

***IVUS-Guided Stent Optimization
from MUSIC to ADAPT-DES***



Evelyn Regar
Heart Center
University Hospital Zürich
Zürich, Switzerland

Disclosure

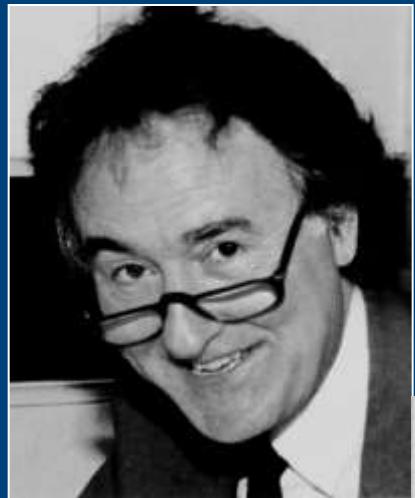
No conflict of interest.



1990ties: IVU

Intravascular ultrasound

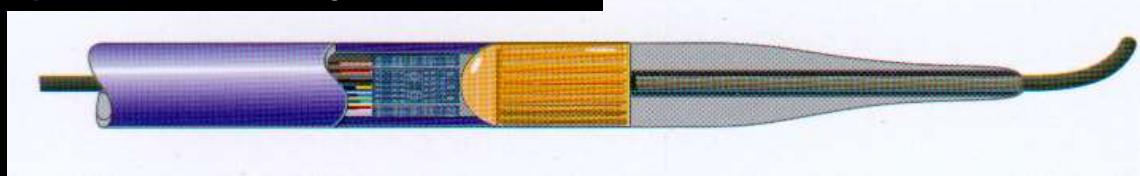
*Intravascular scanner
(1990, DuMed)*



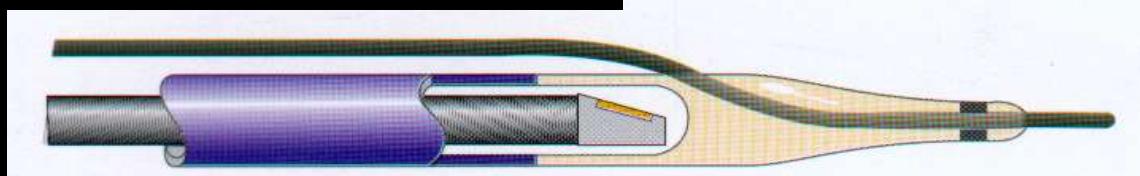
N. Bom



phased array transducer



single rotating transducer



1990ties: IVUS Is Being Invented



N. Bom

Intravascular Ultrasound and Vascular Intervention

ELMA J. GUSSENHOVEN, M.D.,*‡ SALEM H.K., M.D.,** PATRICK W. SERRUYS, M.D.,*
HERO VAN URK, M.D.,** HERMAN PIETERMAN, M.D.,† FRANS C. VAN EGMOND,*
JOS R. ROELANDT, M.D.,* CHARLES T. LANCÉE,* LI WENGUANG,* and YIN ZHONG*

From the *Thoraxcenter, University Hospital Dijkzigt; Departments of **Vascular Surgery, and †Radiology, Erasmus University Rotterdam; and the ‡Interuniversity Cardiology Institute, The Netherlands.

An intravascular ultrasonic imaging device (40 MHz) was used to obtain *in vitro* ultrasonic images and matching histologic cross-sections, derived from human vascular specimens. The feasibility of assessing vessel wall morphology as well as the ability to accurately document plaque thickness was determined. Based on the echogenicity of the arterial media, intravascular ultrasound could distinguish muscular arteries from elastic arteries, veins, and bypass grafts. The hypoechoic media only present in the muscular type of artery proved to be an essential landmark to document superimposed atherosclerosis. Plaque thickness calculated in these arteries showed close relationship with the corresponding histologic cross-section. Using real-time *in vivo* intravascular imaging (30 MHz), the morphology of the vessels interrogated was studied. The dynamic change of the arterial wall, as well as the outcome after intervention, is discussed.

Gussenhoven E et al.

J Interv Cardiol 1991;4(1):41-8.

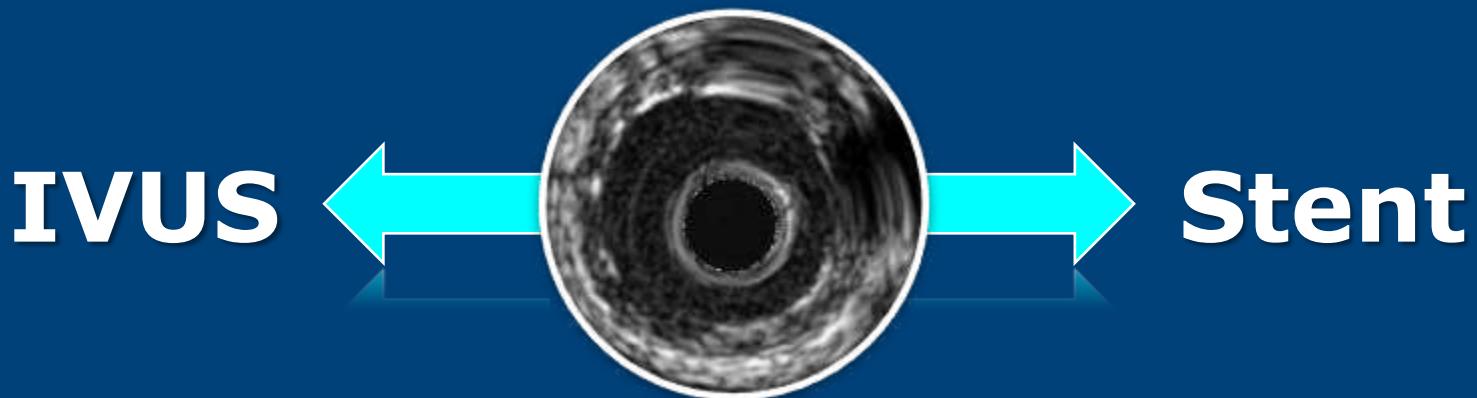
J Am Coll Cardiol. 1989 Oct;14(4):947-52

Eur J Vasc Surg. 1989 Dec;3(6):571-6.



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1990ties: Two Important Innovations



PIVOTAL QUESTION:
**Can IVUS-Guided Stenting
Improve Outcome?**

1990ties: The Role of IVUS

The French Way



Intracoronary stent implantation without ultrasound guidance and with replacement of conventional anticoagulation by anti-platelet therapy.

30-day clinical outcome of the French Multicenter Registry.

Karrillon GJ, Morice MC, Benveniste E, Bunouf P, Aubry P, Cattan S, Chevalier B, Commeau P, Cribier A, Eiferman C, Grollier G, Guerin Y, Henry M, Lefevre T, Livarek B, Louvard Y, Marco J, Makowski S, Monassier JP, Pernes JM, Rioux P, Spaulding C, Zemour G.

Circulation. 1996 Oct 1;94(7):1519-27.



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Colombo A et al. Circulation. 1995;91:1676-1688

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Anti-platelet regimen



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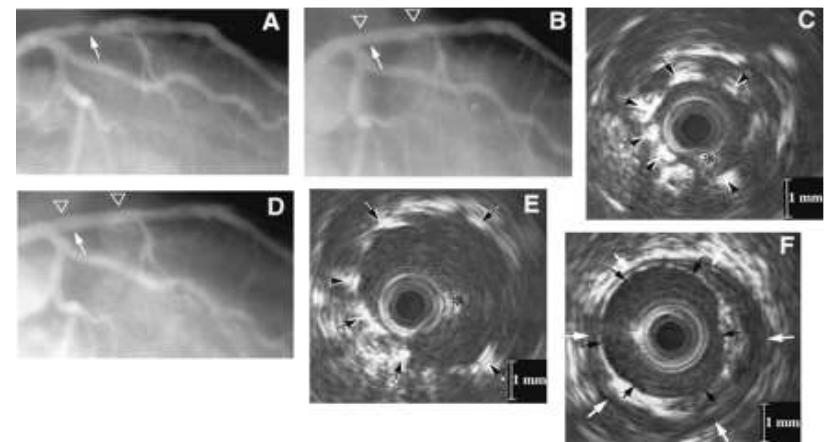
Circulation. 1996 Oct 1;94(7):1519-27.

Anti-platelet regimen

The Italian Way



Intracoronary Stenting
Without Anticoagulation Accomplished
With Intravascular Ultrasound Guidance



Stent expansion

Colombo A et al. Circulation. 1995;91:1676-1688



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1990ties: The Role of IVUS

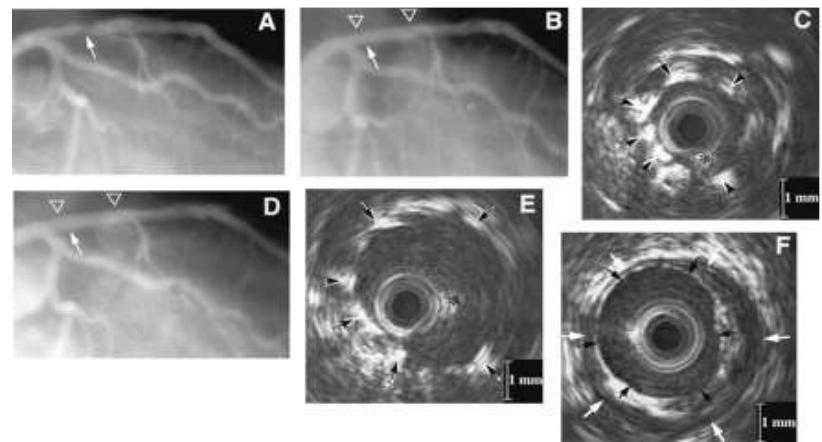
Optimal Stent Expansion:

30% of Lesions

The Italian Way



Intracoronary Stenting
Without Anticoagulation Accomplished
With Intravascular Ultrasound Guidance



Stent expansion



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Colombo A et al. Circulation. 1995;91:1676-1688

1990ties: The MUSIC Study

Intravascular ultrasound-guided optimized stent deployment.
Immediate and 6 months clinical and angiographic results from
the Multicenter Ultrasound Stenting in Coronaries Study
(MUSIC Study)

de Jaegere P, Mudra H, Figulla H, Almagor Y, Doucet S, Penn I, Colombo A, Hamm C, Bartorelli A, Rothman M, Nobuyoshi M, Yamaguchi T, Voudris V, DiMario C, Makovski S, Hausmann D, Rowe S, Rabinovich S, Sunamura M, van Es GA.

Eur. Heart J 1998

IVUS

Prespecified Criteria for Optimal Stent Expansion



Restore Optimal Flow Conditions



Aspirin only

1990ties: The MUSIC Study

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Eur. Heart J 1998

IVUS
guided optimal BMS stent expansion reduces
■ the risk of acute stent thrombosis &
■ the need for dual antiplatelet therapy

1990ties – Today: 1346 Publications



Search 28.04.2018

- Randomized clinical trials
- Observational clinical trials
- Single-center registries
- Multi-center registries
- Meta-analyses
- HTA-Assessments
- Expert-Consensus
- Guidelines

Across geographies, across devices

1990ties – Today: Various IVUS Criteria

MUSIC - criteria

If minimal stent area <9.0mm²:

Minimal stent area $\geq 90\%$ of the mean reference lumen area

Or Minimal stent area $\geq 100\%$ of lumen lowest reference lumen area.

Prox. stent entrance $\geq 90\%$ of proximal reference lumen area.

If minimal stent area >9.0 mm²:

Minimal stent area $\geq 80\%$ of the mean reference lumen area

Or Minimal stent area $\geq 90\%$ of lumen lowest reference lumen area.

Symmetric stent expansion defined by **Stent Dmin/Dmax >0.7**

Complete stent apposition against the vessel wall.

DeJaegere et al. 1998

1990ties – Today: Various IVUS Criteria

Minimal stent area >80% of the mean reference lumen area

RESIST - criteria
Schiele et al. 1998

Minimal stent diameter 80% of the mean reference diameters

TULIP - criteria

Minimal stent area (MLA) \geq 100% of distal reference lumen area

Complete stent apposition

Oemrawsingh et al. 2003

Minimal stent area >80% of mean reference lumen area

DIPOL-criteria

or minimal stent area >7.5 mm² with full stent apposition.

Gil et al. 2007

Minimal stent area \geq 90% of distal reference lumen area

AVID - criteria

Stent fully apposed to vessel wall.

Dissections covered by stent.

Russo et al. 2009

Minimal stent area > 5mm² or >90% of distal reference lumen area

HOME DES - criteria

Apposition of all stent struts

No edge dissections.

Jakabcin et al. 2010

1990ties – Today: What Did We Learn? The Reasons For BMS Failure Are:

BMS	EARLY THROMBOSIS	RESTENOSIS
Under-expansion	<ul style="list-style-type: none">Cheneau et al. Circulation. 2003;108:43-7	<ul style="list-style-type: none">Kasaoka et al. J Am Coll Cardiol. 1998;32:1630-5Castagna et al. Am Heart J. 2001;142:970-4De Feyter et al. Circulation. 1999;100:1777-83Sonoda et al. J Am Coll Cardiol. 2004;43:1959-63Morino et al. Am J Cardiol. 2001;88:301-3Ziada et al. Am Heart J. 2001;141:823-31Doi et al. JACC Cardiovasc Interv. 2009;2:1269-75
Edge Problems	<ul style="list-style-type: none">Cheneau et al. Circulation. 2003;108:43-7	<ul style="list-style-type: none">Liu et al. Am J Cardiol. 2009;103:501-6
Stent Length		<ul style="list-style-type: none">Kasaoka et al. J Am Coll Cardiol. 1998;32:1630-5De Feyter et al. Circulation. 1999;100:1777-83

IVUS Predictors of Restenosis & Early Thrombosis

– BMS References

Courtesy G. Mintz



1990ties – Today: What Did We Learn? The Reasons For DES Failure Are:

DES	EARLY THROMBOSIS	RESTENOSIS
Under-expansion	<ul style="list-style-type: none">Fujii et al. <i>J Am Coll Cardiol.</i> 2005;45:995-8Okabe et al. <i>Am J Cardiol.</i> 2007;100:615-20Liu et al. <i>JACC Cardiovasc Interv.</i> 2009;2:428-34Choi et al. <i>Circ Cardiovasc Interv.</i> 2011;4:239-47	<ul style="list-style-type: none">Sonoda et al. <i>J Am Coll Cardiol.</i> 2004;43:1959-63Hong et al. <i>Eur Heart J.</i> 2006;27:1305-10Doi et al. <i>JACC Cardiovasc Interv.</i> 2009;2:1269-75Fujii et al. <i>Circulation.</i> 2004;109:1085-1088Kang et al. <i>Circ Cardiovasc Interv.</i> 2011;4:9-14Choi et al. <i>Am J Cardiol.</i> 2012;109:455-60Song et al. <i>Catheter Cardiovasc Interv.</i> 2014;83:873-8
Edge Problems	<ul style="list-style-type: none">Fujii et al. <i>J Am Coll Cardiol.</i> 2005;45:995-8Okabe et al. <i>Am J Cardiol.</i> 2007;100:615-20Liu et al. <i>JACC Cardiovasc Interv.</i> 2009;2:428-34Choi et al. <i>Circ Cardiovasc Interv.</i> 2011;4:239-47	<ul style="list-style-type: none">Sakurai et al. <i>Am J Cardiol.</i> 2005;96:1251-3Liu et al. <i>Am J Cardiol.</i> 2009;103:501-6Costa et al., <i>Am J Cardiol.</i> 2008;101:1704-11Kang et al. <i>Am J Cardiol.</i> 2013;111:1408-14Kobayashi et al. ACC2014
Stent Length		<ul style="list-style-type: none">Hong et al. <i>Eur Heart J.</i> 2006;27:1305-10

IVUS Predictors of Restenosis & Early Thrombosis
– DES References
Courtesy G. Mintz

1990ties – Today: What Did We Learn? ADAPT-DES

Assessment of Dual AntiPlatelet Therapy with Drug-Eluting Stents

Prospective, multicenter, real-world study
N=8,583 patients

No clinical or anatomic exclusion criteria
Successful and uncomplicated PCI with ≥ 1 DES

Pre-specified IVUS sub-study:

IVUS

n=3,361 pts (39%)

No IVUS

n=5,221 pts (61%)

Clinical FU

30d

1yr

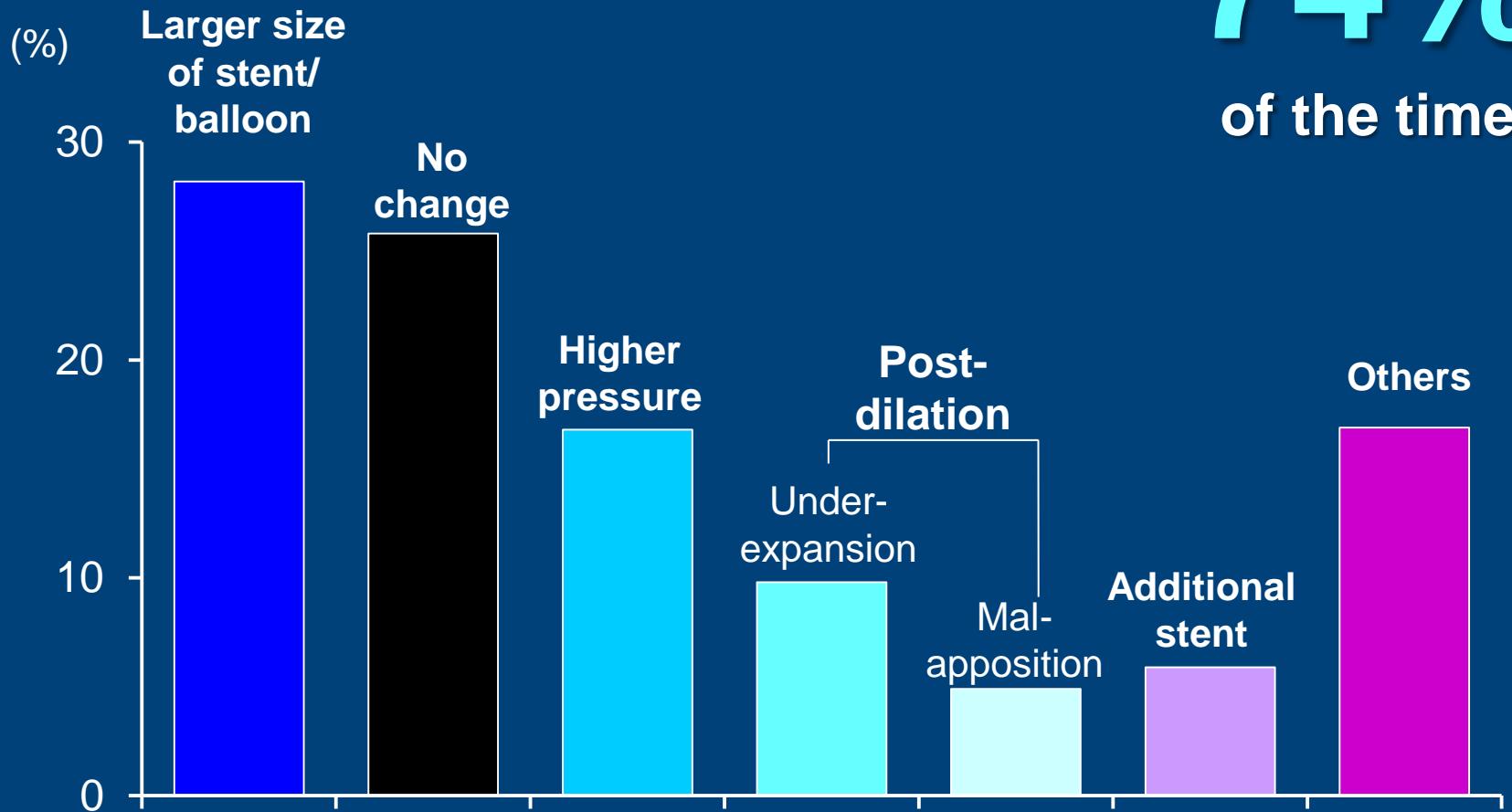
2yr



1990ties – Today: What Did We Learn?

ADAPT-DES

IVUS Changed the Procedure: **74%**



1990ties – Today: What Did We Learn?

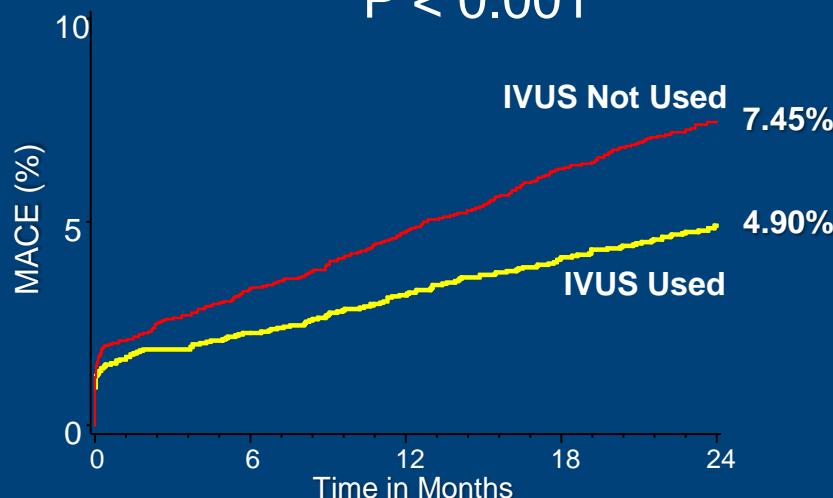
ADAPT-DES

Significantly Lower Event Rates with IVUS

MACE

(Cardiac Death, MI, Definite/Probable ST)

HR: **0.65** [95% CI: 0.54, 0.78]
P < 0.001



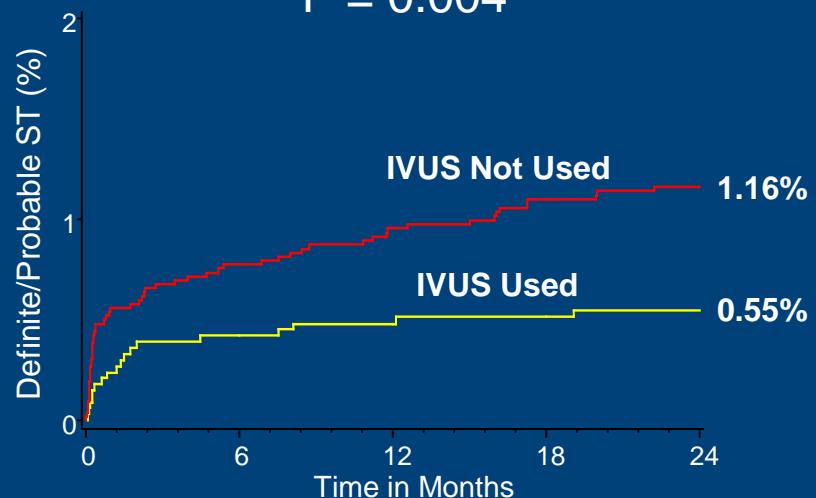
Number at risk:
IVUS Used 3361
IVUS Not Used 5221

3206 3117 2988 1739
4912 4740 4537 2177

Stent Thrombosis

(ARC Definite or Probable)

HR: **0.47** [95% CI: 0.28, 0.80]
P = 0.004



Number at risk:
IVUS Used 3361 3260 3182 3065 1791
IVUS Not Used 5221 5019 4886 4713 2279

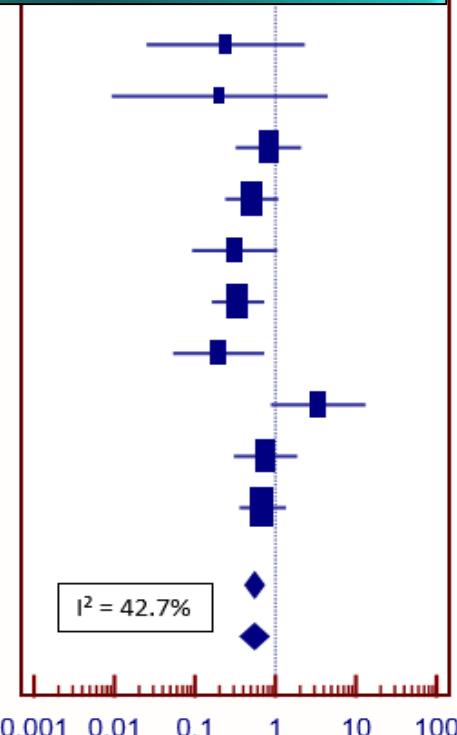
1990ties – Today: What Did We Learn? IVUS Reduces Hard Clinical Endpoints

Meta-analysis n= 14,197 pts Imaging-guided vs. Angiography-guided PCI

Difference: Myocardial Infarction

BMS: Favours IVUS

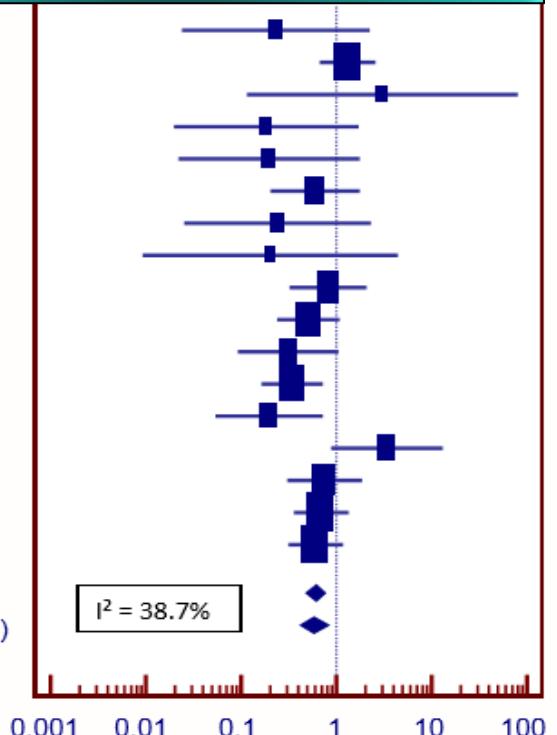
Jakabcin, J
Kim, J
chieffo, A
Hru, SH
Chen, SL
Claessen, B
Kim, JS
Park, KW
Park, SJ
Roy, P
Total (fixed effects)
Total (random effects)



DES: Favours IVUS

Gil, R
Russo, R
Gaster, A.
Oemrawsingh, P
Frey, A
Mudra, H
Jakabcin, J
Kim, J
chieffo, A
Hru, SH
Chen, SL
Claessen, B
Kim, JS
Park, KW
Park, SJ
Roy, P
Prati, F

Total (fixed effects)
Total (random effects)



1990ties – Today: What Did We Learn? IVUS Reduces Hard Clinical Endpoints

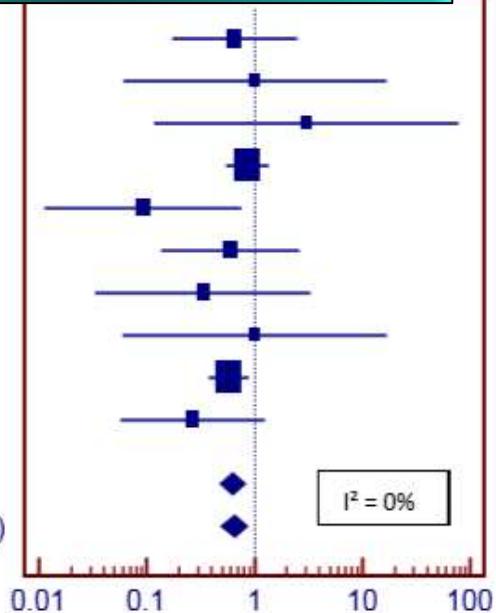
Meta-analysis n= 14,197 pts Imaging-guided vs. Angiography-guided PCI

Difference: Stent Thrombosis

BMS: Favours IVUS

Jakabcin, J
Kim, J
chieffo, A
Hru, SH
Chen, SL
Claessen, B
Kim, JS
Park, KW
Roy, P
Kim, SH

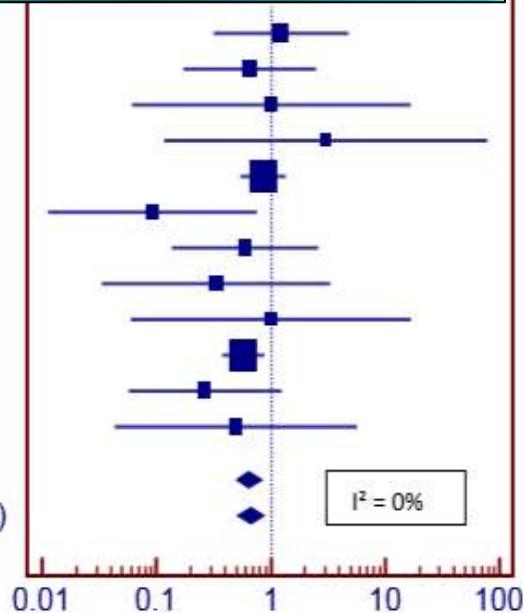
Total (fixed effects)
Total (random effects)



DES: Favours IVUS

Russo, R
Jakabcin, J
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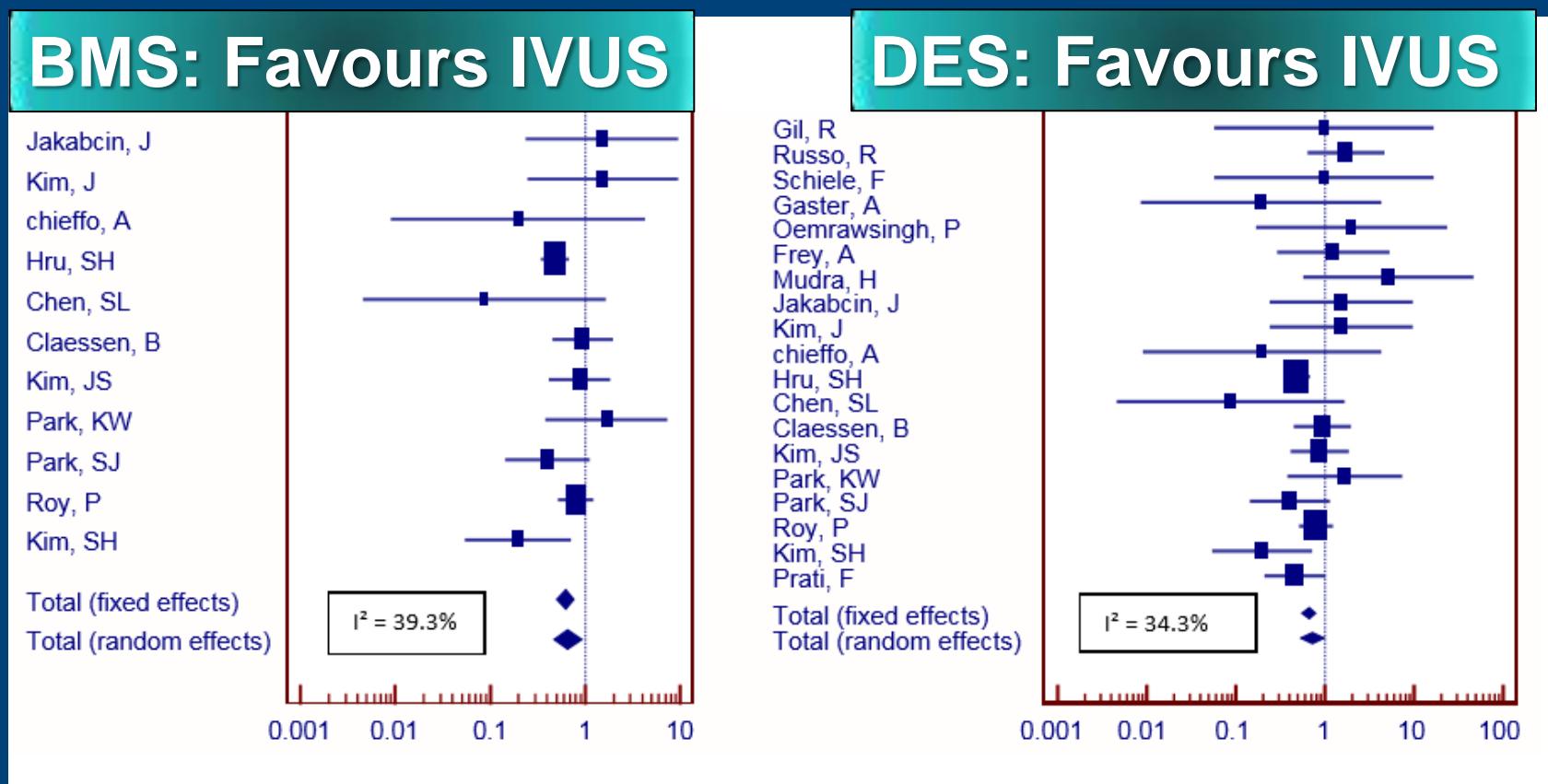
Total (fixed effects)
Total (random effects)



1990ties – Today: What Did We Learn? IVUS Reduces Hard Clinical Endpoints

Meta-analysis n= 14,197 pts Imaging-guided vs. Angiography-guided PCI

Difference: Death

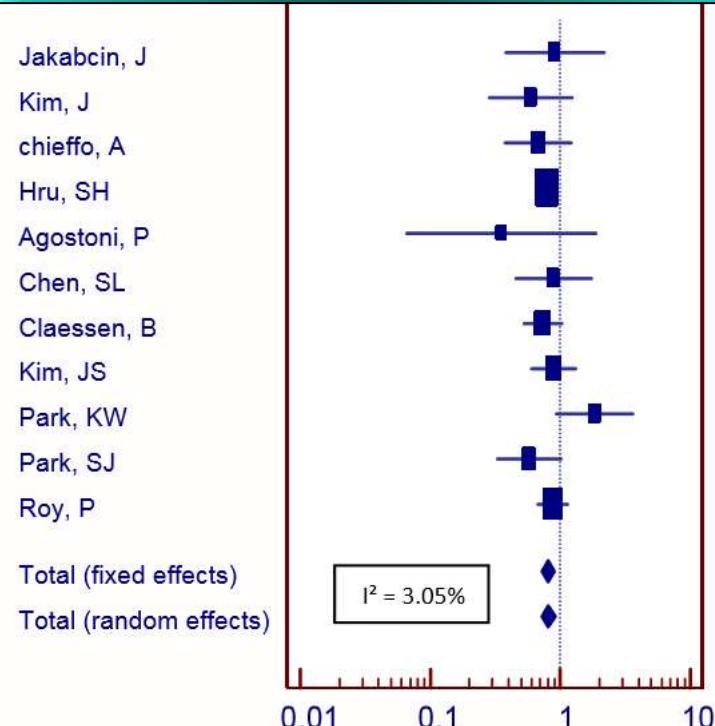


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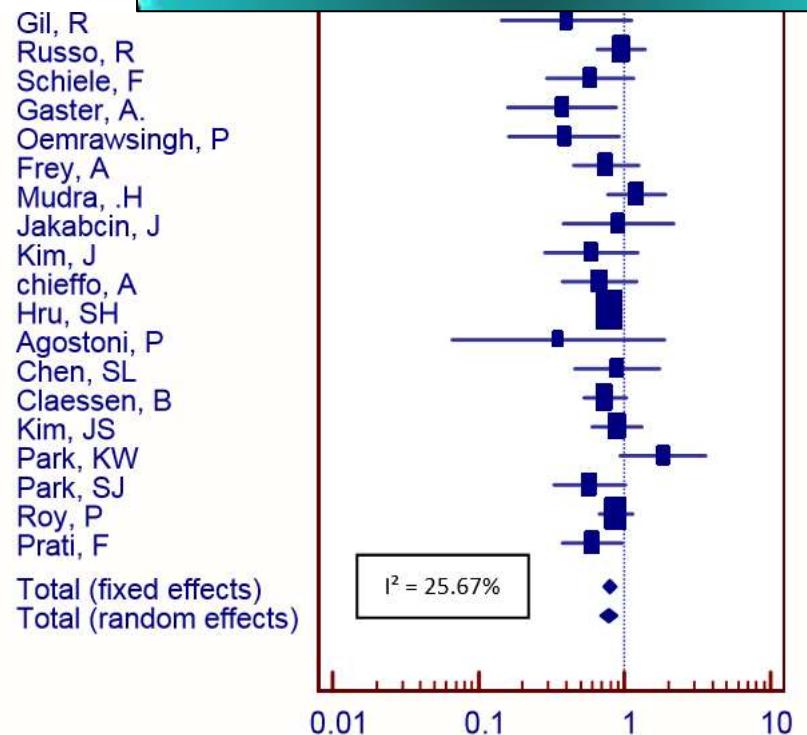
Meta-analysis n= 14,197 pts Imaging-guided vs. Angiography-guided PCI

Difference: MACE

BMS: Favours IVUS



DES: Favours IVUS



IVUS Guided Stenting Practical Implications

**In stenting,
outcome depends on implantation technique!**

Stent diameter must not be too SMALL

Stent diameter must not be too LARGE

Stent length must not be too SHORT

Stent expansion must be OPTIMAL

IVUS Guided Stenting Practical Implications

In order to achieve optimal stenting

Pre-interventional imaging is key!

or before placing a stent

IVUS Guided Stenting Practical Implications

In order to achieve optimal stenting

Pre-interventional imaging is key!

Allows for efficient procedure planning

All metrics easily at hand

Assessment of plaque composition

**which is a major driver for the need
for lesion preparation & postdilation**

Intracoronary Imaging is a Safe Procedure

Thoraxcenter

Consecutive patients undergoing invasive-imaging

1,142 OCT
procedures

2,476 IVUS
procedures

3,042 pullbacks

Comparable, low event rate.
Majority of events was self-limiting.

Complications

12 complications

0.6% per
procedure

0.2% per
pullback

0.5% per
procedure

0.2% per
pullback



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Van der Sijde J et al. Eur Heart J Cardiovasc Imaging. 2016

1990ties – Today: What Did We Learn?

IVUS Imaging Improves Prognosis !

1990ties – Today: What Did We Learn?

IVUS Imaging Improves Prognosis !

**IVUS-guided PCI
significantly reduces the risk of**

- Death
- MI
- Stent thrombosis
- MACE

IVUS Imaging – Future Directions

IVUS needs to be improved

- **Image quality**
- **Pullback speed**
- **User-friendliness**
- **Automated analysis**

IVUS Imaging – Future Directions

IVUS needs to be improved

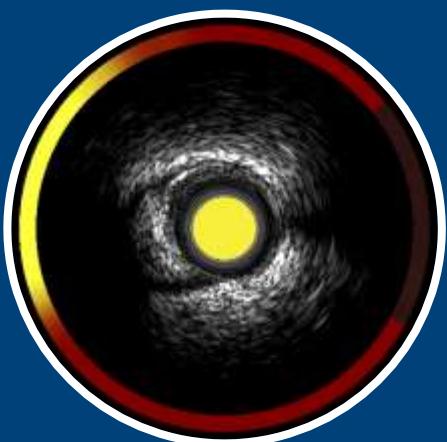
Online coregistration with angiography is mandatory



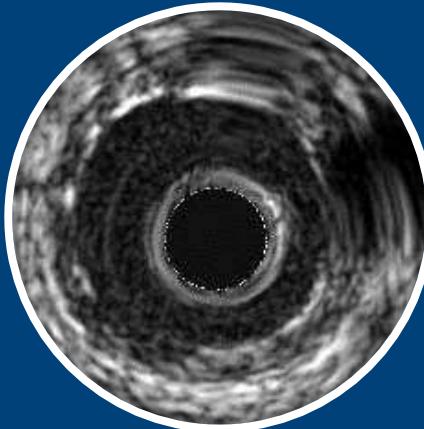
Intravascular Imaging Which To Choose?

Follow your taste

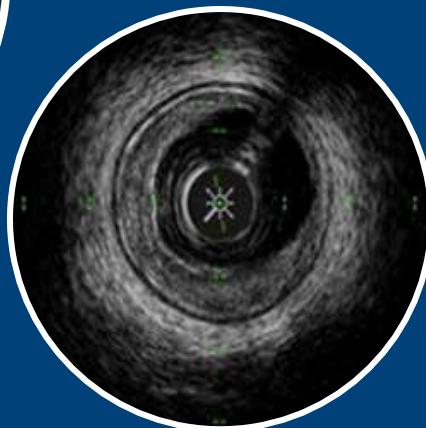
NIR IVUS



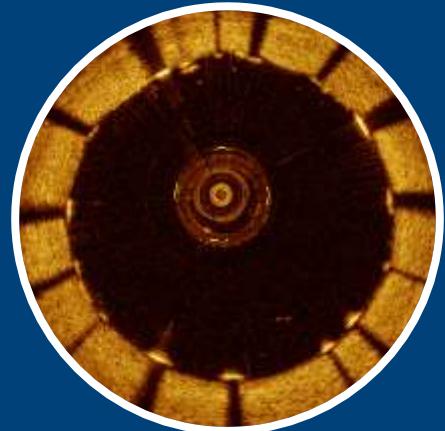
HD IVUS



IVUS



OCT



any invasive imaging modality is better
than angiography alone!