



Avaliação Anatômica e Funcional das Lesões Coronárias no Laboratório de Hemodinâmica

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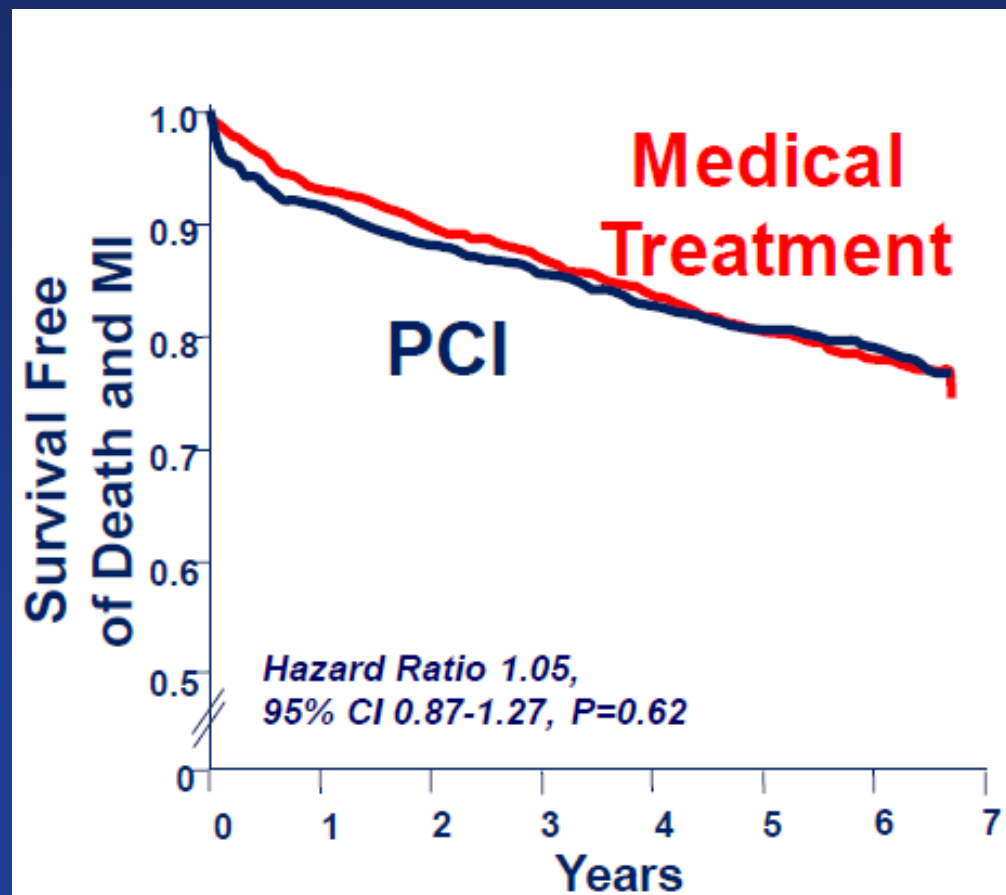


Congresso
Novas Fronteiras em Cardiologia
8 a 10 fevereiro.2013
Hotel Vila Galé Ericeira

- ⇒ A angiografia coronária continua a ser o principal método de avaliação e quantificação das lesões coronárias
- ⇒ Grande variabilidade entre observadores
- ⇒ A presença de isquemia do miocárdio é um importante factor de risco para a ocorrência de eventos clínicos adversos
- ⇒ A decisão de revascularização coronária baseada na angiografia nem sempre está associada com a presença de isquemia do miocárdio nos exames não invasivos
- ⇒ Em lesões sem evidência de isquemia o benefício da revascularização cirúrgica e percutânea é pouco claro mantendo-se os riscos inerentes a revascularização

COURAGE

2287 patients with stable angina randomized to Medical Treatment (MT) versus Percutaneous Coronary Intervention (PCI) plus MT



COURAGE

Criticisms ++

- Elevada compliance da terapêutica médica
- População de baixo risco
- Revascularização incompleta no grupo tratado com PCI
- Muitas lesões não significativas intervencionadas
- Baixa Taxa de sucesso de PCI
- BMS em mais de 95 % dos casos
- Elevado “cross over” para PCI
- Diferenças importantes entre centros

COURAGE

What did I learn?

- ✓ A terapêutica médica é essencial e está sub prescrita na prática clínica diária
- ✓ Quanto maior a extensão da isquemia maior o benefício da angioplastia coronária
- ✓ A revascularização incompleta está associada com menor benefício clínico e com aumento de reintervenções coronárias
- ✓ A terapêutica médica e a angioplastia coronária são terapêuticas complementares e sinérgicas para o tratamento da doença coronária

Functional Evaluation of Coronary Lesions

- Fractional Flow Reserve (FFR)
- Instantaneous Wave-Free Ratio (IFR)

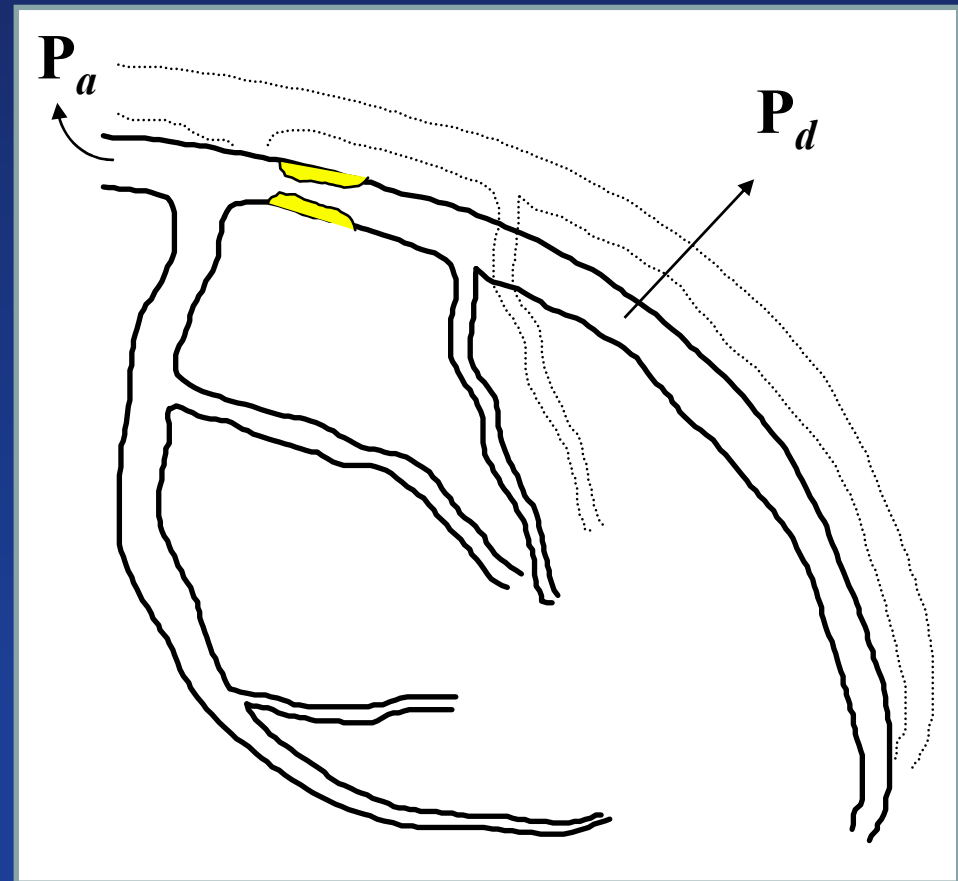
Anatomic Evaluation of Coronary Lesions

- ➔ IntraVascular UltraSound (IVUS)
- ➔ Optical Coherence Tomography (OCT)

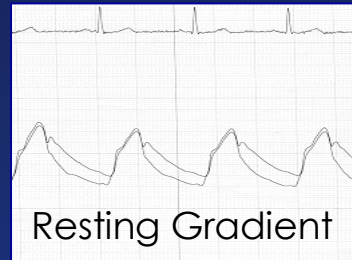
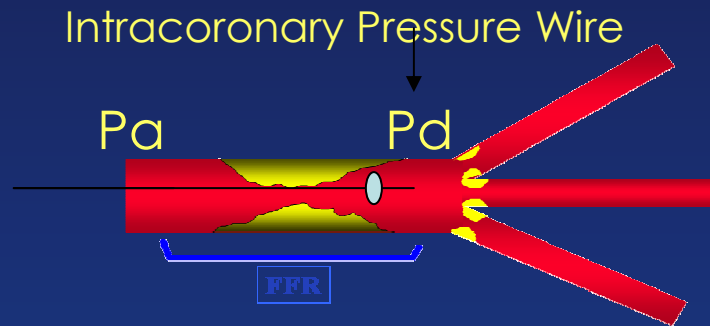
What is Fractional Flow Reserve (FFR) ?

Ratio of distal mean coronary
pressure to mean aortic
pressure in the stenotic vessel
during maximum hyperemia

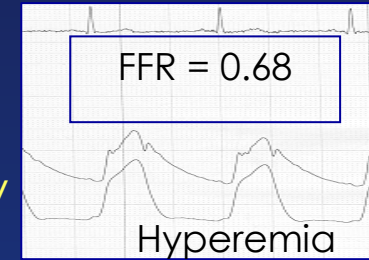
$$FFR = P_d / P_a$$



General Procedure and Outcome



Adenosine IC/IV



- Includes effects of collateral flow
- Applicable in 3 vessels disease
- Real time evaluation post procedure

Conditions	FFR
Normal Vessel	1
Successful Post Stent	>94
Successful PTCA	>90
Deferral Diagnostic	> 0.75-0.80

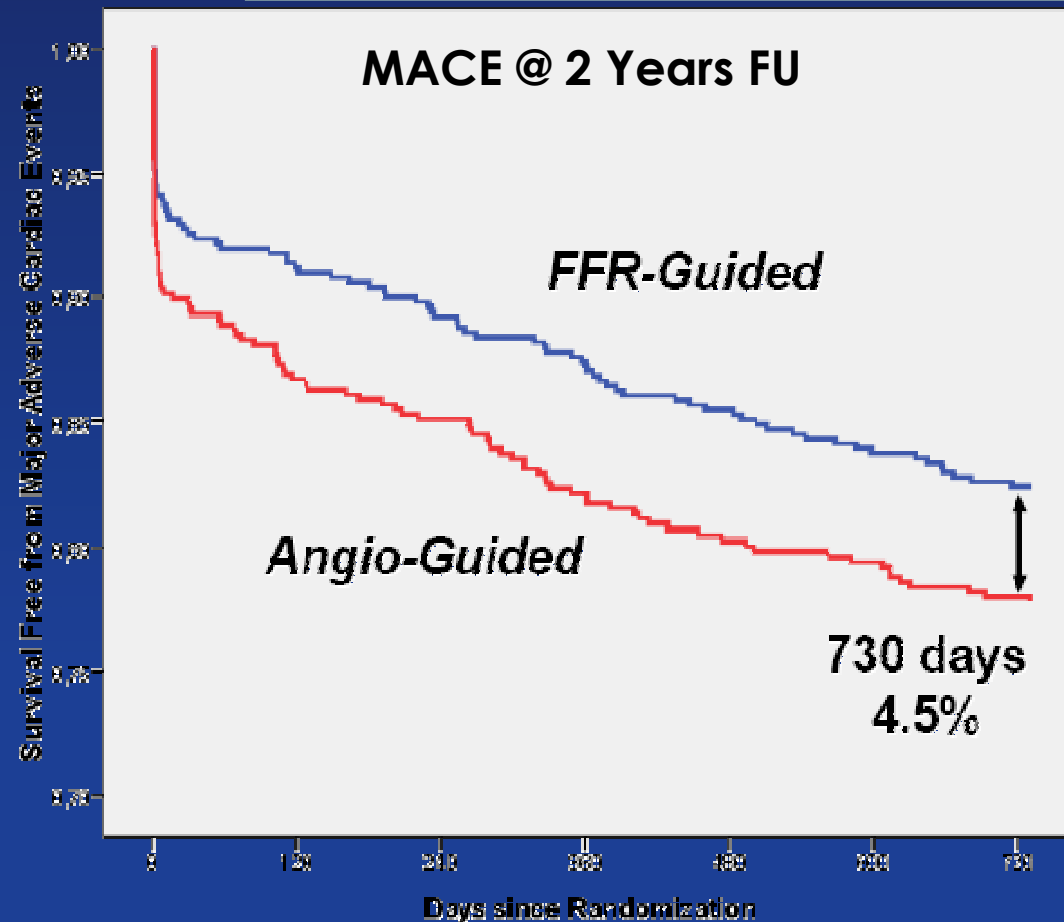
The FAME I Study

The NEW ENGLAND
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JANUARY 15, 2009

VOL. 360 NO. 3

Fractional Flow Reserve versus Angiography
for Guiding Percutaneous Coronary Intervention



**FFR guidance
improves clinical
outcomes in
patients receiving
DES for multi-
vessel disease**

The FAME I Study

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Fractional Flow Reserve versus Angiography
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	Angio-guided	FFR-guided
Stents / Patient	2.7	1.9
Contrast Agent (ml)	302	272
Procedure Materials	\$6,007	\$5,332
Hospital Stay (days)	3.7	3.4
Procedure Time (minutes)	70	71

**FAME shows that, in treating multi-vessel disease,
FFR-guided stenting is more cost effective than
Angio-guided stenting**

The FAME I Study

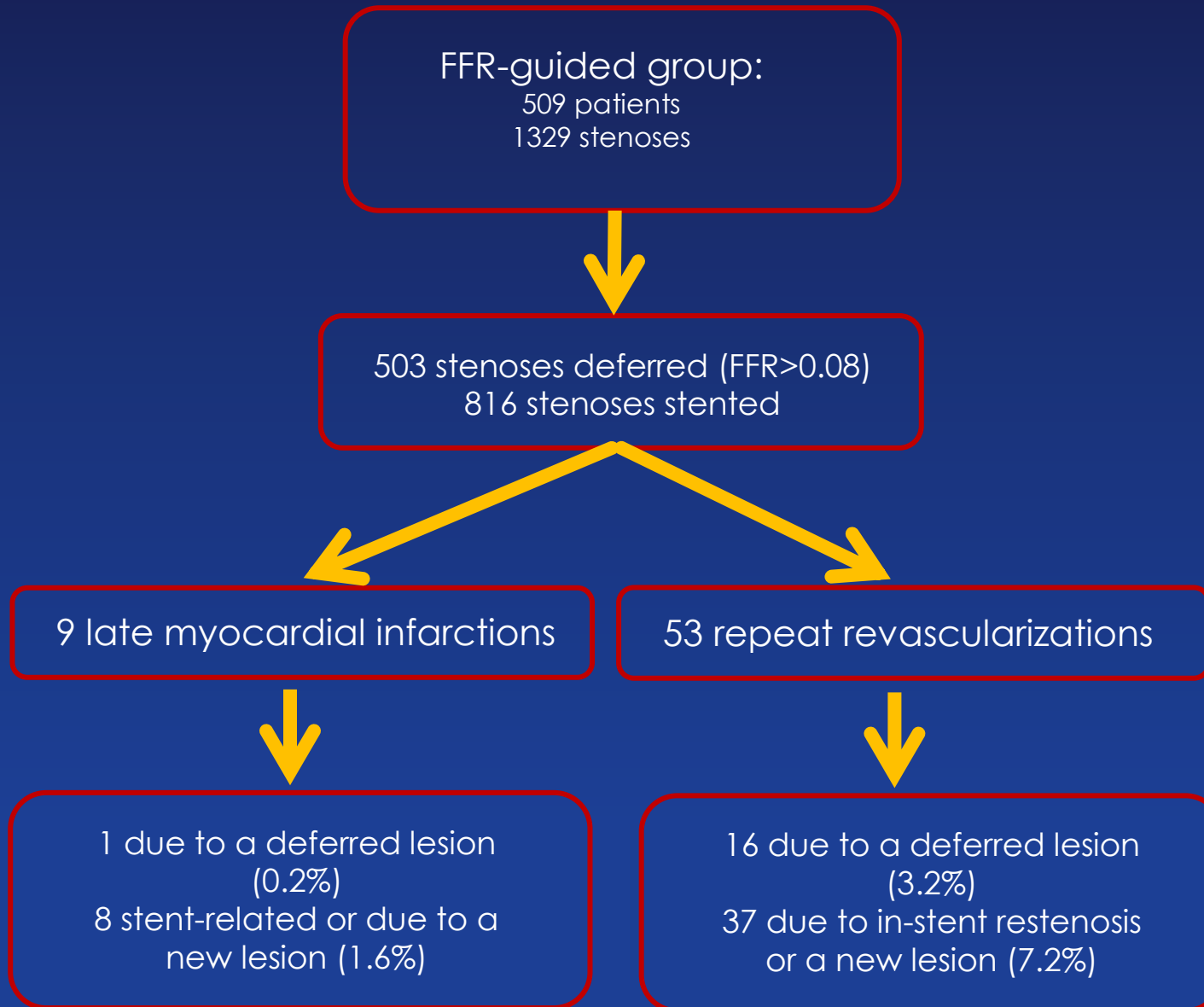


Table 33 Recommendations for specific percutaneous coronary intervention devices and pharmacotherapy

	Class ^a	Level ^b	Ref. ^c
FFR-guided PCI is recommended for detection of ischaemia-related lesion(s) when objective evidence of vessel-related ischaemia is not available.	I	A	15, 28
DES ^d are recommended for reduction of restenosis/re-occlusion, if no contraindication to extended DAPT.	I	A	45, 46, 55, 215
Distal embolic protection is recommended during PCI of SVG disease to avoid distal embolization of debris and prevent MI.	I	B	171, 213
Rotablation is recommended for preparation of heavily calcified or severely fibrotic lesions that cannot be crossed by a balloon or adequately dilated before planned stenting.	I	C	—
Manual catheter thrombus aspiration should be considered during PCI of the culprit lesion in STEMI.	IIa	A	204–208
For PCI of unstable lesions, i.v. abciximab should be considered for pharmacological treatment of no-reflow.	IIa	B	55, 209, 212
Drug-eluting balloons ^d should be considered for the treatment of in-stent restenosis after prior BMS.	IIa	B	174, 175
Proximal embolic protection may be considered for preparation before PCI of SVG disease.	IIb	B	214
For PCI of unstable lesions, intracoronary or i.v. adenosine may be considered for pharmacological treatment of no-reflow.	IIb	B	209
Tornus catheter may be used for preparation of heavily calcified or severely fibrotic lesions that cannot be crossed by a balloon or adequately dilated before planned stenting.	IIb	C	—
Cutting or scoring balloons may be considered for dilatation of in-stent restenosis, to avoid slipping-induced vessel trauma of adjacent segments.	IIb	C	—
MUS-guided stent implantation may be considered for unprotected left main PCI.	IIb	C	—
Mesh-based protection may be considered for PCI of highly thrombotic or SVG lesions.	IIb	C	—
For PCI of unstable lesions, intracoronary nitroprusside or other vasodilators may be considered for pharmacological treatment of no-reflow.	IIb	C	—

^aClass of recommendation.^bLevel of evidence.^cReferences.^dAs recommended in the relevant clinical trial, for example, drug-eluting balloons with paclitaxel or sirolimus, or drug-eluting balloons with everolimus, depending on the specific lesion characteristics of the studies.

ORIGINAL ARTICLE

Fractional Flow Reserve–Guided PCI versus Medical Therapy in Stable Coronary Disease

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for the FAME 2 Trial Investigators*

The FAME 2 Study

Objective

To compare clinical outcomes of FFR-guided contemporary PCI plus the best available medical therapy (MT) versus MT alone in patients with stable coronary disease

Trial Design

Stable patients with 1, 2 or 3 vessel CAD evaluated for PCI with DES
n=1220

FFR in all target lesions

Randomized Trial

At least 1 stenosis with
FFR ≤ 0.8 (n=888)

Randomization 1:1

PCI+MT

MT

Registry

All FFR > 0.8
(n=322)

MT

50% randomly assigned to
follow-up

Primary EndPoint: Death, MI, Urgent Revascularization at 2 years

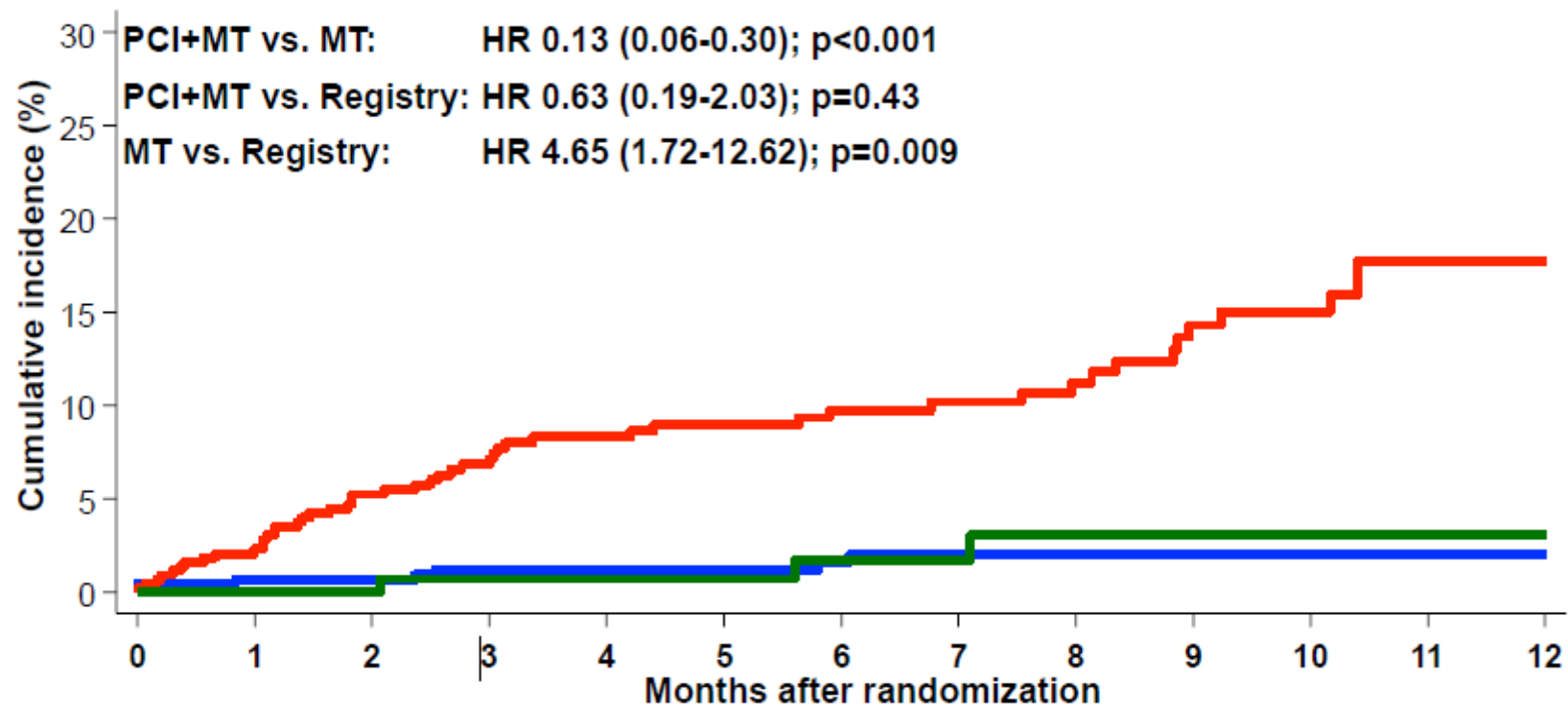
The FAME 2 Study

DSMB Recommendation

On recommendation of the independent Data and Safety Monitoring Board* recruitment was halted on January 15th, 2012 after inclusion of 1220 patients ($\pm$ 54% of the initially planned number of randomized patients)

*DSMB: Stephan Windecker, Chairman, Stuart Pocock, Bernard Gersh

Urgent Revascularization



No. at risk

MT	441	414	371	325	286	256	223	195	164	129	101	71	38
PCI+MT	447	421	395	356	315	285	248	217	180	160	119	93	53
Registry	166	156	145	133	117	106	94	75	65	53	42	26	13

The FAME 2 Study

Trial Results

	FFR-Guided PCI (n=447) %	MT (n=441)	P-Value
Primary EndPoint	4.3	12.7	<0.001
Death	0.2	0.7	0.31
Myocardial Infarction	3.4	3.2	0.89
Urgent Revascularization	1.6	11.1	<0.001
Free from Angina (1 month)	71.0	48.0	<0.001

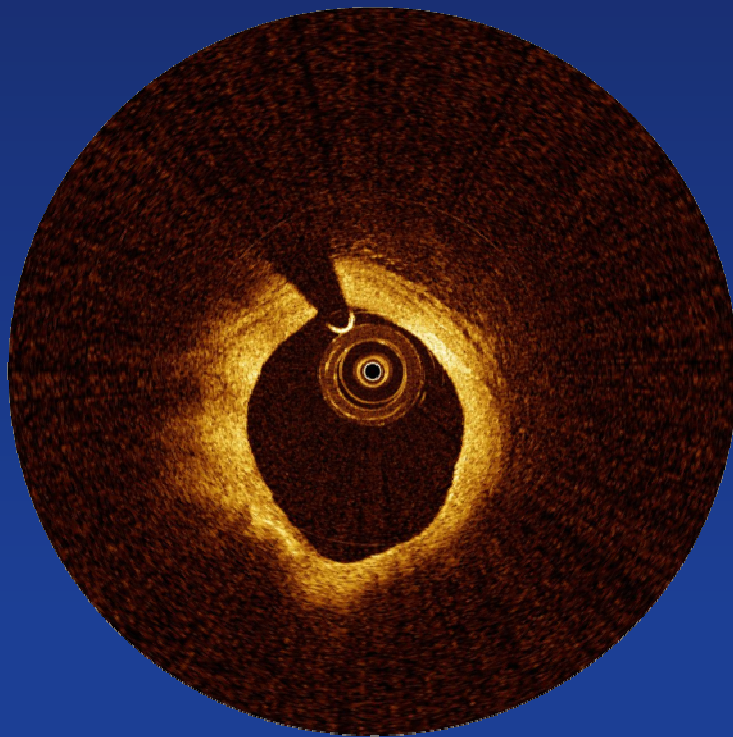
The FAME 2 Study

Conclusions

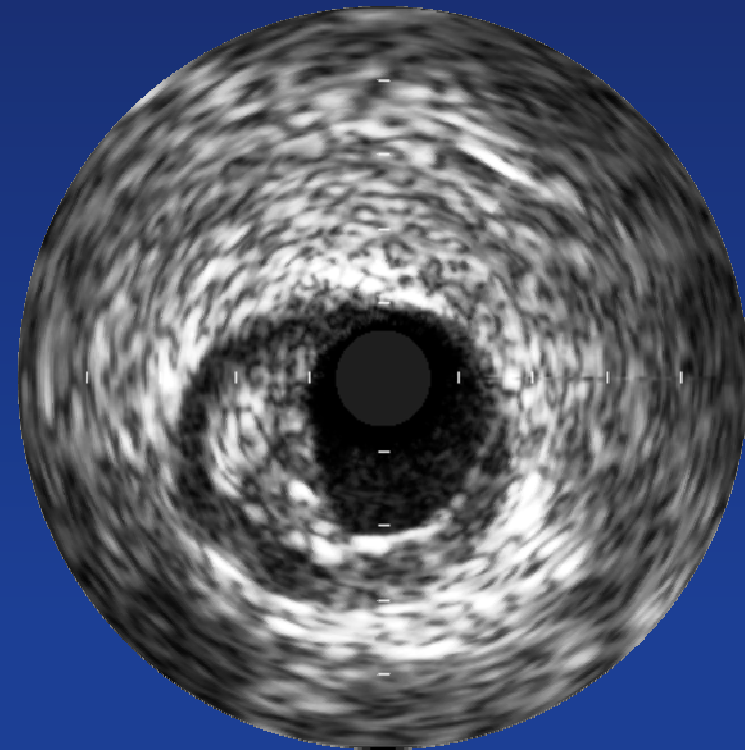
- ✓ In patients with stable coronary artery disease, FFR-guided PCI, improves patient outcomes as compared with medical therapy alone
- ✓ This improvement is driven by a dramatic decrease in the need for urgent revascularization for ACS
- ✓ In patients with functionally non-significant stenoses medical therapy alone resulted in a excellent outcome, regardless of angiographic appearance of the stenoses

Anatomic Evaluation of Coronary Lesions

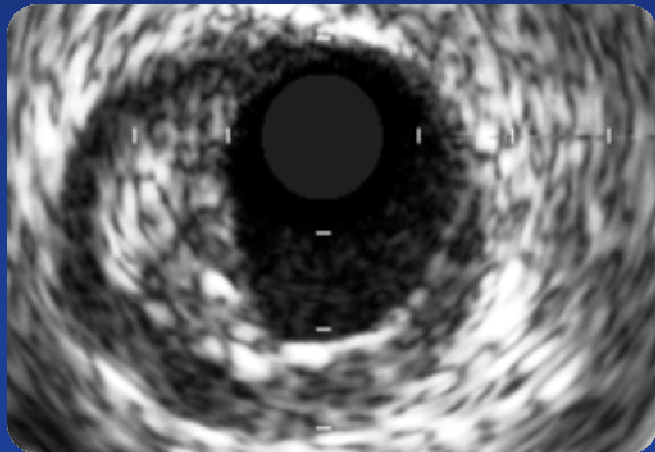
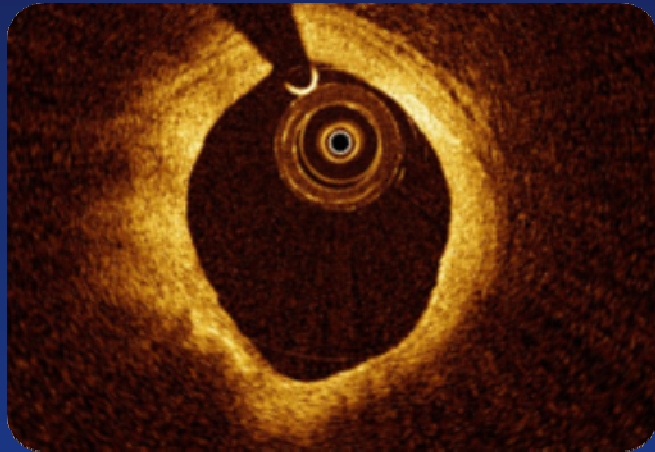
OCT



IVUS



Which Image Provides You What?



	OCT	IVUS
Lumen Size	✓	✓
Vessel Size		✓
Stent Apposition	✓	✓
Dissection	✓	✓
Thrombus	✓	✓
Plaque Burden		✓
Vessel Remodeling		✓
Calcified Plaque	✓	✓
Strut Coverage	✓	
Plaque Characterization		✓

Which Technology Has More To Offer?

Optical Coherence Tomography

- High resolution image
- Easy lumen border identification
- Easy stent identification
- Fast automated pullback

Intravascular Ultrasound

- Easy plug and play imaging¹
- Imaging through blood
- Unlimited pullback length¹
- Deep tissue penetration
- Less need for contrast

Weaknesses

- Low tissue penetration
- Cannot image through blood

- Lower image resolution
- Slower pullback speed

IVUS Guidance Improves Acute & Long Term PCI Outcomes

- 👉 89% reduction in All-Cause Mortality in Bifurcations (Kim)
- 👉 70% reduction in Mortality with LM PCI (SJ Park)
- 👉 65% reduction in Stent Thrombosis (Roy)
- 👉 62% reduction in Late Stent Thrombosis (Constantini)
- 👉 63% reduction in MI at 2 years (MATRIX)

All Studies showed advantages within first 30 days

DES Era

6000+ Patients

ADAPT-DES

Assessment of Dual AntiPlatelet Therapy with Drug-Eluting Stents

Background

Whether IVUS guidance reduces stent thrombosis (ST) and improves clinical outcomes associated with DES treatment is controversial.

ADAPT-DES - Current Cohort -

Assessment of Dual AntiPlatelet Therapy with Drug-Eluting Stents

8,583 pts prospectively enrolled
No clinical or anatomic exclusion criteria
11 sites in US and Germany



PCI with ≥ 1 non-investigational DES
Successful and uncomplicated



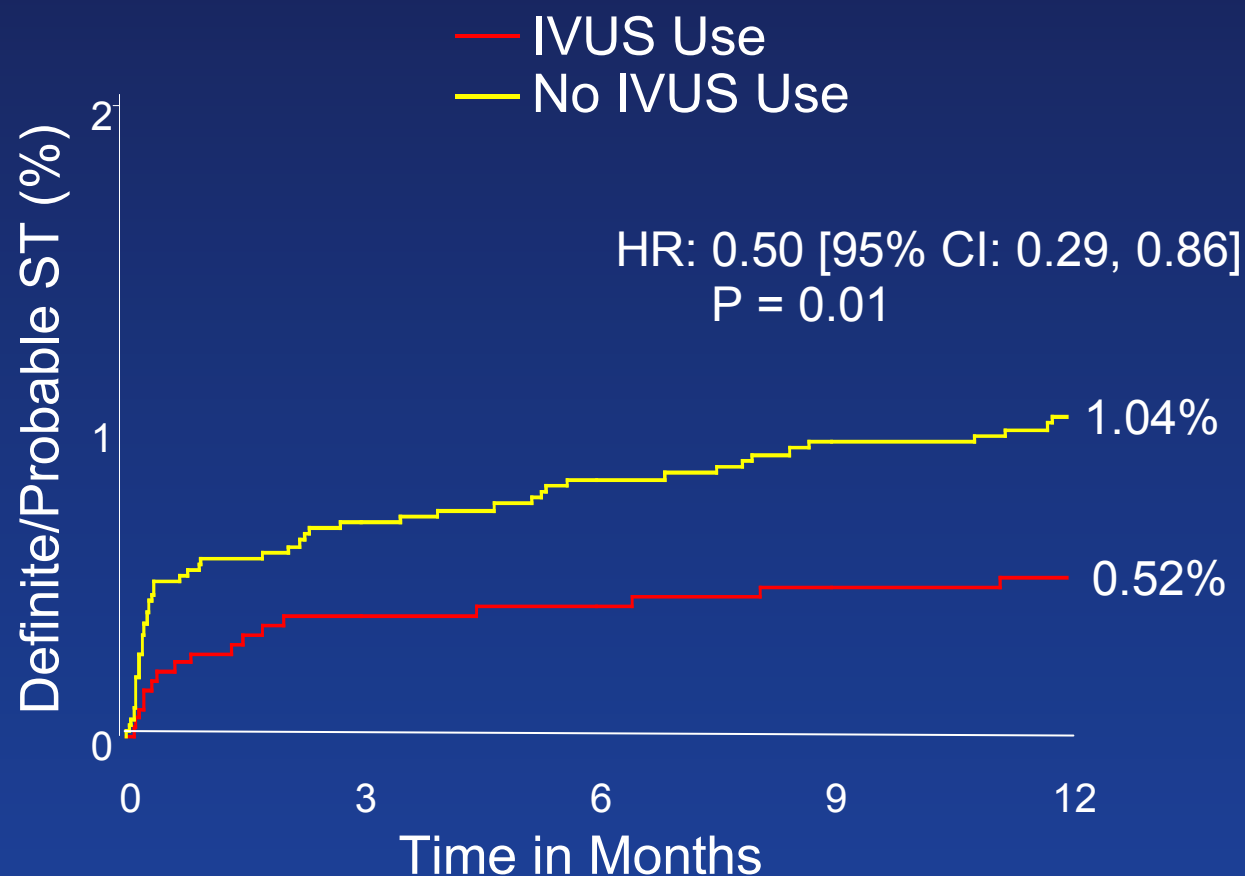
IVUS Use: 3349 pts

No IVUS: 5234 pts



Clinical FU at 30 days, 1 year

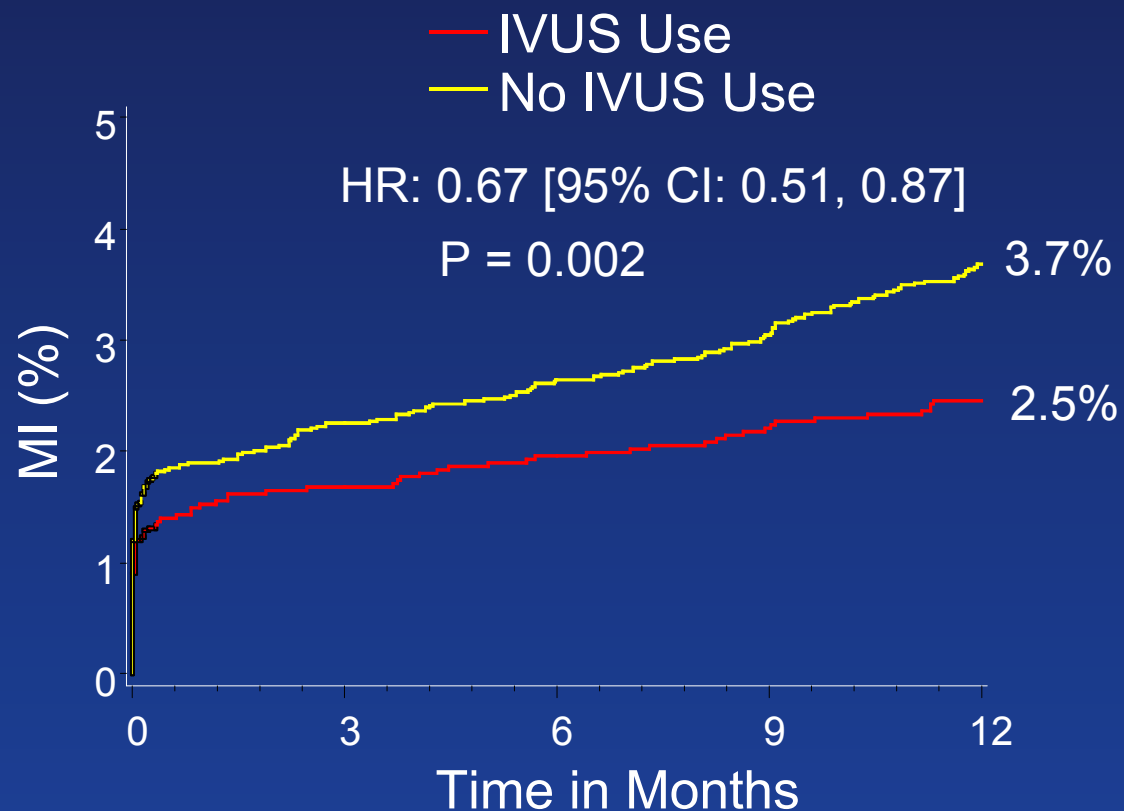
Relationship between IVUS Use and Definite/Probable Stent Thrombosis within 1 year



Number at risk:

IVUS Use	3349	3251	3221	3197	3023
No IVUS Use	5234	5015	4978	4938	4585

Relationship between IVUS Use and MI within 1 year



Number at risk:

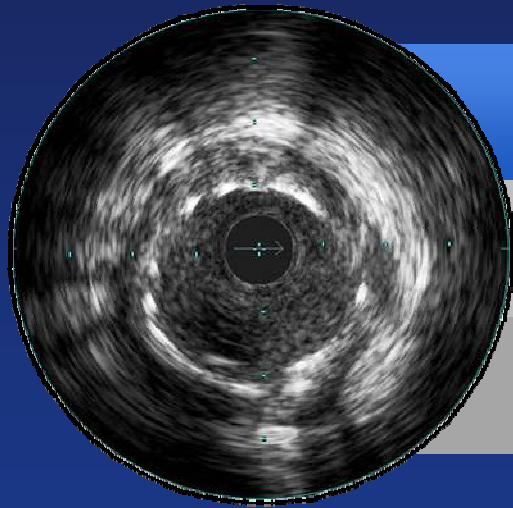
IVUS Use	3349	3209	3171	3141	2969
No IVUS Use	5234	4932	4882	4830	4460

ADAPT-DES: Conclusions and Implications

- ❖ IVUS use resulted in longer stent length and larger stent size without increasing peri-procedural MI.
- ❖ These data, drawn from the largest prospective registry of IVUS use to date, suggest that IVUS guidance during DES PCI may result in less stent thrombosis beginning at the time of implantation as well as fewer myocardial infarctions.

Which Tool Has Undergone More Clinical Use?

Guidelines recommendations



	ESC/EACTS ²	ACCF/AHA/SCAI ³
IVUS	Class II b - Level C	Class II a - Level B
OCT	none	none

- 6425 published articles on “intravascular IVUS”¹
- 334 published articles on “intravascular OCT”¹

1) <http://www.ncbi.nlm.nih.gov/pubmed>, as of 8/20/2012, searching for “intravascular ultrasound” and “intravascular optical coherence tomography”
2) ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation – Hamm, et al., Eur Heart J. 2011 Dec;32(23):2999-3054
3) 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention – Levine, et al., Circulation. 2011;124:e574-e651

Final Conclusion

- ✎ A angiografia coronária nem sempre é um método exacto e suficiente para avaliação das lesões coronárias
- ✎ O FFR permite seleccionar doentes e lesões para revascularização coronária tendo como base a evidência de isquemia, resultando numa melhoria dos resultados clínicos a longo prazo, evitando procedimentos desnecessários e reduzindo os custos
- ✎ O IVUS permite tornar a angioplastia coronária mais segura através de uma mais correcta avaliação anatómica do vaso, permitindo uma optimização do resultado da implantação do stent
- ✎ Apesar de já terem sido comparados por diversas vezes, o FFR e o IVUS são técnicas complementares, não existindo uma clara superioridade de uma relativamente à outra

Country	Number of PCI	IVUS Penetration
United States	1,313,000	15.2%
Japan	220,000	60.7%
Germany	320,000	2.8%
Portugal	12,000	2.5%

The penetration rate of IVUS varies enormously by Country