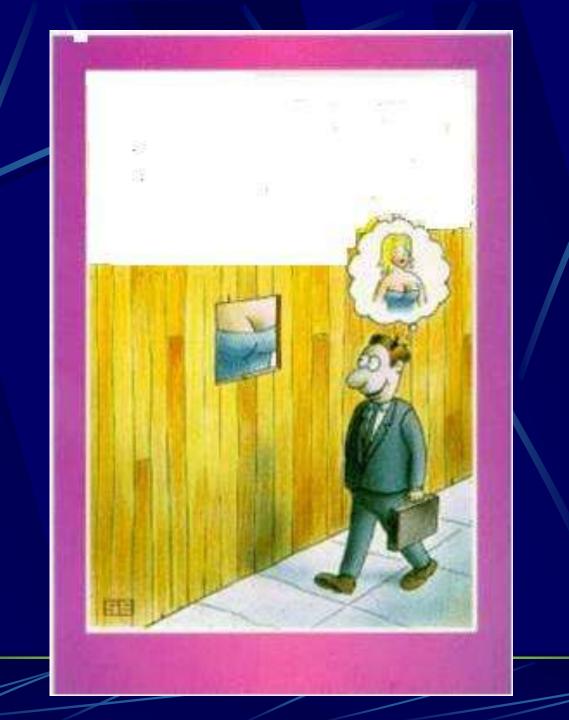
## Tam revaskülarizasyonda CABG standart tedavidir

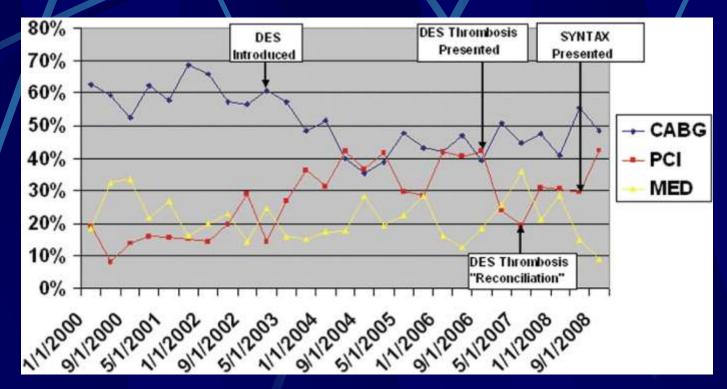
Dr. Cem Alhan



Gögüs Kalp Damar Anestezi ve Yoğun Bakım Derneği



Changing patterns of initial treatment selection among medical therapy (MED, yellow line), percutaneous coronary intervention (PCI, red line), and coronary artery bypass grafting (CABG, blue line) from 2000 to 2008 at Duke University in 10,149 patients



Smith P. K.; Ann Thorac Surg 2009;87:1328-1331

# The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

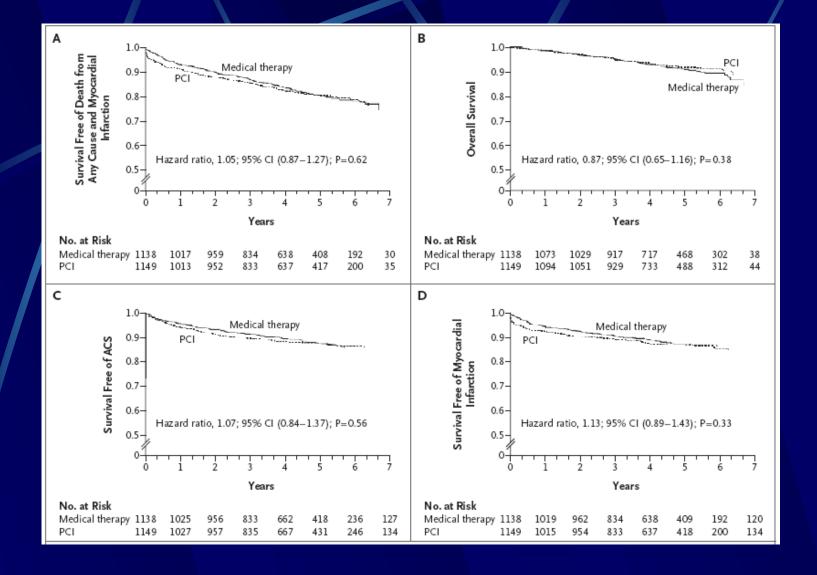
APRIL 12, 2007

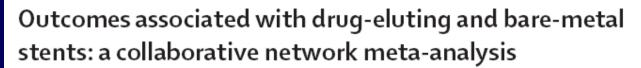
VOL. 356 NO. 15

## Optimal Medical Therapy with or without PCI for Stable Coronary Disease

William E. Boden, M.D., Robert A. O'Rourke, M.D., Koon K. Teo, M.B., B.Ch., Ph.D., Pamela M. Hartigan, Ph.D., David J. Maron, M.D., William J. Kostuk, M.D., Merril Knudtson, M.D., Marcin Dada, M.D., Paul Casperson, Ph.D., Crystal L. Harris, Pharm.D., Bernard R. Chaitman, M.D., Leslee Shaw, Ph.D., Gilbert Gosselin, M.D., Shah Nawaz, M.D., Lawrence M. Title, M.D., Gerald Gau, M.D., Alvin S. Blaustein, M.D., David C. Booth, M.D., Eric R. Bates, M.D., John A. Spertus, M.D., M.P.H., Daniel S. Berman, M.D., G.B. John Mancini, M.D., and William S. Weintraub, N.D., for the COURAGE Trial Research Group\*

Table 1. (Continued.)			
Characteristic	PCI Group (N=1149)	Medical-Therapy Group (N=1138)	P Value
Angiographic			
Vessels with disease — no. (%)			0.72
1	361 (31)	343 (30)	
2	446 (39)	439 (39)	
3	341 (30)	355 (31)	
Disease in graft¶	77 (62)	85 (69)	0.36
Proximal LAD disease	360 (31)	417 (37)	0.01
Ejection fraction	60.8±11.2	60.9±10.3	0.86





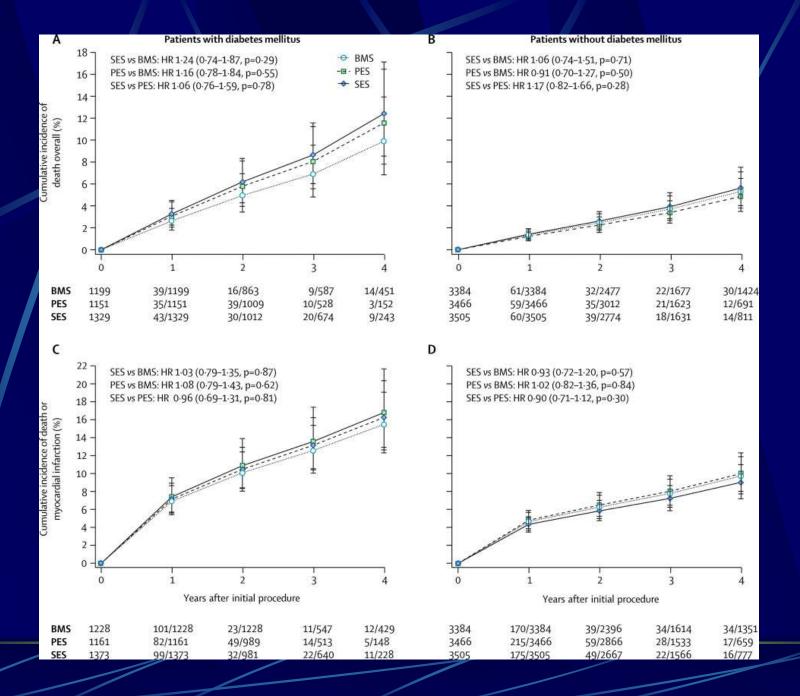


Christoph Stettler, \* Simon Wandel, \* Sabin Allemann, Adnan Kastrati, Marie Claude Morice, Albert Schömig, Matthias E Pfisterer, Gregg W Stone, Martin B Leon, José Suarez de Lezo, Jean-Jacques Goy, Seung-Jung Park, Manel Sabaté, Maarten J Suttorp, Henning Kelbaek, Christian Spaulding, Maurizio Menichelli, Paul Vermeersch, Maurits T Dirksen, Pavel Cervinka, Anna Sonia Petronio, Alain J Nordmann, Peter Diem, Bernhard Meier, Marcel Zwahlen, Stephan Reichenbach, Sven Trelle, Stephan Windecker, Peter Jüni

#### Summary

Background Whether the two drug-eluting stents approved by the US Food and Drug Administration—a sirolimus-eluting stent and a paclitaxel-eluting stent—are associated with increased risks of death, myocardial infarction, or stent thrombosis compared with bare-metal stents is uncertain. Our aim was to compare the safety and effectiveness of these stents.

Lancet 2007; 370: 937-48
See Comment page 914
\*Contributed equally to this report

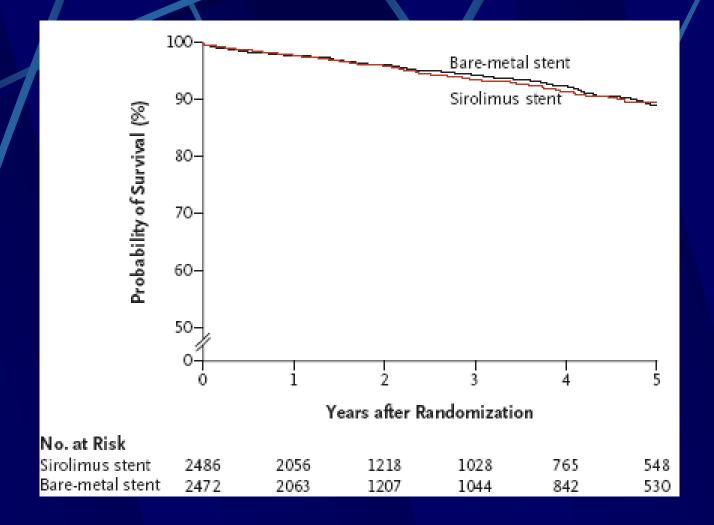


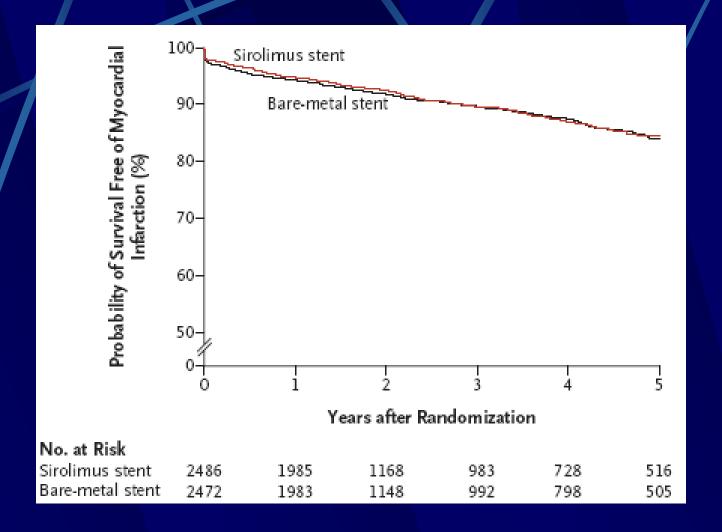
The NEW ENGLAND JOURNAL of MEDICINE

#### ORIGINALARTICLE

### Analysis of 14 Trials Comparing Sirolimus-Eluting Stents with Bare-Metal Stents

Adnan Kastrati, M.D., Julinda Mehilli, M.D., Jürgen Pache, M.D., Christoph Kaiser, M.D., Marco Valgimigli, M.D., Ph.D., Henning Kelbæk, M.D., Maurizio Menichelli, M.D., Manel Sabaté, M.D., Maarten J. Suttorp, M.D., Ph.D., Dietrich Baumgart, M.D., Melchior Seyfarth, M.D., Matthias E. Pfisterer, M.D., and Albert Schömig, M.D.





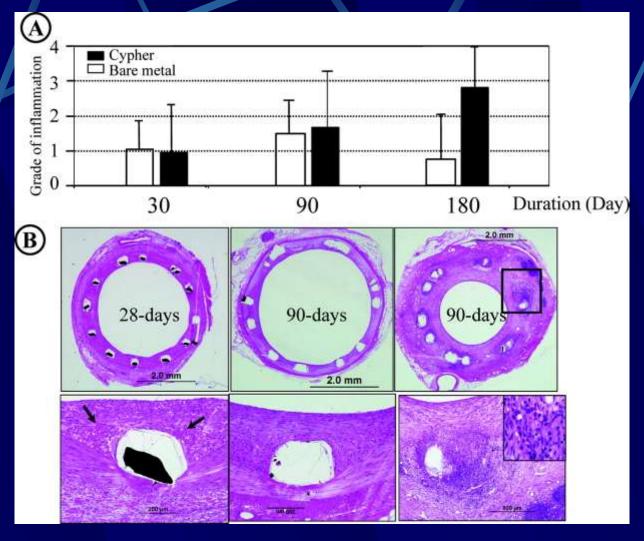
### DES; 'gecikmiş arteryel iyileşme'

### Vascular Responses to Drug Eluting Stents Importance of Delayed Healing

Aloke V. Finn, Gaku Nakazawa, Michael Joner, Frank D. Kolodgie, Erik K. Mont, Herman K. Gold, Renu Virmani

Abstract—Polymer-based sirolimus- (Cypher) and paclitaxel-eluting (Taxus) drug eluting stents have become the treatment of choice for patients with symptomatic coronary artery disease undergoing percutaneous coronary intervention (PCI). Although these stents reduce rates of restenosis compared with bare metal stents (BMS), late thrombosis, a life threatening complication, has emerged as a major safety concern. Our understanding of the pathophysiology of late DES thrombosis is derived from animal and human pathologic samples taken after implantation of these devices. These data indicate that both DES cause substantial impairment in arterial healing characterized by lack of complete reendothelialization and persistence of fibrin when compared with BMS. This delayed healing is the primary substrate underlying all cases of late DES thrombosis at autopsy. Several additional risk factors for late stent thrombosis such as penetration of necrotic core, malapposition, overlapping stent placement, excessive stent length, and bifurcation lesions represent additional barriers to healing and should be avoided if DES are to be used to minimize the risk of late thrombosis. Because the time course of complete healing with DES in man is unknown, the optimal duration of antiplatelet treatment remains to be determined. (Arterioscler Thromb Vasc Biol. 2007;27:1500-1510.)

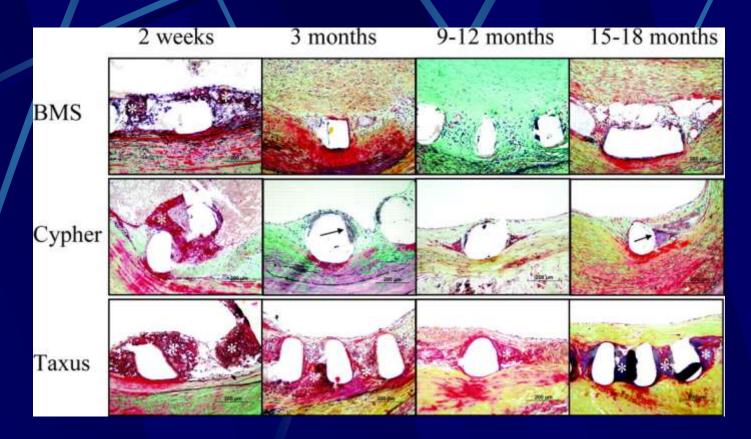
## İnflamasyonun karşılaştırılması; BMS vs. Cypher



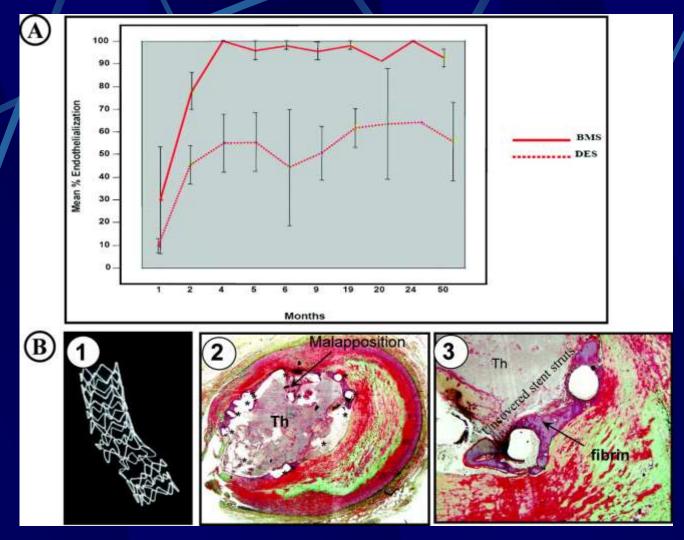
Finn, A. V. et al. Arterioscler Thromb Vasc Biol 2007;27:1500-1510



# Stent sonrası morfolojik değişikliler; DES (Cypher, Taxus) vs. BMS



## Reendotelizasyon; BMS vs. DES







### DES; endotelyal disfonksiyon



European Heart Journal (2006) 27, 166-170 doi:10.1093/eurheartj/ehi571 Clinical research

## Indication of long-term endothelial dysfunction after sirolimus-eluting stent implantation

Sjoerd H. Hofma, Wim J. van der Giessen\*, Bas M. van Dalen, Pedro A. Lemos, Eugene P. McFadden, Georgios Sianos, Jurgen M.R. Ligthart, Dirk van Essen, Pim J. de Feyter, and Patrick W. Serruys

Department of Cardiology, Thoraxcenter, Erasmus MC, Bd 412, Dr Molewaterplein 40, 3015 GD Rotterdam, The Netherlands

Received 5 October 2004; revised 11 August 2005; accepted 25 August 2005; online publish-ahead-of-print 25 October 2005

See page 125 for the editorial comment on this article (doi:10.1093/eurheartj/ehi641)

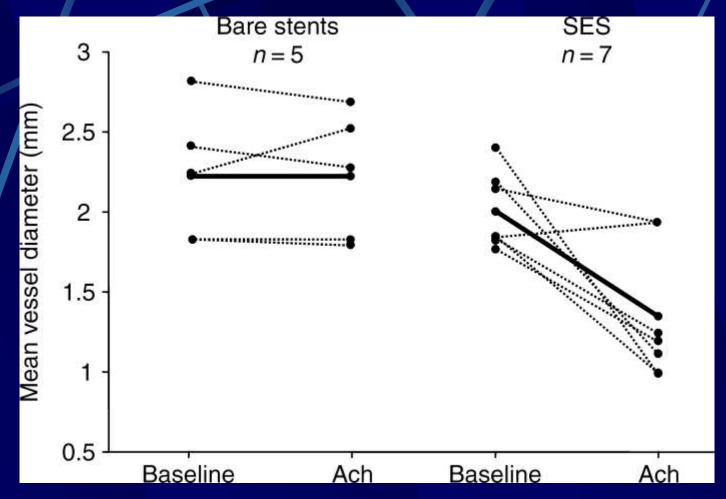
#### **KEYWORDS**

Coronary stents; Drugs; Endothelium Aims Endothelial dysfunction has been related both to progression of atherosclerotic disease and to future cardiovascular events. We assessed local epicardial endothelial function 6 months after sirolimus-eluting stent (SES) or bare metal stent (BS) implantation.

Methods and results In 12 patients (seven SES, five BS), endothelium-dependent vasomotion of a coronary segment 15 mm in length, starting 2 mm distal to the stent, was assessed with quantitative coronary angiography immediately after the procedure and at 6 months follow-up, after intracoronary infusion of acetylcholine. Intravascular ultrasound (IVUS) was performed and coronary flow reserve (CFR) assessed in all patients. At follow-up significant vasoconstriction was seen in SES (median 32% diameter reduction from baseline) but not in BS (median 2% reduction) patients after acetylcholine infusion (P = 0.03 for SES vs. BS); endothelium-independent vasodilatation to nitrates did not differ significantly between groups (20% SES, 5% BS, P = 0.14). IVUS revealed no late unhealed dissections and CFR was comparable between groups (SES 3.1 vs. BS 3.2, n.s.).

Conclusion SES implantation may have an adverse effect on local endothelium-dependent vasomotor responses compared with BS implantation at 6 months. Long-term clinical consequences of this observation are still unknown.

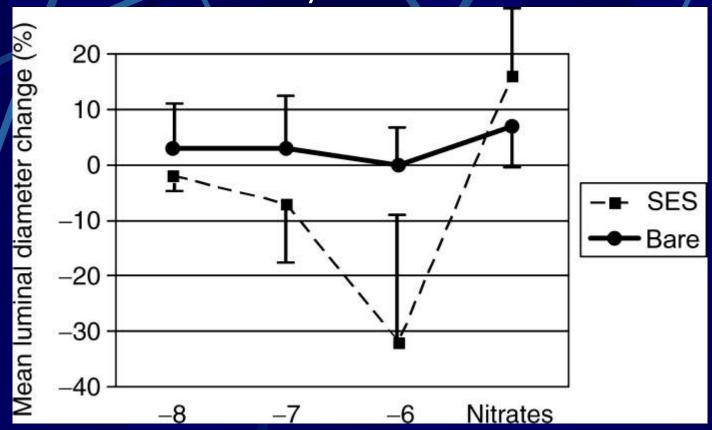
# Koroner arter segment çapı; BMS vs. DES ortalama ve Ach infüzyonu sonrası max. değerler (6aylık takip)



Hofma, S. H. et al. Eur Heart J 2006 27:166-170

### Koroner intraluminal çap: BMS vs DES

6 aylık takip; artan konsantrasyonlarda intrakoroner Ach infüzyonu sonrası



Hofma, S. H. et al. Eur Heart J 2006 27:166-170

### DES; kollateral dolaşım

## Coronary Collateral Function Long After Drug-Eluting Stent Implantation

Pascal Meier, MD, Rainer Zbinden, MD, Mario Togni, MD, Peter Wenaweser, MD, Stephan Windecker, MD, Bernhard Meier, MD, FACC, FESC, Christian Seiler, MD, FACC, FESC Bern, Switzerland

**Objectives** 

This study was designed to compare coronary collateral function in patients after bare-metal stent (BMS) or drug-eluting stent (DES) implantation.

Background

Drug-eluting stents have an inhibitory effect on the production of cytokines, chemotactic proteins, and growth factors, and may therefore negatively affect coronary collateral growth.

Methods

A total of 120 patients with long-term stable coronary artery disease (CAD) after stent implantation were included. Both the BMS group and the DES group comprised 60 patients matched for in-stent stenosis severity of the vessel undergoing collateral flow index (CFI) measurement at follow-up and for the duration of follow-up. The primary end point of the investigation was invasively determined coronary collateral function 6 months after stent implantation. Collateral function was assessed by simultaneous aortic, coronary wedge, and central venous pressure measurements (yielding CFI) and by intracoronary electrocardiogram during balloon occlusion.

Results

There were no differences between the groups regarding age, gender, body mass index, frequency of cardiovascular risk factors, use of cardiovascular drugs, severity of CAD, or site of coronary artery stenoses. Despite equal in-stent stenosis severity ( $46 \pm 34\%$  and  $45 \pm 36\%$ ) and equal follow-up duration ( $6.2 \pm 10$  months and  $6.5 \pm 5.4$  months), CFI was diminished in the DES versus BMS group ( $0.154 \pm 0.097$  vs.  $0.224 \pm 0.142$ ; p = 0.0049), and the rate of collaterals insufficient to prevent ischemia during occlusion (intracoronary electrocardiographic ST-segment elevation  $\geq 0.1$  mV) was higher with 50 of 60 patients in the DES group and 33 of 60 patients in the BMS group (p = 0.001).

Conclusions

Collateral function long after coronary stenting is impaired with DES (sironmus and paclitaxel) when compared with BMS. Considering the protective nature of collateral vessels, this could lead to more serious cardiac events in the presence of an abrupt coronary occlusion. (J Am Coll Cardiol 2007;49:15–20) © 2007 by the American College of Cardiology Foundation

# Coronary Stenting and Inflammation: Implications for Further Surgical and Medical Treatment

Walter J. Gomes, MD, PhD, and Enio Buffolo, MD, PhD

Cardiovascular Surgery Discipline, Escola Paulista de Medicina, Federal University of São Paulo, São Paulo, Brazil

The introduction of percutaneous coronary interventions (PCI) with stent implant has substantially shifted the treatment of coronary artery disease. The current approach to coronary artery disease treatment includes first-choice PCI in selected subgroups; and once this therapy fails, frequently the patient is referred for coronary artery bypass graft surgery. However, evidence of chronic inflammatory reaction and endothelial dysfunction after PCI has been emerging and that might be interfering with patient outcome when surgical or medical treatments are subsequently required. The clinical

significance of these complications after PCI, herein examined, has been less studied and needs better assessment. Also, the premise that coronary artery bypass graft surgery can safely be performed in patients with esconary stenting failure may not hold true, as graft patency might be adversely affected. Furthermore, the superior posed inflammatory reaction may blunt the efficacy of medical treatment.

(Ann Thorac Surg 2006;81:1918-25) © 2006 by The Society of Thoracic Surgeons

## Koroner endarterektomi materyali



Fukui T. et al.; Ann Thorac Surg 2005;79:558-563

### Patients With In-Stent Restenosis Have an Increased Risk of Mid-Term Venous Graft Failure

Mario Gaudino, MD, Nicola Luciani, MD, Franco Glieca, MD, Carlo Cellini, MD, Claudio Pragliola, MD, Carlo Trani, MD, Francesco Burzotta, MD, Giovanni Schiavoni, MD, Amedeo Anselmi, MD, and Gianfederico Possati, MD

Departments of Cardiac Surgery and Cardiology, Catholic University, Rome, Italy

Background. This study was designed to evaluate if patients in whom in-stent restenosis developed had an higher risk of early venous graft failure compared with normal patients.

Methods. The study cohort comprised 120 patients (60 with previous in-stent restenosis and 60 controls) who received a total of 165 complementary venous grafts on the circumflex or right coronary artery system (84 in the restenosis group and 81 in the control group). All patients were prospectively followed-up and underwent reanging maps at 5-years follow-up.

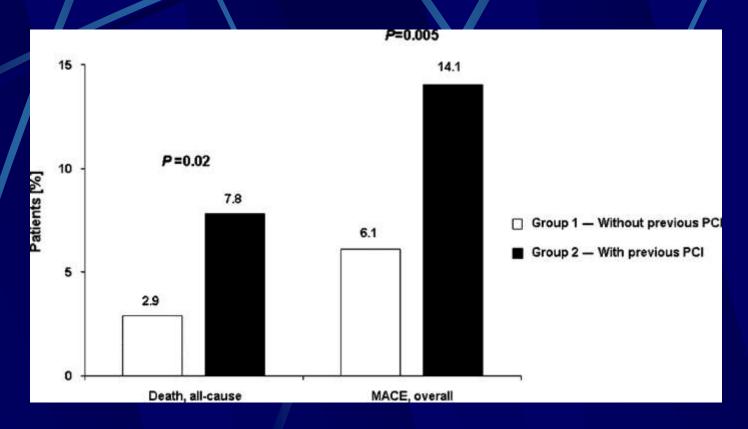
Results. In the restenosis group, 28 venous grafts (33.%) were perfectly patent, 10 showed major irregularities,

and 46 were occluded. In the control patients, 50 grafts (61.7%) were perfectly patent (p < 0.001 compared with the restenosis series), 12 showed major irregularities (p = .74), and 19 were occluded (p < 0.0001). In contrast, the 5-year outcome of internal thoracic artery grafts was not affected by history of in-stent restenosis.

Conclusions. Patients who developed in-stent restenosis have an higher risk of early venous graft failure compared with the control patients. Arterial grafts should probably be preferred in these patients.

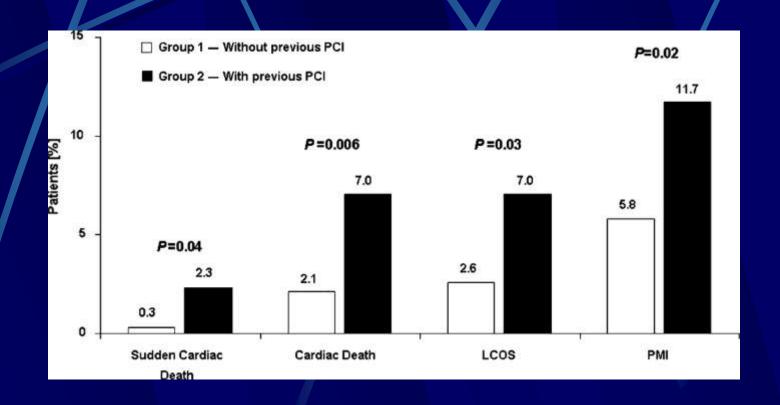
(Ann Thorac Surg 2006;82:802-5)
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### Hastane kalış süresinde mortalite ve 'MACE' oranları



Thielmann M. et al.; J Thorac Cardiovasc Surg 2007;134:470-476

## 'Sekonder sonuçlar'

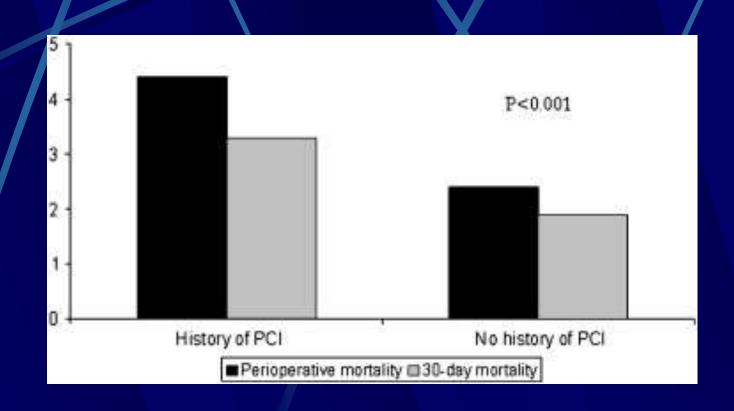


Thielmann M. et al.; J Thorac Cardiovasc Surg 2007;134:470-476

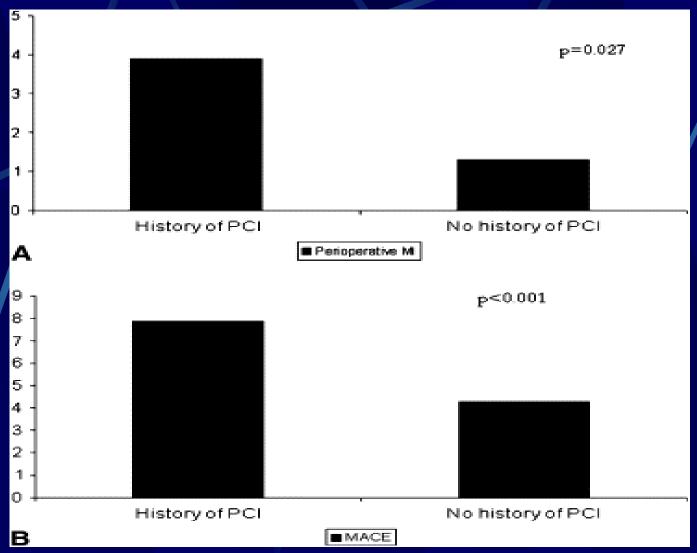
Increased mortality and perioperative complications in patients with previous elective percutaneous coronary interventions undergoing coronary artery bypass surgery

Nikolaos Bonaros, MD, a Diana Hennerbichler, MD, Guy Friedrich, MD, Alfred Kocher, MD, Otmar Pachinger, MD, Günther Laufer, MD, and Johannes Bonatti, MD

J Thorac Cardiovasc Surg 2009;137:846-52



Bonaros et al. J Thorac Cardiovasc Surg 2009;137:846-52



Bonaros et al. J Thorac Cardiovasc Surg 2009;137:846-52

## Impact of prior percutaneous coronary intervention on the outcome of coronary artery bypass surgery: A multicenter analysis

Parwis Massoudy, MD, <sup>a</sup> Matthias Thielmann, MD, <sup>a</sup> Nils Lehmann, PhD, <sup>b</sup> Anja Marr, PhD, <sup>b</sup> Georg Kleikamp, MD, <sup>c</sup> Ariane Maleszka, MD, <sup>c</sup> Armin Zittermann, MD, <sup>c</sup> Reiner Körfer, MD, <sup>c</sup> Miriam Radu, MD, <sup>d</sup> Arno Krian, MD, <sup>d</sup> Jens Litmathe, MD, <sup>e</sup> Emmeran Gams, MD, <sup>e</sup> Ömer Sezer, MD, <sup>f</sup> Hans Scheld, MD, <sup>f</sup> Wolfgang Schiller, MD, <sup>g</sup> Armin Welz, MD, <sup>g</sup> Guido Dohmen, MD, <sup>h</sup> Rüdiger Autschbach, MD, <sup>h</sup> Ingo Slottosch, MD, <sup>i</sup> Thorsten Wahlers, MD, <sup>i</sup> Markus Neuhäuser, PhD, <sup>b</sup> Karl-Heinz Jöckel, PhD, <sup>b</sup> and Heinz Jakob, MD<sup>a</sup>

The Journal of Thoracic and Cardiovascular Surgery • April 2009

Objectives: Do prior percutaneous coronary interventions adversely affect the outcome of subsequent coronary artery bypass grafting? We investigated this effect on a multicenter basis.

Methods: Eight cardiac surgical centers provided outcome data of 37,140 consecutive patients who underwent isolated first-time coronary bypass grafting between January 2000 and December 2005. Twenty-two patient characteristics and outcome variables were retrieved. Three groups of patients were analysed for in-hospital mortality and in-hospital major adverse cardiac events: patients without a previous percutaneous coronary intervention, with 1 previous intervention, and with 2 or more previous percutaneous coronary interventions before bypass grafting. A total of 29,928 patients with complete information for prior percutaneous coronary intervention underwent final analysis. Unadjusted univariate and risk-adjusted multivariate logistic regression analysis as well as computed propensity score matching were performed, based on 14 major risk factors to correct for and minimize selection bias.

Results: A total of 10.3% of patients had 1 previous percutaneous coronary intervention, and 3.7% of patients had 2 or more previous interventions. Risk-adjusted multivariate logistic regression analysis revealed a significant association of 2 or more previous percutaneous coronary interventions with in-hospital mortality (odds ratio [OR], 2.0; confidence interval [CI], 1.4–3.0; P = .0005) and major adverse cardiac events (OR, 1.5; CI, 1.2–1.9; P = .0013). After propensity score matching, conditional logistic regression analysis confirmed the results of adjusted analysis. A history of 2 or more previous percutaneous coronary interventions was significantly associated with in-hospital mortality (OR, 1.9; CI, 1.3–2.7; P = .0016) and major adverse cardiac events (OR, 1.5; CI, 1.2–1.9; P = .0019).

Conclusions: Multicenter analysis confirms that a history of multiple previous percutaneous coronary interventions increases in-hospital mortality and the incidence of major adverse cardiac events after subsequent coronary artery bypass grafting. Critical discussion of the treatment strategy in these patients is warranted.

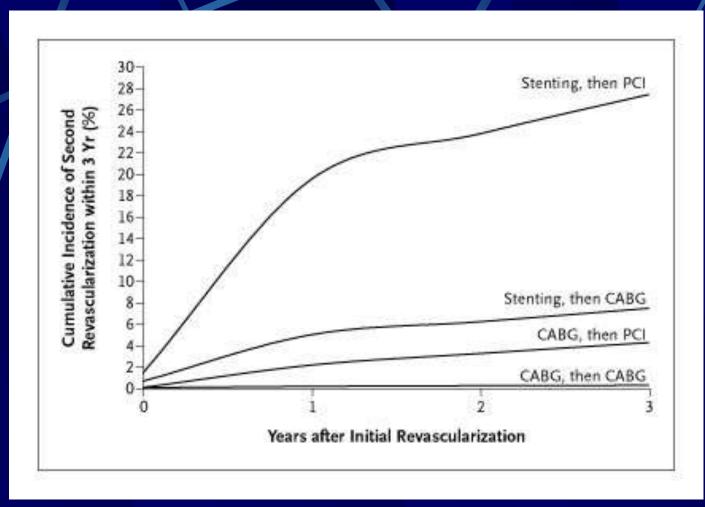
The NEW ENGLAND JOURNAL of MEDICINE

#### ORIGINAL ARTICLE

### Long-Term Outcomes of Coronary-Artery Bypass Grafting versus Stent Implantation

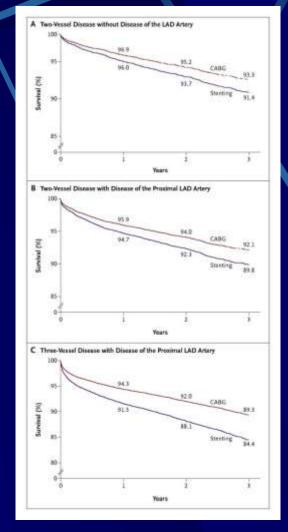
Edward L. Hannan, Ph.D., Michael J. Racz, Ph.D., Gary Walford, M.D., Robert H. Jones, M.D., Thomas J. Ryan, M.D., Edward Bennett, M.D., Alfred T. Culliford, M.D., O. Wayne Isom, M.D., Jeffrey P. Gold, M.D., and Eric A. Rose, M.D.

### 3 yılda ikinci revaskülarizasyona gidiş



Hannan E et al. N Engl J Med 2005;352:2174-2183

# A- LAD'siz iki damar hastalığı B- LAD'li iki damar hastalığı C- LAD'li 3 damar hastalığı



Hannan E et al. N Engl J Med 2005;352:2174-2183

### Coronary Artery Bypass is Superior to Drug-Eluting Stents in Multivessel Coronary Artery Disease\*

Robert A. Guyton, MD

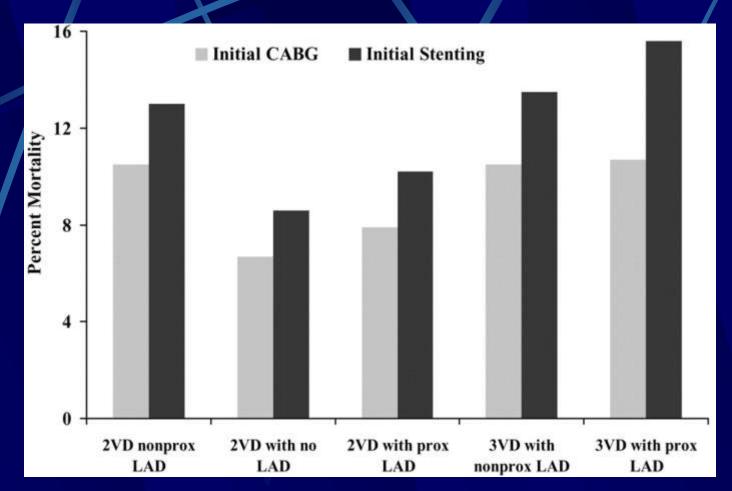
Division of Cardiothoracic Surgery, Department of Surgery, Emory University School of Medicine, Atlanta, Georgia

Percutaneous intervention for the treatment of multivessel coronary artery disease continues to displace coronary artery bypass graft surgery. But controlled trials of percutaneous intervention versus coronary bypass, in meta-analysis, have shown a significant survival advantage for coronary bypass. Studies of bare metal stents have not presented any data to prompt reversal of this conclusion for all but the small portion of patients most suited for stenting. Drug-eluting stents have no survival advantage compared with bare metal stents. Data from

real-world registries have shown that the current therapy of multivessel disease patients has resulted in a relative excess mortality of as much as 46% in patients with initial stenting compared with patients with initial coronary bypass. Ethical considerations demand that patients with multivessel disease be informed of the documented mortality benefit of coronary bypass graft surgery.

(Ann Thorac Surg 2006;81:1949-57) © 2006 by The Society of Thoracic Surgeons

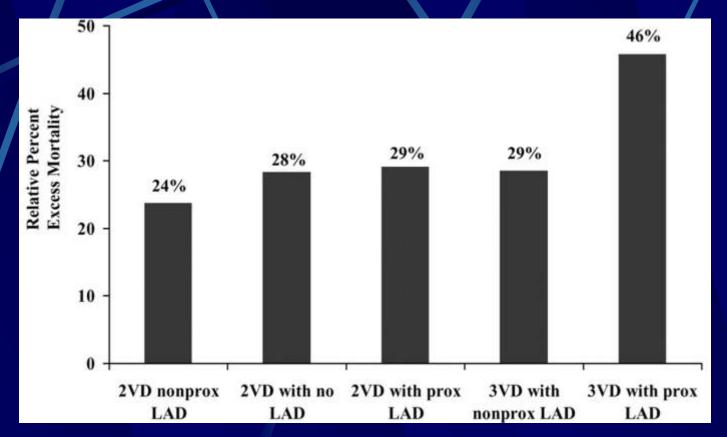
### İlk girişime göre 3 yıllık ölüm oranları



Guyton R. A.; Ann Thorac Surg 2006;81:1949-1957



# İlk girişim olarak stent yapılanlarda CABG yapılanlara göre 3 yılda gözlenen ölüm oranı fazlalığı



Guyton R. A.; Ann Thorac Surg 2006;81:1949-1957



### Selection of Surgical or Percutaneous Coronary Intervention Provides Differential Longevity Benefit

Peter K. Smith, MD, Robert M. Califf, MD, Robert H. Tuttle, MSPH, Linda K. Shaw, MHS, Kerry L. Lee, PhD, Elizabeth R. Delong, PhD, R. Eric Lilly, MD, Michael H. Sketch, Jr, MD, Eric D. Peterson, MD, and Robert H. Jones, MD

Division of Thoracic Surgery, Department of Surgery, Division of Cardiology, Department of Medicine, Duke University Medical Center, and Duke Clinical Research Institute, Durham, North Carolina

Background. Treatment of coronary artery disease (CAD) is evolving with better medications, improvements in percutaneous coronary intervention (PCI), and enhanced techniques for coronary artery bypass grafting (CABG).

Methods. In this study, 18,481 patients with significant (>75% stenosis) CAD treated at a single center between 1966 and 2000 were serigued to one of three groups based on initial treatment strategy: medical therapy (MED) (n = 68(2)). PCI (n = 6292), or CABG (n = 5327). Each group was categorized into 3 groups according to baseline severity of CAD: low-severity (predominantly 1-vessel), intermediate-severity (predominantly 2-vessel), and high-severity (all 3-vessel), and prospectively evaluated in Cox models for all-cause mortality adjusted for cardiac risk, comorbidity, and propensity for selection of a specific treatment. Treatments were compared for the entire period and three eras (1: 1986 to 1990; 2: 1991 to 1995; 3:

1996 to 2000), the last encompassing widespread availability of PCI with stenting.

Results. Survival significantly improved in all groups for all degrees of CAD, despite increasing severity of illness. Revascularization strategies provided significant survival over MED with 8.1, 10.6, and 23.6 additional months per 15 years of follow-up for low-severity, intermediate-severity, and high-severity CAD, respectively. Therapeutic improvements led to increased survival of 5.3 additional months per 7 years of follow-up (95% confidence interval, 0.2 to 10.2; p=0.039) in era 3 for CABG compared with PCI for high severity CAD.

Conclusions. Initial revascularization strategies result in significant survival advantage over MED for all CAD levels. Patients with high-severity CAD have reduced survival of PCI compared with those initially treated with CABC.

(Ann Thorac Surg 2006,92,1420-9) © 2006 by The Society of Thoracic Surgeons

### Surgical Revascularization Is Associated With Improved Long-Term Outcomes Compared With Percutaneous Stenting in Most Subgroups of Patients With Multivessel Coronary Artery Disease

#### **Results From the Intermountain Heart Registry**

Tami L. Bair, BS; Joseph B. Muhlestein, MD; Heidi T. May, MSPH; Kent G. Meredith, MD; Benjamin D. Horne, PhD, MPH; Robert R. Pearson, PharmD; Qunyu Li, MD; Kurt R. Jensen, MS; Jeffrey L. Anderson, MD; Donald L. Lappé, MD

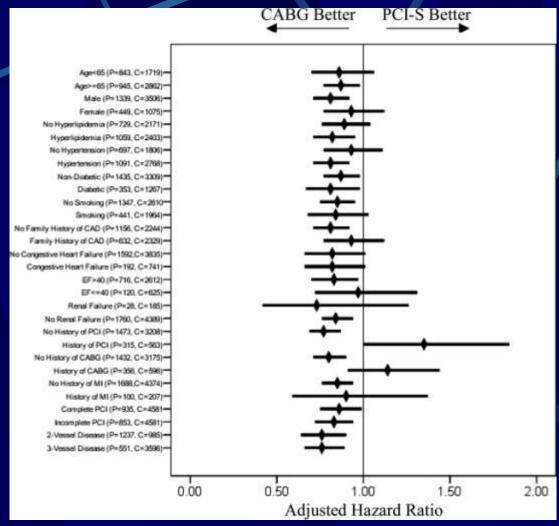
Background—Coronary artery bypass surgery (CABG) and percutaneous coronary intervention with stenting (PCI-S) are both safe and effective approaches for revascularization in patients with multivessel coronary artery disease. However, conflicting information exists when comparing the efficacy of the two methods. In this study, we examined the outcomes of major adverse cardiovascular events and death for subgroups of typical "real-world" patients undergoing coronary revascularization in the modern era.

Methods and Results—Patients were included if they were revascularized by CARC or PCI-S, had ≥5 years of follow-up, and had ≥2-vessel disease. Patients were followed for an average of 7.0±3.2 years for Dicidence of death and major adverse cardiovascular events (death, myocardial infarction, or repeat revascularization). Multivariate regression models were used to correct for standard cardiac risk factors including age, sex, hyperlipidemia, diabetes mellitus, family history of coronary artery disease, smoking, hypertension, heart failure, and renal failure. Subgroup analyses were also performed, stratified by age, sex, diabetes, ejection fraction, and history of PCI-S, CABG, or myocardial infarction. A total of 6369 patients (CABG 4581; PCI-S 1788) were included. Age averaged 66±10.9 years, 76% were male, and 26% were diabetic. Multivariate risk favored CABG over PCI-S for both death (hazard ratio 0.85; P=0.001) and major adverse cardiovascular events (hazard ratio 0.51; P<0.0001). A similar advantage with CABG was also found in most substrata, including diabetes.

Conclusions—In this large observational study of patients undergoing revascularization for multivessel coronary artery disease, a long-term benefit was found, in relationship to both death and major adverse cardiovascular events, for CABG over PCI-S regardless of diabetic status or other stratifications. (Circulation. 2007;116[suppl I]:I-226–I-231.)

Key Words: CABG ■ stents ■ coronary artery disease ■ clinical outcomes ■ mortality

# Adjusted HRs for death among patient subgroups undergoing CABG or PCI-S.



Bair, T. L. et al. Circulation 2007;116:I-226-I-231





# Gelinen son nokta

# The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

MARCH 5, 2009

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### Percutaneous Coronary Intervention versus Coronary-Artery Bypass Grafting for Severe Coronary Artery Disease

Patrick W. Serruys, M.D., Ph.D., Marie-Claude Morice, M.D., A. Pieter Kappetein, M.D., Ph.D., Antonio Colombo, M.D., David R. Holmes, M.D., Michael J. Mack, M.D., Elisabeth Stähle, M.D., Ted E. Feldman, M.D., Marcel van den Brand, M.D., Bric J. Bass, B.A., Nic Van Dyck, R.N., Katrin Leadley, M.D., Keith D. Dawkins, M.D., and Friedrich W. Mohr, M.D., Ph.D., for the SYNTAX Investigators\*

### ABSTRACT

### BACKGROUMB

Percutaneous coronary intervention (PCI) involving drug-eluting stents is increas- Rom Guarrus University Medical Center ingly used to treat complex coronary artery disease, although coronary-amery bypass. Rotterdam, Rotterdam, the Netherlands grafting (CABG) has been the treatment of choice historical ampared PCI and CABG for treating patients with or main cotonary artery disease (or both)

### HETHODS

We randomly assigned 1800 patients who tonary artery disease to undergo CABG or PCI (in a 1 atients, the local cardiac surgeon and interventional cardio that equivalent anatomical revascularization could be achieved with rearment. A non inferiority comparison of the two groups was performed for the primary end point — a major adverse cardiac or cerebrovascular event (i.e., death from any cause, stroke, myocardial infarction, or repeat revascularization) during the 12-month period after randomization. Patients for whom only one of the two treatment options would be beneficial, because of an atomical features or clinical conditions, were entered into a parallel, nested CABG or PCI registry.

Most of the preoperative characteristics were similar in the two groups. Rates of major adverse cardiac or cerebrovascal ar events at 12 months were sign if can by higher in the PCI group (17.8%, vs. 12.4% for CABG; P=0.002), in large part because of an increased rate of repeat revascularization (13.5% vs. 5.9%, 100.001); as a result, the criterion for noninferiority was not met. At 12 months, the rates of death and N Engl J Med 2009;360:560.72. myocardial infarction were similar between the two groups; stroke was significantly copyring to not sunstantium of sody. more likely to occur with CABG (2.2%, vs. 0.6% with PCI; P=0.003).

CABG remains the standard of care for patients with three-vessel or left main coronary artery disease, since the use of CABG, as compared with PCI, resulted in lower rates of the combined end point of major adverse cardiac or cerebrovasquiar events at 1 year. (ClinicalTrials.gov number, NCT00114972.)

(P.W.S., A.R.K., M.S.); Institut Cardiovasculaire Paris Sud, Massy, France (M.-C.M.); or left San Raffaele Scientific Institute, Milan (A.C.); Mayo Clinic, Rochester, MN (D.R.H.); Medical City Hospital, Dallas (M.J.M.); University Hospital Uppsals, Uppsals, Sweden (E.S.); Evansion Hospital, Evanston, IL (T.E.F.); Boston Scientific, Marlborough, MA (E.J.B., NV.D., K.L., K.D.D.); and Herzzentrum Universität Leipzig, Leipzig, Germany (F.W.M.). Address reprint requests to Dr. Serroys at the Ensures University Medical Center, Rotterdam, Gravendijkwal 230, 3015 CE Rotterdam, the Netherlands, or st.p.w.j.c. serveys@ensmusmc.nl.

> \*The other Synergy between Percutane-ous Coronary Intervention with Taxus and Cardiac Surgery (SYNTAX) investgators are listed in the Supplementary Appendix, available with the full text of this article at NEJM.org.

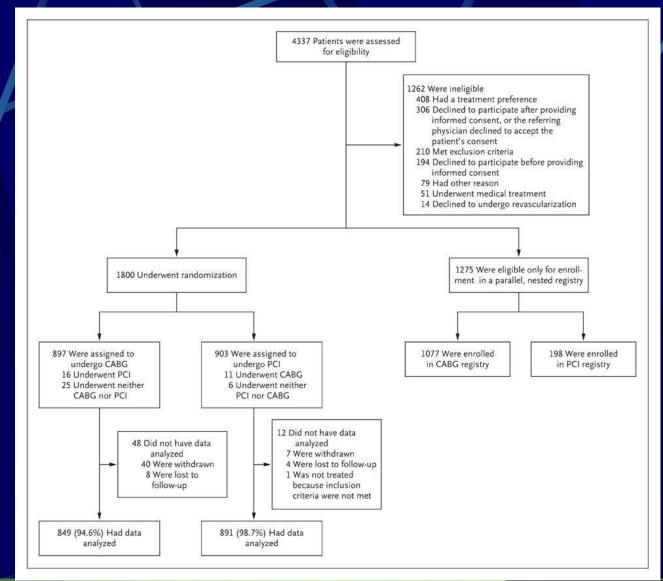
> This article (00.1056) NEJMos0804526) was published at NEJM org on February 18,

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### STUDY DESIGN

The SYNTAX trial is a prospective, clinical trial conducted in 85 sites and approved by the institutional review board at each participating center. The study had an "all-comers" design involving the consecutive enrollment of all eligible patients with three-vessel or left main coronary artery disease at sites in 17 countries in Europe and the United States. The study design has been described previously.28 Criteria for study and registry enrollment and outcome data are described in the Supplementary Appendix. The authors designed the study, as part of their role on the steering committee, in collaboration with the sponsor, Boston Scientific. The sponsor was involved in collection and source verification of the data, with oversight by an independent clinical events committee. The sponsor's biostatisticians performed the analyses; however, data analyses were verified independently by a statistician on the data and safety monitoring committee. The authors wrote the manuscript and vouch for the completeness and accuracy of the data gathering and analysis.

# Enrollment and Randomization of Patients with Previously Untreated Three-Vessel or Left Main Coronary Artery Disease in the SYNTAX Trial



# **Baseline Characteristics of the Patients, According to Study Group**

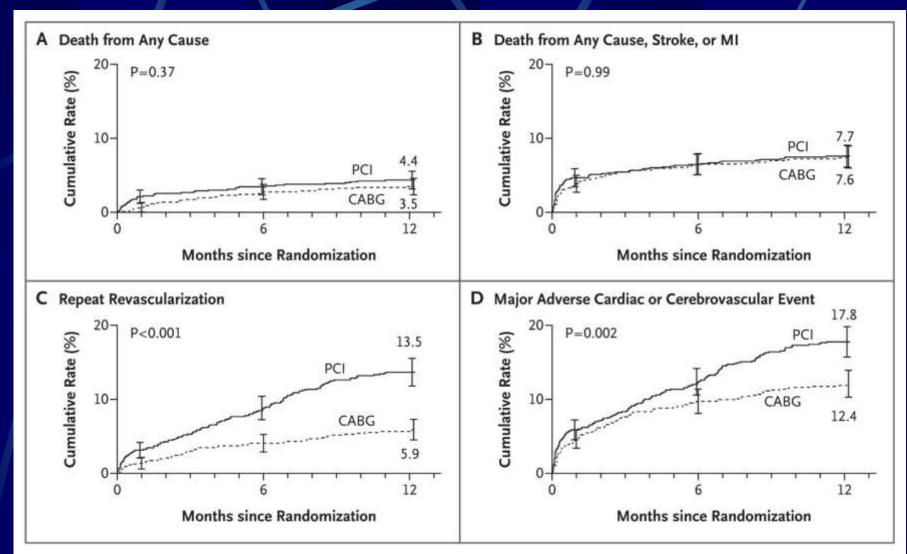
Table 1. Baseline Characteristics of the Patients, Aco	The Control of the Co		
Characteristic	PCI (N = 903)	CABG (N=897)	P Value
Age — yr	65.2±9.7	65.0x9.8	0.55
Male sex %	76.4	78.9	0.20
Body-mass index?	28.1±4.8	27.9±4.3	0.37
Medically treated diabetes — % :			
Any	25.6	24.6	0.64
Requiring insulin	3.3	10.4	0.72
Metabolic syndrome — %	46.0	45.5	0.86
Current smoker — %	18.5	27.0	0.06
Previous myocardial infarction — %	31.9	33.8	0.39
Previous stroke — %	3.9	4.8	0.33
Previous transient ischemic attack %	43	5.1	0.46
Blood pressure x130/85 mm Hg — %	68.9	54.0	0.03
Congestive heart failure — %	4.0	5.3	0.18
Carotid artery disease — %	9.1	8.4	0.83
Hyperlipidemia — %	78.7	77.2	0.44
Triglycerides ±130 mg/dl (1.7 mmol/liter) — %	32.3	38.7	0.007
HDL chalesterol <40 mg/dl (1.0 mmal/liter) for men or <30 mg/dl (1.3 mmal/liter) for warren — %	46.2	52.5	0.01
Angina — %			
Stable	56.5	57.2	0.91
Unstable	28.9	28.0	0.66
Ejection fraction < 30% — %	1.3	2.5	0.08
euroSCORE value	3.8±2.6	3.8±2.7	0.78
Parsonnet score	8.5±7.0	8.416.8	0.76
SYNTAX score	28.4±11.5	29.1±11.4	0.19
No. of lesions	4.3±1.8	4.4±1.8	0.44
Total acclusion — %	24.2	22.2	0.33
Bifurcation %	22.4	71.3	Ass
Time to procedure — days	6.9a13.0	17.4±28.0	< 0.001
Procedure duration — hr.	17.00	111	< 0.001
Postprocedural hospital stay days	3.4±4.5	9.5±8.0	<0.001
Complete revascularization — %	56.7	63.2	0.005

Plus-minus values are means ±50. Data are given for the intention-to-treat population. Pivalues, the average SYNTAX score, the average number of lessons, and the percentages of patients with setal occlusion and bifurcation were calculated at the core laboratory. The European System for Cardiac Operative Risk Evaluation (exempSCORE) value could range from 0 to 18, with increasing values reflecting a higher predicted operative mortality. The Parsonner score could range from 0 to 47, with increasing values reflecting a higher predicted in-hospital mortality. The Parsonner score reflects a congreteensive anatomical assessment, with scores ranging from 0 to 83 and higher scores indicating more complex cononary disease (see the Supplementary Appendix for details). CABIG denotes coronary arriery bypass grafting, HOL high-density spoprotein, and PCI pecultaneous coronary intervention.

The body-mass index is the weight in kilograms divided by the square of the height in meters.

Medically treated diabetes was defined as diabetes for which the patient was receiving oral hypoglycemic agents or insulin at the time of enrollment.

# Rates of Outcomes among the Study Patients, According to Treatment Group



# Clinical End Points Occurring in the Hospital or after Discharge, According to Study Group

Variable	PCI	CABG	P Value	Relative Risk with PCI (95% CI)
	no./tot	al no. (%)		
Major adverse cardiac or cerebrovascular event				
In hospital	39/896 (4.4)	47/870 (5.4)	0.31	0.81 (0.53-1.22)
30 Days after procedure	54/895 (6.0)	45/866 (5.2)	0.45	1.16 (0.79–1.71)
6 Mo after randomization	111/893 (12.4)	85/860 (9.9)	0.09	1.26 (0.96–1.64)
12 Mo after randomization	159/891 (17.8)	105/849 (124)	0.002	1.44 (1.15-1.81)
Death, stroke, or MI	68/891 (7.6)	65/849 (7.7)	0.98	1.00 (0.72-1.38)
Death	39/891 (4.4)	30/849 (3.5)	0.37	1.24 (0.78-1.98)
From cardiac causes	33/891 (3.7)	18/849 (2.1)	0.05	1.75 (0.99-3.08)
From cardiovascular causes	1/891 (0.1)	3/849 (0.4)	0.36†	0.32 (0.03-3.05)
From noncardiovascular causes	5/891 (0.6)	9/849 (1.1)	0.24	0.53 (0.18-1.57)
Stroke	5/891 (0.6)	19/849 (2.2)	0.003	0.25 (0.09-0.67)
MI	43/891 (4.8)	28/849 (3.3)	0.11	1.46 (0.92-2.33)
Repeat revascularization‡	120/891 (13.5)	50/849 (5.9)	< 0.001	2.29 (1.67-3.14)
CABG	25/891 (2.8)	11/849 (1.3)	0.03	2.17 (1.07-4.37)
PCI	102/891 (11.4)	40/849 (4.7)	< 0.001	243 (1.71–3.46)
Graft occlusion or stent thrombosis§	28/848 (3.3)	27/784 (3.4)	0.89	0.96 (0.57–1.62)
Acute (at ≤1 day)	2/896 (0.2)	3/870 (0.3)	0.68†	0.65 (0.11-3.86)
Early (within 2-30 days)	18/893 (2.0)	3/868 (0.3)	0.001	5.83 (1.72–19.73
Late (within 31-365 days)	9/874 (1.0)	21/854 (2.5)	0.02	0.42 (0.19-0.91)

<sup>\*</sup> Percentages are from the intention-to-treat analysis. P values were calculated with the use of the chi-square test, unless otherwise noted. CABG denotes coronary-artery bypass grafting, MI myocardial infarction, and PCI percutaneous coronary intervention.

<sup>†</sup> The P value was calculated with the use of Fisher's exact test.

<sup>‡</sup> One patient randomly assigned to undergo CABG and seven patients randomly assigned to undergo PCI underwent both repeat PCI and repeat CABG.

<sup>§</sup> Stent thrombosis was adjudicated according to the protocol definition.

# Syntax (prosedür öncesi)

Supplemental Table 6. Preprocedure MACCE events in the Randomized Cohort.

	CABG	PCI		Relative Risk
Variable*	(N=897)	(N=903)	P value	[95% CI]
Preprocedure MACCE	0.9% (8/897)	0.3% (3/903)	0.13	0.37 [0.10, 1.40]
Death, Any, %	0.2% (2/897)	0.1% (1/903)	0.62 <sup>†</sup>	0.50 [0.05, 5.47]
Cardiac Death, %	0.2% (2/897)	0.1% (1/903)	0.62 <sup>†</sup>	0.50 [0.05, 5.47]
Vascular Death, %	0.0% (0/897)	0.0% (0/903)	NE	NE
Noncardiovascular Death, %	0.0% (0/897)	0.0% (0/903)	NE	NE
Cerebrovascular Event, %	0.3% (3/897)	0.0% (0/903)	0.12 <sup>†</sup>	NE
MI, %	0.4% (4/897)	0.2% (2/903)	0.45†	0.50 [0.09, 2.70]

<sup>\*</sup>Number (percent) based on an intent-to-treat analysis

NE= not evaluable

<sup>†</sup>Binary rates P value from chi-square test

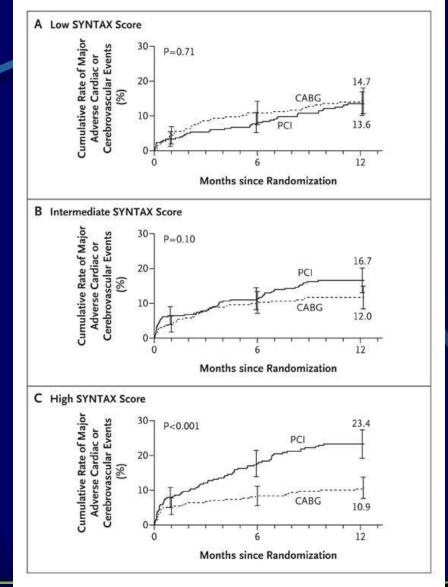
# **Cardiac-Related Medications Given after the Study Procedure**

Table 2. Cardiac-Related Medications Given after the Study Procedure.\* Medication PCI CABG P Value percent 98.9 0.62 Aspirin At discharge 96.3 88.5 < 0.001 I Mo after procedure 93.5 85.4 < 0.001 6 Mo after randomization 93.2 82.7 < 0.001 12 Mo after randomization < 0.001 91.2 84.3 Thienopyridine At discharge 96.8 19.5 < 0.001 1 Mo after procedure 95.5 18.4 < 0.001 6 Mo after randomization 91.3 < 0.001 16.1 12 Mo after randomization 71.1 < 0.001 15.0 Any antiplatelet drug At discharge 97.0 23.7 < 0.001 1 Mo after procedure 95.8 21.2 < 0.001 6 Mo after randomization 91.4 18.4 < 0.001 12 Mo after randomization 72.8 17.2 < 0.001 Nonthienopyridine antiplatelet drug 1.9 4.8 < 0.001 Warfarin derivative 2.6 7.1 < 0.001 86.7 74.5 < 0.001 Statin Beta-blocker 81.3 78.6 0.17 55.1 < 0.001 ACE inhibitor 44.6 Calcium-channel blocker 25.8 18.4 < 0.001 Angiotensin II-receptor antagonist 13.3 7.0 < 0.001 Amiodarone 1.5 < 0.001 12.8 H2-receptor blocker 14.5 21.7 < 0.001

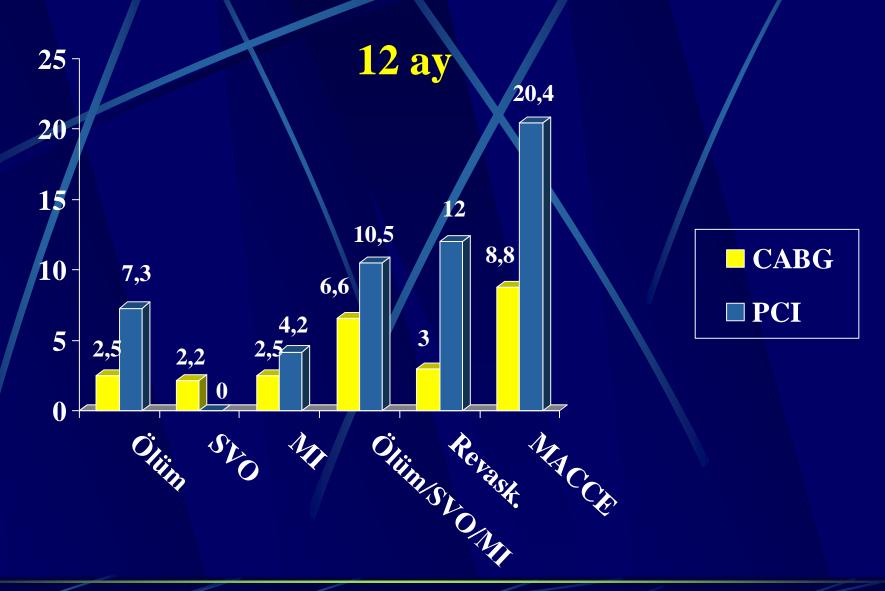
<sup>\*</sup> Percentages are from the intention-to-treat analysis. ACE denotes angiotensinconverting enzyme, CABG coronary-artery bypass grafting, and PCI percutaneous coronary intervention.



Rates of Major Adverse Cardiac or Cerebrovascular Events among the Study Patients, According to Treatment Group and SYNTAX Score Category

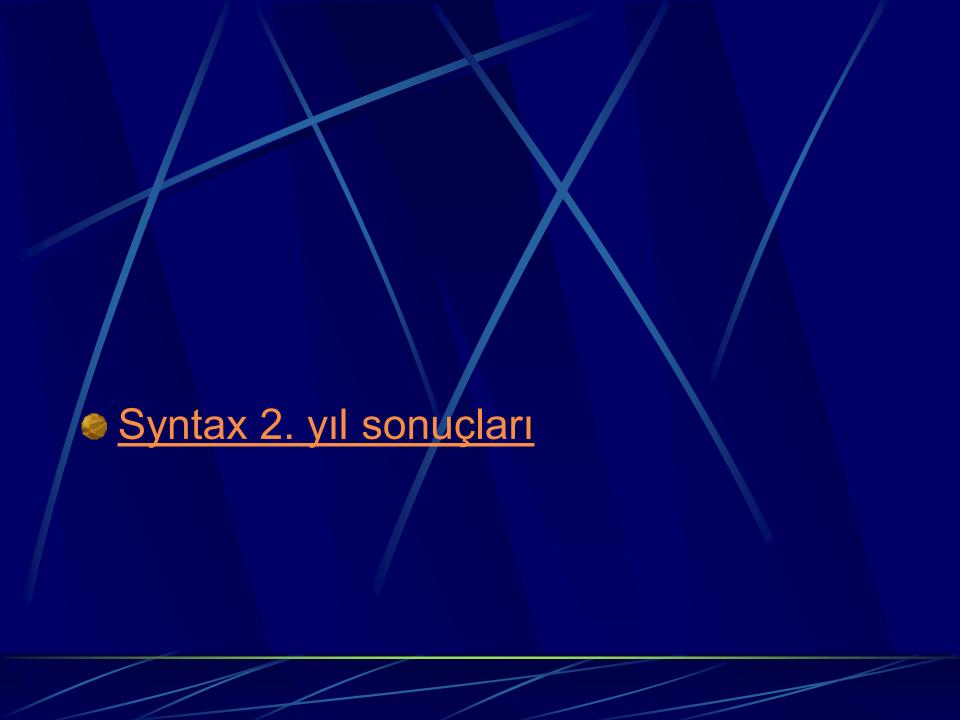


# SYNTAX REGISTRY



### CONCLUSIONS

CABG remains the standard of care for patients with three-vessel or left main coronary artery disease, since the use of CABG, as compared with PCI, resulted in lower rates of the combined end point of major adverse cardiac or cerebrovascular events at 1 year. (ClinicalTrials.gov number, NCT00114972.)



Comparison of mid-term outcome in patients with three-vessel and/or left main disease undergoing percutaneous coronary intervention and coronary artery bypass graft surgery

Evgenia Biryukova, Frances M. Williams, Oswaldo Valencia, Juan Carlos Kaski, Martin Bland and Marjan Jahangiri

Eur J Cardiothorac Surg 2010;37:905-911 DOI: 10.1016/j.ejcts.2009.09.040

Table 1 Baseline clinical characteristics.

	PCI (N = 313)	CABG (N = 333)
Age, years (mean ± SD)	68.4 ± 11.7	$\textbf{67.9} \pm \textbf{9.6}$
Male	231 (74%)	282 (85%)
Female	82 (24%)	51 (15%)
Stable angina	153 (49%)	230 (69%)
CCS grade III-IV	236 (75%)	152 (45%)
NYHA class III—IV	71 (23%)	49 (15%)
Hypertension	205 (66%)	251 (75%)
Diabetes	75 (24%)	105 (32%)
Chronic renal insufficiency	5 (2%)	4 (1%)
Previous PCI	53 (17%)	28 (8%)
LVEF		
49-30	32 (10%)	71 (21%)
<30	8 (3%)	25 (8%)

Table 2 Outcome of patients undergoing PCI versus CABG.

	PCI, n (%) a	CABG, n (%)a
In-hospital outcome		
No. of patients	313	333
Myocardial infarction	2 (0.6%)	0
Re-CABG	0	0
Re-PCI	1	0
Stroke/TIA	0	8 (2.4%)
Death	3 (1.0%)	8 (2.4%)
12 months follow-up		
No. of patients	282 (90.1%)	325 (97.6%)
Recurrent angina	84 (26.8%)	18 (5.4%)
Re-intervention	67 (21.4%)	3 (0.9%)
PCI	51 (16.3%)	3 (0.9%)
CABG	16 (5.1%)	0
TVR	35 (11.2%)	0
Myocardial infarction	18 (5.8%)	2 (0.6%)
Stroke/TIA	4 (1.3%)	7 (2.1%)
Death	20 (9.4%)	18 (5.4%)

PCI: percutaneous intervention; CABG: coronary artery bypass graft; TIA: transient ischaemic attack; TVR: target-vessel revascularisation; Re-PCI: re-intervention PCI; Re-CABG: re-intervention CABG.

a Percentage figures refer to the numbers of patients out of the total number at the outset.

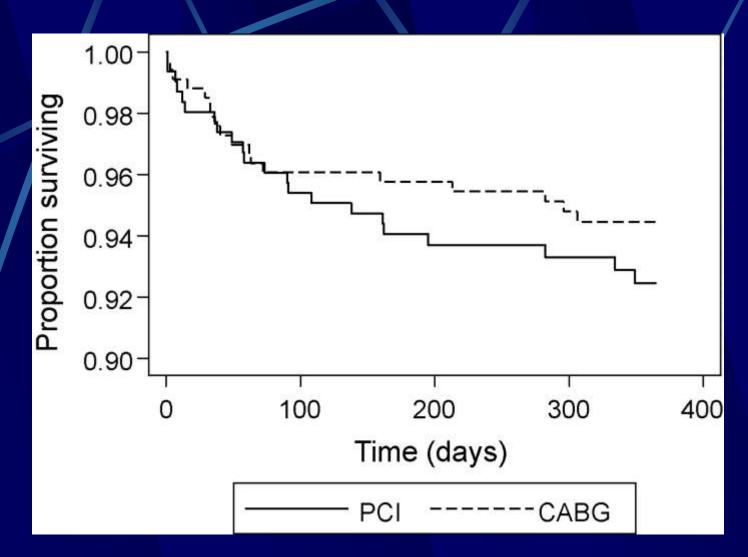
Table 4 Composite of death, MI, or stroke at 6 months.

Covariate	CABG/PCI		Covariate		
	Odds ratio a	P value	Odds ratio b	P value	
None	0.40	(0.05)			
Female	0.44	(0.01)	2.78	(0.002)	
Age (per year)	0.40	(0.006)	1.01	(0.5)	
Ever smoked	0.42	(0.01)	1.11	(0.8)	
Previous MI	0.47	(0.03)	1.08	(0.2)	
Hypertension	0.38	(0.004)	1.57	(0.2)	
Diabetes	0.38	(0.004)	1.90	(0.06)	
MI on admission	0.46	(0.02)	1.60	(0.2)	
CCS grade 3-4	0.59	(0.2)	2.22	(0.09)	
NYHA class III or IV	0.43	(0.01)	2.89	(0.002)	
LVEF	0.31	(0.001)		P = 0.003	
30-49		,	1.78		
<30			5.77		
Left main stem disease	0.35	(0.003)	1.54	(0.2)	
Vessel score = 3	0.33	(0.007)	1.34	(0.5)	

Table 6 Composite of death, MI, stroke, re-intervention, or recurrent angina at 6 months.

Covariate	CABG/PCI		Covariate		
	Odds ratio <sup>a</sup>	P value	Odds ratio b	P value	
None	0.16	(<0.001)			
Female	0.17	(<0.001)	2.14	(0.002)	
Age (per year)	0.16	(<0.001)	1.00	(0.7)	
Ever smoked	0.19	(<0.001)	1.03	(0.9)	
Previous MI	0.16	(<0.001)	0.91	(0.7)	
Hypertension	0.16	(<0.001)	1.05	(0.9)	
Diabetes	0.16	(<0.001)	1.19	(0.5)	
MI on admission	0.17	(<0.001)	1.10	(0.7)	
CCS grade 3-4	0.22	(<0.001)	2.45	(0.005)	
LVEF	0.15	(<0.001)	P = 0.2		
30-49			1.48		
<30			1.99		
NYHA class III or IV	0.17	(<0.001)	2.01	(0.007)	
Left main stem disease	0.16	(<0.001)	1.15	(0.6)	
Vessel score = 3	0.13	(<0.001)	1.43	(0.2)	

# Survival curves for all patients, by treatment



Biryukova E. et al.; Eur J Cardiothorac Surg 2010;37:905-911





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### APPROPRIATENESS CRITERIA

# ACCF/SCAI/STS/AATS/AHA/ASNC 2009 Appropriateness Criteria for Coronary Revascularization

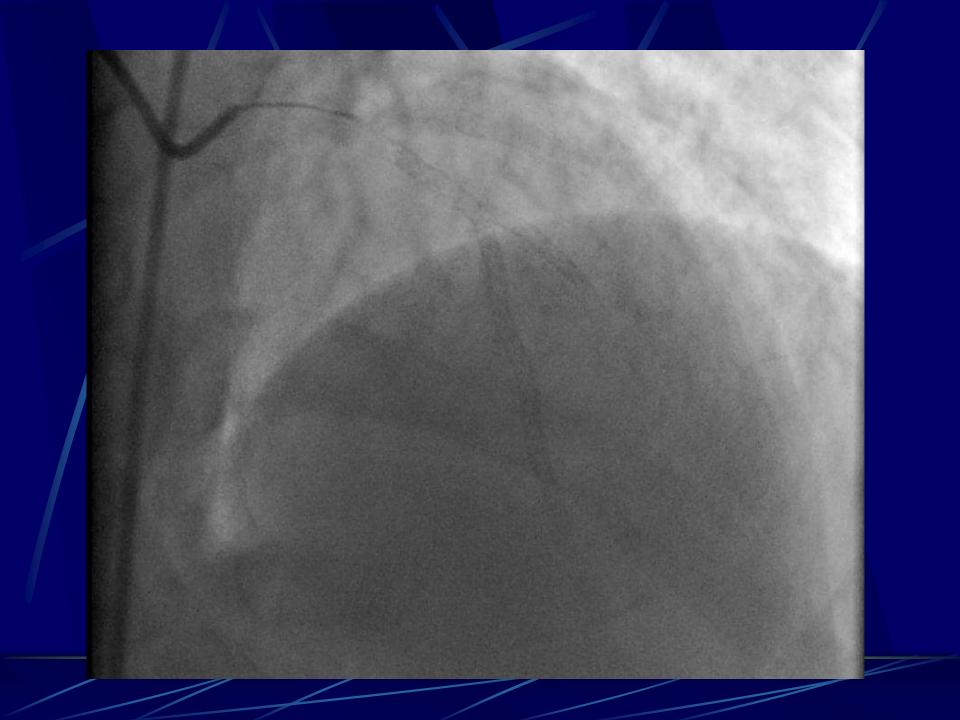
A Report of the American College of Cardiology Foundation Appropriateness Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, and the American Society of Nuclear Cardiology

Endorsed by the American Society of Echocardiography, the Heart Failure Society of America, and the Society of Cardiovascular Computed Tomography

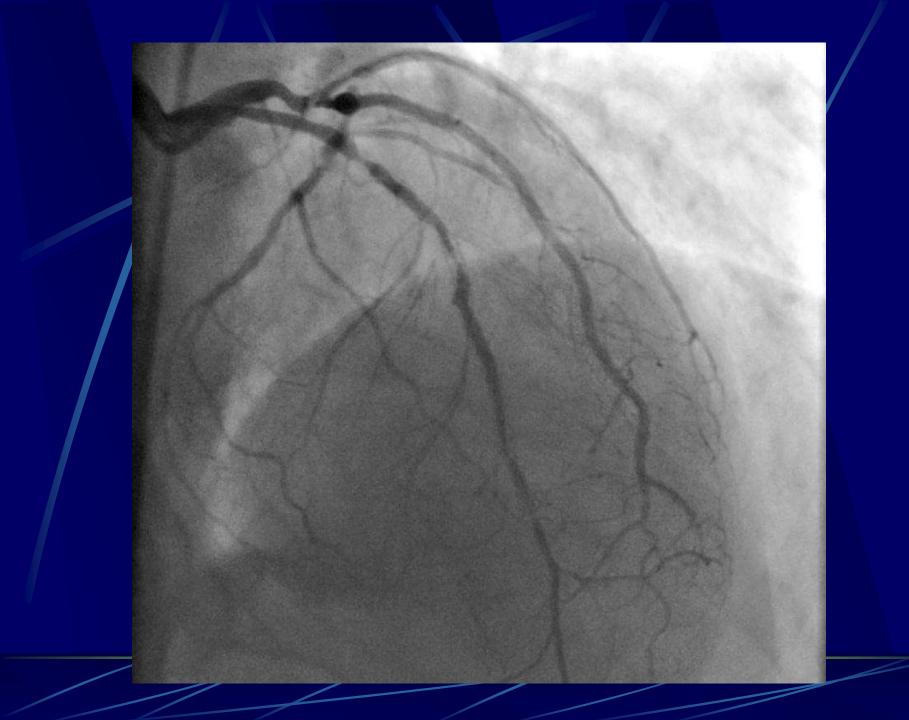
# **Method of Revascularization of Advanced Coronary Artery Disease**

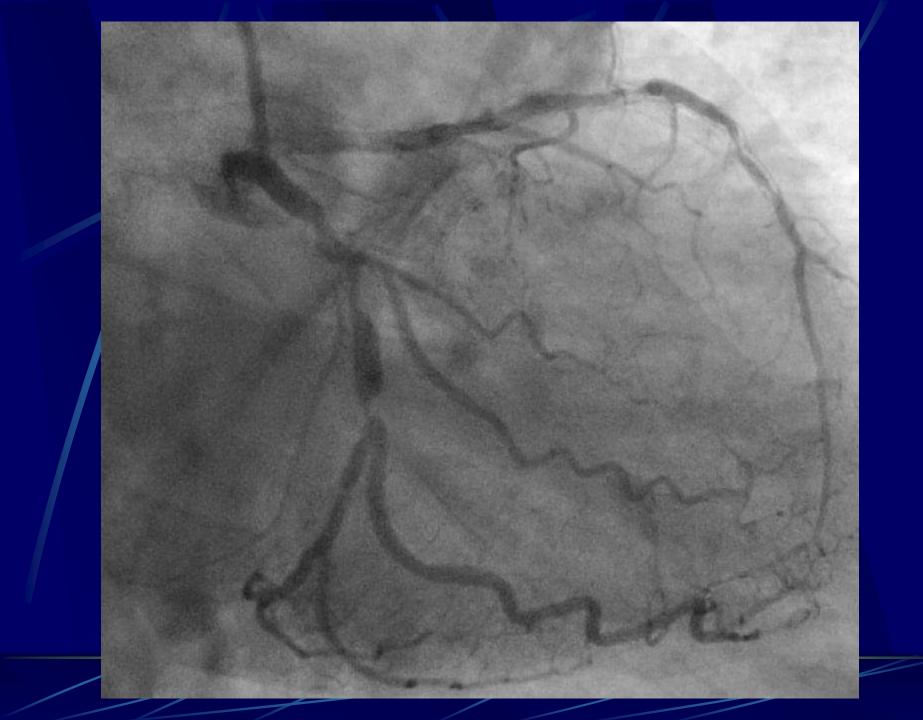
ĺ	CABG			PCI		
	No diabetes and normal LVEF	Diabetes	Depressed LVEF	No diabetes and normal LVEF	Diabetes	Depressed LVEF
Two vessel coronary artery disease with proximal LAD stenosis	А	A	A	A	A	A
Three vessel coronary artery disease	A	A	А	U	U	U
Isolated left main stenosis	A	A	А	¥.	1	1
Left main stenosis and additional coronary artery disease	A	A	A	1	(1)	1

Patel, M. R. et al. J Am Coll Cardiol 2009;53:530-553

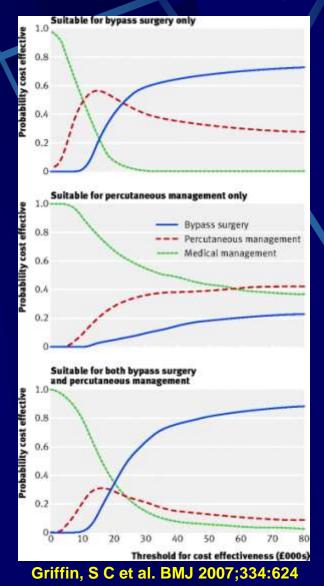








# Cost effectiveness acceptability curves



- Coronary Stents Market to Exceed \$7.2 Billion by 2012, According to New Report by Global Industry Analysts, Inc.
  - Coronary stents, one of the fastest growing categories in the global medical device industry, registered rapid growth due to rapid advancements in the area of drug-eluting stents. Driven by the introduction of Drug Eluting Stents (DES) in 2002, the market for coronary stents is slated to exceed \$7.2 billion by 2012.

## Coronary stent disease: When will enough be enough?

Igor E. Konstantinov, MD, PhD, Pankaj Saxena, MCh, DNB, and Jaffar Shehatha, FRCS, FRACS, Perth, Australia

Drug-eluting stents significantly modify and often complicate the natural history of coronary artery disease. This report emphasizes that every patient with multivessel coronary artery disease must be reviewed by a surgeon and properly informed before stenting.

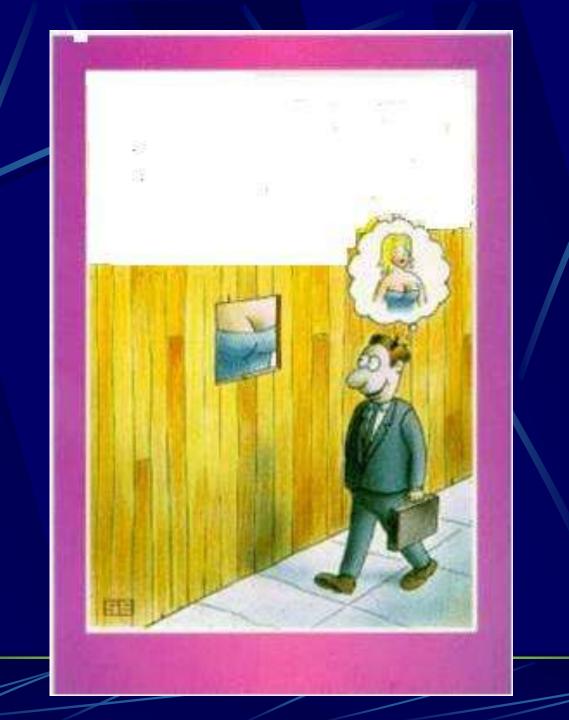
### CLINICAL SUMMARY

A 60-year-old man was transferred to the Sir Charles Gairdner Hospital with unstable angina. His comorbidities were obesity (body mass index 33.6 kg/m²), hypertension, type II diabetes mellitus requiring insulin, hypercholesterolemia, and chronic renal failure (creatinine 150 mmol/L) due to diabetic nephropathy. The patient was an ex-smoker. Left ventricular ejection fraction was 45% with hypokinesis of the inferolateral wall. He had severely diseased left anterior descending (LAD) and left circumflex (LCx) coronary arteries with multiple in-stent stenoses (Figure 1) and a small nondominant right coronary artery.

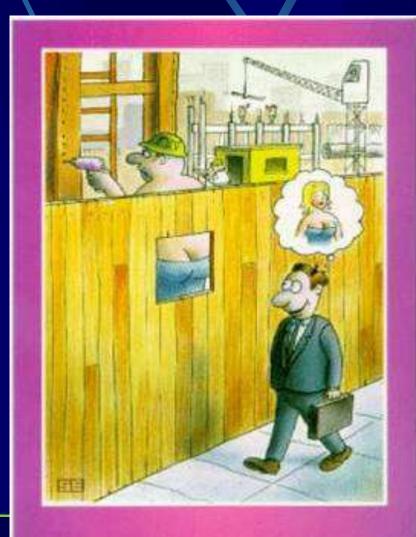
70% in-stent stenosis of the LAD. The patient underwent repeat PTCA with 2 Cypher stents placed in the LAD and distal LCx. Unstable angina recurred in 1 week. The patient was transferred to the Sir Charles Gairdner Hospital and seen by a cardiothoracic surgeon for the first time.

On admission, the patient continued to have unstable angina at rest despite receiving aspirin, clopidogrel, and heparin infusion. An intraaortic balloon pump was inserted. Levosimendan infusion was started, and the patient underwent urgent coronary artery bypass surgery with a standard cardiopulmonary bypass. The left internal thoracic artery was anastomosed to the LAD. A sequential saphenous vein graft was anastomosed to the first and second diagonal branches. An individual saphenous vein graft was anastomosed to the OM. The terminal branch was completely obliterated and not graftable. At 3 month of follow-up, the patient was doing well and free of angina.

To properly describe this iatrogenic course of coronary artery disease, we coined the term "coronary stent disease." It seems that coronary stent disease may affect both patients and cardiologists. Both may require urgent surgical intervention.



# Daima büyük resime bakın !!!





# Late Outcome After Stenting or Coronary Artery Bypass Surgery for the Treatment of Multivessel Disease: A Single-Center Matched-Propensity Controlled Cohort Study

Ron T. van Domburg, PhD, Johanna J. M. Takkenberg, MD, PhD, Leo J. Noordzij, MD, Francesco Saia, PhD, Lex A. van Herwerden, MD, PhD, Patrick W. J. C. Serruys, MD, PhD, and Ad J. J. C. Bogers, MD, PhD

Thoraxcenter, Brasmus Medical Center, Rotterdam, The Netherlands

Background. Although several randomized controlled trials examined the relative benefits of coronary artery bypass graft (CABG) surgery and percutaneous coronary intervention (PCD, the most appropriate treatment remains a matter of debate, at least in some subsets of patients. Therefore, we evaluated the 8-year outcome after multivessel stent implantation (stent group) or coronary artery bypass surgery (CABG group) in a single-center propensity-matched cohort study.

Methods. The stent study population consisted of all 409 consecutive patients who underwent an elective coronary intervention between 1995 and 1999 in whom at least 2 stents were implanted in multiple vessels. They were matched by using the propensity score method with 409 CABG patients of 1,723 CABG patients with multivessel disease who underwent elective CABG in the same period of time. The two populations were very different before matching. After matching, the CABG

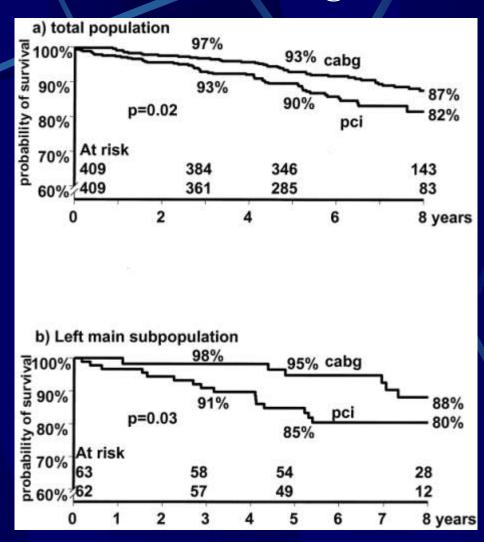
population resembled a stent population.

Results. The cumulative survival rates after stent were 93%, 90%, and 82% at, respectively, 3, 5, and 8 years; and after CABG 97%, 93%, and 87% (p=0.02). This was caused mainly by patients with left main disease (p=0.03). Event-free survival was only 70%, 68%, and 64% after stent and 89%, 82%, and 78% after CABG at, respectively, 3, 5, and 8 years (p<0.0001). After adjusting, stent was an independent predictor of higher mortality.

Conclusions. In this matched cohort study with an 8-year follow-up, survival was better and less repeat revascularizations were needed among patients undergoing elective CABG for the treatment of multivessel disease as compared with the stent group.

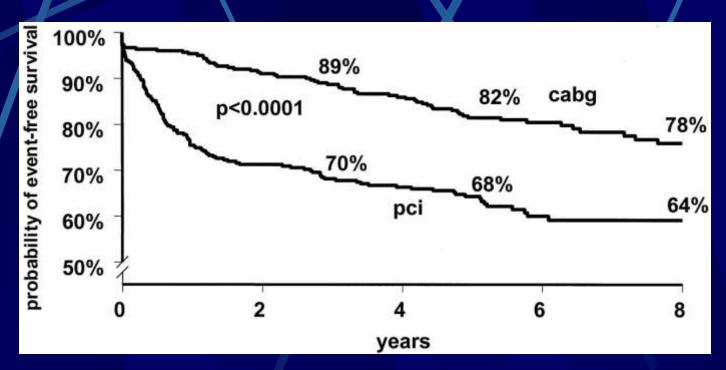
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# PCI vs CABG sağkalım



van Domburg R. T. et al.; Ann Thorac Surg 2005;79:1563-1569

# PCI vs CABG sağkalım ve MACE



van Domburg R. T. et al.; Ann Thorac Surg 2005;79:1563-1569

# **Predictors of 8-Year Survival**

Factors that independently predicted late mortality after CABG and stent were age (hazard ratio [HR]: 1.11; 95% confidence interval [95%CI]: 1.09 to 1.15), male sex (HR: 1.6; 95%CI: 1.1 to 2.5), hypertension (HR: 1.9; 95%CI: 1.2 to 3.0), and stent versus CABG (HR: 1.7; 95%CI: 1.1 to 2.6). In the stent group, independent predictors of mortality were threevessel disease (HR: 2.1; 95%CI: 1.1 to 3.7), age (HR: 1.10; 95%CI: 1.07 to 1.14), and hypertension (HR: 2.6; 95%CI: 1.3 to 3.1). In the CABG population, only age (HR: 1.11; 95%CI: 1.01 to 1.15) and male sex (HR: 2.1; 95%CI: 1.0 to 4.7) were predictive of higher mortality. Left main disease was no independent predictor of higher mortality.