

We Should Be Offering More PCI to Patients With Complex Multivessel Disease

LEFT MAIN PCI MADE EASY

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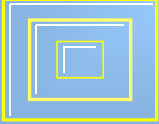
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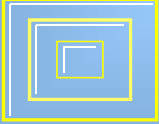
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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<u>Affiliation/Financial Relationship</u>	<u>Company</u>
Grant/Research Support	Boston, Abbott, Medtronic, Edwards
Consulting Fees/Honoraria	Boston, Abbott, Medtronic, Abiomed, Shockwave
President (unpaid)	NBPAS



- **I encourage you to interpret our trial data from the patient's perspective...ie don't worship "p" values.**



EXCEL

Five-year Outcomes from a Randomized
Trial of PCI vs. CABG in Patients with
Left Main Coronary Artery Disease

Gregg W. Stone MD

for A. Pieter Kappetein, Joseph F. Sabik,
Patrick W. Serruys and the EXCEL investigators



Study Design

2900 pts with unprotected left main disease

↓
SYNTAX score ≤ 32

Consensus agreement of eligibility and equipoise by heart team



Yes
(N=1900)

→ No
(N=1000)

↓
Enrollment
registry

Stratified by diabetes, SYNTAX score and center



FU = 93.3%

PCI (Xience EES)
(N=950)

CABG
(N=950)

FU = 91.0%

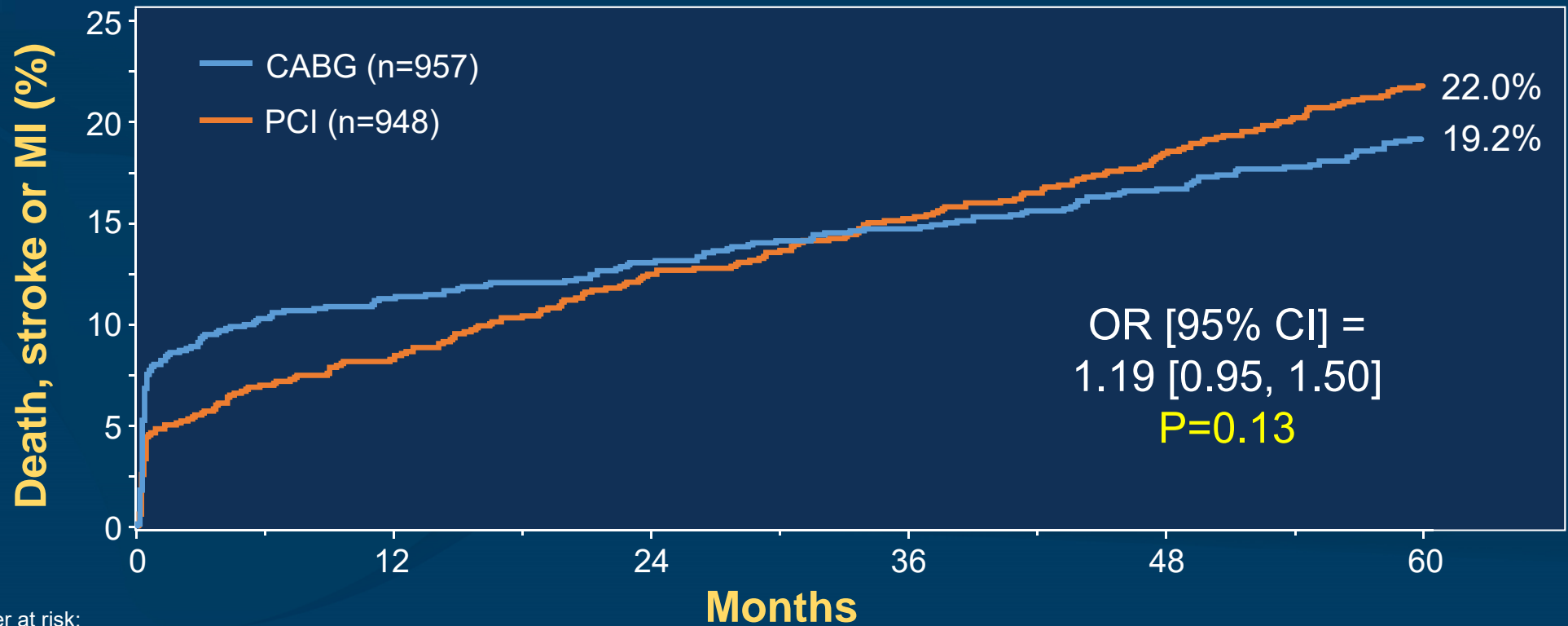
Follow-up: 1 month, 6 months, 1 year, annually through 5 years

Primary endpoint: Measured at a median 3-yr FU, minimum 2-yr FU



Primary Endpoint

All-cause Death, Stroke or MI at 5 Years



Number at risk:

Number at risk:	0	12	24	36	48	60
PCI	948	854	809	778	738	486
CABG	957	818	789	763	734	532

Death at 5 Years

	PCI (N=948)	CABG (N=957)	Difference [95% CI]	Odds ratio [95% CI]
Death, all-cause	13.0% (119)	9.9% (89)	3.1% [0.2%, 6.1%]	1.38 [1.03, 1.85]
- Cardiovascular	6.8% (61)	5.5% (49)	1.3% [-0.9%, 3.6%]	1.26 [0.85, 1.85]
- Definite cardiovascular	5.0% (45)	4.5% (40)	0.5% [-1.4%, 2.5%]	1.13 [0.73, 1.74]
- Undetermined cause	1.9% (16)	1.1% (9)	0.9% [-0.3%, 2.0%]	1.78 [0.78, 4.06]
- Non-cardiovascular	6.6% (58)	4.6% (40)	2.0% [-0.2%, 4.2%]	1.47 [0.97, 2.23]



Death at 5 Years

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PCI was associated with a relative 38% increase in death



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PCI was associated with a relative 38% increase in death				
Freedom from death, i.e. your chance of being alive	87.0%	90.1%	3.1%	
CABG was associated with an absolute 3.1% reduction in death				
NNT to save one life is 32.2 ie we have to do 32 open chest surgeries to save a life				



Repeat Revascularization at 5 Years

	PCI (N=948)	CABG (N=957)	Difference [95% CI]	Odds ratio [95% CI]
Ischemia Driven revascularization	16.9% (150)	10.0% (88)	6.9% [3.7%, 10.0%]	1.84 [1.39, 2.44]
- PCI	14.1% (125)	9.1% (80)	4.9% [1.9%, 7.9%]	1.65 [1.22, 2.22]
- CABG	4.3% (38)	0.9% (8)	3.4% [1.9%, 4.9%]	4.90 [2.27, 10.56]
All revascularization	17.2% (153)	10.5% (92)	6.7% [3.5%, 9.9%]	1.79 [1.36, 2.36]

PCI was associated with a relative 57% increase in subsequent revascularization



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PCI was associated with a relative 57% increase in subsequent revascularization

Freedom from revascularization

ie, your chance of not needing another procedure

82.8%

89.5%

6.7%

CABG was associated with an absolute 6.7% reduction in subsequent revascularization

NNT to avoid one revasc is 14.96 ie we have to do 15 open chest surgeries to avoid one repeat radial PCI

Stroke/TIA at 5 Years

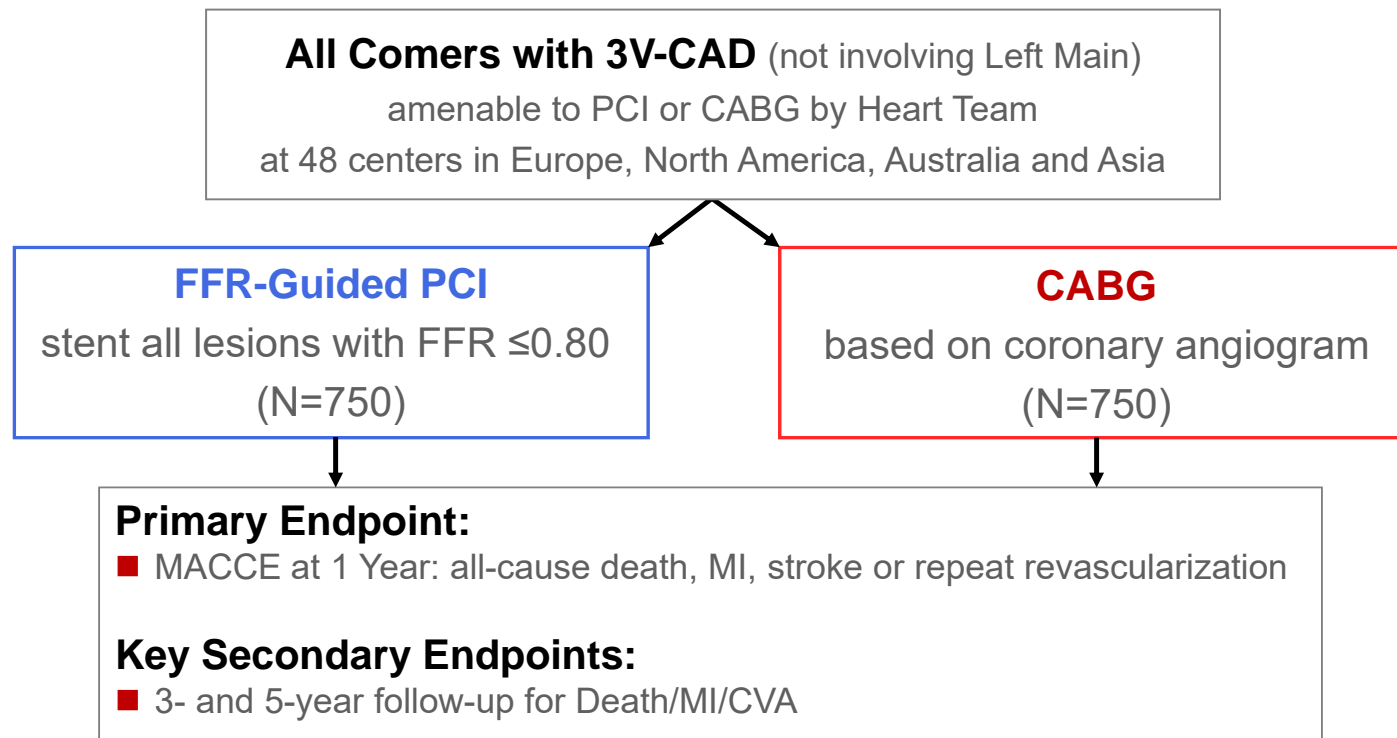
	PCI (N=948)	CABG (N=957)	Difference [95% CI]	Odds ratio [95% CI]
Cerebrovascular events	3.3% (29)	5.2% (46)	-1.9% [-3.8%, 0.0%]	0.61 [0.38, 0.99]
- Stroke	2.9% (26)	3.7% (33)	-0.8% [-2.4%, 0.9%]	0.78 [0.46, 1.31]
- Transient ischemic attack	0.3% (3)	1.6% (14)	-1.3% [-2.2%, -0.4%]	0.21 [0.06, 0.74]

Should we say CABG was associated with a relative 58% increase in stroke/TIA?

Fractional Flow Reserve-Guided PCI Compared with Coronary Bypass Surgery:

Study Design

The FAME 3 Trial





The FAME 3 Trial

PCI (N=757)

CABG (N=743)

HR

p

	PCI (N=757)	CABG (N=743)	HR	p
Death, MI, CVA, Revasc	10.6%	6.9%	1.5	0.35 non-inf
- Death	1.6	0.9	1.7	
- MI	1.7	1.2	1.5	
- Stroke	0.9	1.1	0.9	
- Revascularization	5.9	3.9	1.5	

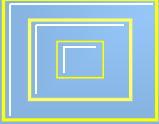
PCI was associated with a 54% increase in MACE

Freedom from Death, MI, CVA, Revasc	89.4	93.1
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CABG was associated with an absolute 3.7% reduction in MACE

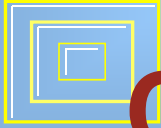
NNT to avoid one MACE is 27, ie we have to do 27 open chest surgeries to avoid one MACE and that includes revascularization.

Absolute reduction in revascularization only 2%, ie NNT is 50 bypasses to avoid one repeat PCI



There is PLENTY of data that support complex, multivessel PCI

Stop worshipping “p” values and start seeing things from the patient’s perspective!



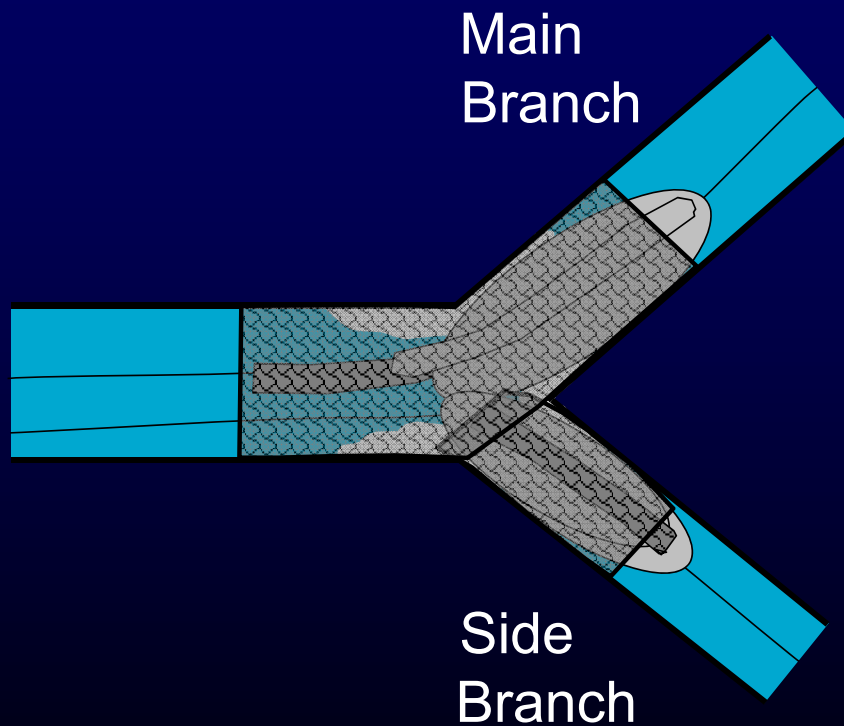
Complex Unprotected left main PCI Made Simple

**Your patients DESERVE: Imaging, physiology,
bifurcation stenting, microcatheters, guide extensions,
Wiggle wires, advanced CTO techniques, atheroablation,
Shockwave, Impella, ECMO, TAVR, etc...**

These technologies are becoming easier to use

The TAP Technique

T stent And Protrusion



- ▶ Wire both vessels
- ▶ Pre-dilate as needed and image
- ▶ Position and deploy main branch stent
- ▶ Rewire side branch and balloon dilate
- ▶ Position side branch stent so proximal edge protrudes slightly into main branch, 'backstop' balloon in main branch
- ▶ Deploy side branch stent first, then inflate main branch balloon to kiss

TAP Technique

Advantages:

- Less metal at side branch ostium compared to crush or coluttes
- Assures ostium coverage
- Relatively simple, usually 7 FR radial.

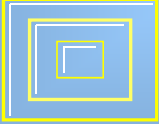
TAP Technique

Advantages:

Relatively simple. 7 FR radial most of the time.

Assures ostium coverage

Less metal at side branch ostium compared to crush or coluttes



The “Heart Team” and informed consent

What’s missing from the PCI vs CABG trial data discussion?

- Why does the debate seem to always focus on mortality and repeat revascularization?
- Shouldn’t we include morbidity endpoints?
- What about return to work?
- What about pain?
- What about depression?
- AFIB, RENAL FAILURE, BLEEDING...?

POD #1 after multi vessel revascularization: CABG



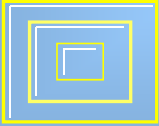
POD # 0, 3 hours after multi vessel revascularization: PCI



What is adequate informed consent? Risks and alternatives.

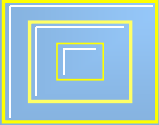
What risks should be disclosed...mortality, stroke, infection, renal failure, atrial fibrillation, pain, soreness, discomfort????





**Something never heard from the podium:
“The Heart Team and ‘Shared Decision Making’ are overrated”
---Paul S. Teirstein**

- **“Medicine is not a democracy” – Alvin S. Teirstein**
- **I find our “Heart Team” is rarely in agreement with respect to CAD**
- **I find few patients can really analyze the data and make an informed decision**
 - **Patients make decisions based mostly on**
 - The confidence they get from the surgeon or interventionalist
 - Their fear of open chest surgery
 - The experiences of their friends and family
- **If a decision is controversial, I tell the patient:**
- **1) You have alternatives**
- **2) Our heart team isn’t in agreement on the best way to treat you, but if it were me or my family member, I would recommend...**



You Can Call Me Now...

...Or You Can Call Me Later

- Bypa
- You
- You
- You
- But,
- An
- So
- Or,



CLINIC