

*Percutaneous Therapy for
Left Main & Multivessel CAD:*
SYNTAX

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Angioplasty Summit

April 25-27th 2007

Seoul, Korea



EVANSTON
NORTHWESTERN
HEALTHCARE

Ted Feldman MD, FACC, FSCAI

Disclosure Information

The following relationships exist:

Grant support: Abbott, Atritech, BSC, Cardiac Dimensions, Cordis, Evalve,
EV3, St Jude, .

Consultant: BSC, Cardiac Dimensions, Cordis, Edwards, Myocor

Speaker: Boston Scientific

*Off label use of products and investigational devices
will be discussed in this presentation*

Letters to the Editor

TRANSLUMINAL DILATATION OF CORONARY-ARTERY STENOSIS

SIR,—In September, 1977, we introduced a technique for percutaneous transluminal coronary angioplasty (P.T.A.). This technique consists of a catheter system introduced via the femoral artery under local anaesthesia. A preshaped guiding catheter is positioned into the orifice of the coronary artery and through this catheter a dilatation catheter is advanced into the branches of the artery. This dilatation catheter (outer diameter 0.5–1.25 mm) has a sausage-shaped distensible segment (balloon) at the tip.

After traversing the stenotic lesion the distensible segment is inflated with fluid (50% contrast material, 50% saline) to a maximum outer diameter of 3.0–3.8 mm by a pump-controlled pressure of 5 atmospheres (about 500 kPa). This pressure compresses the atherosclerotic material in a direction perpendicular to the wall of the vessel thereby dilating the lumen.

DETAILS OF FIVE CASES TREATED BY P.T.A.

| Patient | Age | Sex | Date of dilatation | Stenosis | Primary success |
|---------|-----|-----|--------------------|---------------------------|-----------------|
| 1 | 38 | M | Sept. 16, 1977 | L.A.D. 85% | + |
| 2* | 44 | M | Oct. 18, 1977 | L.C.A. 70% (calcified) | — |
| 3 | 43 | M | Jan. 10, 1978 | R.C.A. 80% | + |
| | | | Nov. 21, 1977 | L.A.D. 75% | + |
| 4* | 43 | M | Nov. 21, 1977 | R.C.A. 95% | + |
| | | | Nov. 24, 1977 | L.C.A. 80% | + |
| 5 | 61 | M | Dec. 20, 1977 | L.A.D. 95% | + |

L.C.A.=main left coronary artery; L.A.D.=left anterior descending; R.C.A.=right coronary artery.

*Dilatation done at University Hospital, Frankfurt.

Experience with over 250 peripheral-artery lesions treated by this technique has demonstrated, via morphological studies, that the atheroma can be compressed leaving a smooth luminal surface. The patency-rate, two years after dilatation of iliac and femoropopliteal atherosclerotic lesions, was greater than 70%.¹

After experimental² and intraoperative³ studies the first percutaneous coronary dilatation was done on Sept. 16, 1977. Five patients with severe stenotic lesions of the coronary arteries associated with refractory angina have so far been treated by coronary P.T.A. (table). Angiograms for one of these patients are shown in the figure. No complications were noted. Follow-up studies by serial stress-testing with myocardial imaging (thallium-201) and angiography suggest that P.T.A. may be an effective treatment in certain patients with severe discrete non-calcified lesions of the coronary arteries.

This technique, if it proves successful in long-term follow-up studies, may widen the indications for coronary angiography and provide another treatment for patients with angina pectoris.

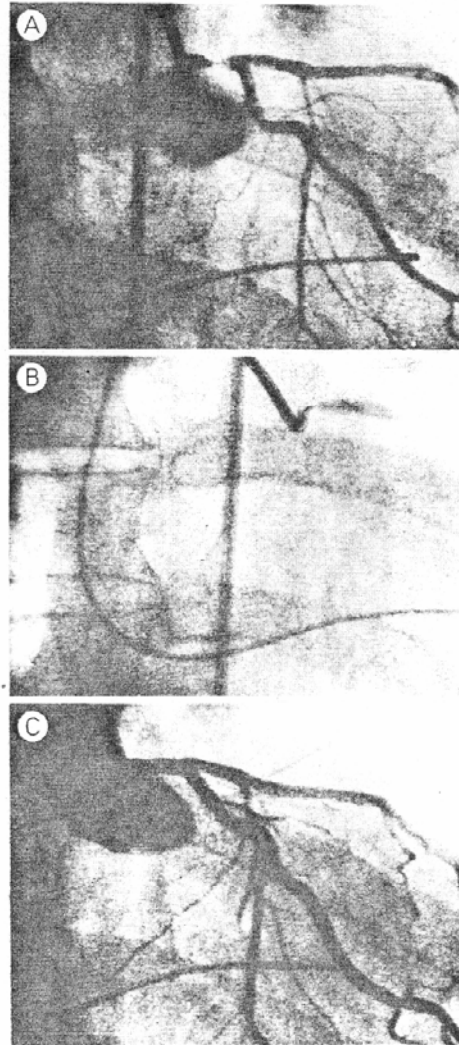
Department of Internal Medicine,
Medical Policlinic,
University Hospital,
8091 Zürich, Switzerland

ANDREAS GRÜNTZIG

1. Grüntzig, A. Die perkutane transluminale Rekanalisation chronischer Arterienverschlüsse mit einer neuen Dilatationstechnik; p. 50. Baden-Baden, 1977.

2. Grüntzig, A., Ruedhammer, H. H., Turina, M., Rutishauser, W. *Verh. Dtsch. Kreislaufforsch.* 1976, **42**, 282.

3. Grüntzig, A., Myler, R., Hanna, E., Turina, M. *Circulation*, 1977, **56**, 84 (abstr.).



Details of patient 3.

43-year-old man with severe angina pectoris since September, 1977. First angiogram (Nov. 11) revealed severe stenosis of the main L.C.A. and only slight wall abnormalities in some of the branches of L.C.A. After informed consent P.T.A. was done on Nov. 21.

(A) The angiogram before P.T.A. (done under nitroglycerine cover), with the guiding catheter in the orifice showed 80% proximal stenosis of the L.C.A.

(B) After passage of the dilatation catheter the distensible balloon segment was inflated twice to a maximum outer diameter of 3.7 mm. During the dilatation the patient experienced a short period of angina pectoris which quickly disappeared after deflation of the balloon.

(C) The angiogram after the procedure showed a good result without complications. There was no enzyme rise or E.C.G. change after the treatment. A good clinical result has persisted in the following weeks, confirmed by stress tests.

The LANCET
FEBRUARY 4, 1978

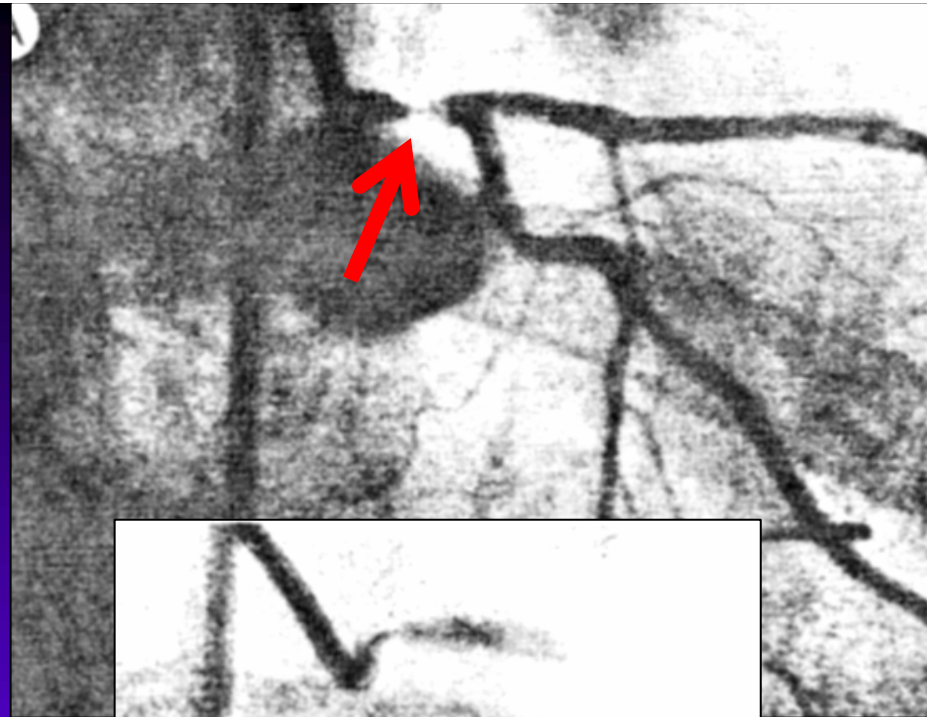
Letters to the
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CABG is better...

The NEW ENGLAND JOURNAL *of* MEDICINE

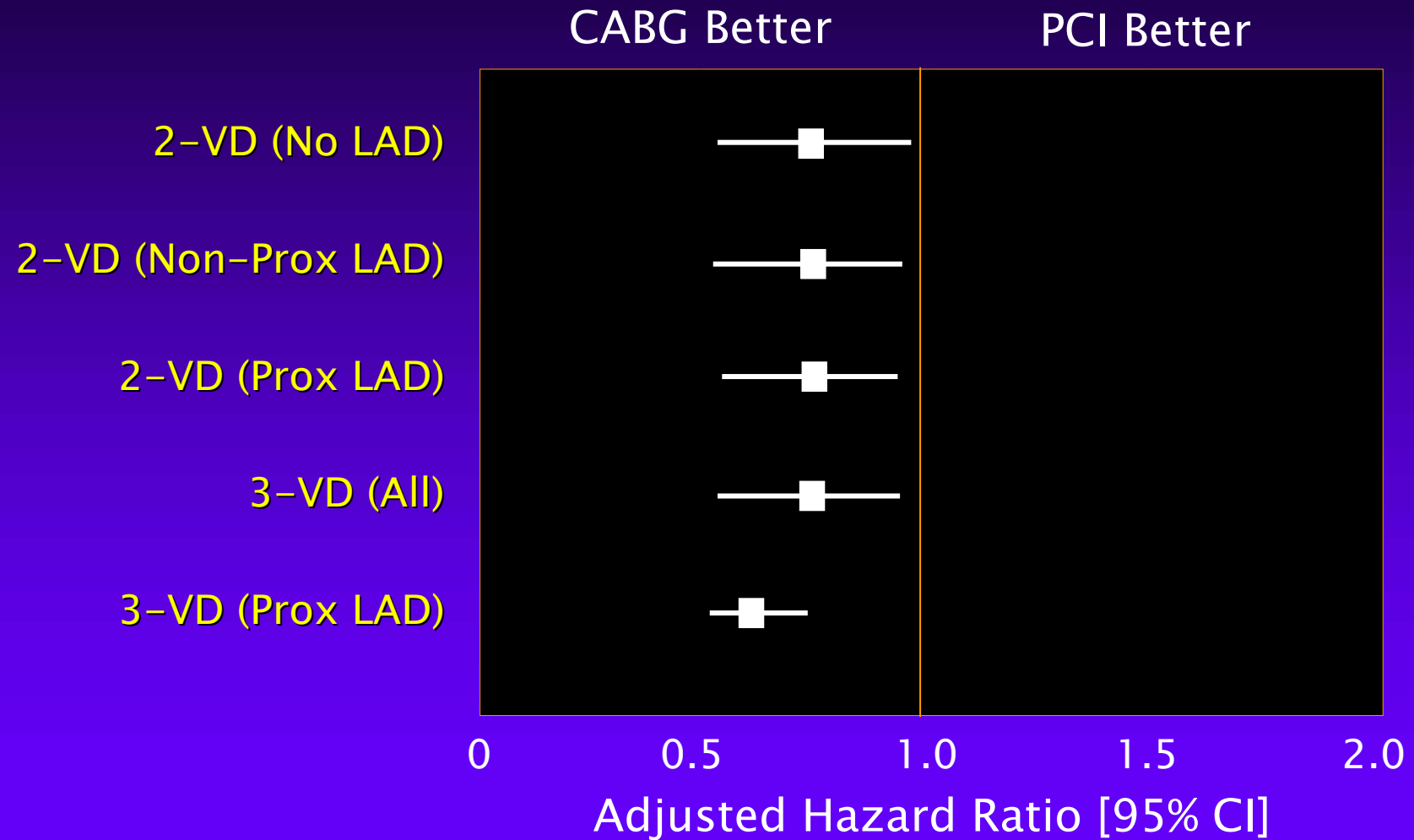
ORIGINAL ARTICLE

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.

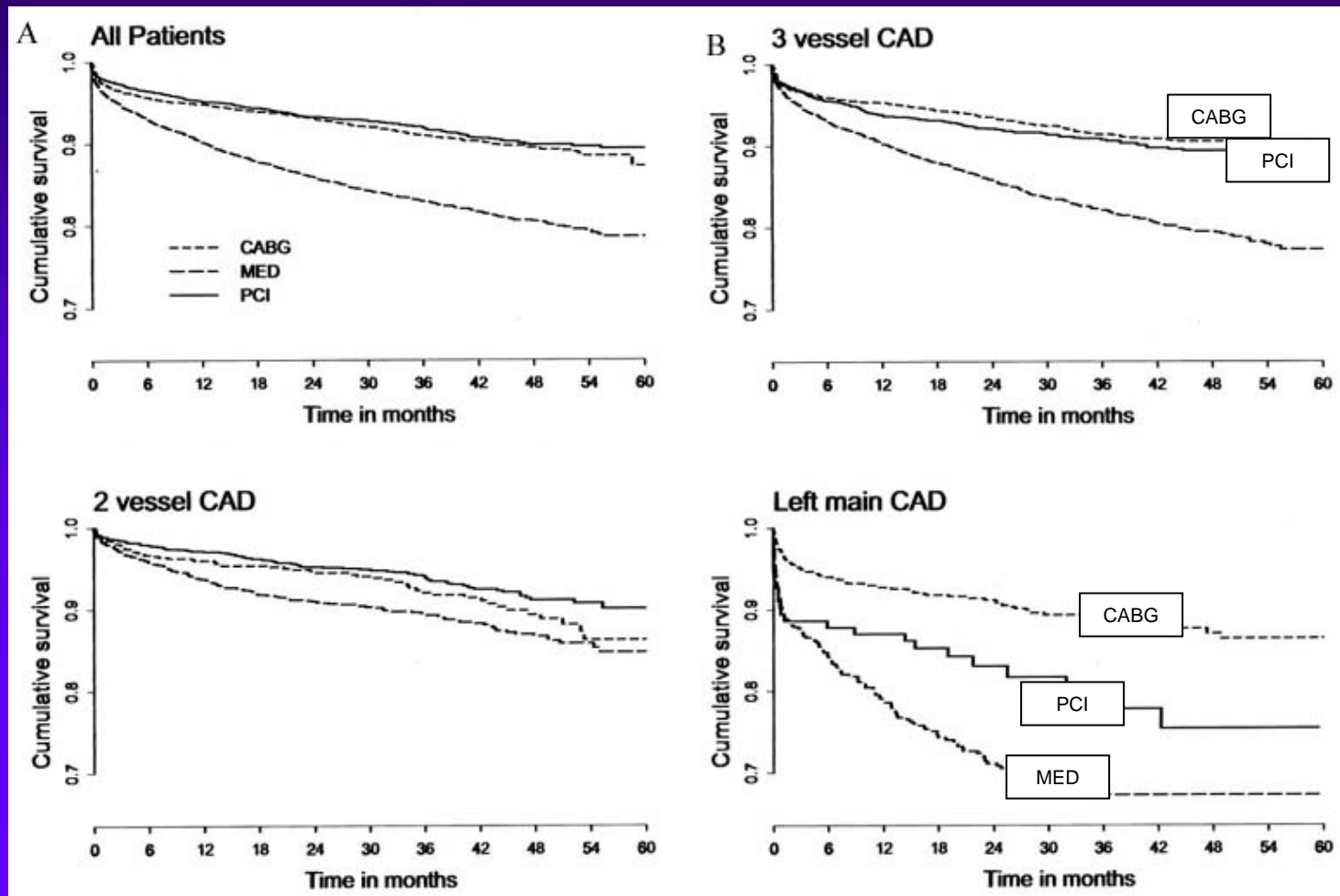
NEJM 2005;352:2174-2183

Hazard Ratio for Death following CABG *vs.* PCI



Long-term survival in 11,661 patients with multivessel CAD in the era of stenting (1995-98):

A report from the Alberta Provincial Project for Outcome Assessment in Coronary Heart Disease (APPROACH) Investigators



PCI is better...

Superior Treatment Modality

CABG PCI No difference

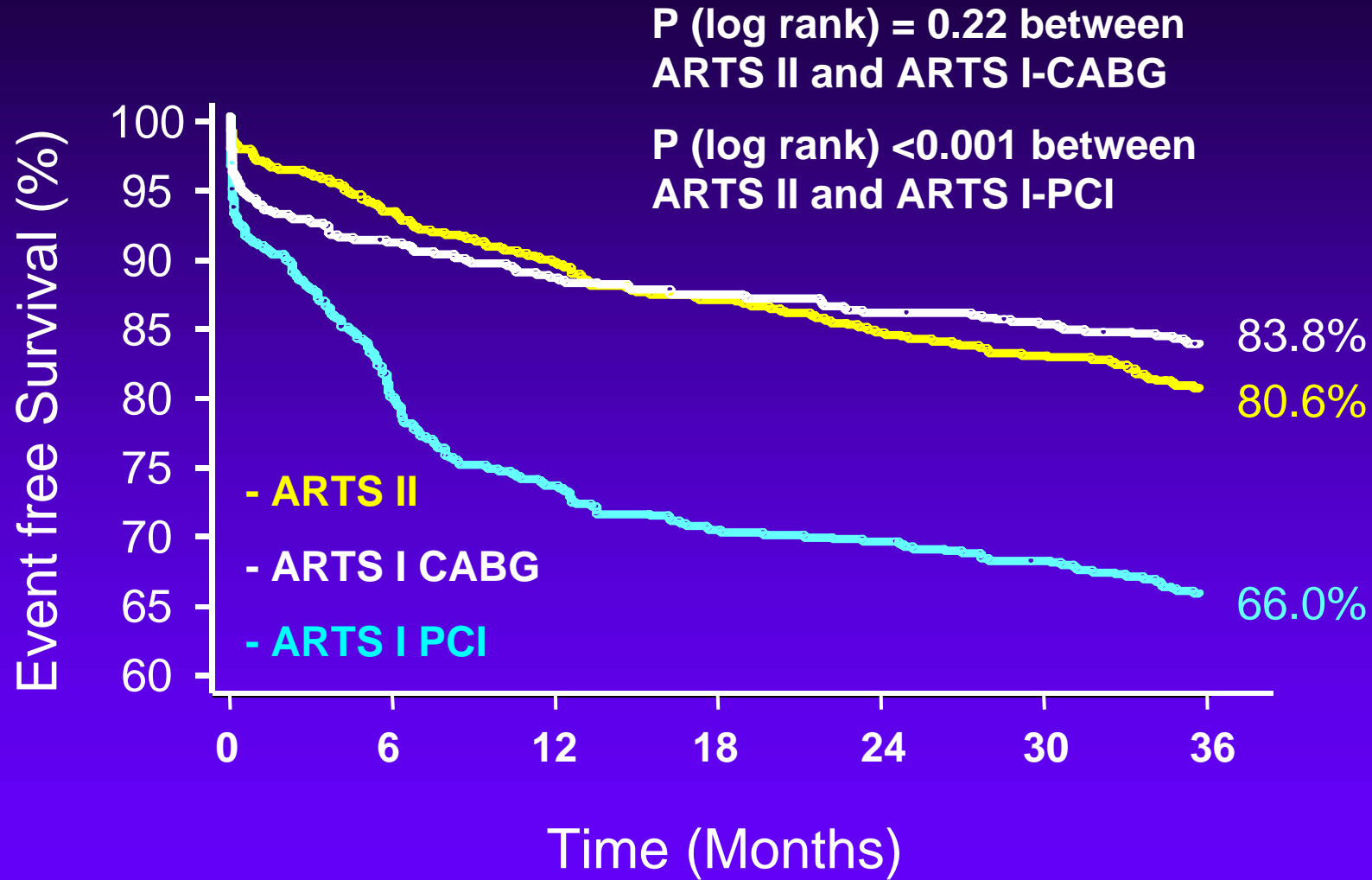
| Trial | Clinical Parameters | | | Angiographic Endpoints | Cost Assessment |
|---------|---------------------|---------------|---|------------------------|-----------------|
| | Mortality & MI | Angina Relief | Repeat Revascularization | | |
| GABI | PCI | PCI | Significant decrease of revascularization expected with DES | No difference | n/a |
| EAST | No difference | CABG | | CABG | PCI |
| RITA | No difference | CABG | | n/a | n/a |
| ERACI | No difference | CABG | | n/a | PCI |
| CABRI | No difference | CABG | | n/a | n/a |
| BARI | No difference | n/a | | n/a | n/a |
| MASS-2 | CABG (MI) | n/a | | n/a | No difference |
| AWESOME | No difference | No difference | | n/a | n/a |
| ERACI-2 | PCI | n/a | | CABG | No difference |
| SoS | CABG (Mortality) | CABG | | n/a | n/a |
| ARTS | No difference | n/a | | CABG | PCI |

ARTS II - Procedural Characteristics

| | ARTS II N=607 pts N=2160 les. | ARTS I (CABG) N=605 pts N=1638 les. | ARTS I (PCI) N=600 pts N=1606 les. |
|--|--|---|--|
| Lesions, # | 3.6 ↗ | 2.8 | 2.8 |
| Stented les. / anast. seg., # | 3.2 ↗ | 2.8 | 2.5 |
| Stents, # | 3.7 ↗ | - | 2.8 |
| Max. inflation pressure, atm | 16.4 ↗ | - | 14.6 |
| Total stent length, mm (range) | 72 ↗ 12-253 | - | 48 8-165 |
| GP IIb/IIIa inhibitor use, % | 32 | - | - |
| Use of arterial conduit, % | - | 93 | - |
| Duration of procedure, mins | 85 ↘ | 193 | 99 |
| Hospital stay, days since procedure | 3.4 | 9.6 | 3.9 |

Figures in Orange indicate statistical difference (95% CI) between ARTS II and ARTS I groups

ARTS II - MACCE up to 3 years

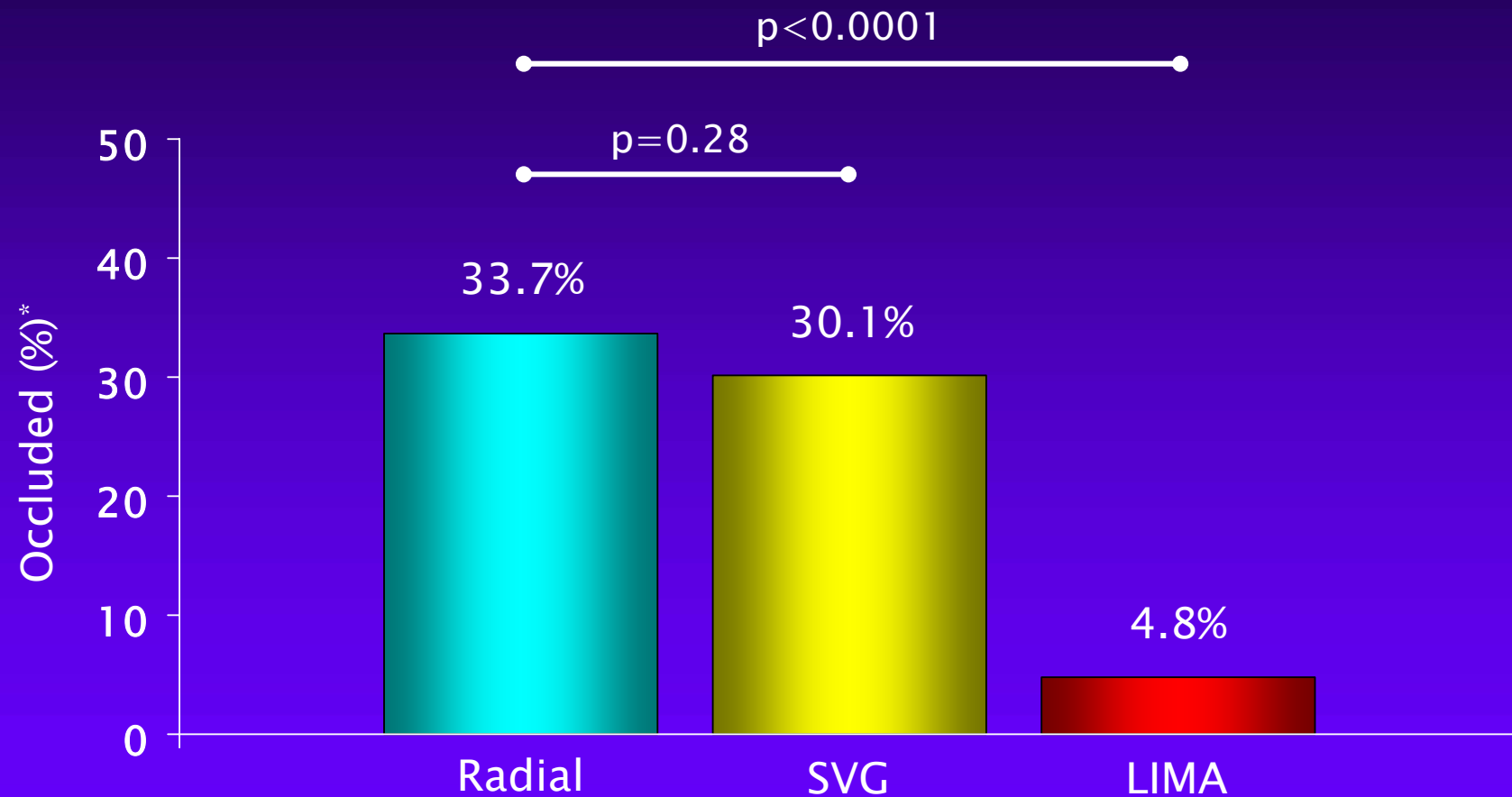


The old vein graft...



Graft Patency

LIMA, SVG and Radial artery grafts



*Mean follow-up 565 ± 511 days

Medicine enough for pain in chest?

Study sees way to avoid angioplasty

By Steve Sternberg
USA TODAY

NEW ORLEANS — Thousands of people with crushing chest pain who once opted for angioplasty as a quick fix may change their minds based on a landmark study out Monday showing that medication costs less, poses fewer risks and works just as well.

"I think this will change the discussion between the patient and doctor," says Raymond Gibbons of the



March 27, 2007

Angioplasty vs. medication

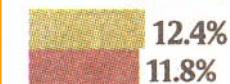
A landmark trial of 2,287 patients pitted angioplasty and medication vs. medication alone.

 **Angioplasty group**
 **Drug group**

Rate of deaths, heart attacks and strokes



Hospitalization rate for heart attacks and worsening chest pain



Hospitalization rate for heart attacks alone

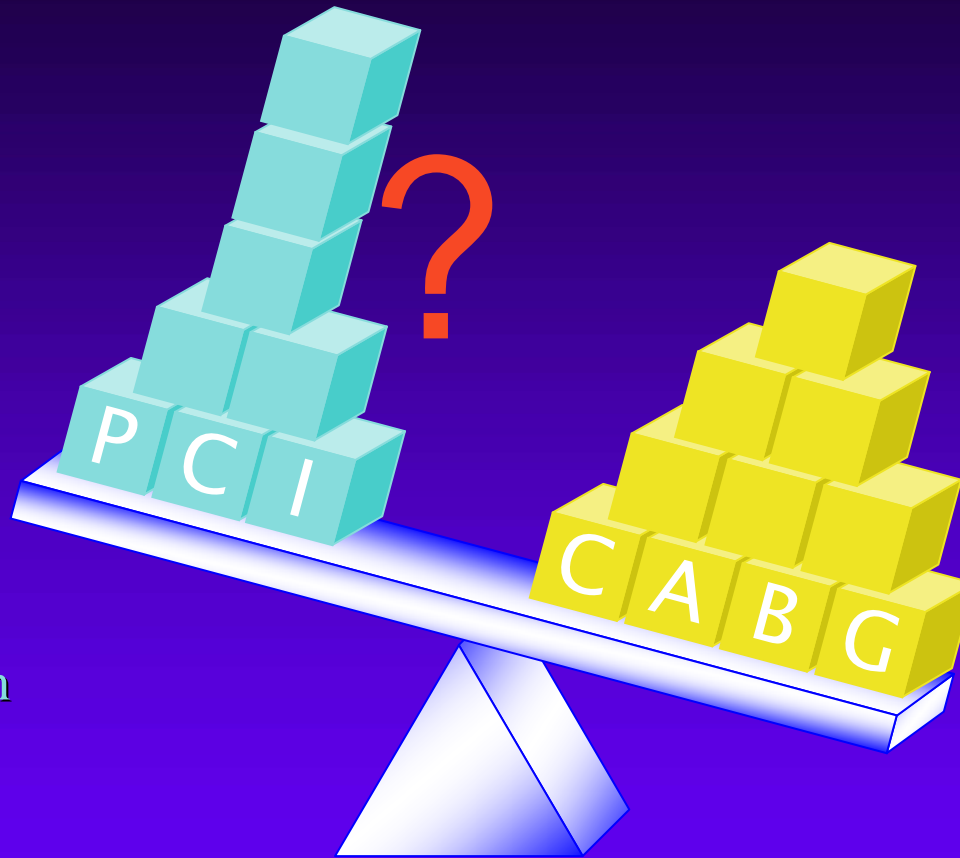


Source: *The New England Journal of Medicine*

PCI is just as good...

Evolution of Revascularization

- + Improved technique
- + Improved stent design
- + DES
- Restenosis
- Repeat revascularization



- + Off pump technique
- + Less invasive approach
- + Increased arterial revascularization
- + Optimal perioperative monitoring
- High costs
- Invasive

→ *Over the last decade, the standard of care for both CABG and PCI has continuously improved, leveling the playing field.*

Inclusions

- Stable/unstable angina
- De novo 3VD
- Left Main
- Left Main equivalent
- Left main with 1,2,3 vessel disease

Exclusions

- Age < 21 Years
- Previous CABG or PCI
- Acute Myocardial Infarction (CK > 2 x ULN)
- Concomitant cardiac Surgery
- Participation in other trial
- Uncertainty Adherence to protocol
- Pregnancy

Patient Flow

screening

Patients with de novo 3-vessel-disease ^{and} /or left main disease

registration

Physician Team
(surgeon and interventionalist)

amenable for both
treatments options

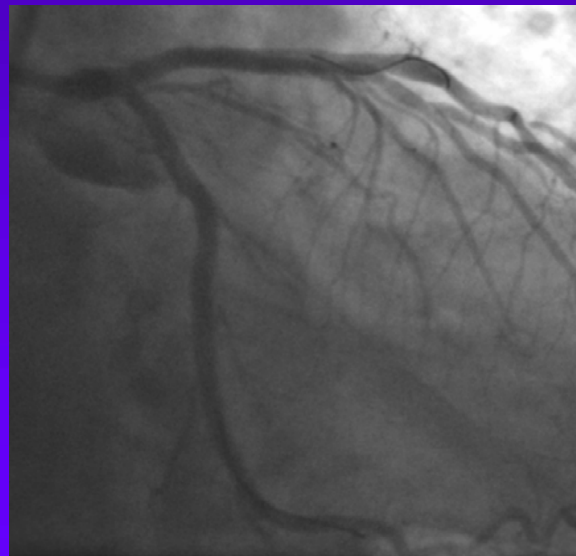
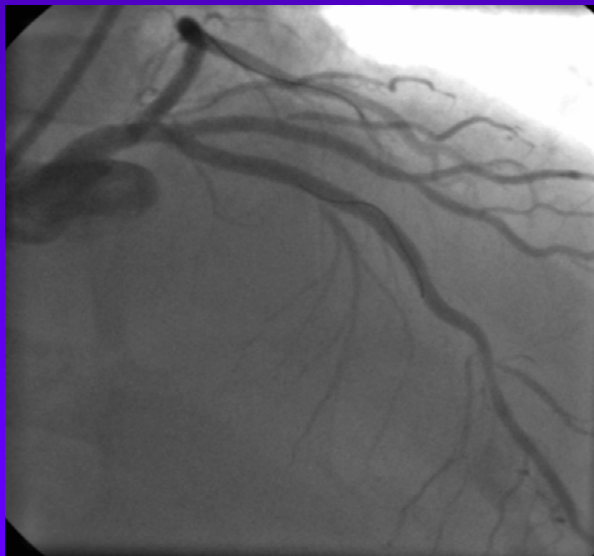
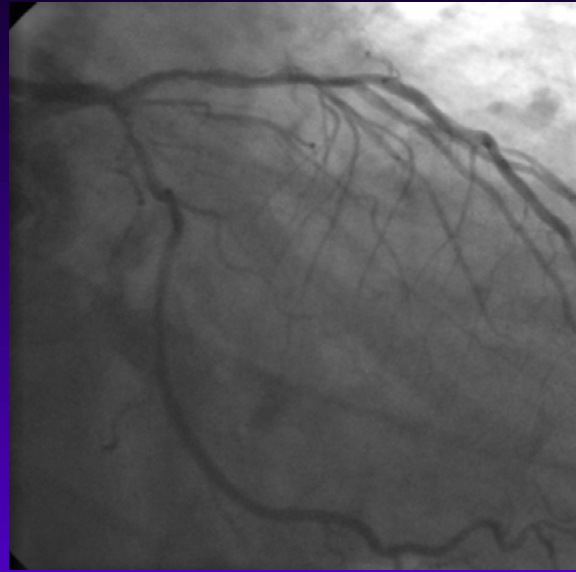
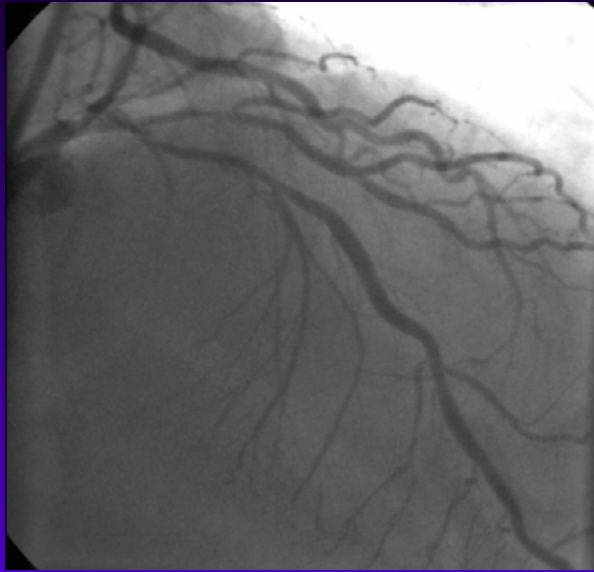
amenable for ≤ 1
interventional treatment

Multi-center randomized
controlled trial

Randomization
TAXUS vs CABG

Registries

- define CABG only population
- define PCI only population
- define patients/physicians refusing randomization



| Patient-related factors | | | Cardiac-related factors | | |
|--|--------|---|-------------------------------------|--------|---|
| Age (years) | 0 | 0 | Unstable angina ⁶ | No | 0 |
| Gender | Select | 0 | LV function | Select | 0 |
| Chronic pulmonary disease ¹ | No | 0 | Recent MI ⁷ | No | 0 |
| Extracardiac arteriopathy ² | No | 0 | Pulmonary hypertension ⁸ | No | 0 |
| Neurological dysfunction ³ | No | 0 | Operation-related factors | | |
| Previous Cardiac Surgery | No | 0 | Emergency ⁹ | No | 0 |
| Creatinine > 200 µmol/ L | No | 0 | Other than isolated CABG | No | 0 |
| Active endocarditis ⁴ | No | 0 | Surgery on thoracic aorta | No | 0 |
| Critical preoperative state ⁵ | No | 0 | Post infarct septal rupture | No | 0 |

Standard **EuroSCORE**

Note: Standard is now default calculator

About the "logistic"euroSCORE

Two risk calculators are available on this website: the simple additive EuroSCORE and the full logistic EuroSCORE. The reason for having both is explained below.

The simple additive EuroSCORE model is now well established and has been validated in many patient populations across the world. It is easy to use, even at the bedside. It is very valuable in quality control in cardiac surgery and gives quite a useful estimate of risk in individual patients. However, particularly in very high risk patients, the simple additive model may sometimes underestimate the risk when certain combinations of risk factors co-exist. The full logistic version of EuroSCORE produces more accurate risk prediction for a particular high risk patient. Its main disadvantage is that the risk has to be calculated in quite a complex way - not by mental arithmetic or "on the back of an envelope".

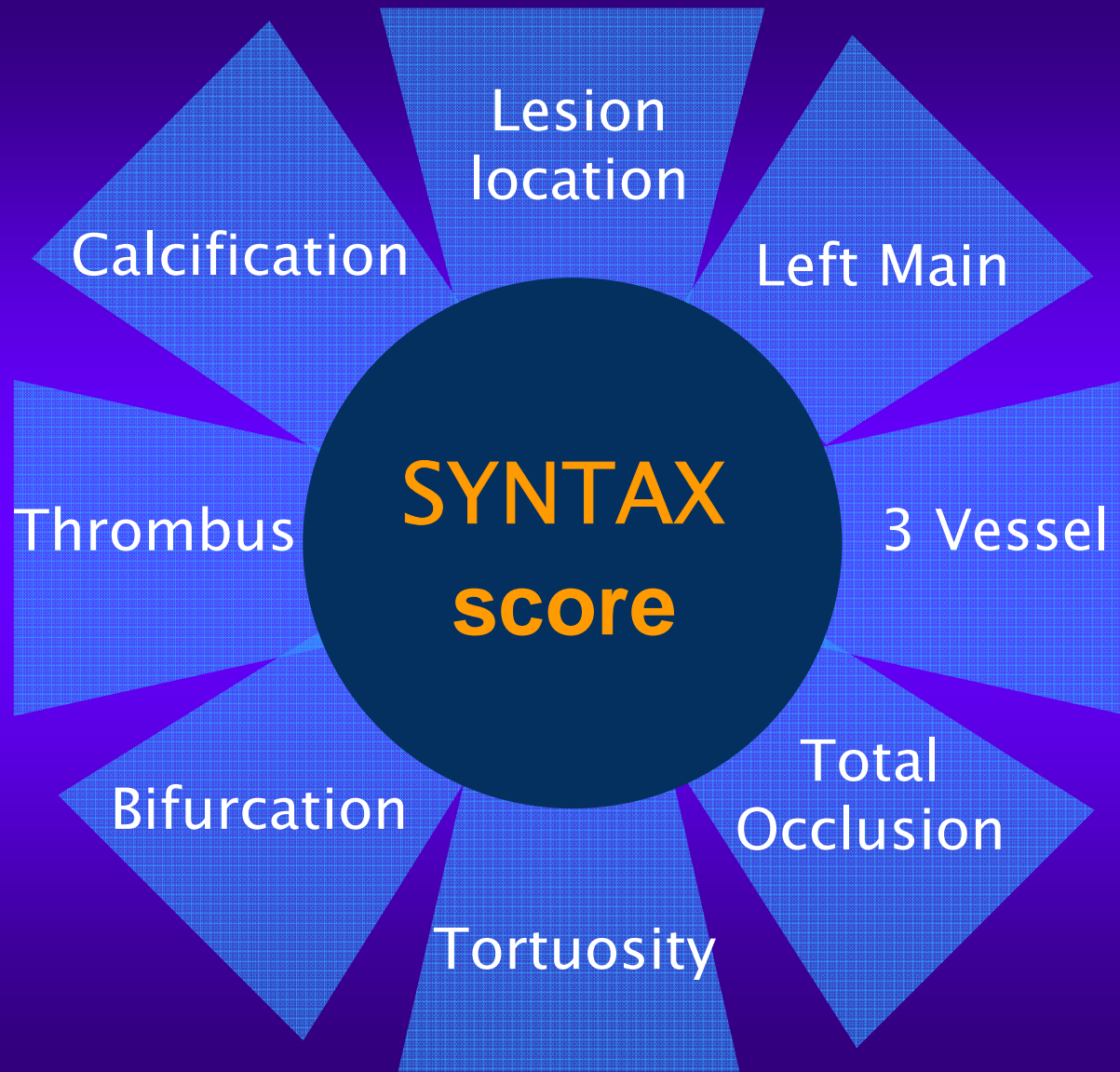
You are invited to try out both models and to use the one most suitable to your practice.

By selecting "Standard euroSCORE" euroSCORE values are simply added to estimate risk of death as described in Roques F, Nashef SA, et al. *Eur J Cardiothorac Surg.* 1999 Jun;15(6):816-22

By selecting "Logistic euroSCORE" - euroSCORE predicted mortality is calculated as described in Roques F, Michel P, Goldstone AR, Nashef SA. *Eur Heart J.* 2003 May;24(9):882-3

Notes

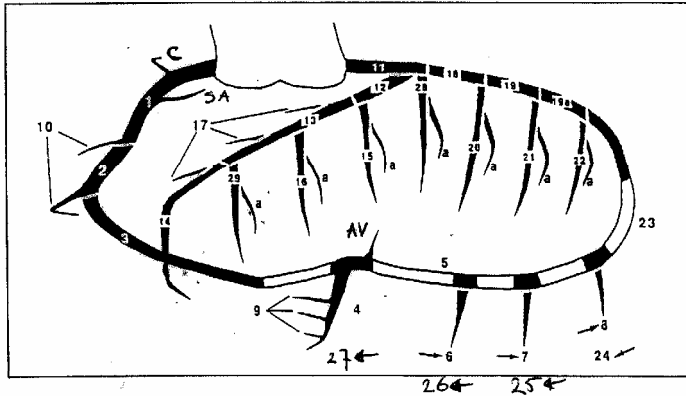
- [1] **Chronic pulmonary disease** Long term use of bronchodilators or steroids for lung disease
- [2] **Extracardiac arteriopathy** One or more of claudication, carotid occlusion or >50% stenosis, previous or planned intervention on the abdominal aorta, limb arteries or carotids
- [3] **Neurological dysfunction** Disease severely affecting ambulation or day-to-day functioning
- [4] **Active endocarditis** Patient still on antibiotic treatment for endocarditis at time of surgery
- [5] **Critical preoperative state** Ventricular Tachycardia / Ventricular Fibrillation or aborted sudden death, preoperative cardiac massage, preoperative ventilation before anaesthetic room, preoperative inotropes or IABP, preoperative Acute Renal Failure (anuria or oliguria <10ml/hr)
- [6] **Unstable angina** Rest angina requiring i.v. nitrates until arrival in anaesthetic room
- [7] **Recent MI** Myocardial infarction within 90 days
- [8] **Pulmonary hypertension** Systolic pulmonary artery pressure >60mmHg
- [9] **Emergency** Operation before beginning of next working day



Goal: SYNTAX score to provide guidance on optimal revascularization strategies for patients with high risk lesions

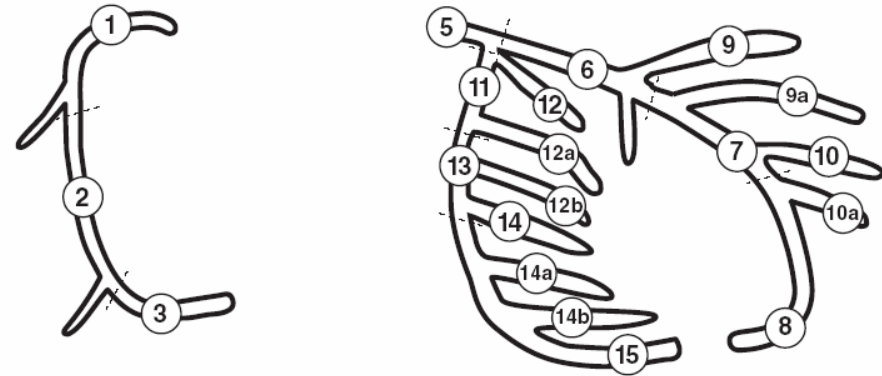
Identify coronary segment(s) with significant (> 50%) stenosis at previous angiography
(tick all that apply)

- | | | | |
|---|--|--|--|
| <input type="checkbox"/> 1. Prox RCA | <input type="checkbox"/> 11. LMCA | <input type="checkbox"/> 19. Mid CX | <input type="checkbox"/> 25. 2nd LPL |
| <input type="checkbox"/> 2. Mid RCA | <input type="checkbox"/> 12. Prox LAD | <input type="checkbox"/> 19a. Dist CX | <input type="checkbox"/> 26. 3rd LPL |
| <input type="checkbox"/> 3. Dist RCA | <input type="checkbox"/> 13. Mid LAD | <input type="checkbox"/> 20. 1st OM | <input type="checkbox"/> 27. LPDA |
| <input type="checkbox"/> 4. RPDA | <input type="checkbox"/> 14. Dist LAD | <input type="checkbox"/> 20a. LAT 1st OM | <input type="checkbox"/> 28. Ramus/OD |
| <input type="checkbox"/> 5. RPLS | <input type="checkbox"/> 15. 1st Diag | <input type="checkbox"/> 21. 2nd OM | <input type="checkbox"/> 28a. LAT Ramus/OD |
| <input type="checkbox"/> 6. 1st RPL | <input type="checkbox"/> 15a. LAT 1st Diag | <input type="checkbox"/> 21a. LAT 2nd OM | <input type="checkbox"/> 29. 3rd Diag |
| <input type="checkbox"/> 7. 2nd RPL | <input type="checkbox"/> 16. 2nd Diag | <input type="checkbox"/> 22. 3rd OM | <input type="checkbox"/> 29a. LAT 3rd Diag |
| <input type="checkbox"/> 8. 3rd RPL | <input type="checkbox"/> 16a. LAT 2nd Diag | <input type="checkbox"/> 22a. LAT 3rd OM | <input type="checkbox"/> C. Conus |
| <input type="checkbox"/> 9. Inf. Septal | <input type="checkbox"/> 17. 1st Septal | <input type="checkbox"/> 23. LAV | <input type="checkbox"/> SA. Sinoatrial |
| <input type="checkbox"/> 10. AC Marg | <input type="checkbox"/> 18. Prox CX | <input type="checkbox"/> 24. 1st LPL | <input type="checkbox"/> AV. AV Nodal |



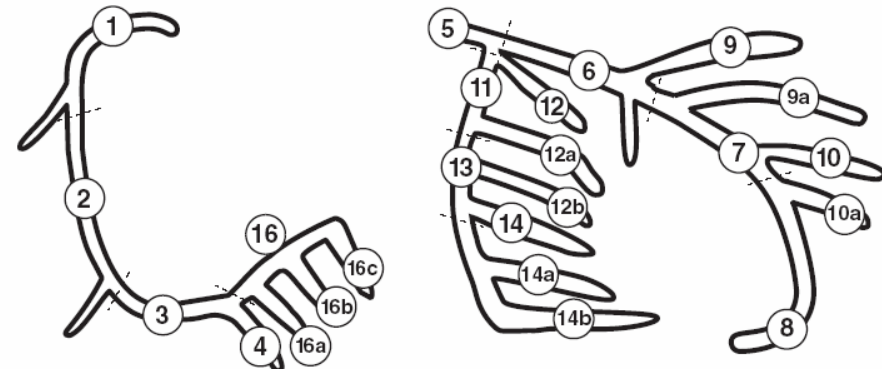
BARI

Left dominance

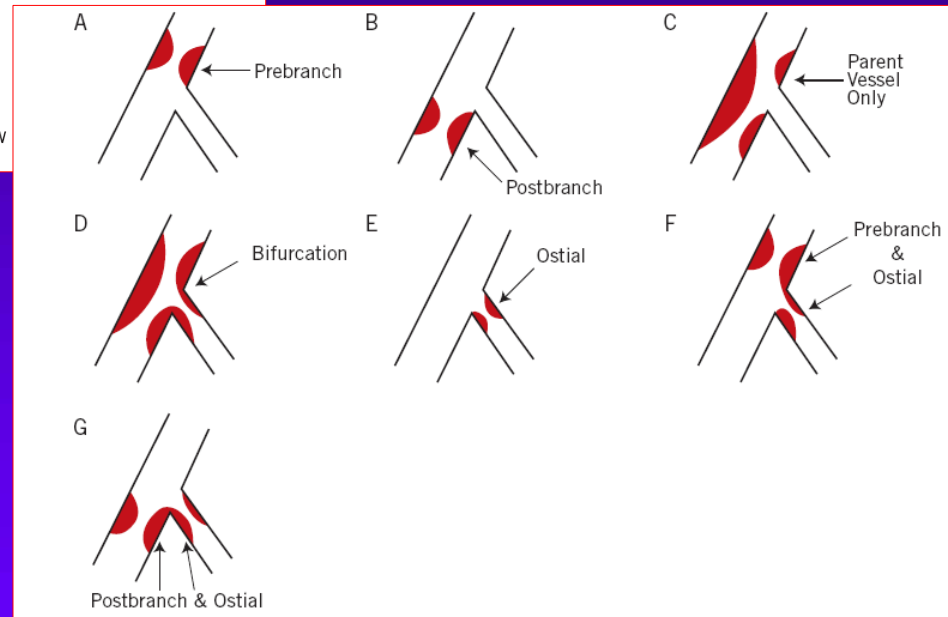
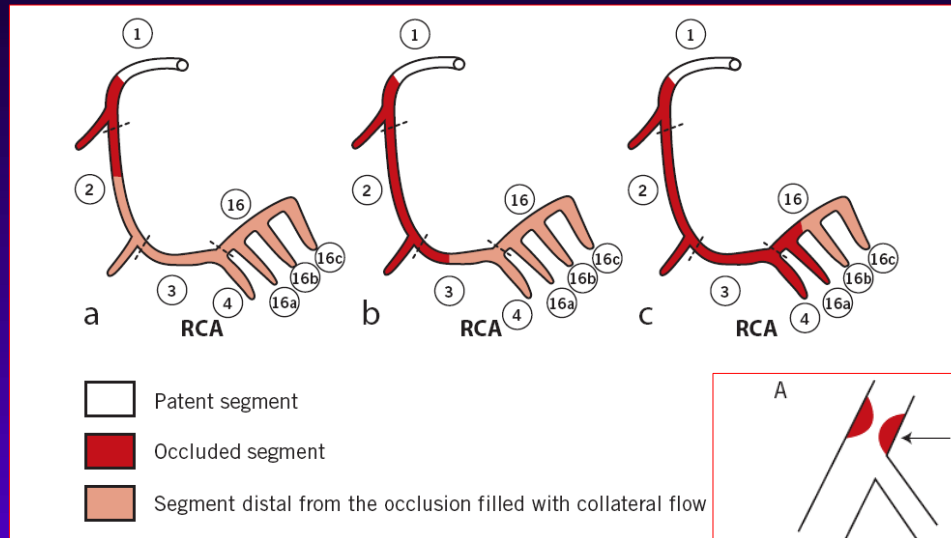


ARTS 1&2/ Syntax

Right dominance



SYNTAX Score

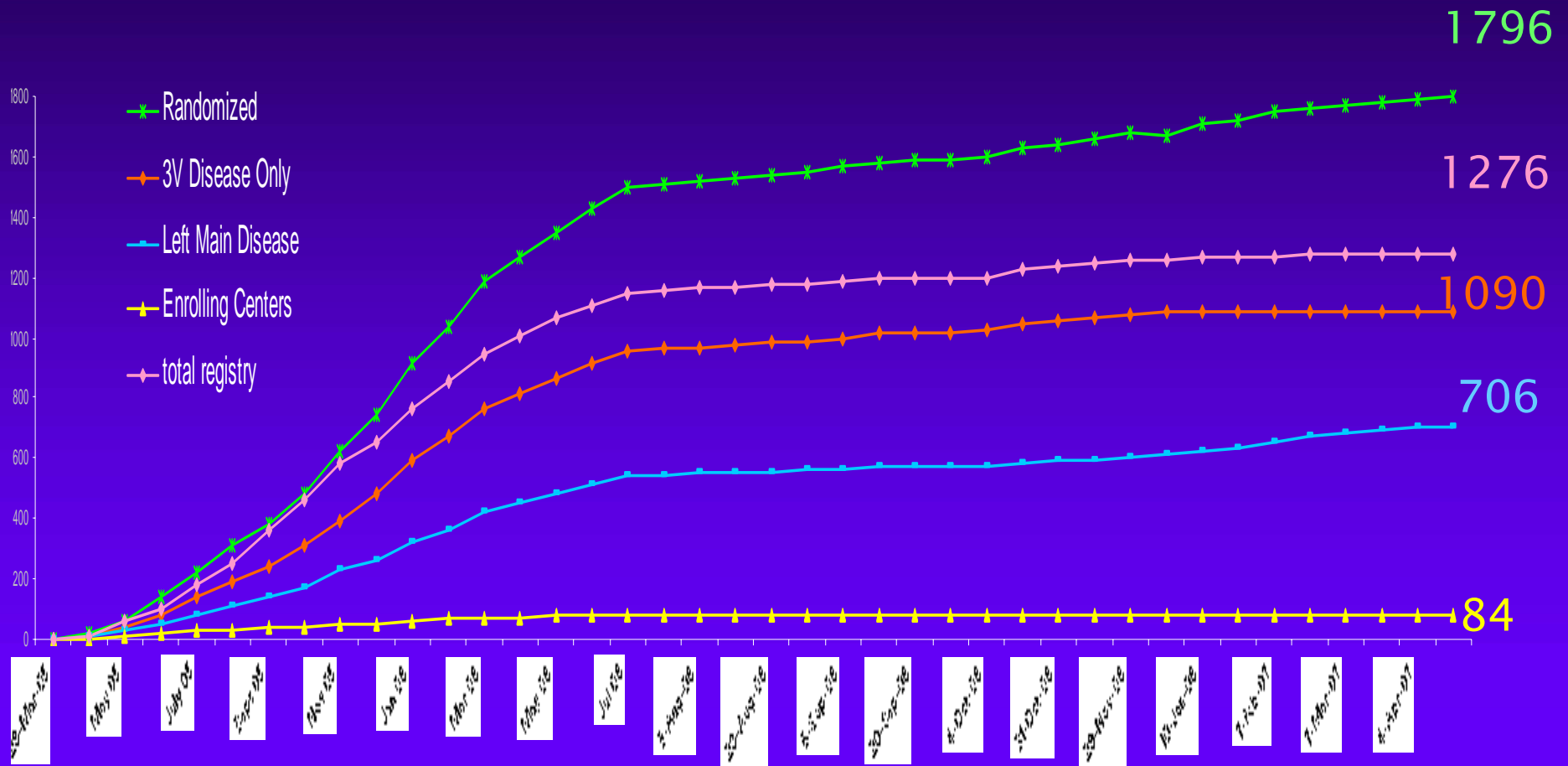


- Occlusion
- Ostial location
- Tortuosity
- Length >20mm
- Heavy calcification
- Thrombus
- Diffuse disease

Raw SYNTAX Score $\xrightarrow{\text{MACE (1 yr)}}$ Weighted SYNTAX Score



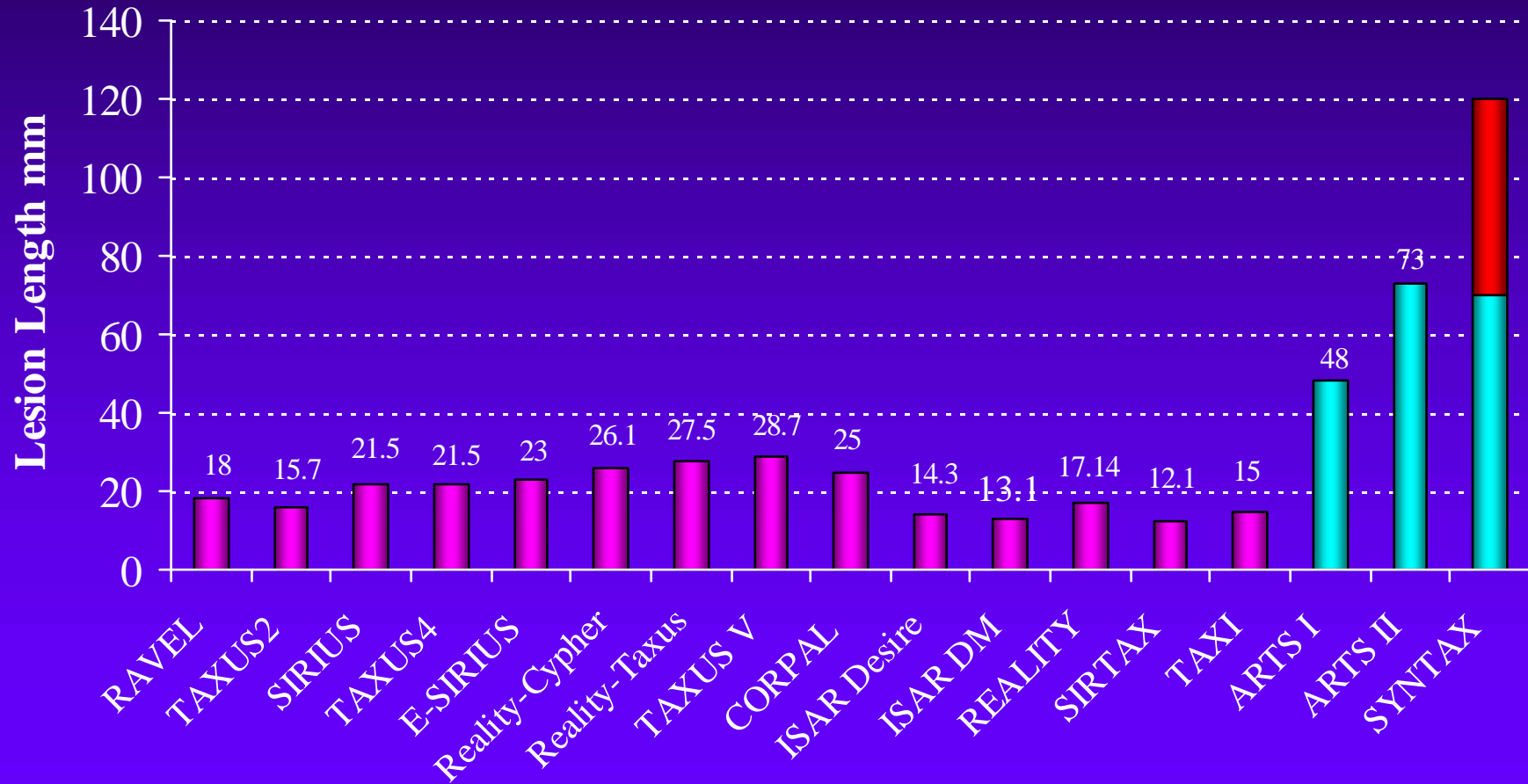
Overall enrollment – Apr 18



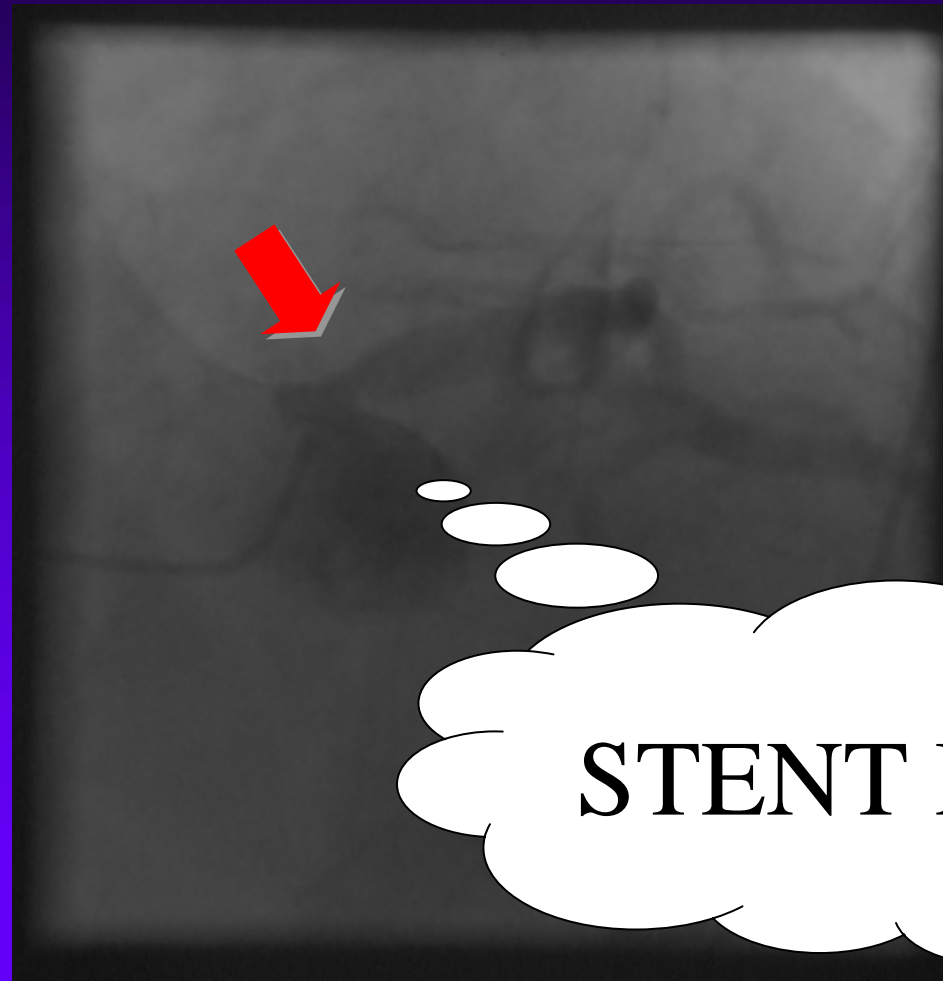
One patient to go 4/24/2007.....

DES Trial Comparison

Lesion Length



Left Main Stenosis



STENT ME !!