

# INSIDE INFORMATION YOU CAN'T IGNORE



 **VOLCANO**  
PRECISION GUIDED THERAPY

# A preponderance of evidence that IVUS benefits patients

Large studies reported evidence that **IVUS benefits patients**

## ADAPT-DES<sup>1</sup>

(Assessment of Dual AntiPlatelet Therapy with Drug-Eluting Stents)

- Largest study ever conducted with IVUS guidance
- Multi-center global registry with 8583 consecutive patients
- 3349 patients had PCI with IVUS Guidance
- 64% Xience / Promus stents



## Ahn Meta-Analysis<sup>2</sup>

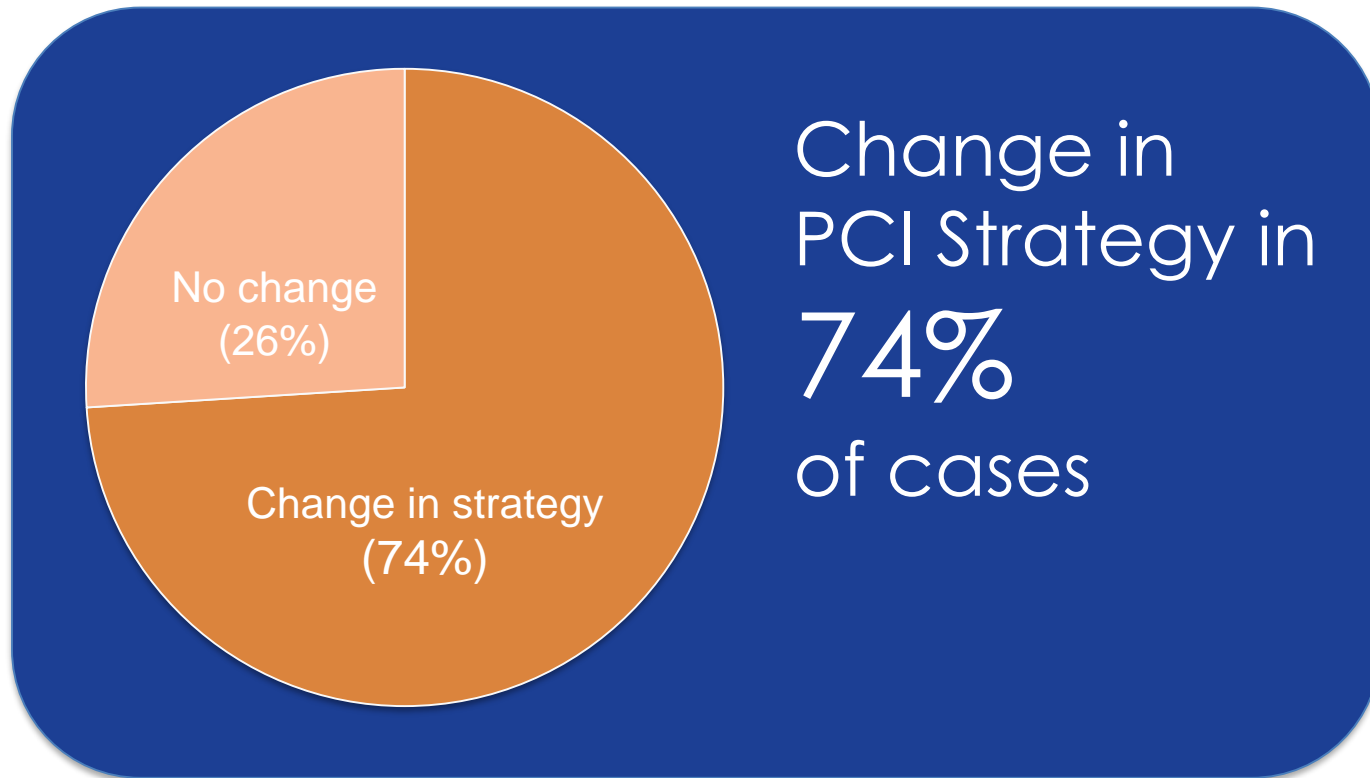
- Includes 17 studies covering 26,503 patients
- 12,499 patients had PCI with IVUS Guidance
- Comprehensive analysis reflecting DES studies over the last decade



1. Witzenbichler B et al. Relationship Between Intravascular Ultrasound Guidance and Clinical Outcomes After Drug-Eluting Stents: The ADAPT-DES Study. *Circulation* 2014 Jan; 129,4:463-470.  
2. Ahn JM, Kang SJ, Yoon SH, et al. "Meta-Analysis of Outcomes After Intravascular Ultrasound - Guided Versus Angiography-Guided Drug-Eluting Stent Implantation in 26,503 Patients Enrolled in Three Randomized Trials and 14 Observational Studies" *J Am Cardiol.* 2014;113:1338-1347.

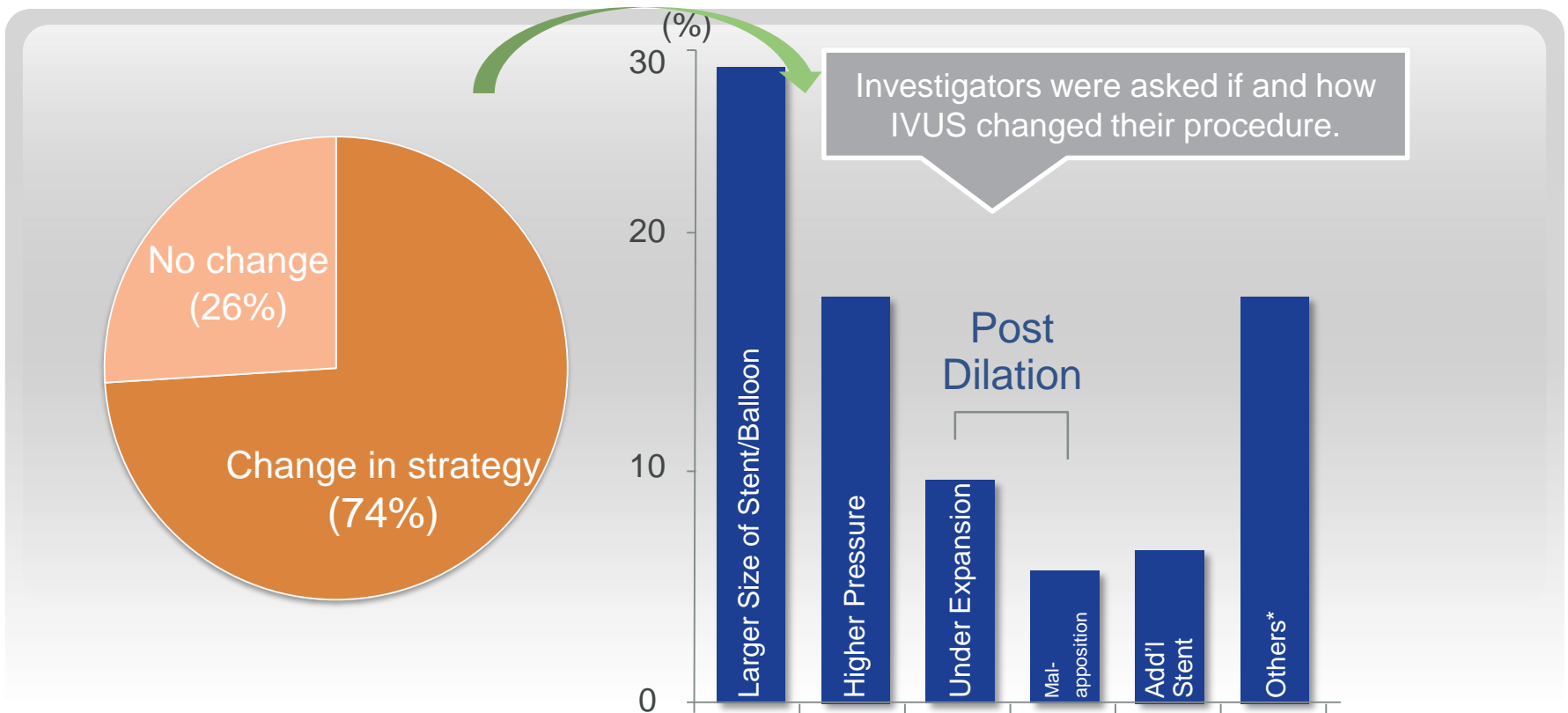
# ADAPT-DES

Study data reported IVUS guidance was associated with:



# ADAPT-DES

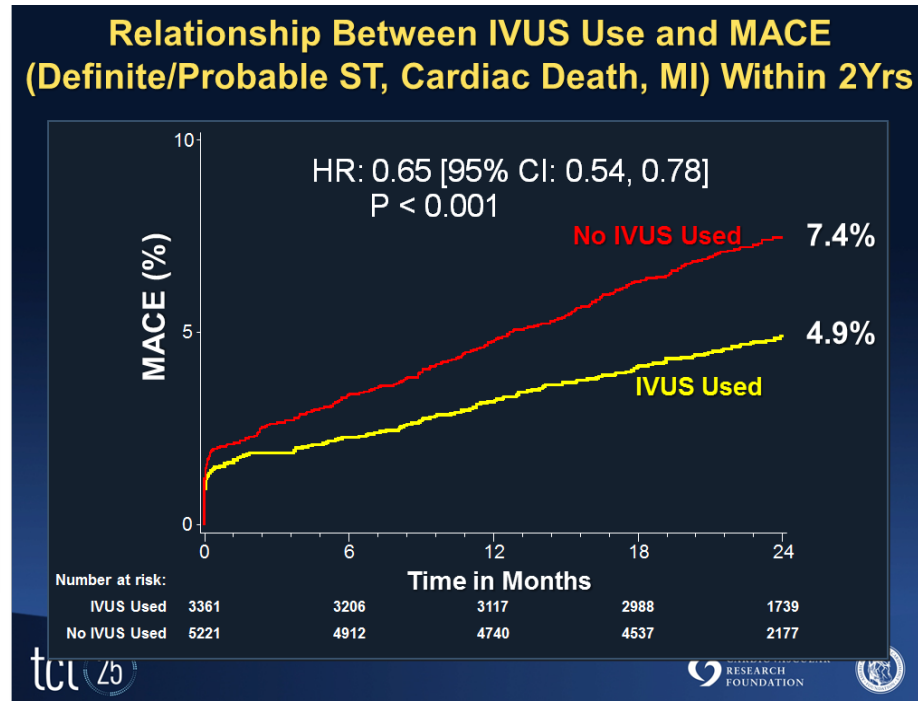
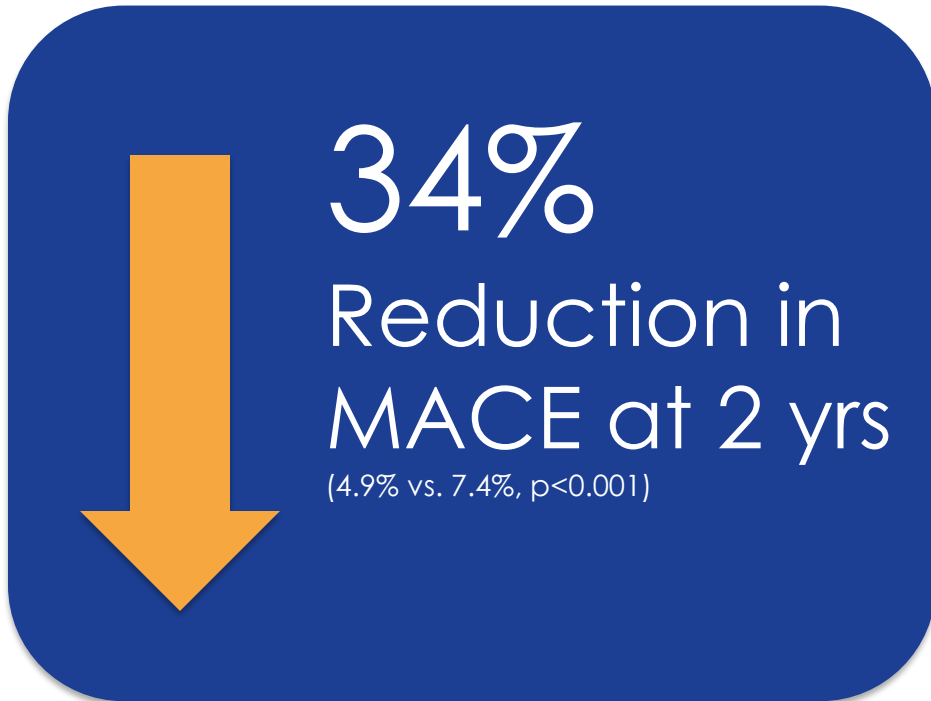
How investigators reported IVUS changed their procedure



\*"Others" category may include a combination of "Higher Pressure", "Under Expansion", "Malapposition", and "Additional Stent".  
Witzenbichler B. ADAPT-DES: Two-Year Insights from the Largest IVUS Substudy. TCT 2013. Lecture conducted from San Francisco, CA.  
Graphics adapted from slide presentation.

# ADAPT-DES

Study data reported IVUS Guidance was associated with:



# Ahn Meta-Analysis

Study data reported IVUS outcomes



Based on  
17 studies and  
26,503 patients

# Ahn Meta-Analysis builds on a large body of evidence



## 2005-2014 IVUS in Clinical Research

17 STUDIES (14 OBSERVATIONAL AND 3 RANDOMIZED) INCLUDED IN THE AHN META-ANALYSIS OF OUTCOMES AFTER INTRAVASCULAR ULTRASOUND-GUIDED VERSUS ANGIOGRAPHY-GUIDED DRUG-ELUTING STENT IMPLANTATION



Total IVUS Patients: n=12,499 | Total DES Patients: 26,503 | Studies Included: 17

- 17 studies total, includes US, EU, Asia
- 12,499 IVUS, 26,503 total DES patients
- Documenting real-world advantages

# Ahn Meta-Analysis

Study data reported IVUS guidance was associated with:

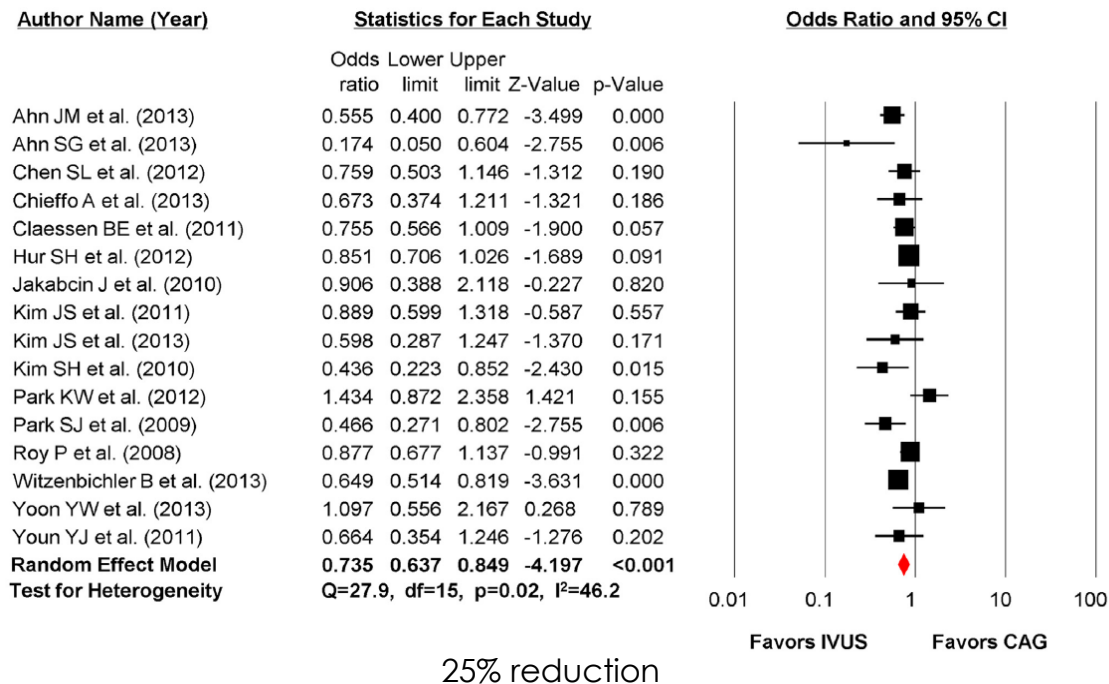




# Ahn Meta-Analysis

Study data reported IVUS guided DES-implantation was associated with a significant reduction of MACE

## Major Adverse Cardiovascular Events

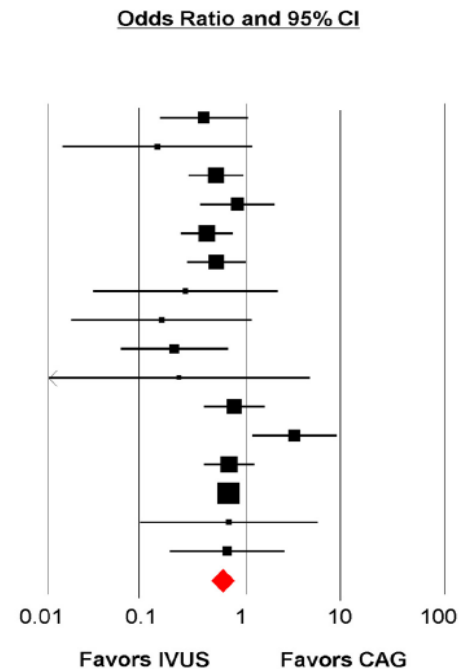


# Ahn Meta-Analysis

Study data reported IVUS-guided DES implantation was associated with a significant reduction of MI

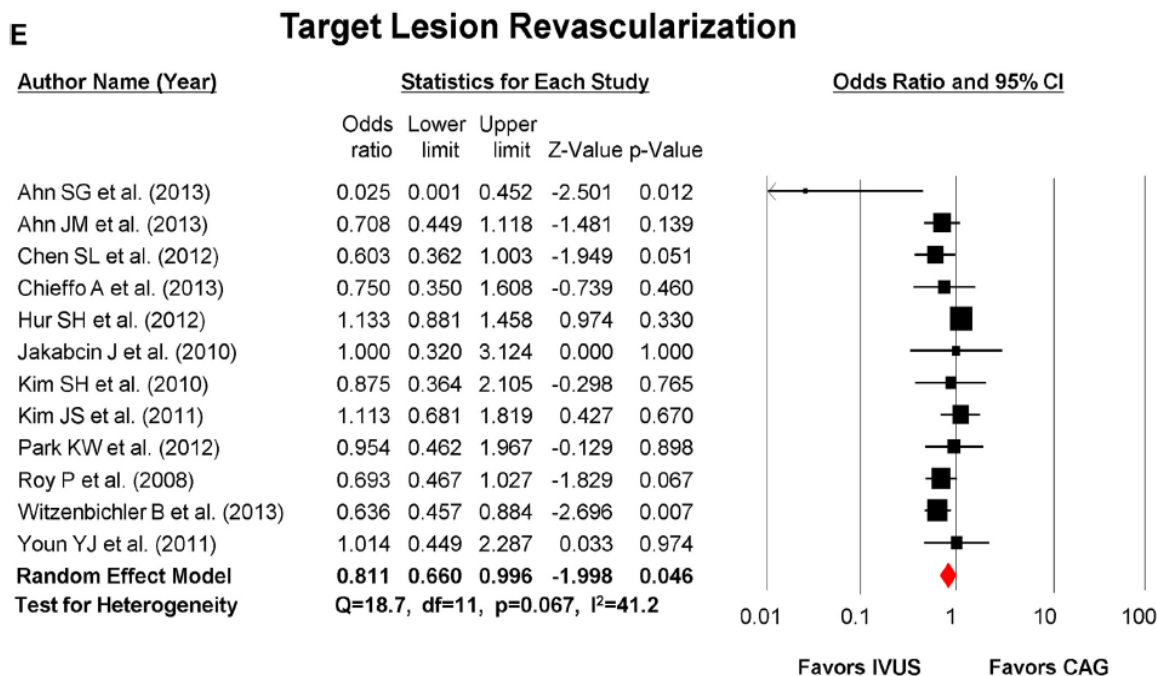
## Myocardial Infarction

Author Name (Year)	Statistics for Each Study				
	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Ahn JM et al. (2013)	0.373	0.131	1.061	-1.849	0.064
Ahn SG et al. (2013)	0.126	0.014	1.154	-1.833	0.067
Chen SL et al. (2012)	0.494	0.257	0.948	-2.120	0.034
Chieffo A et al. (2013)	0.810	0.338	1.941	-0.472	0.637
Claessen BE et al. (2011)	0.399	0.214	0.744	-2.893	0.004
Hur SH et al. (2012)	0.497	0.247	1.004	-1.949	0.051
Jakabcin J et al. (2010)	0.242	0.028	2.094	-1.288	0.198
Kim SH et al. (2010)	0.139	0.017	1.150	-1.830	0.067
Kim JS et al. (2011)	0.189	0.054	0.665	-2.596	0.009
Kim JS et al. (2013)	0.209	0.010	4.414	-1.006	0.315
Park SJ et al. (2009)	0.757	0.369	1.550	-0.762	0.446
Park KW et al. (2012)	3.043	1.125	8.234	2.191	0.028
Roy P et al. (2008)	0.670	0.369	1.218	-1.313	0.189
Witzenbichler B et al. (2013)	0.660	0.508	0.858	-3.110	0.002
Yoon YW et al. (2013)	0.666	0.083	5.317	-0.383	0.701
Youn YJ et al. (2011)	0.640	0.167	2.458	-0.650	0.516
<b>Random Effect Model</b>	<b>0.571</b>	<b>0.435</b>	<b>0.751</b>	<b>-4.011</b>	<b>&lt;0.001</b>
<b>Test for Heterogeneity</b>	<b>Q=22.9, df=15, p=0.086, I<sup>2</sup>=34.5%</b>				



# Ahn Meta-Analysis

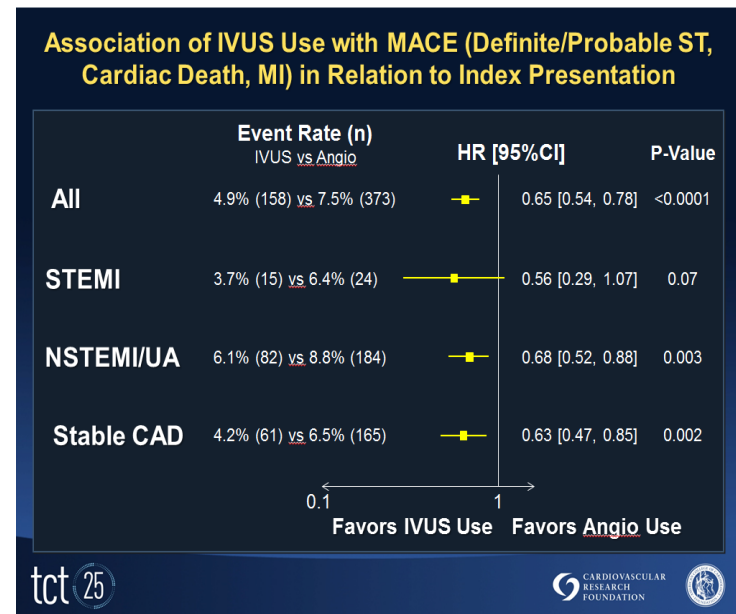
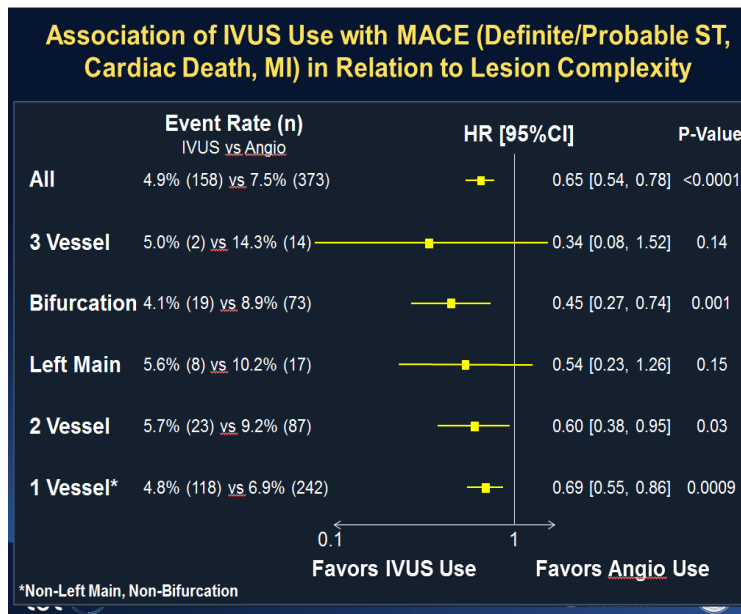
Study data reported IVUS-guided PCI was associated with a significantly reduced risk of TLR



# ADAPT-DES

Study data reported IVUS use benefited even the simplest cases (1 vessel, non-LM/bifurcation, stable CAD)<sup>1</sup>

2

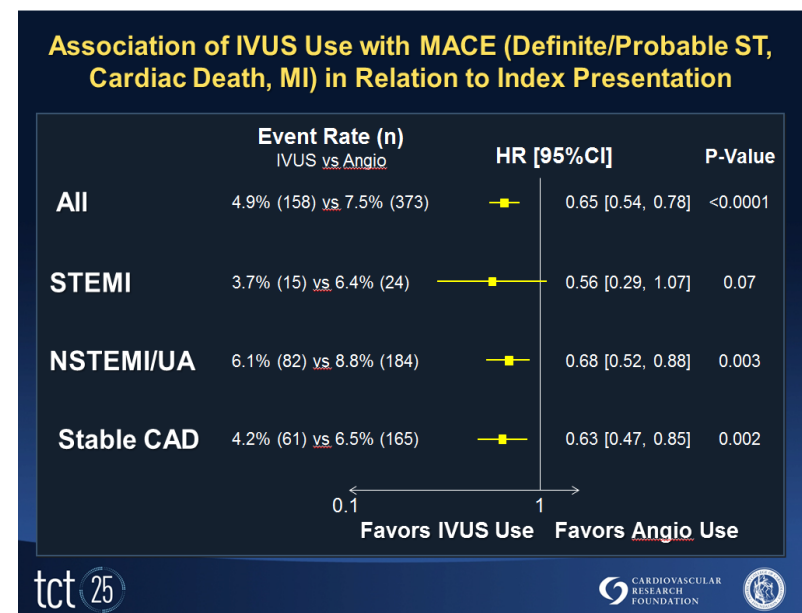
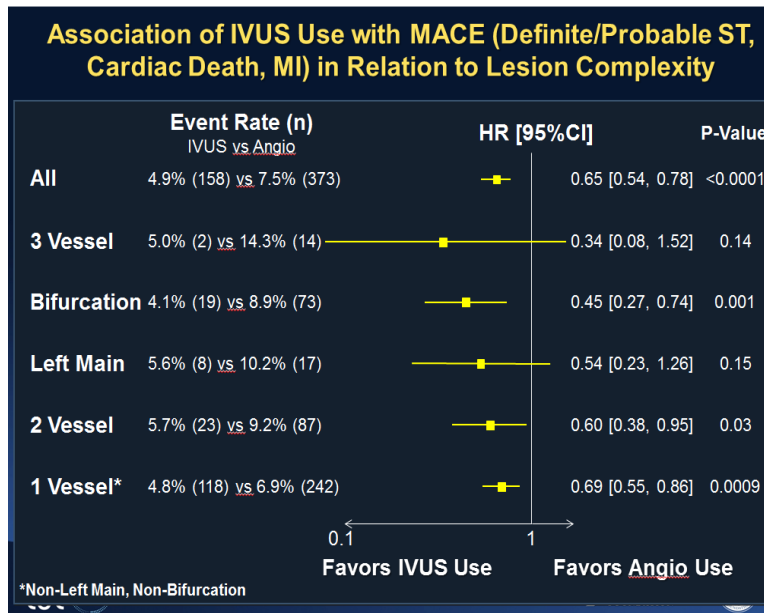


1. Witzenbichler B et al. Relationship Between Intravascular Ultrasound Guidance and Clinical Outcomes After Drug-Eluting Stents: The ADAPT-DES Study. Circulation 2014 Jan; 129,4:463-470.

# ADAPT-DES

Study data reported that IVUS guidance was of greatest benefit in the most complex lesions and acute patient presentations<sup>1</sup>

2



1. Witzensbichler B et al. Relationship Between Intravascular Ultrasound Guidance and Clinical Outcomes After Drug-Eluting Stents: The ADAPT-DES Study. Circulation 2014 Jan; 129,4:463-470.

# SCAI Expert Consensus Statement

on IVUS in PCI Guidance:



**Expert Consensus Statement on the Use of Fractional Flow Reserve, Intravascular Ultrasound, and Optical Coherence Tomography:** A Consensus Statement of the Society of Cardiovascular Angiography and Interventions

Amir Lotfi,<sup>1</sup> MD, FSCAI, Allen Jeremias,<sup>2</sup> MD, FSCAI, William F. Fearon,<sup>3</sup> MD, FSCAI, Marc D. Feldman,<sup>4</sup> MD, FSCAI, Roxana Mehran,<sup>5</sup> MD, John C. Messenger,<sup>6</sup> MD, FSCAI, Cindy L. Grines,<sup>7</sup> MD, FSCAI, Larry S. Dean,<sup>8</sup> MD, FSCAI, Morton J. Kern,<sup>9</sup> MD, FSCAI, and Lloyd W. Klein,<sup>10</sup> MD, FSCAI

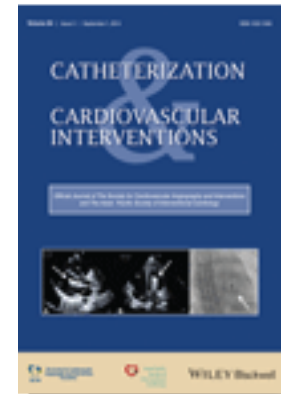
## Intravascular ultrasound (IVUS).

**Definitely Beneficial.** IVUS is an accurate method for determining optimal stent deployment (complete stent expansion and apposition and lack of edge dissection or other complications after implantation), and the size of the vessel undergoing stent implantation.

**Probably Beneficial.** IVUS can be used to appraise the significance of LMCA stenosis and, employing a cutoff MLA = 6 mm<sup>2</sup>, assess whether revascularization is warranted.

**Possibly Beneficial.** IVUS can be useful for the assessment of plaque morphology.

**No Proven Value/Should be Discouraged.** IVUS measurements for determination of non-LMCA lesion severity should not be relied upon, in the absence of additional functional evidence, for recommending revascularization.



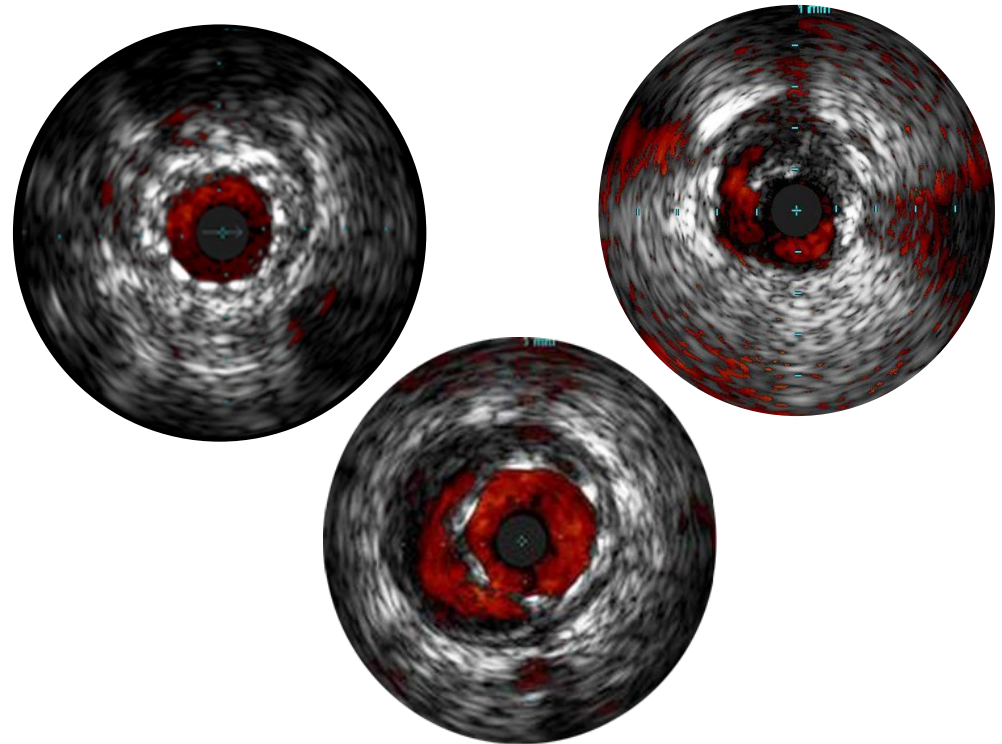
# SCAI Expert Consensus Statement

on IVUS in PCI Guidance:



“Definitely  
Beneficial”

“For determining optimal stent deployment (complete stent expansion and apposition and lack of edge dissection or other complications after implantation)”

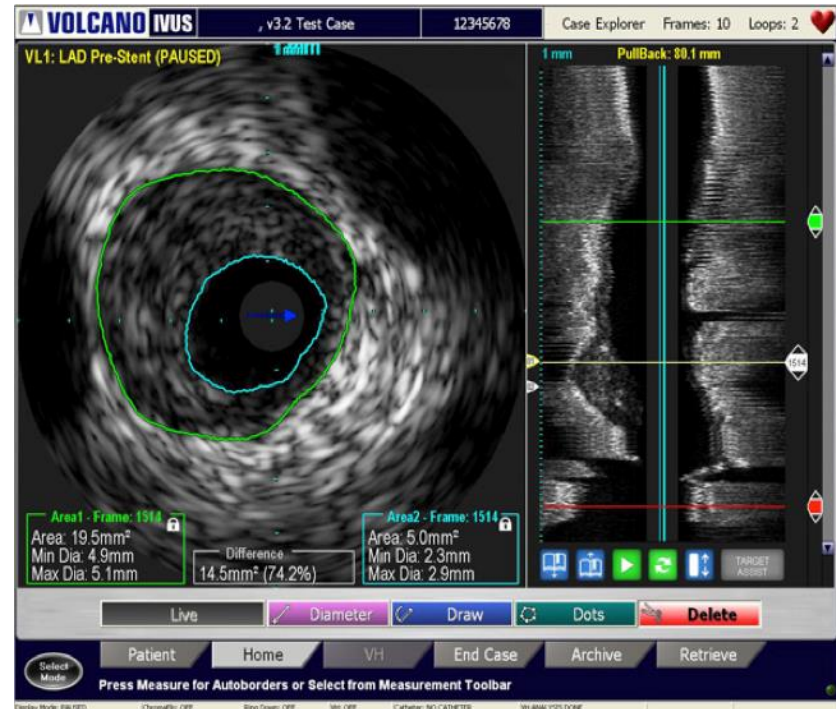


# SCAI Expert Consensus Statement

on IVUS in PCI Guidance:



“For determining the size of the vessel undergoing stent implantation”





# ACC/AHA/SCAI Guidelines

Use of IVUS (actual wording)	Class	Level of Evidence
For the assessment of angiographically indeterminate left main CAD	IIa	B
4 to 6 weeks and 1 year after cardiac transplantation to exclude donor CAD, detect rapidly progressive cardiac allograft vasculopathy, and provide prognostic information	IIa	B
To determine the mechanism of stent restenosis	IIa	C
For the assessment of non-left main coronary arteries with angiographically intermediate coronary stenoses (50% to 70% diameter stenosis)	IIb	B
For <u>guidance</u> of coronary stent implantation, particularly in cases of left main coronary artery stenting	IIb	B
To determine the mechanism of stent thrombosis	IIb	C

Class IIa: “is reasonable”, Class IIb: “may be considered.”

# ESC Guidelines 2014:

## Paradigm shift to “should be considered”

Recommendation (actual wording)	Class	Level of Evidence
IVUS to assess severity and optimize treatment of unprotected left main lesions.	IIa <b>(upgraded from IIb, C)</b>	B
IVUS in selected patients to optimize stent implantation	IIa <b>(upgraded from IIb, B)</b>	B
IVUS and/or OCT should be considered to detect stent-related mechanical problems.	IIa	C
IVUS or OCT to assess mechanisms of stent failure.	IIa	C

Class IIa: “should be considered”, Class IIb: “may be considered.”

# Appropriate Use Criteria

**Table 1.4. Adjunctive Invasive Diagnostic Testing in Patients Undergoing Appropriate Diagnostic Coronary Angiography**

Indication		Appropriate Use Score (1–9)		
		Unexpected Angiographic Finding or No Prior Noninvasive Testing	Prior Testing = No Ischemic Findings	Prior Testing = Concordant* Ischemic Findings
<b>FFR for Lesion Severity</b>				
40.	• Angiographically indeterminate severity left main stenosis (defined as 2 or more orthogonal views contradictory whether stenosis >50%)	A (7)	A (7)	A (7)
41.	• Nonobstructive disease by angiography (non-left main) <50%	I (3)	I (2)	U (5)
42.	• Angiographically intermediate disease (non-left main) 50% to 69%	A (7)	U (6)	A (7)
43.	• Angiographically obstructive significant disease (non-left main) ≥70% stenosis	A (7)	A (7)	I (3)
<b>IVUS for Lesion Severity</b>				
44.	• Angiographically indeterminate left main stenosis (defined as 2 or more orthogonal views contradictory whether stenosis >50%)	A (7)	A (7)	A (7)
45.	• Nonobstructive disease by angiography (non-left main) <50%	I (3)	I (3)	U (6)
46.	• Angiographically intermediate disease (non-left main) 50% to 69%	U (5)	U (5)	U (6)
47.	• Angiographically obstructive significant disease (non-left main) ≥70% stenosis	U (4)	U (5)	I (3)
<b>IVUS—Examination of Lesion or Artery Morphology</b>				
48.	• Coronary lesions or structures difficult to characterize angiographically (e.g., aneurysm, extent of calcification, stent fracture, stent apposition, stent expansion, dissections) or for sizing of vessel before stent placement			A (8)

\*Concordance refers to noninvasive imaging studies that demonstrate evidence of abnormal myocardial perfusion that is in the same distribution as a coronary artery stenosis, or degree of valvular disease that is similar to clinical impression.

A = appropriate; FFR = fractional flow reserve; I = inappropriate; IVUS = intravascular ultrasound; U = uncertain.

# A preponderance of evidence that IVUS benefits patients

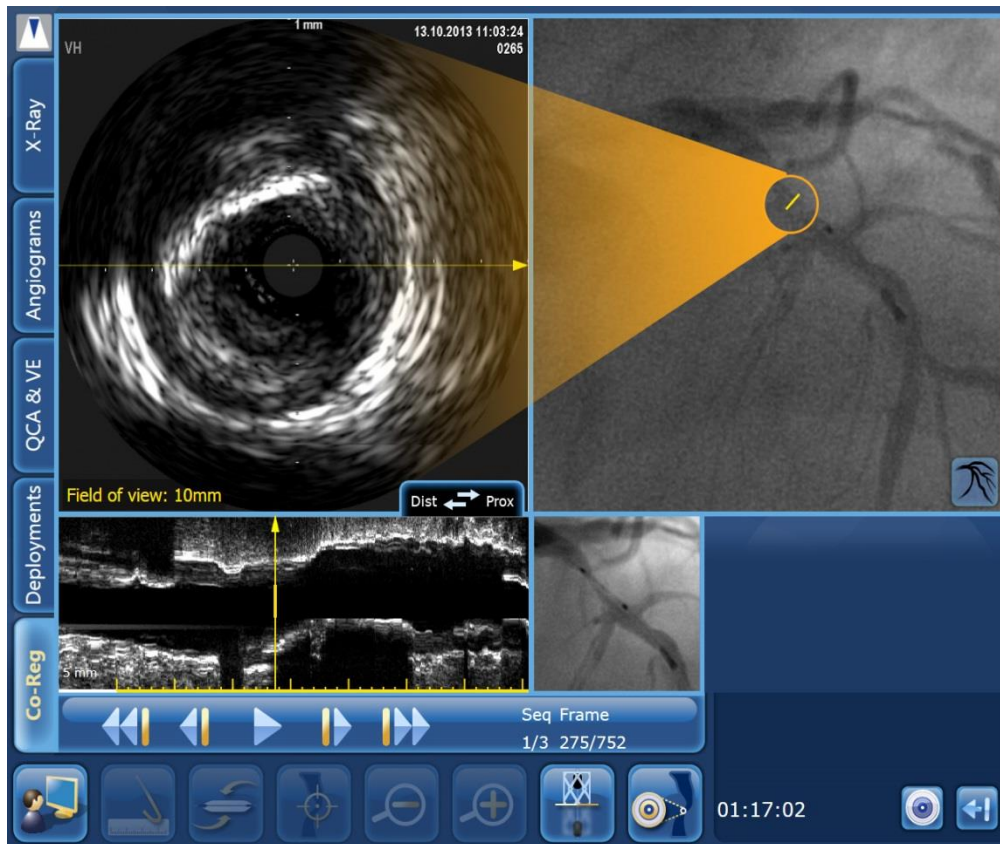
- **Ahn Meta-Analysis of 17 studies covering 26,503 patients<sup>1</sup>**
- **ADAPT-DES – largest study of IVUS guidance<sup>2</sup>**
- **SCAI Expert Consensus Statement: “Definitely Beneficial”<sup>3</sup>**

1. Ahn JM, Kang SJ, Yoon SH, et al. “Meta-Analysis of Outcomes After Intravascular Ultrasound - Guided Versus Angiography-Guided Drug-Eluting Stent Implantation in 26,503 Patients Enrolled in Three Randomized Trials and 14 Observational Studies” Am J Cardiol. 2014;113:1338-1347.

2. Witzensbichler B et al. Relationship Between Intravascular Ultrasound Guidance and Clinical Outcomes After Drug-Eluting Stents: The ADAPT-DES Study. Circulation 2014 Jan; 129,4;463-470.

3. Lotfi A, et al. Expert consensus statement on the use of fractional flow reserve, intravascular ultrasound, and optical coherence tomography: a consensus statement of the society of cardiovascular angiography and interventions. Catheter Cardiovasc Interv. 2014 Mar 1;83(4):509-18.

# SYNCVISION®



SyncVision® co-registration simplifies IVUS by bringing IVUS and angiography together.

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