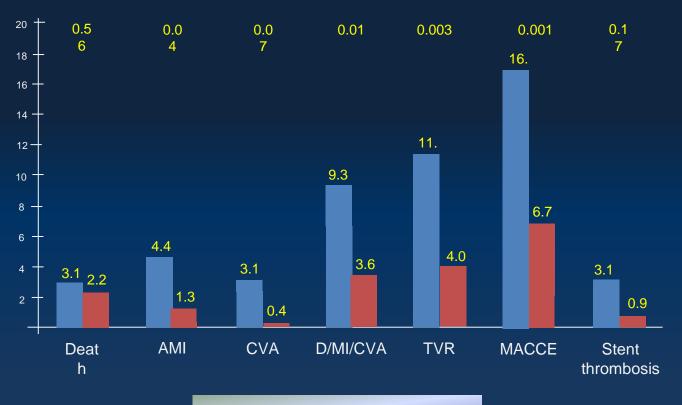


NU

- -Intermediate lesions (50-69%)
- -Severe lesions in vessels with RD ≤ 2 mm

ERACI III vs ERACI IV

Events progression comparison at 2 years of follow-up

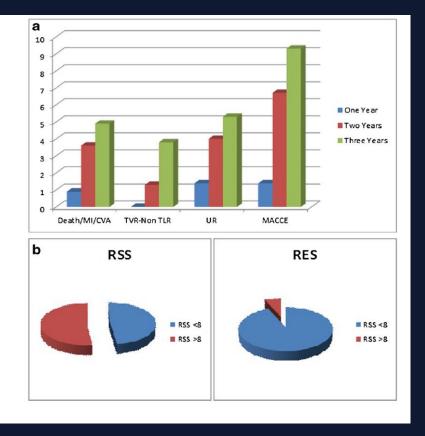


Two years follow-up

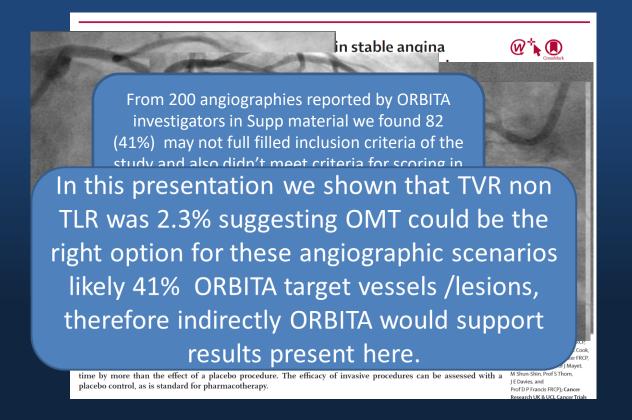
Haiek C, Rodriguez AE et al. Catheter Cardiovasc Interv. 2016 Mar 7



Fig. 1 a Annual follow-up events rate of ERACI IV study, including death, MI, CVA, UR, TVR-non-TLR, and MACCE. b Original Residual Syntax Score (RSS) and Residual ERACI Score (RES) <8 or >8 after PCI in ERACI IV study (P = 0.002between both). MI myocardial infarction, CVA cerebral vascular accident, TVR target vessel revascularization, TLR target lesion revascularization, UR unplanned revascularization, MACCE major adverse cardiovascular events



Lack of External Validation?

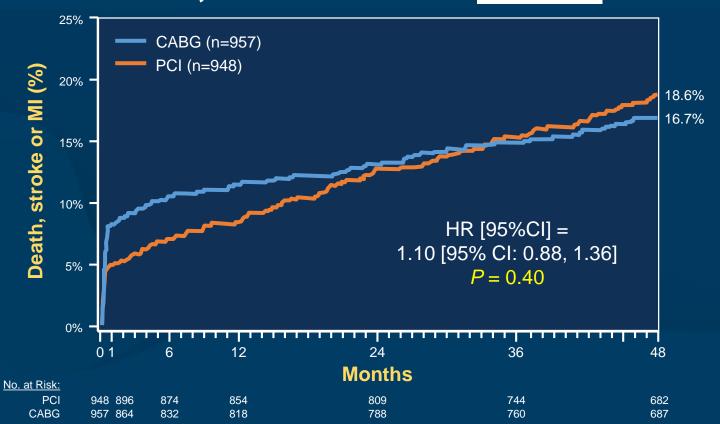


The ORBITA trial: Why is it not the last nail for coronary angioplasty in stable angina patients?

Rodriguez AE; Cardiovasc Revasc Medicine, 2019 Jan;20(1).



Primary Endpoint Death, Stroke or MI at 4 Years





Adjudicated Outcomes at 4 Years (i)

	PCI (n=948)	CABG (n=957)	HR [95%CI]	P-value
Death, stroke or MI (1° endpoint)	18.6%	16.7%	1.10 [0.88, 1.36]	0.40
- Death	10.3%	7.4%	1.39 [1.02, 1.89]	0.04
- Definite cardiovascular	4.3%	3.6%	1.17 [0.74, 1.86]	0.50
- Definite non-cardiovascular	5.3%	3.3%	1.61 [1.01, 2.56]	0.04
- Undetermined cause	1.1%	0.7%	1.49 [0.53, 4.19]	0.45
- Stroke	2.6%	3.3%	0.76 [0.44, 1.31]	0.32
- MI	9.5%	8.8%	1.05 [0.77, 1.42]	0.76
- Peri-procedural	3.9%	6.1%	0.65 [0.43, 0.98]	0.04
- Spontaneous	5.7%	3.2%	1.77 [1.12, 2.82]	0.01
- STEMI	1.9%	2.8%	0.65 [0.35, 1.19]	0.16
- Non-STEMI	7.8%	6.3%	1.22 [0.86, 1.72]	0.26



Primary Endpoint Landmark Analysis (post hoc)

	From randomization to 30 days			From 30 days to 4 years				
	PCI (n=948)	CABG (n=957)	HR [95%CI]	P value	PCI (n=933)	CABG (n=929)	HR [95%CI]	P value
Death, stroke or MI	4.9%	7.9%	0.61 [0.42, 0.88]	0.008	14.8%	10.1%	1.48 [1.14, 1.93]	0.003
- Death	1.0%	1.1%	0.90 [0.37, 2.22]	0.82	9.4%	6.5%	1.47 [1.05, 2.05]	0.02
- Stroke	0.6%	1.3%	0.50 [0.19, 1.33]	0.15	2.0%	2.2%	0.94 [0.49, 1.79]	0.85
- MI	3.9%	6.2%	0.63 [0.42, 0.95]	0.02	5.7%	3.0%	1.92 [1.19, 3.08]	0.006

Stroke and MI rates are non-hierarchical; i.e. include fatal and non-fatal events. The 30-day to 4-year landmark period includes all randomized pts at day 30 except those who died before day 30. Thus there may be some patients with a stroke or MI within 30 days who have a second event between 30 days and 4 years.

10-Year Outcomes of Stents Versus Coronary Artery Bypass Grafting for Left Main Coronary Artery Disease



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ABSTRACT

BACKGROUND Comparative outcomes of coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) for left main coronary artery (LMCA) disease were previously reported. However, data on very long-term (>10 years) outcomes are limited.

OBJECTIVES The authors compare 10-year outcomes after PCI and CABG for LMCA disease.

METHODS In this observational study of the MAIN-COMPARE (Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty versus Surgical Revascularization) registry, the authors evaluated 2,240 patients with unprotected LMCA disease who underwent PCI (n=1,102) or underwent CABG (n=1,138) between January 2000 and June 2006. Adverse outcomes (death; a composite outcome of death, Q-wave myocardial infarction, or stroke; and target-vessel revascularization) were compared with the use of propensity scores and inverse-probability-weighting adjustment. The follow-up was extended to at least 10 years of all patients (median 12.0 years).

RESULTS In the overall cohort, there was no significant difference in adjusted risks of death and the composite outcome between the groups up to 10 years. The risk of target-vessel revascularization was significantly higher in the PCI group. In the cohort comparing drug-eluting stents and concurrent CABG, the 2 study groups did not differ significantly in the risks of death and the composite outcome at 5 years. However, after 5 years, drug-eluting stents were associated with higher risks of death (hazard ratio: 1.35; 95% confidence interval: 1.00 to 1.81) and the composite outcome (hazard ratio: 1.46; 95% confidence interval: 1.10 to 1.94) compared with CABG.

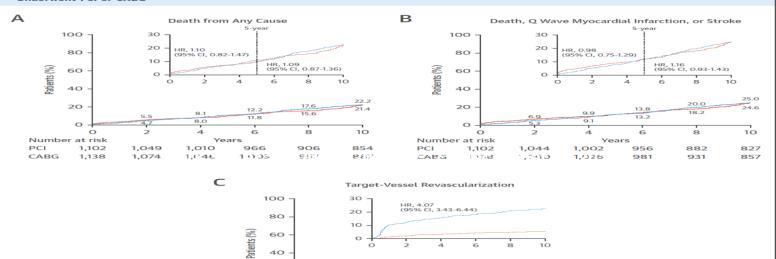
CONCLUSIONS In patients with significant LMCA disease, as compared with CABG, PCI showed similar rates of death and serious composite outcomes, but a higher rate of target-vessel revascularization at 10 years. However, CABG showed lower mortality and serious composite outcome rates compared with PCI with drug-eluting stents after 5 years. (Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty versus Surgical Revascularization [MAIN-COMPARE]; NCTO2791412) (J Am Coll Cardiol 2018;72:2813–22) © 2018 by the American College of Cardiology Foundation.

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CIT 2019 10 Years Outcome of Stents vs CABG



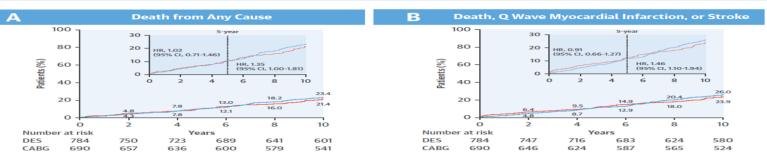


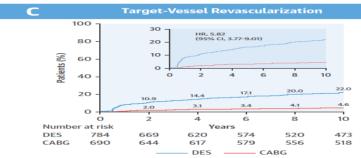


22.6 20.7 18.1 20 12.5 5.4 3.4 4.3 5.0 O 4 6 8 10 Number at risk Years PCI 1,102 920 854 793 724 667 CABG 1.138 1.052 1.011 910 840

(A) Death from any cause. (B) Death, Q-wave myocardial infarction, or stroke. (C) Target-vessel revascularization. In each panel, the inset shows the same data on an enlarged y-axis. HRs are for the PCI group, as compared with the CABG group. CABG = coronary artery bypass grafting; CI = confidence interval; DES = druq-eluting stent(s); HR = hazard ratio; PCI = percutaneous coronary intervention.

CENTRAL ILLUSTRATION Long-Term Outcomes of Drug-Eluting Stents Versus Coronary Artery Bypass Grafting for Left Main Disease





Park, D.-W. et al. J Am Coll Cardiol. 2018;72(23):2813-22.

Adjusted 10-year event rates with the use of inverse probability weighting in the wave 2 cohort of patients who underwent DES or concurrent CABG. (A) Death from any cause. (B) Death, Q-wave myocardial infarction, or stroke. (C) Target-vessel revascularization. In each panel, the inset shows the same data on an enlarged y-axis. HRs are for the DES group, as compared with the CABG group. CABG = coronary artery bypass grafting: CI = confidence interval: DES = drug-eluting stent(s): HR = hazard ratio: PCI = percutaneous coronary intervention.

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Late Mortality After Drug-Eluting, Bare-Metal Stents, and Coronary Bypass Surgery in Left Main Disease



In a recent issue of the *Journal*, Park et al. (1) published the 10-year follow-up results of the MAIN-COMPARE (Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty versus Surgical Revascularization) study in patients with unprotected left main (LM) stenosis.

Once again, a significant late loss of the initial benefit of drug-eluting stents (DES) over coronary artery bypass grafting (CABG) was observed in terms of serious composite events and mortality. Of interest, mortality benefit with CABG was only noted in the DES group, whereas in patients treated with bare-metal stents (BMS), no differences were seen (1).

The findings of this study should not be a surprise; despite the fact that patients treated with BMS may have a lower-risk profile and BMS are mostly used in ostial and midshaft lesions, we are seeing an attrition in the efficacy of DES over time to the extent we have not seen with BMS (1-3).

The results of this study are in agreement with a recent meta-analysis of randomized trials in which low CABG mortality compared with that of stents was only seen in the DES group (3).

The EXCEL (Evaluation of XIENCE Everolimus Eluting Stent Versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization) and NOBLE (Nordic-Baltic-British Left Main Revascularization Study) trials at 4 and 5 years of follow-up, respectively (4,5), have shown a significantly greater incidence of hard late adverse events, compared with CABG despite the use of newgeneration DES.

In fact, all DES randomized data, old and new, consistently showed a benefit with CABG in patients with multiple-vessel and LM disease (1,3-5).

It is time to explore plausible explanations for these results, searching for potential solutions: percutaneous coronary intervention strategy, stent designs including DES/BMS effectiveness, and adjunctive medications. Otherwise, percutaneous coronary intervention in multiple-vessel or LM disease, in intermediate- or high-risk patients (3), should be indicated only if patients were poor CABG candidates or had a short life expectancy.

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Please note: All authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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REPLY: Late Mortality After Drug-Eluting, Bare-Metal Stents, and Coronary Bypass Surgery in Left Main Disease



Although a randomized clinical trial is the ideal method to evaluate the unbiased treatment effect of myocardial revascularization strategies, well-conducted observational studies, such as the MAIN-COMPARE (Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty Versus Surgical Revascularization) registry, can provide insightful information on long-term effectiveness and safety of revascularization methods in a broader range of patients encountered in the real-world setting.

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Interpretacion de estos Hallazgos

- -Existirian claras diferencias en la "performance" entre DES, BMS y CABG durante diferentes periodos del follow up.
- En el 1er ano DES (2da generacion) muestra claros beneficios de seguridad y eficacia comparado con BMS y CABG. Menor TVR-MI y TLR comparado a BMS y menor incidencia a 30 dias de muerte/IAM y CVA comparado a CABG.
- -Sin embargo, estamos viendo una perdida de esta ganancia con DES luego del 1er ano de follow up que no es vista en el mismo tiempo de follow up tanto con BMS y CABG. Estas desventajas se trasladan a una mayor incidencia de mortalidad e infarto espontaneo con DES cuando comparamos con la CABG.
- -De manera que nosotros necesitamos una estrategia de PCI que combine la seguridad y eficacia de DES (2da generacion) dentro del 1er ano con la eficacia de BMS luego del mismo.

La estrategia de PCI quiada por FFR (SYNTAX II) o con escores de riesgo como el ERACI score asociados a DES con muy poca cantidad de droga y localizada solo en zonas abluminales (polimeros BIO) podrian ser la respuesta adecuada para reducir este reciente e inesperado "gap" entre PCI y CABG en MVD.

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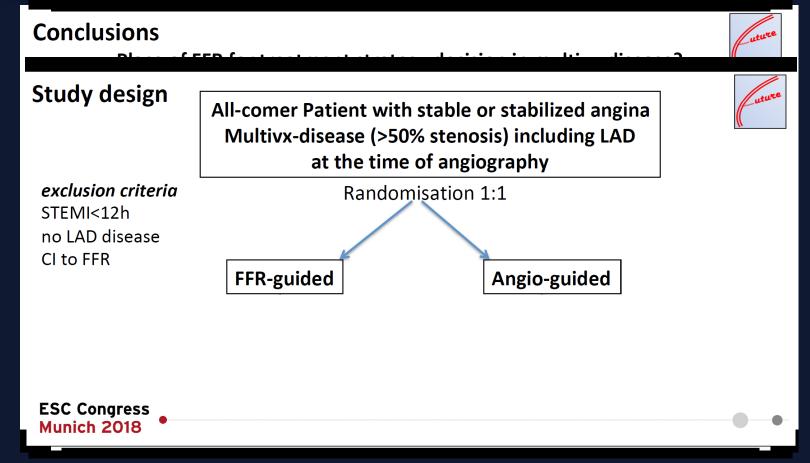
ORIGINAL STUDIES

Safety and efficacy of a novel abluminal groove-filled biodegradable polymer sirolimus-eluting stent for the treatment of de novo coronary lesions: Final five-year results of the patient-level pooled analysis from the TARGET I and TARGET II trials

TABLE 2 Clinical outcomes up to 5 years

	1 year (n = 1,003)	2 years (n = 992)	3 years (n = 983)	4 years (n = 971)	5 years (n = 947)
Death	8 (0.8%)	14 (1.4%)	24 (2.4%)	26 (2.7%)	39 (4.1%)
Cardiac death	5 (0.5%)	8 (0.8%)	14 (1.4%)	15 (1.5%)	18 (1.9%)
MI	28 (2.8%)	31 (3.1%)	35 (3.6%)	42 (4.3%)	45 (4.8%)
Target vessel MI	28 (2.8%)	29 (2.9%)	32 (3.3%)	34 (3.5%)	36 (3.8%)
Any revascularization	29 (2.9%)	41 (4.1%)	58 (5.9%)	76 (7.8%)	90 (9.5%)
ID-TLR	9 (0.9%)	12 (1.2%)	19 (1.9%)	27 (2.8%)	33 (3.5%)
TLF	39 (3.9%)	46 (4.6%)	59 (6.0%)	68 (7.0%)	77 (8.1%)
PoCE	41 (4.1%)	77 (7.8%)	101 (10.3%)	121 (12.5%)	149 (15.7%)
Definite/probable ST	1 (0.1%)	1 (0.1%)	3 (0.3%)	4 (0.4%)	5 (0.5%)

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Fractional Flow Reserve Versus Angiographically-Guided Coronary Artery Bypass Grafting



Anne Langhoff Thuesen, MD, ^a Lars Peter Riber, MD, PhD, ^b Karsten Tange Veien, MD, ^a Evald Høj Christiansen, MD, PhD, ^c Svend Eggert Jensen, MD, PhD, ^d Ivy Modrau, MD, DMScI, ^e Jan Jesper Andreasen, MD, PhD, ^{f,g} Anders Junker, MD, PhD, ^a Poul Erik Mortensen, MD, bLisette Okkels Jensen, MD, DMScI, PhD^a

ABSTRACT

BACKGROUND The value of fractional flow reserve (FFR) evaluation of coronary artery stenosis in coronary artery bypass grafting (CABG) is uncertain, and stenosis assessments usually rely on visual estimates of lesion severity.

OBJECTIVES This randomized clinical trial evaluated graft patency and clinical outcome after FFR-guided CABG versus angiography-guided CABG.

METHODS A total of 100 patients referred for CABG were randomly assigned to FFR-guided or angiography-guided CABG. Based on the coronary angiogram, a heart team made a graft plan for all patients, and FFR evaluations were performed. In FFR-guided CABG, coronary lesions with FFR >0.80 were deferred, and a new graft plan was designed accordingly, whereas the surgeon was blinded to the FFR values in patients who underwent angiography-guided CABG. The primary endpoint was graft failure in the percentage of all grafts after 6 months.

RESULTS Angiographic follow-up at 6 months was available for 72 patients (39 vs. 33 in the FFR-guided and angiography-guided groups, respectively). Graft failures of all grafts were similar in both groups (16% vs. 12%; p=0.97). Rates of death, myocardial infarction, and stroke were also similar in the study groups, and no difference was seen in revascularization before angiographic follow-up. After 6 months, deferred lesions (n=24) showed a significant reduction in mean FFR from index to follow-up (0.89 ± 0.05 vs. 0.81 ± 0.11 ; p=0.002). Index FFR did not influence graft patency.

CONCLUSIONS FFR-guided CABG had similar graft failure rates and clinical outcomes as angiography-guided CABG. However, FFR was reduced significantly after 6 months in deferred lesions. (Fractional Flow Reserve Versus Angiography Randomization for Graft Optimization [FARGO]; NCTO2477371) (J Am Coll Cardiol 2018;72:2732-43) © 2018 by the American College of Cardiology Foundation.

Fractional Flow Reserve Versus Angiographically-Guided Coronary Artery Bypass Grafting



Anne Langhoff Thuesen, MD, ^a Lars Peter Riber, MD, PhD, ^b Karsten Tange Veien, MD, ^a Evald Høj Christiansen, MD, PhD, ^c Svend Eggert Jensen, MD, PhD, ^d Ivy Modrau, MD, DMScI, ^e Jan Jesper Andreasen, MD, PhD, ^{f,g} Anders Junker, MD, PhD, ^a Poul Erik Mortensen, MD, bLisette Okkels Jensen, MD, DMScI, PhD^a

ABSTRACT

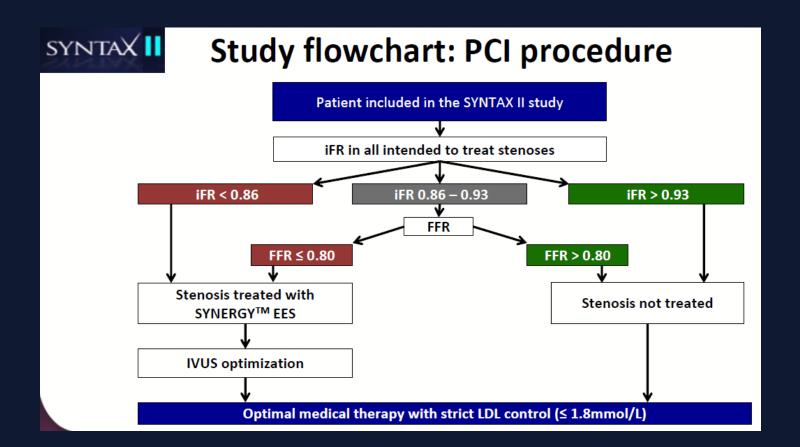
BACKGROUND The value of fractional flow reserve (FFR) evaluation of coronary artery stenosis in coronary artery bypass grafting (CABG) is uncertain, and stenosis assessments usually rely on visual estimates of lesion severity.

OBJECTIVES This randomized clinical trial evaluated graft patency and clinical outcome after FFR-guided CABG versus angiography-guided CABG.

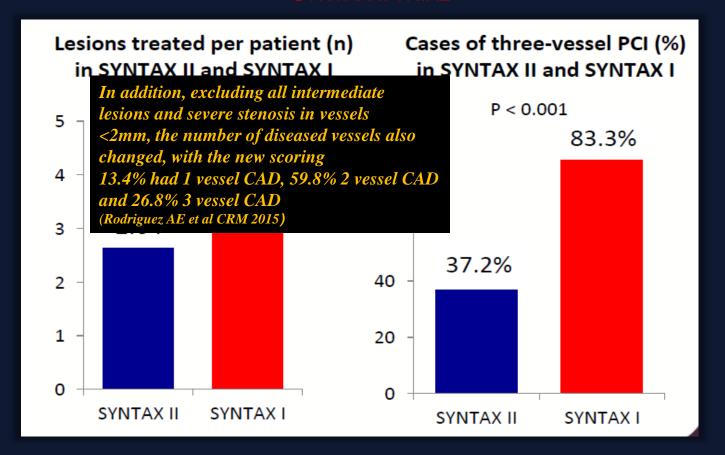
METHODS A total of 100 patients referred for CABG were randomly assigned to FFR-guided or angiography-guided CABG. Based on the coronary angiogram, a heart team made a graft plan for all patients, and FFR evaluations were performed. In FFR-guided CABG, coronary lesions with FFR >0.80 were deferred, and a new graft plan was designed accordingly, whereas the surgeon was blinded to the FFR values in patients who underwent angiography-guided CABG. The primary endpoint was graft failure in the percentage of all grafts after 6 months.

RESULTS Angiographic follow-up at 6 months was available for 72 patients (39 vs. 33 in the FFR-guided and angiography-guided groups, respectively). Graft failures of all grafts were similar in both groups (16% vs. 12%; p=0.97). Rates of death, myocardial infarction, and stroke were also similar in the study groups, and no difference was seen in revascularization before angiographic follow-up. After 6 months, deferred lesions (n=24) showed a significant reduction in mean FFR from index to follow-up (0.89 ± 0.05 vs. 0.81 ± 0.11 ; p=0.002). Index FFR did not influence graft patency.

CONCLUSIONS FFR-guided CABG had similar graft failure rates and clinical outcomes as angiography-guided CABG. However, FFR was reduced significantly after 6 months in deferred lesions. (Fractional Flow Reserve Versus Angiography Randomization for Graft Optimization [FARGO]; NCTO2477371) (J Am Coll Cardiol 2018;72:2732-43) © 2018 by the American College of Cardiology Foundation.



Impact of intracoronary physiology on PC SYNTAX II TRIAL



ORIGINAL STUDIES

Safety and efficacy of a novel abluminal groove-filled biodegradable polymer sirolimus-eluting stent for the treatment of de novo coronary lesions: Final five-year results of the patient-level pooled analysis from the TARGET I and TARGET II trials

TABLE 2 Clinical outcomes up to 5 years

	1 year (n = 1,003)	2 years (n = 992)	3 years (n = 983)	4 years (n = 971)	5 years (n = 947)
Death	8 (0.8%)	14 (1.4%)	24 (2.4%)	26 (2.7%)	39 (4.1%)
Cardiac death	5 (0.5%)	8 (0.8%)	14 (1.4%)	15 (1.5%)	18 (1.9%)
MI	28 (2.8%)	31 (3.1%)	35 (3.6%)	42 (4.3%)	45 (4.8%)
Target vessel MI	28 (2.8%)	29 (2.9%)	32 (3.3%)	34 (3.5%)	36 (3.8%)
Any revascularization	29 (2.9%)	41 (4.1%)	58 (5.9%)	76 (7.8%)	90 (9.5%)
ID-TLR	9 (0.9%)	12 (1.2%)	19 (1.9%)	27 (2.8%)	33 (3.5%)
TLF	39 (3.9%)	46 (4.6%)	59 (6.0%)	68 (7.0%)	77 (8.1%)
PoCE	41 (4.1%)	77 (7.8%)	101 (10.3%)	121 (12.5%)	149 (15.7%)
Definite/probable ST	1 (0.1%)	1 (0.1%)	3 (0.3%)	4 (0.4%)	5 (0.5%)

Thanks CIT on behalf of

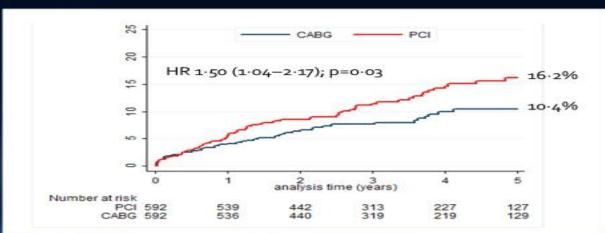
• CACI

NOBLE

Randomized (n=1201)

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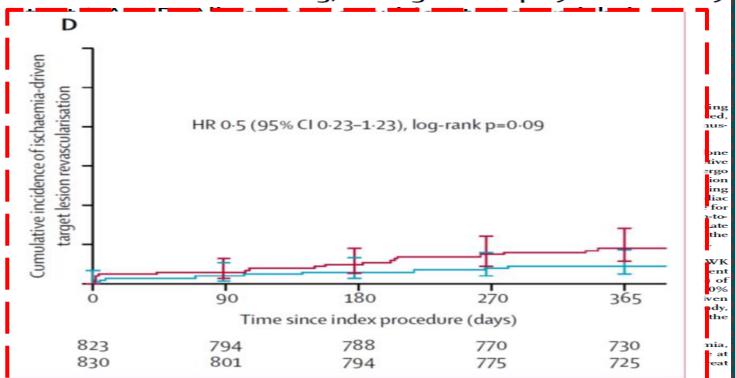
Results Total repeat revascularization

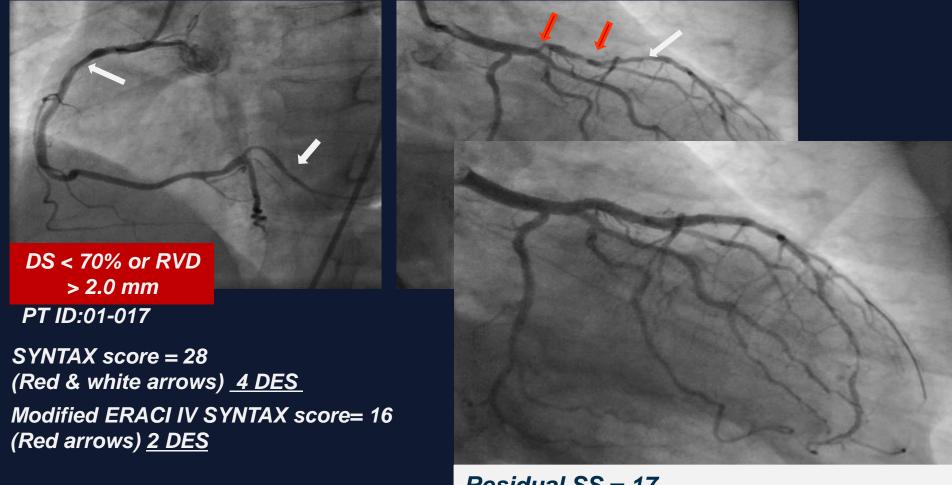


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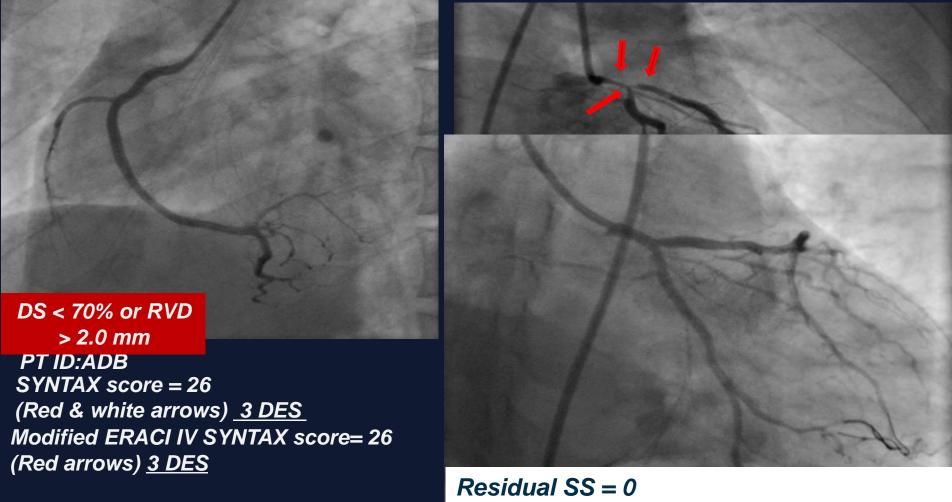


Targeted therapy with a localised abluminal groove, low-dose sirolimus-eluting, biodegradable polymer coronary





Residual SS = 17 Residual ERACI IV SS = 3.5



Residual SS = 0 Residual ERACI IV SS = 0

En Conclusion

- Obviamente no es el Fin de la Controversia entre CABG y PCI en pacientes con multiples vasos y TCI.
- Porque la Controversia lleva 30 anos y nunca termina...
- A partir de estos meta-analisis persisten muchos interrogantes para analizar en futuros sub-analisis:
- Diabetes
- Impact of revascularization on repeat revascularization
- Interaction of age on PCI vs CABG
- Gender
- Geographic disparitis on PCI vs CABG etc

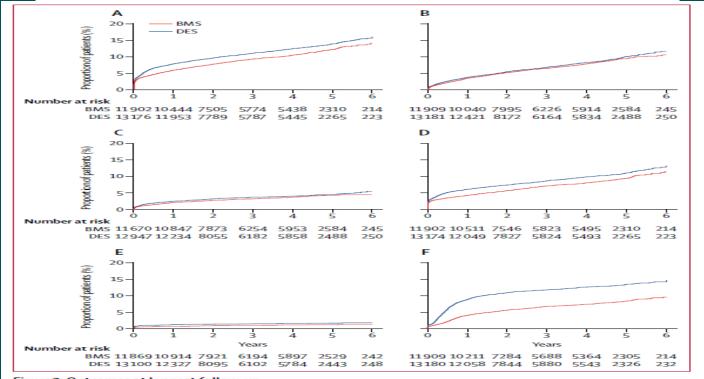
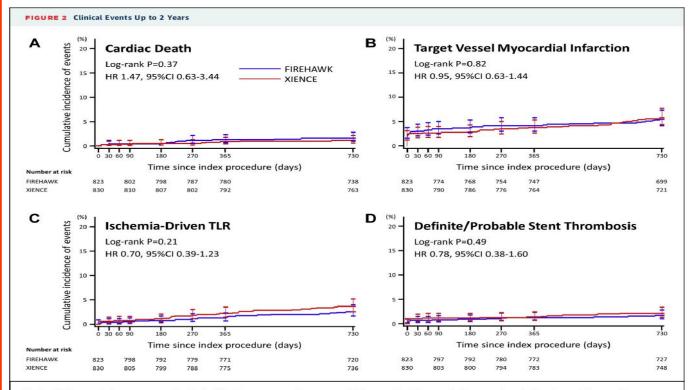


Figure 2: Outcomes at longest follow-up

(A) Cardiac death or myocardial infarction (primary outcome). (B) All-cause death. (C) Cardiac death.

(D) Myocardial infarction. (E) Definite stent thrombosis. (F) Target-vessel revascularisation. BMS=bare-metal stents. DES=new-generation drug-eluting stents.



Kaplan-Meier cumulative event curves for the individual components of target vessel failure and definite or probable stent thrombosis at 2-year follow-up. Events are cardiac death (A), target vessel myocardial infarction (B), ischemia-driven target lesion revascularization (TLR) (C), and definite or probable stent thrombosis (D). CI = confidence interval; HR = hazard ratio.

FIGURE 2 Adjusted 10-Year Event Rates With the Use of Inverse Probability Weighting in the Wave 1 Cohort of Patients Who Underwent BMS or Concurrent CABG

A

Death from Any Cause

B

Death, Q Wave Myocardial Infarction, or Stroke

CONCLUSIONS

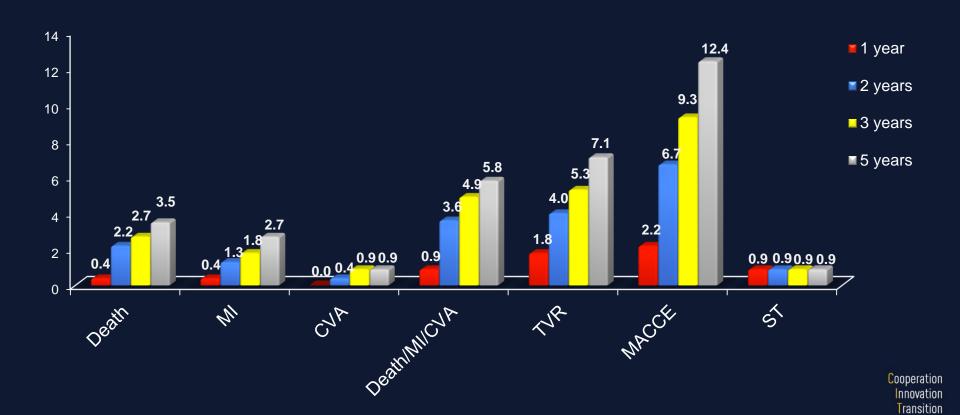
This longest follow-up study of patients with LMCA disease showed no difference in the rates of death and a composite endpoint of death, Q-wave myocardial infarction, or stroke between PCI and CABG at 10 years. However, in the cohort comparing DES and concurrent CABG among patients with more complex clinical and anatomic characteristics, a long-term benefit of CABG over PCI on mortality and hard clinical endpoints was detected after 5 years.

(A) Death from any cause. (B) Death, Q-wave myocardial infarction, or stroke. (C) Target-vessel revascularization. In each panel, the inset shows the same data on an enlarged y-axis. HRs are for the BMS group, as compared with CABG group. BMS = bare-metal stent(s); other abbreviations as in Figure 1.

Cooperation Innovation Transition

CIT 2018

ERACIIV Cumulative outcome of hard clinical endpoints comparison between first, second, third and five years of follow-up



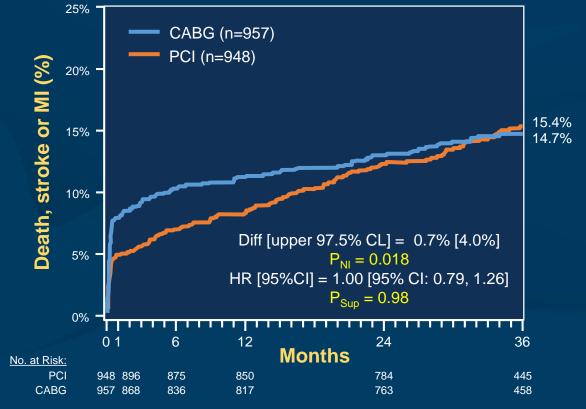
Interpretation of These Findings

- -There are diffrences in outcome among DES, BMS and CABG during different follow up periods.
- During 1st year DES showed clear safety /efficacy advantages over BMS and CABG. Less TVR-MI and TLR compared to BMS and less 30 days death/MI and CVA compared to CABG.
- -However, beyond 1st year we are seeing and attrition of efficacy of DES over the time to the extend we have not seen either with BMS or CABG. These disadvantages translated to poor overall outcome when compared to CABG.
- -Therefore, we should needed a PCI strategy /stent design who combined safety/effectiveness of 1st year DES designs with late safety /effectiveness of old BMS designs.

Cooperation Innovation Transition



Primary Endpoint Death, Stroke or MI at Median 3 Years



Stone GW et al. N Engl J Med 2016;375:2223-35