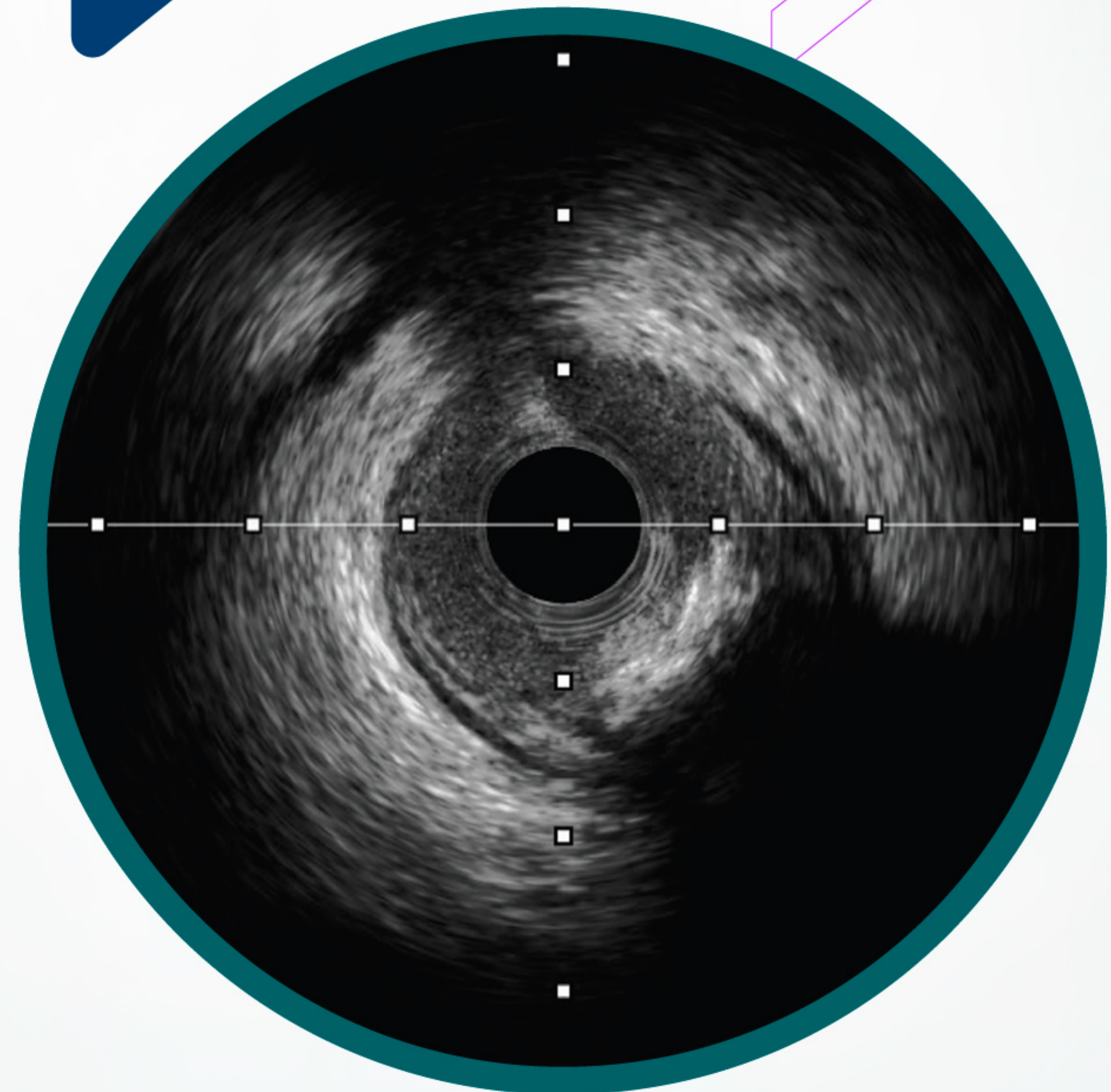
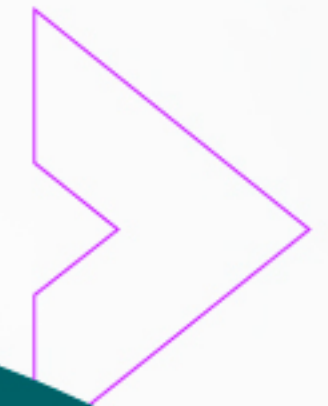




# IVUS Clinical Compendium





# ➤ Clinical Evidence



ESC<sup>1</sup>

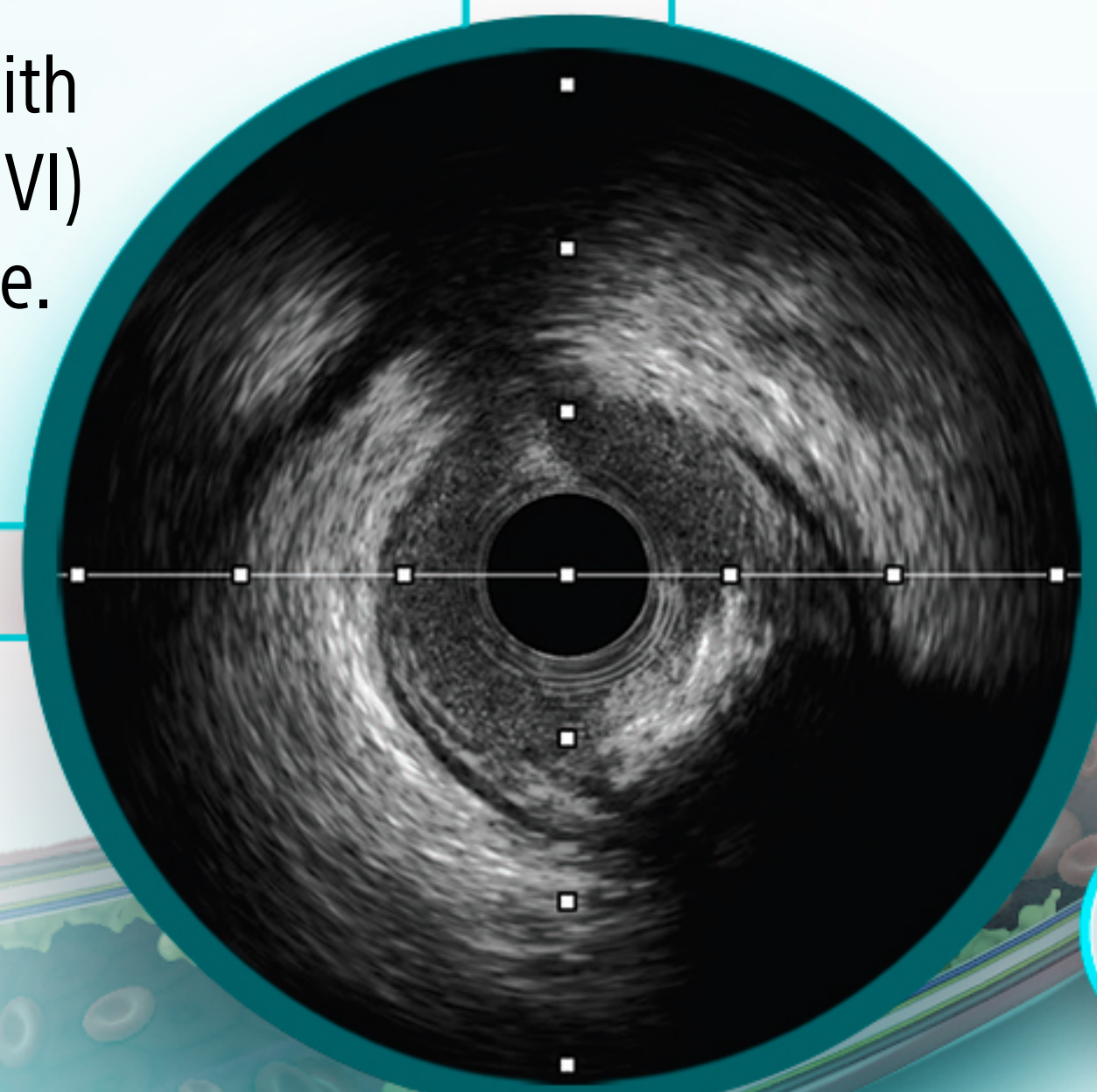


Meta analysis of 20 trials showed **REDUCED** all-cause mortality and myocardial infarction (MI) rates with PCI guided by intravascular imaging (IVI) than with angiography guidance alone.



RENOVATE<sup>2</sup>

Intravascular imaging-guided PCI led to a **LOWER RISK** of a composite of cardiac death, target vessel MI, and clinically driven target vessel revascularization.



ULTIMATE<sup>3</sup>



IVUS guidance was associated with a **LOWER RISK** for 3-year target vessel failure (TVF)



IVUS XPL<sup>4</sup>

IVUS guidance led to a **50% REDUCTION** in the relative risk of major adverse cardiac events (MACE) in patients with long (≥28 mm) lesions



1. <https://www.escardio.org/The-ESC/Press-Office/Press-releases/Intravascular-imaging-associated-with-improved-outcomes-compared-with-angiography>

2. J.M. Lee, et al. The New England Journal of Medicine. "Intravascular Imaging-Guided or Angiography-Guided Complex PCI." 2023. DOI: 10.1056/NEJMoa2216607

3. X. Gao, et al. JACC: Cardiovascular Interventions. "3-Year Outcomes of the ULTIMATE Trial Comparing Intravascular Ultrasound Versus Angiography-Guided Drug-Eluting Stent Implantation." 2021. <https://doi.org/10.1016/j.jcin.2020.10.001>

4. S. Hong, et al. JACC: Cardiovascular Interventions. "Effect of Intravascular Ultrasound-Guided Drug-Eluting Stent Implantation. 5-Year Follow-Up of the IVUS-XPL Randomized Trial." 2020. <https://doi.org/10.1016/j.jcin.2019.09.033>



# ➤ Clinical Evidence Summary

## ESC<sup>1</sup>

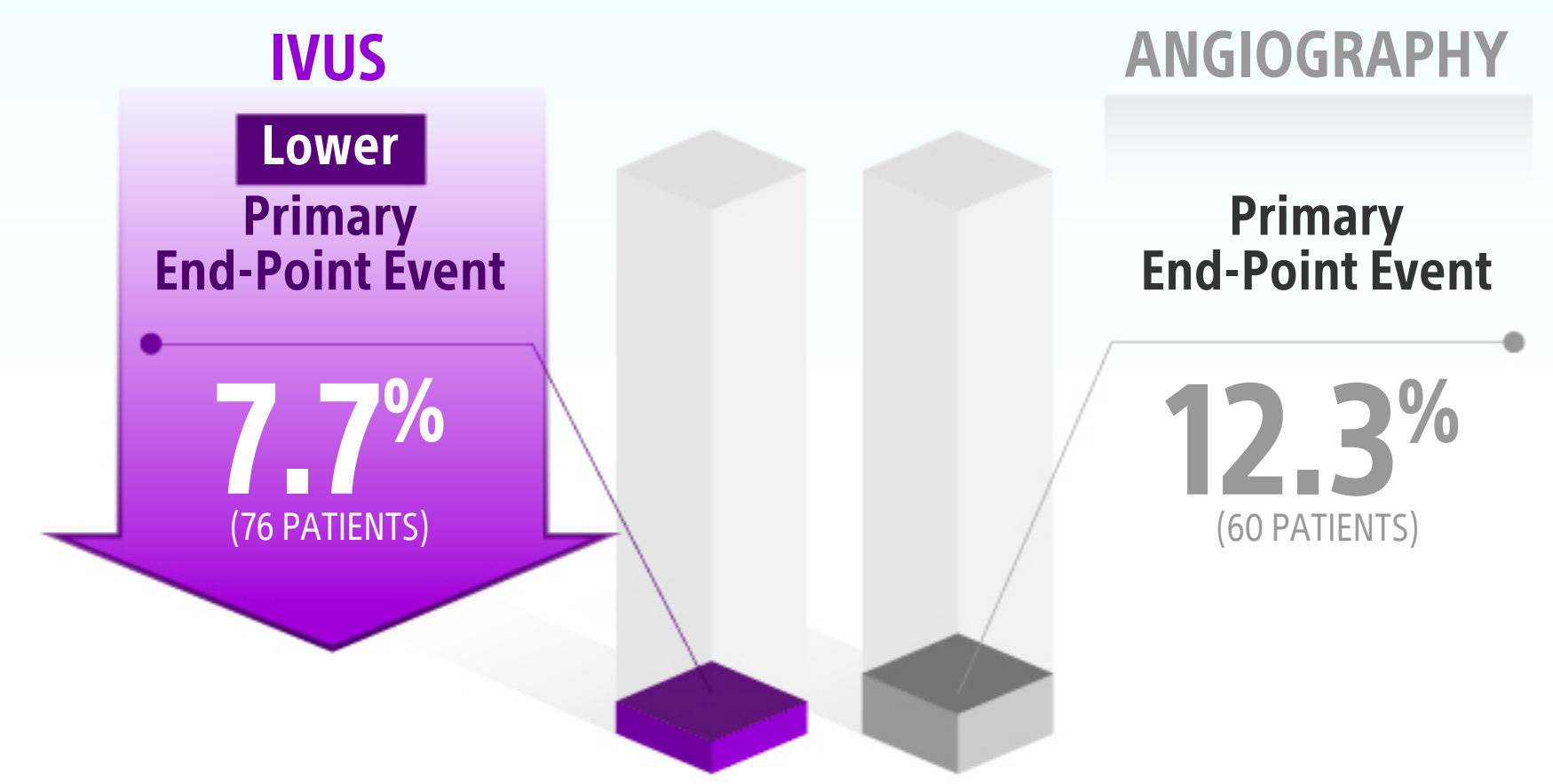
Meta analysis of 20 trials showed **REDUCED all-cause mortality** and MI rates with PCI guided by IVI than with angiography guidance alone.



Intravascular imaging (IVUS or OCT) guidance of PCI compared with angiography guidance of PCI resulted in **31% REDUCTION** in the primary composite outcome of **target lesion failure**

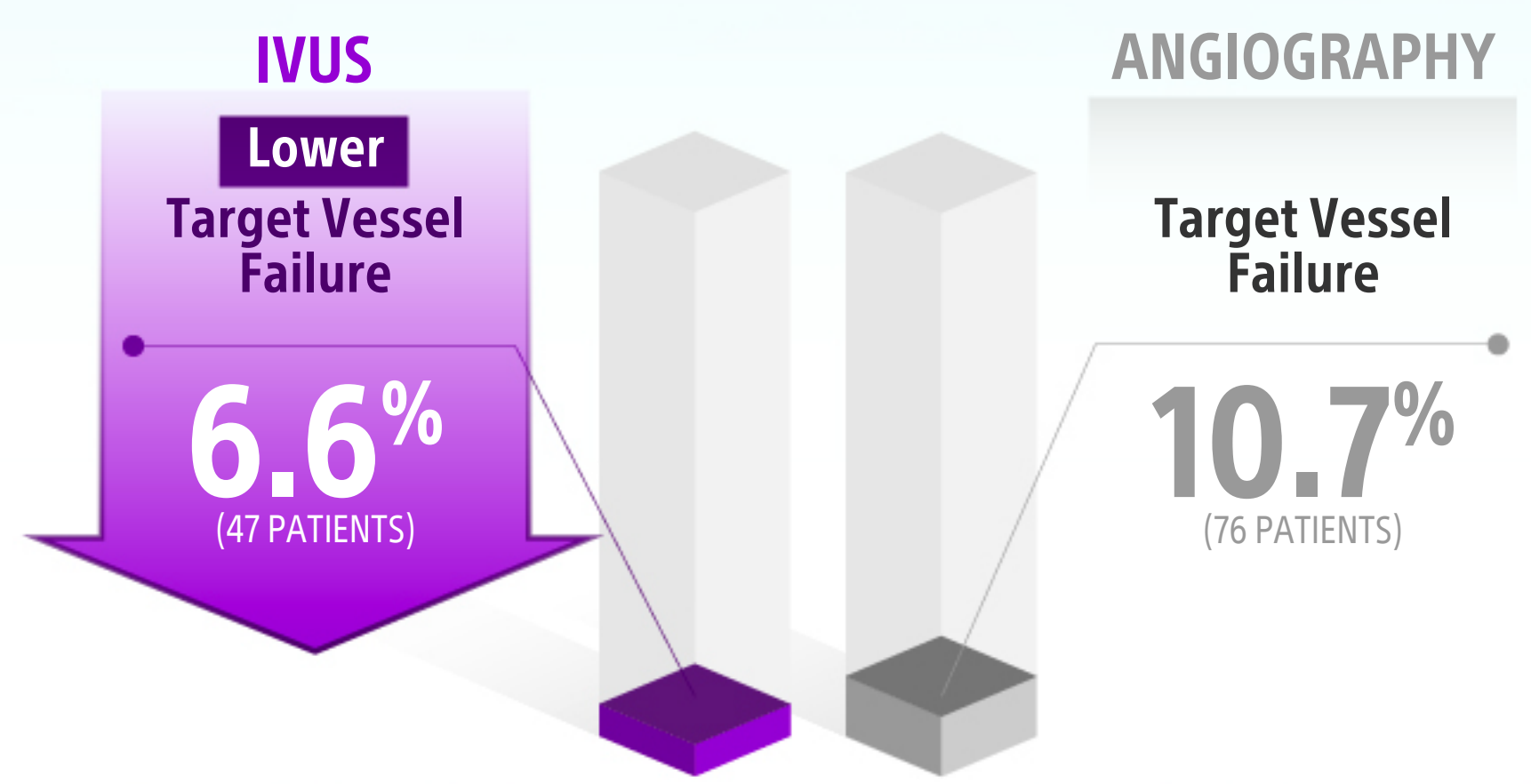
## RENOVATE<sup>2</sup>

Intravascular imaging-guided PCI led to a **LOWER RISK** of a composite of cardiac death, target vessel MI, and clinically driven target vessel revascularization.



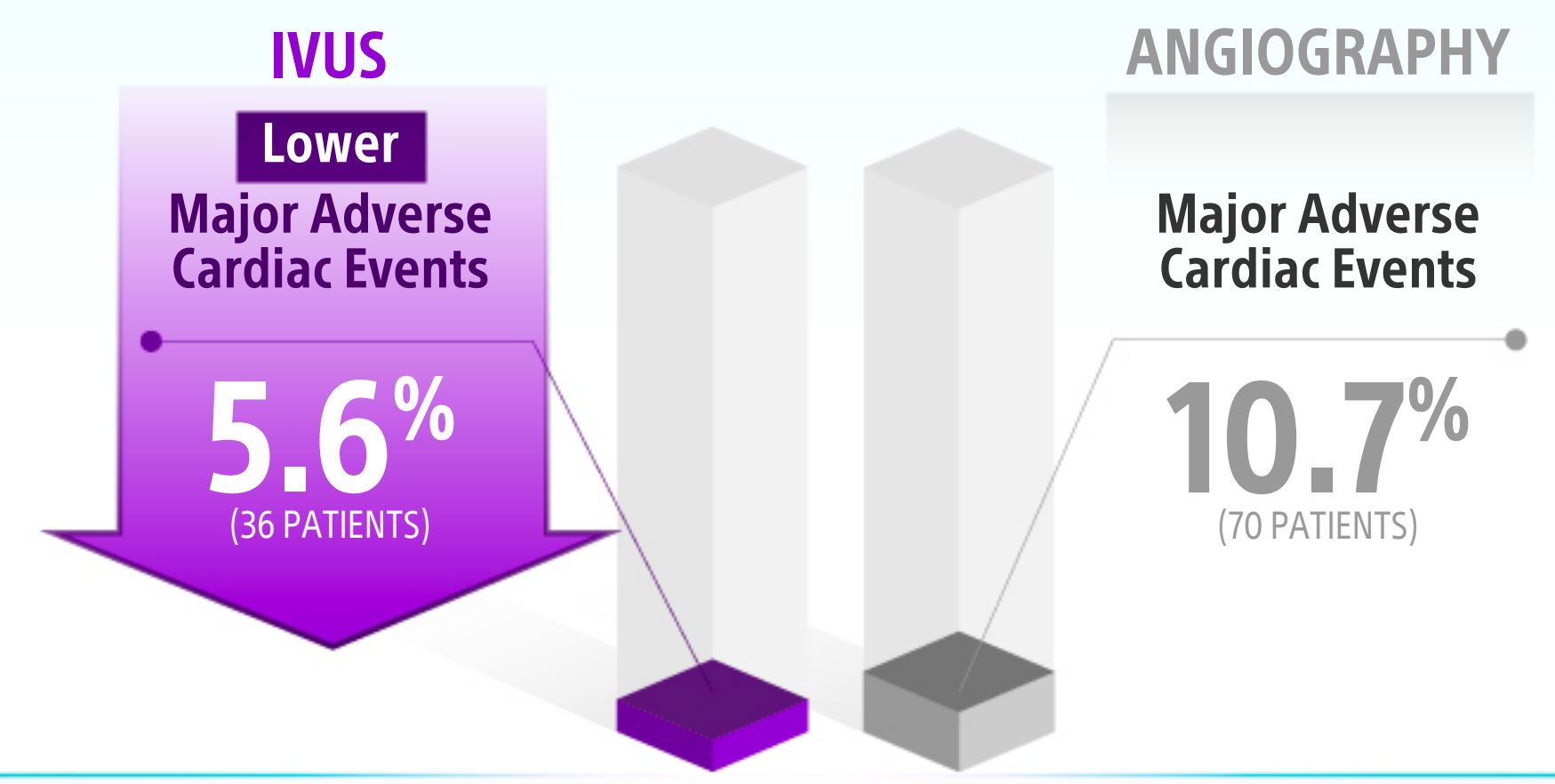
## ULTIMATE<sup>3</sup>

IVUS guidance was associated with a **LOWER RISK** for 3-year TVF



## IVUS XPL<sup>4</sup>

IVUS guidance led to a **50% REDUCTION** in the **relative risk of MACE** in patients with long ( $\geq 28$  mm) lesions



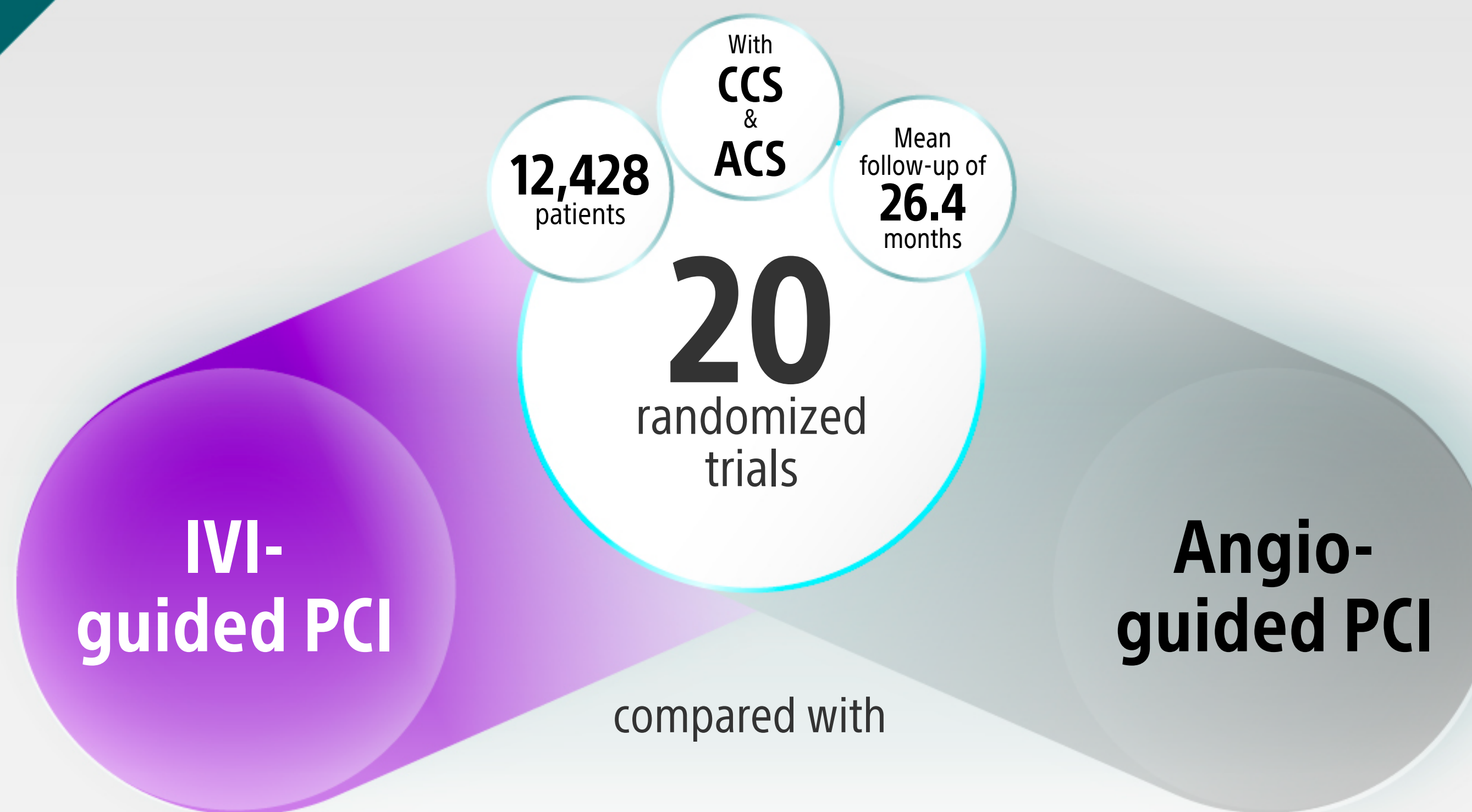
1. <https://www.escardio.org/The-ESC/Press-Office/Press-releases/Intravascular-imaging-associated-with-improved-outcomes-compared-with-angiography>  
 2. J.M. Lee, et al. The New England Journal of Medicine. "Intravascular Imaging-Guided or Angiography-Guided Complex PCI." 2023. DOI: 10.1056/NEJMoa2216607  
 3. X. Gao, et al. JACC: Cardiovascular Interventions. "3-Year Outcomes of the ULTIMATE Trial Comparing Intravascular Ultrasound Versus Angiography-Guided Drug-Eluting Stent Implantation." 2021. <https://doi.org/10.1016/j.jcin.2020.10.001>  
 4. S. Hong, et al. JACC: Cardiovascular Interventions. "Effect of Intravascular Ultrasound-Guided Drug-Eluting Stent Implantation. 5-Year Follow-Up of the IVUS-XPL Randomized Trial." 2020. <https://doi.org/10.1016/j.jcin.2019.09.033>






# Clinical Evidence

## Overview ESC





### Endpoints:


#### Primary


 Target lesion failure

#### Secondary

 Cardiac death

 Target vessel myocardial infarction

 Target lesion revascularization

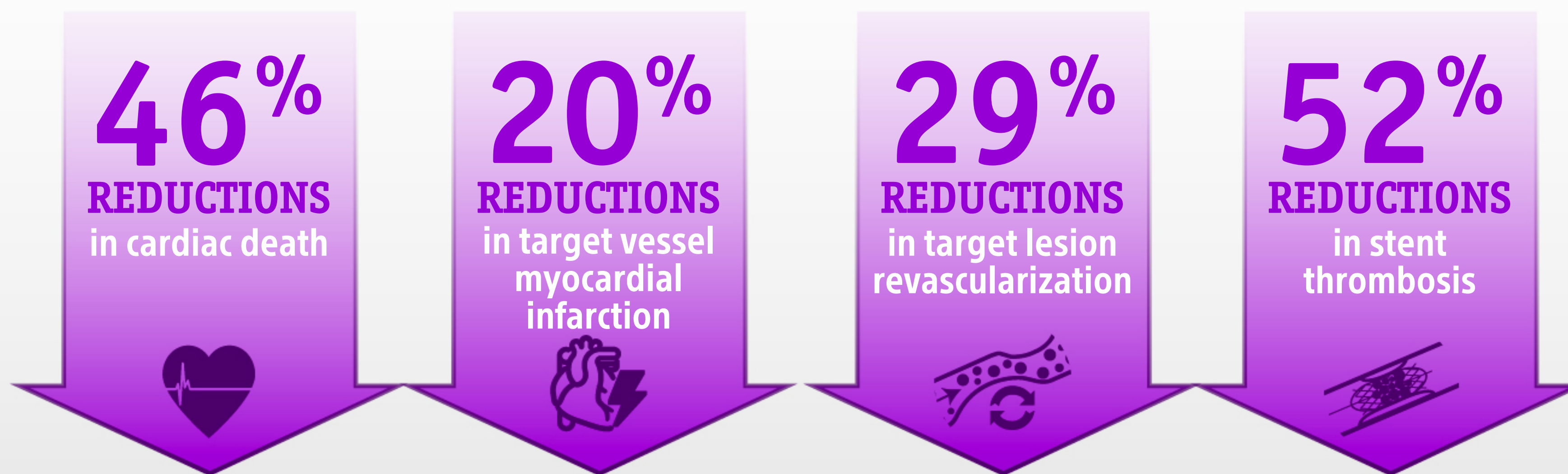
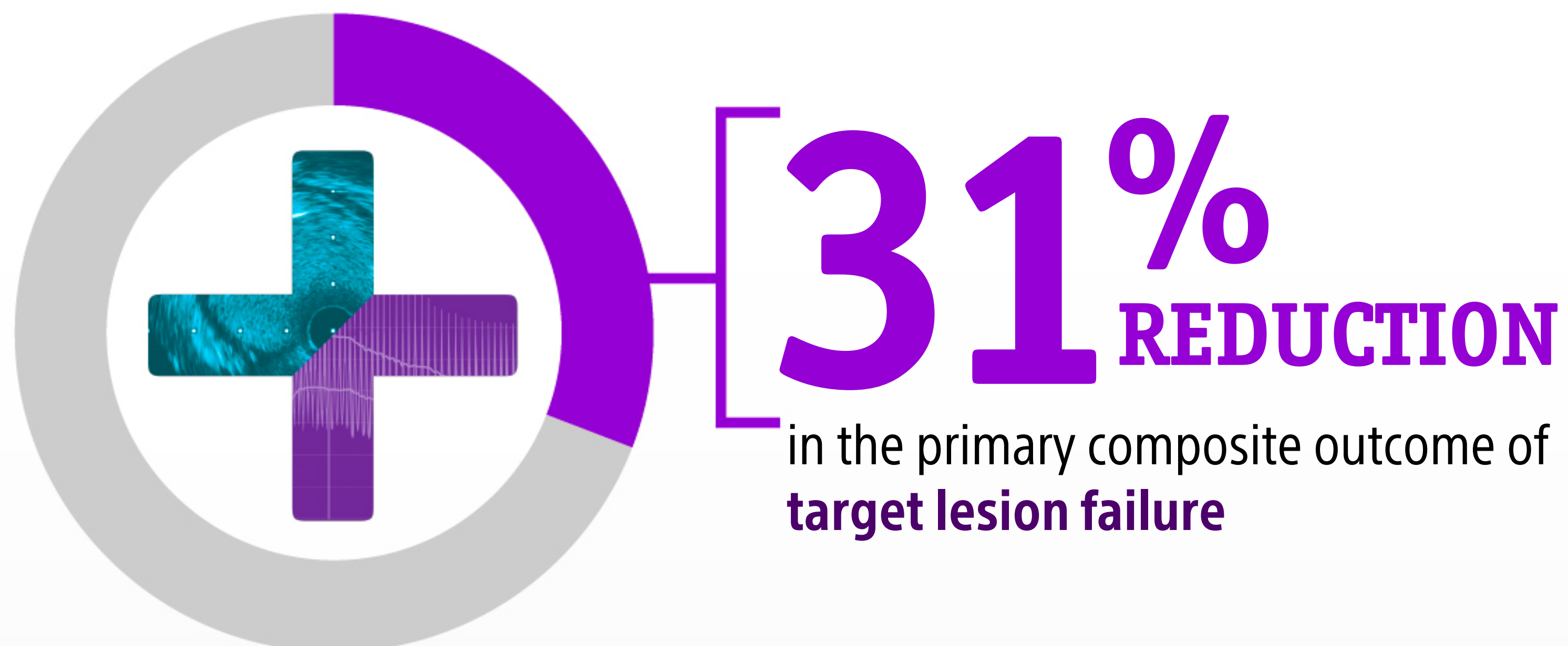
 Stent thrombosis





## Outcome ESC

Intravascular imaging (IVUS or OCT) guidance of PCI compared with angiography guidance of PCI resulted in:

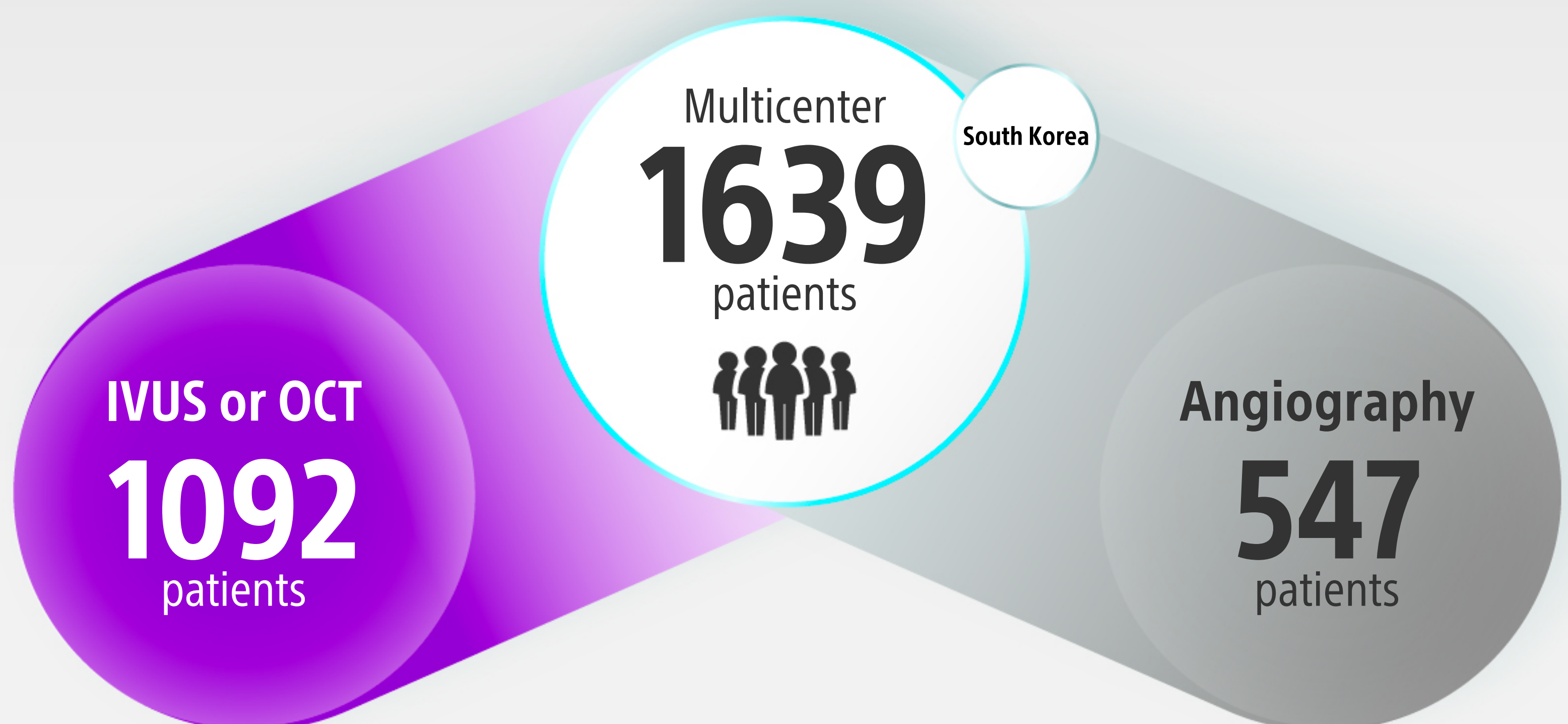







# Clinical Evidence

## Overview

RENOVATE  
(2.1 YEARS OUTCOME)



The **primary end point** was a composite of:

-  Death from cardiac causes
-  Target-vessel-related myocardial infarction
-  Clinically driven target-vessel revascularization



# Clinical Evidence



## Outcome

**RENOVATE**  
(2.1 YEARS OUTCOME)

### IVUS

**Lower**  
**Primary End-Point Event**

Hazard ratio, 0.64; 95% confidence interval, 0.45 to 0.89; P=0.008

**7.7%**  
(76 PATIENTS)

### ANGIOGRAPHY

**Primary End-Point Event**

Hazard ratio, 0.64; 95% confidence interval, 0.45 to 0.89; P=0.008

**12.3%**  
(60 PATIENTS)

### IVUS

**Lower**

Death from cardiac causes

**1.7%**  
(16 PATIENTS)

### ANGIOGRAPHY

Death from cardiac causes

**3.8%**  
(17 PATIENTS)

### IVUS

**Lower**

Target-vessel-related myocardial infarction

**3.7%**  
(38 PATIENTS)

### ANGIOGRAPHY

Target-vessel-related myocardial infarction

**5.6%**  
(30 PATIENTS)

### IVUS

**Lower**

Clinically driven target-vessel revascularization

**3.4%**  
(32 PATIENTS)

### ANGIOGRAPHY

Clinically driven target-vessel revascularization

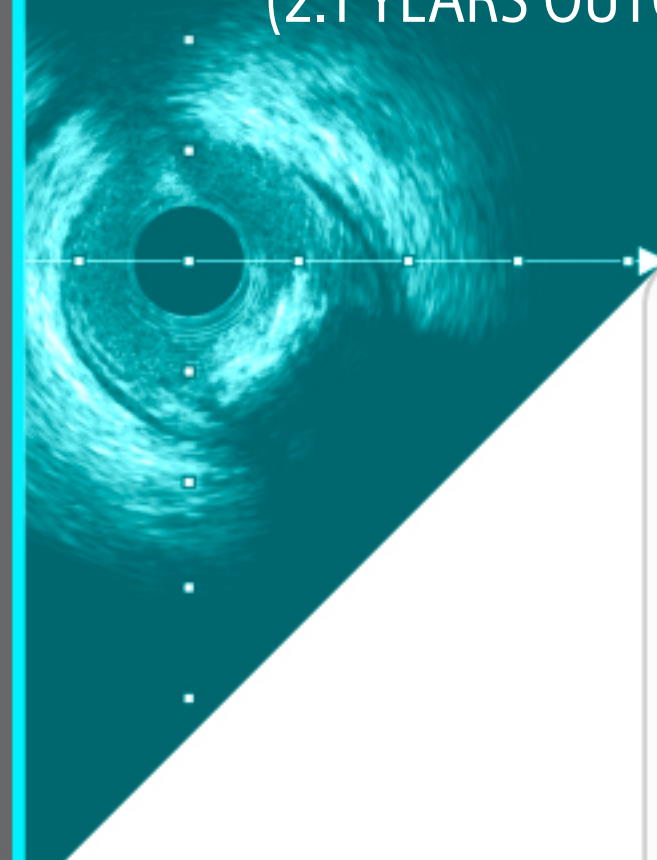
**5.5%**  
(25 PATIENTS)



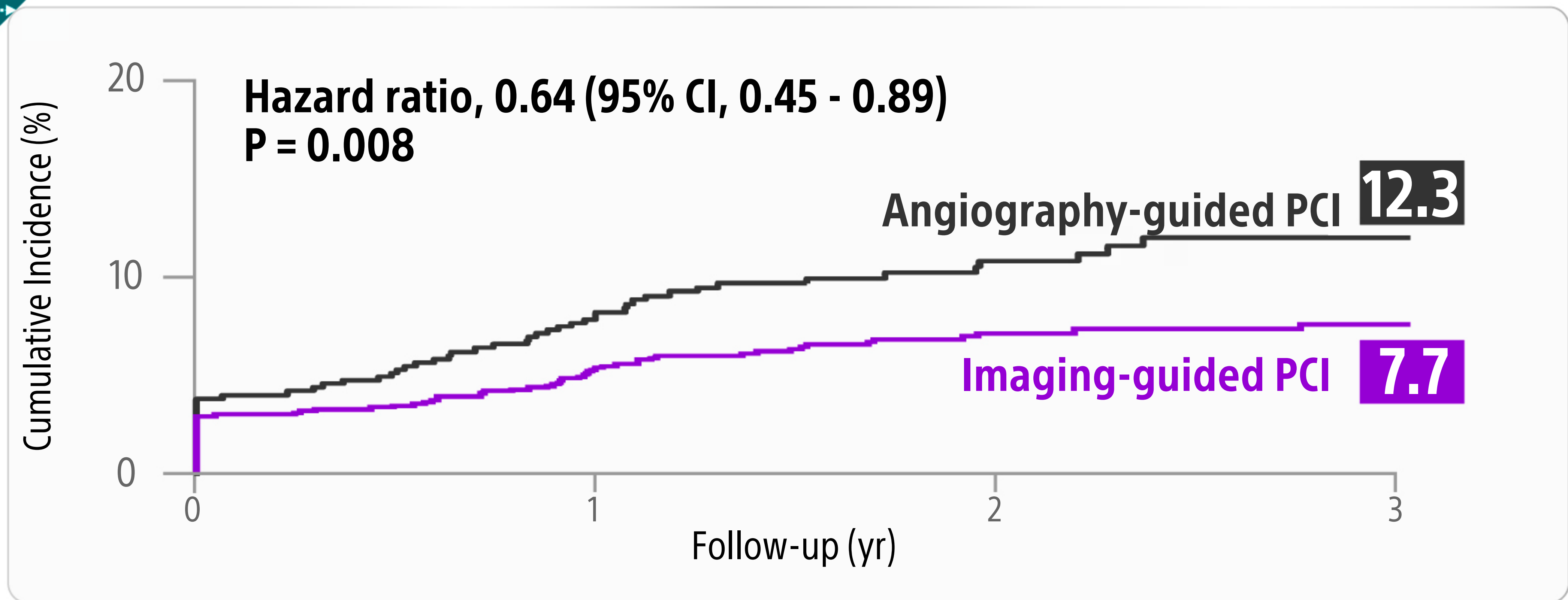


## Outcome

**RENOVATE**  
(2.1 YEARS OUTCOME)



**A. Target-Vessel Failure**



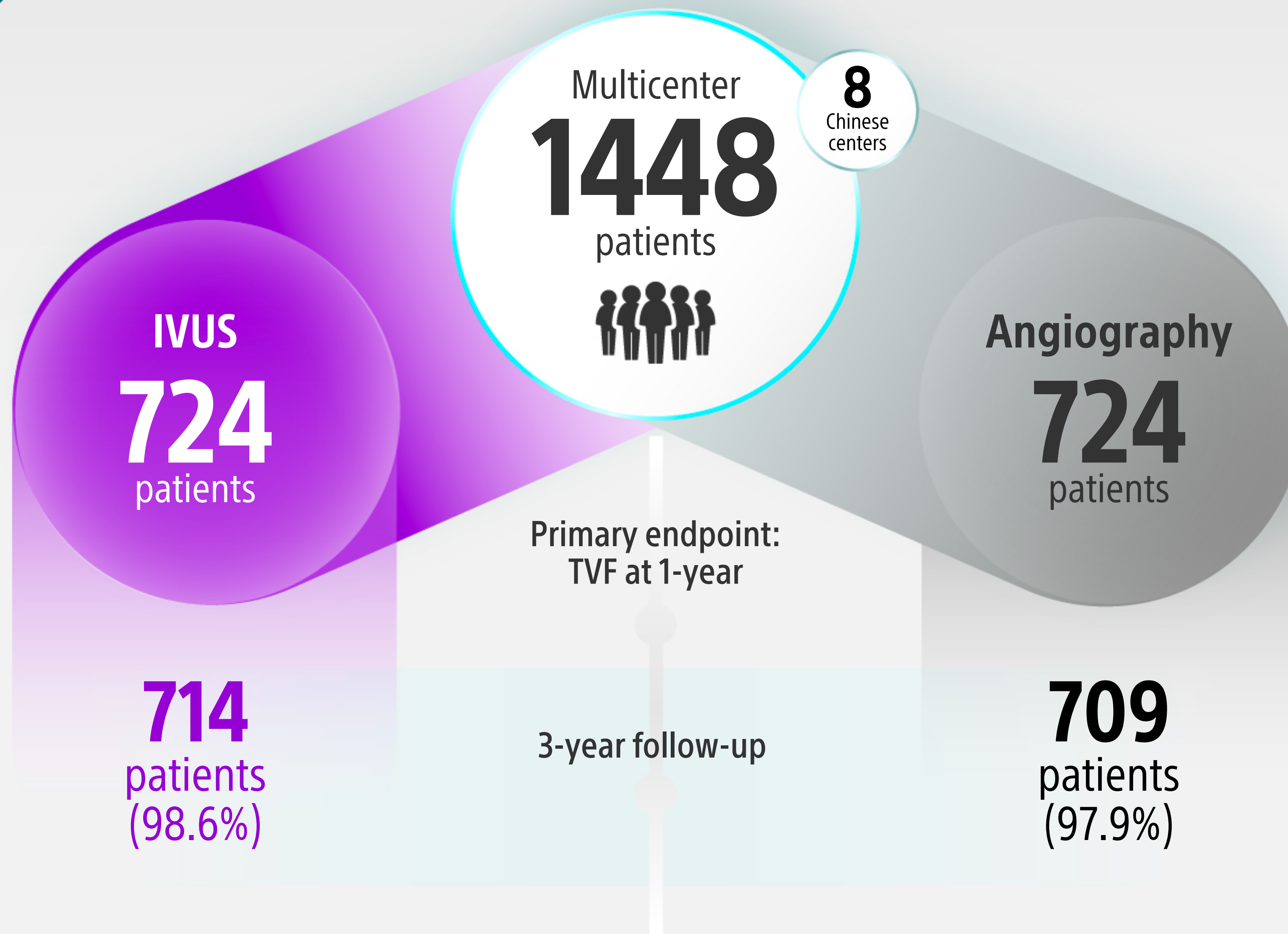
	Number at risk			
Angiography-guided PCI	547	496	280	120
Imaging-guided PCI	1092	1023	591	255



# Clinical Evidence

## Overview

ULTIMATE  
(3 YEARS OUTCOME)





# Clinical Evidence



## Outcome ULTIMATE (3 YEARS OUTCOME)

### IVUS

**Lower**

**Target Vessel Failure**

Hazard ratio 0.6, (p 1/4 0.01)

**6.6%**  
(47 PATIENTS)

### ANGIOGRAPHY

**Target Vessel Failure**

Hazard ratio 0.6, (p 1/4 0.01)

**10.7%**  
(76 PATIENTS)

### IVUS

**Lower**

Driven mainly by the decrease in  
**clinically driven target vessel revascularization**

Hazard ratio 0.64, (p 1/4 0.05)

**4.5%**

### ANGIOGRAPHY

Driven mainly by the decrease in  
**clinically driven target vessel revascularization**

Hazard ratio 0.64, (p 1/4 0.05)

**6.9%**

### IVUS

**Lower**

**The rate of definite or probable ST**

Hazard ratio 0.12, (p 1/4 0.02)

**0.1%**

### ANGIOGRAPHY

**The rate of definite or probable ST**

Hazard ratio 0.12, (p 1/4 0.02)

**1.1%**



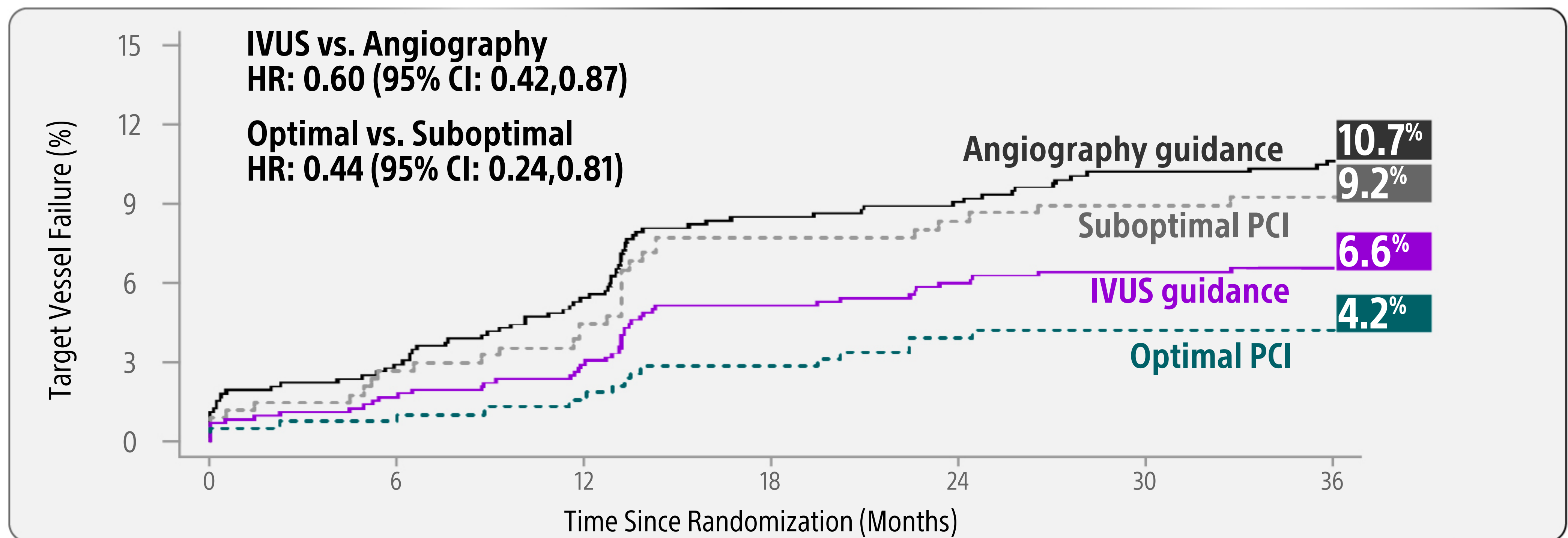
# Clinical Evidence

## Outcome

ULTIMATE  
(3 YEARS OUTCOME)



IVUS-defined optimal procedure was associated with a significant reduction in 3-year TVF relative to that with the suboptimal procedure.



Number at risk	0	6	12	18	24	30	36
Angiography guidance	724	698	676	651	643	634	631
IVUS guidance	724	710	696	676	660	655	654
Suboptimal PCI	340	329	320	309	300	296	295
Optimal PCI	384	381	376	367	360	359	359

X. Gao, et al. JACC: Cardiovascular Interventions. "3-Year Outcomes of the ULTIMATE Trial Comparing Intravascular Ultrasound Versus Angiography-Guided Drug-Eluting Stent Implantation." 2021.  
<https://doi.org/10.1016/j.jcin.2020.10.001>





# Clinical Evidence

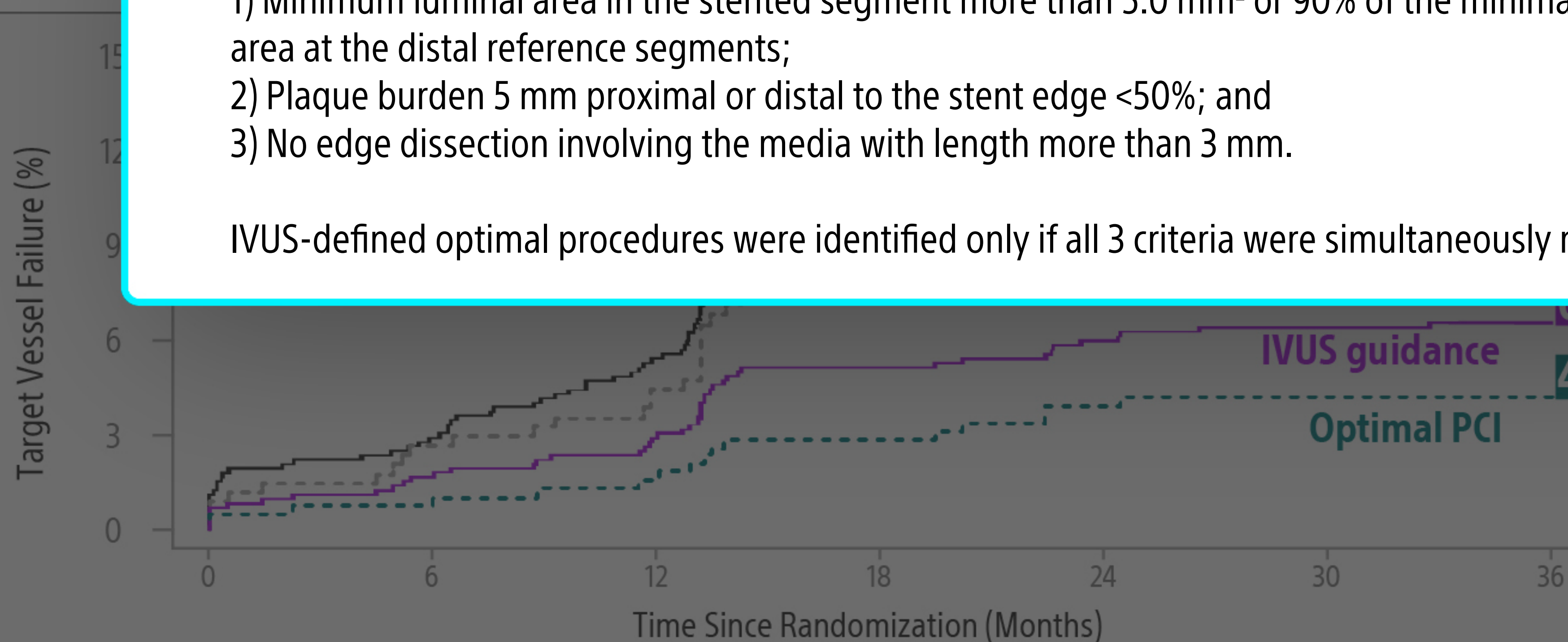
## Outcome ULTIMATE (3 YEARS OUTCOME)



IVUS- defined optimal criteria for DES implantation in this trial included:

- 1) Minimum luminal area in the stented segment more than 5.0 mm<sup>2</sup> or 90% of the minimal luminal area at the distal reference segments;
- 2) Plaque burden 5 mm proximal or distal to the stent edge <50%; and
- 3) No edge dissection involving the media with length more than 3 mm.

IVUS-defined optimal procedures were identified only if all 3 criteria were simultaneously met.



Number at risk	0	6	12	18	24	30	36
Angiography guidance	724	698	676	651	643	634	631
IVUS guidance	724	710	696	676	660	655	654
Suboptimal PCI	340	329	320	309	300	296	295
Optimal PCI	384	381	376	367	360	359	359

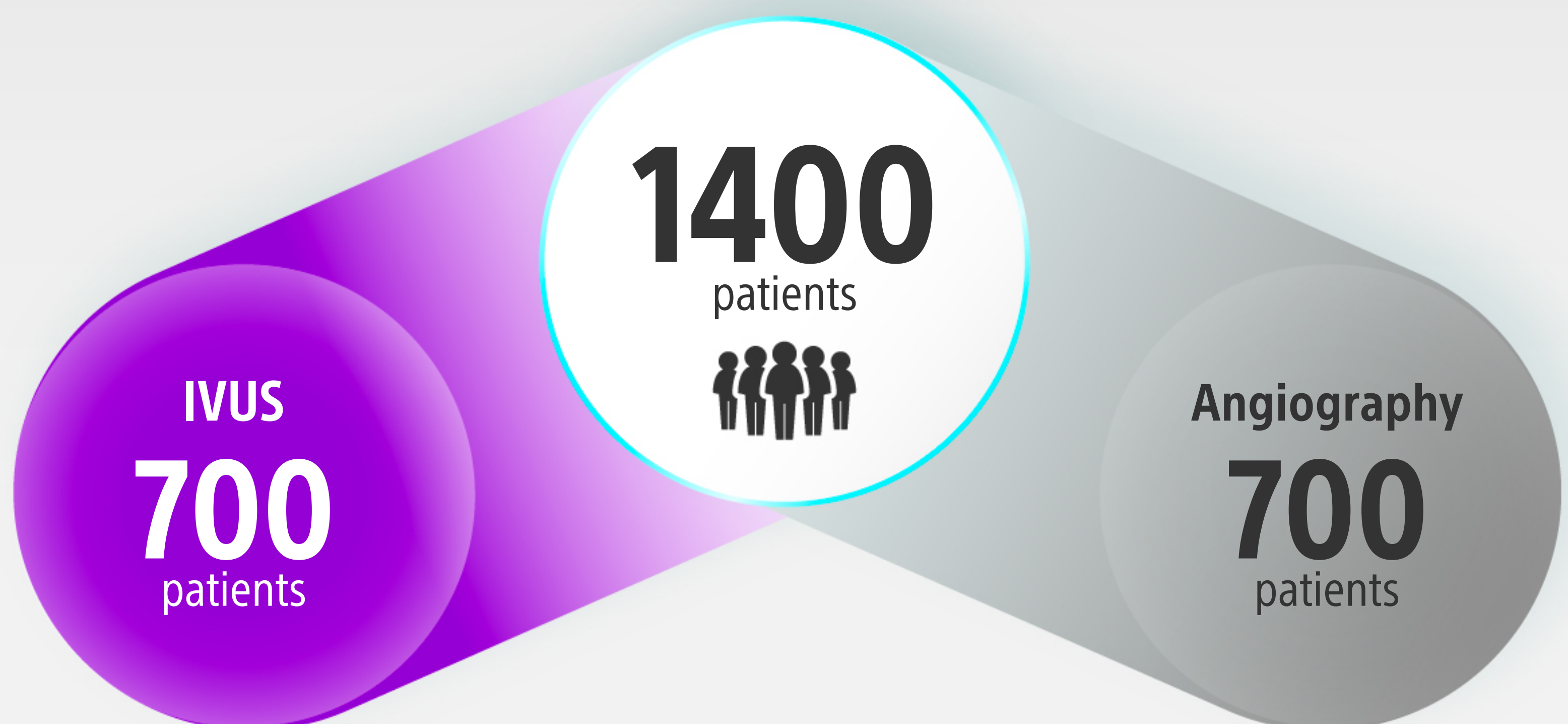
X. Gao, et al. JACC: Cardiovascular Interventions. "3-Year Outcomes of the ULTIMATE Trial Comparing Intravascular Ultrasound Versus Angiography-Guided Drug-Eluting Stent Implantation." 2021. <https://doi.org/10.1016/j.jcin.2020.10.001>



# Clinical Evidence

## Overview

IVUS-XPL  
(5 YEAR FOLLOW-UP)



Assess through major adverse cardiac event:

Cardiac death

Target lesion-related myocardial infarction

Ischemia-driven target lesion revascularization

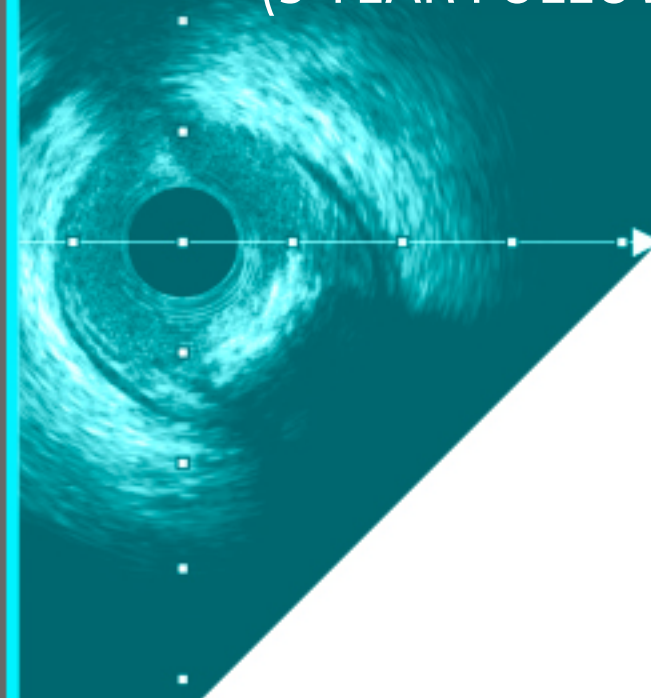


# Clinical Evidence



## Outcome

IVUS-XPL  
(5 YEAR FOLLOW-UP)



Completed in  
**1183**  
patients  
(85%)

**IVUS**

**Lower**

**Major Adverse  
Cardiac Events**

Hazard ratio 0.50, (p 1/4 0.001)

**5.6%**  
(36 PATIENTS)

**ANGIOGRAPHY**

**Major Adverse  
Cardiac Events**

Hazard ratio 0.50, (p 1/4 0.001)

**10.7%**  
(70 PATIENTS)

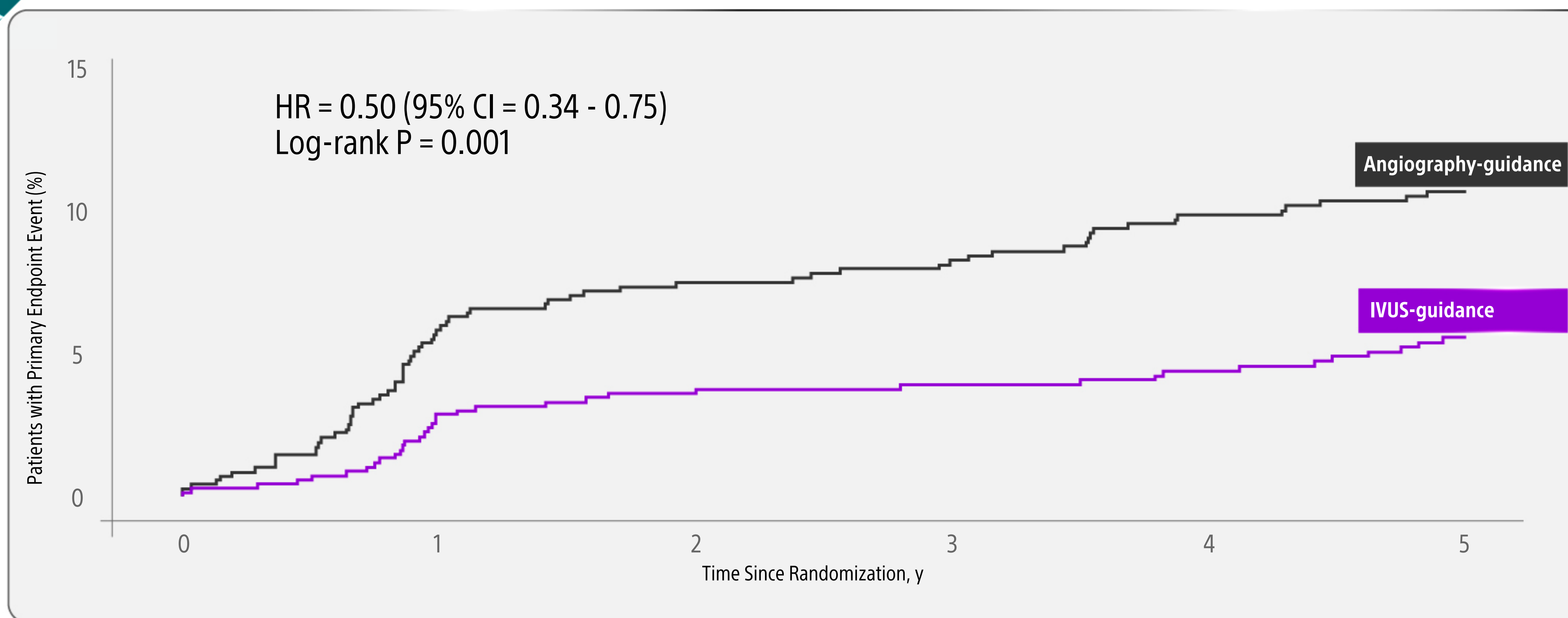


# Clinical Evidence



## Outcome

IVUS-XPL  
(5 YEAR FOLLOW-UP)



Number at risk	0	1	2	3	4	5
Angiography arm	700	624	603	586	562	543
IVUS arm	700	641	624	609	591	562

S. Hong, et al. JACC: Cardiovascular Interventions. "Effect of Intravascular Ultrasound-Guided Drug-Eluting Stent Implantation. 5-Year Follow-Up of the IVUS-XPL Randomized Trial." 2020. <https://doi.org/10.1016/j.jcin.2019.09.033>





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