A Clinical and Economic Compendium of Evidence on the Use of Intravascular Ultrasound for Percutaneous Coronary Intervention

Literature Review Report

Final

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Contents

List of Abbreviations

Abbreviation	Definition
ACC	American College of Cardiology
ACEP	American College of Emergency Physicians
ACS	Acute coronary syndrome
AHA	American Heart Association
AMI	Acute myocardial infarction
AUD	Australian dollars
BGN	Bulgarian lev
BIM	Budget impact model
BMS	Bare metal stent
CAD	Coronary artery disease
CCS	Chronic coronary syndrome
CEA	Cost-effectiveness analysis
CKD	Chronic kidney disease
CNY	Chinese yuan
DES	Drug-eluting stent
ESC	European Society of Cardiology
GBP	Great British pounds
HR	Hazard ratio
HTA	Health technology assessment
ICER	Incremental cost-effectiveness ratio
INAHTA	International Network of Agencies for Health Technology Assessment
ISPOR	Professional Society for Health Economics and Outcomes Research
IVI	Intravascular imaging
IVUS	Intravascular ultrasound
KRW	South Korean won
LMCA	Left main coronary artery
LY	Life-year
MACE	Major adverse cardiac events
MI	Myocardial infarction
MSAC	Medical Services Advisory Committee
NA	Not applicable
NAEMSP	National Association of EMS Physicians
NCT	National Clinical Trial
NHS	National Health Service
NR	Not reported
NRD	Nationwide Readmissions Database
NSTEMI	Non-ST-elevation myocardial infarction
OCT	Optical coherence tomography
OR	Odds ratio
PCI	Percutaneous coronary intervention
PICOS	Population, intervention, comparator, outcome, study design
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSS	Personal Social Services

PTCA	Percutaneous transluminal coronary angioplasty
QALY	Quality-adjusted life-year
SCAI	Society for Cardiovascular Angiography & Interventions
ST	Stent thrombosis
STEMI	ST-elevation myocardial infarction
TLR	Target lesion revascularization
TVF	Target vessel failure
TVR	Target vessel revascularization
UA	Unstable angina
UA/STEMI	Unstable angina/ST-elevation myocardial infarction
USD	US dollars
WTP	Willingness to pay

Introduction

This report summarizes the global evidence on the use of intravascular ultrasound (IVUS) as an adjunct to angiography in patients undergoing percutaneous coronary intervention (PCI). Evidence was identified through a targeted literature review with predefined inclusion and exclusion criteria to identify published clinical trials, real-world studies, and economic evaluations:

- The clinical review included comparative studies of IVUS plus angiography versus angiography alone, published between January 2016 and January 2025, with more than 300 patients in the IVUS arm. Searches were conducted in PubMed, MEDLINE, and Embase.
- The economic review included cost-effectiveness analyses (CEAs) and budget impact models (BIMs) published during the same period, identified from the above databases as well as the Tufts CEA Registry, International Network of Agencies for Health Technology Assessment (INAHTA), and ISPOR. Abstracts were included when no full-text publication was available.

No language restrictions were applied. Full methodological details are provided in Appendix 1: Targeted Literature Review Methods

The report summarizes key guideline recommendations and evidence from randomized trials, real-world studies, and economic evaluations. A full list of included studies, detailed methods, and comprehensive outcome data are available in the appendices.

Guidelines and Consensus Statements

Summary of Guidelines and Consensus Statements for the Management of Patients With ACS and CCS

Both the 2025 ACC/AHA/ACEP/NAEMSP/SCAI and 2024 ESC guidelines provide Class I recommendations for the use of intracoronary imaging—IVUS or optical coherence tomography (OCT)—particularly in complex PCI cases. While neither guideline expresses a preference between IVUS and OCT, they affirm the importance of image guidance in improving procedural outcomes.

- The 2025 ACC/AHA/ACEP/NAEMSP/SCAI Guidelines for ACS recommend the use of intracoronary imaging with IVUS or OCT to guide stent implantation in patients with left main or anatomically complex coronary lesions, with the goal of reducing ischemic events (Rao et al. 2025). This is a Class I, Level A recommendation, where the use of IVUS was based on 3 key clinical trials:
    - ULTIMATE: A prospective, multicenter, randomized, single-blind study in China of 1,448 patients with complex coronary artery disease (CAD). IVUS-guided PCI was associated with significantly lower rates of target vessel failure (TVF) and stent thrombosis (ST) at 3 years (Gao et al. 2021).
    - RENOVATE-COMPLEX-PCI: A randomized trial of 1,639 patients with complex CAD, including left main lesions. IVUS- or OCT-guided PCI resulted in lower rates of cardiac death, target vessel MI, or clinically driven target vessel revascularization (TVR) by 2 years compared to angiography-guided PCI (Lee et al. 2023).
    - IVUS-XPL: A randomized trial of 1,400 patients with long lesions showing that IVUS guidance reduced major adverse cardiovascular events (MACE) at 1 year compared to angiography guidance (Hong et al. 2022).
- The 2024 European Society of Cardiology (ESC) Guidelines for chronic cardiac syndrome (CCS) recommend intracoronary imaging with IVUS or OCT for anatomically complex lesions, in particular left main stem, true bifurcations, and long lesions. This is a Class I, Level A recommendation based predominantly on the RENOVATE-COMPLEX-PCI study by (Lee et al. 2023).

Outcomes in Clinical Studies

The clinical review identified 13 publications related to 4 key trials: IVUS-ACS, ULTIMATE, a pooled analysis of ULTIMATE and IVUS-XPL, and RENOVATE-COMPLEX-PCI. The primary trial publications and separately published subgroup analyses are summarized below.

IVUS-ACS

The IVUS-ACS trial (Intravascular Ultrasound–Guided Percutaneous Coronary Intervention in Acute Coronary Syndrome) was a multicenter, randomized study of patients with acute coronary syndrome (ACS) undergoing PCI with a second-generation drug-eluting stent (DES). The study was conducted in China, Italy, Pakistan, and the UK. Patients received either IVUS-guided PCI or angiography only guided PCI. The review identified the primary publication (Li et al. 2024) and a prespecified analysis of patients with diabetes (Gao et al. 2025). Full outcome data for the IVUS-ACS trial are provided in Table 18.

A total of 3,505 patients with ACS were randomized to either IVUS-guided PCI (n=1,753) or angiography-guided PCI (n=1,752).

Primary endpoint:

- The primary endpoint was TVF at 1 year, defined as a composite of cardiac death, target vessel myocardial infarction, or clinically driven TVR. TVF occurred in 70 patients in the IVUS group compared to 128 patients in the angiography group (hazard ratio [HR]: 0.55; 95% CI: 0.41-0.74; *P*=0.0001). IVUS-guided PCI therefore led to a significant reduction in TVF, driven by reductions in target vessel MI and TVR.

Secondary endpoints:

- Other outcomes, including non-procedural myocardial infarction (MI), target vessel MI, and target lesion revascularization (TLR), were also significantly reduced with IVUS guidance.

IVUS-ACS Subgroup: Patients with diabetes

A prespecified exploratory analysis randomized 1,105 patients with diabetes. Patients were randomized 1:1 to IVUS-guided PCI (n=554) and to angiography-guided PCI (n=551) (Gao et al. 2025).

Primary endpoint:

- At 1 year, TVF (defined as a composite of cardiac death, target vessel MI, or clinically driven TVR) occurred in 20 patients in the IVUS-guided group compared to 46 patients in the angiography group (Kaplan-Meier event rates: 3.6% compared to 8.3%; HR: 0.46; 95% CI: 0.27-0.81; *P*=0.007), indicating a significant reduction with IVUS guidance (Gao et al. 2025).

Secondary endpoints:

- TVF reductions were largely driven by lower rates of clinically driven TVR (0.9% vs 3.8%; *P*=0.003). IVUS guidance also significantly reduced TVF without

procedural MI (2.0% vs 6.7%; HR: 0.29; 95% CI: 0.15-0.57; *P* <0.001) and all-cause mortality (HR: 0.30; 95% CI: 0.10-0.93; *P*=0.037).

As the IVUS-ACS trial was not specifically powered to detect differences within the diabetic subgroup, these findings should be interpreted as hypothesis-generating.

ULTIMATE

ULTIMATE (Ultrasound Imaging to Guide Stent Implantation in Myocardial Infarction Treatment Evaluation) was a prospective, multicenter, randomized, single-blind study in China. It included 1,448 patients with complex CAD undergoing PCI with second-generation DES implantation. Patients were randomized 1:1 to IVUS-guided PCI (n=724) or angiography-guided PCI (n=724). Outcomes were reported at 30 days, 1 year, 2 years, and 3 years. The literature review identified the primary trial publications reporting year 1 and year 3 data ((Zhang et al. 2018) and (Gao et al. 2021), respectively) and a subgroup analysis of patients with and without chronic kidney disease (CKD) at 3 years (Gao et al. 2021). Full outcome data for the ULTIMATE trial are reported in Table 19.

Primary endpoint:

- At 30 days, TVF (defined as a composite of cardiac death, target vessel myocardial infarction (MI), or clinically driven TVR) was numerically lower, yet non-significant, in the IVUS-guided group (Zhang et al. 2018). Statistically significant reductions in TVF were observed at 1 year, 2 years, and 3 years, favoring IVUS guidance (Zhang et al. 2018, Gao et al. 2021).

Secondary endpoints:

- TLR followed a similar temporal pattern. Differences between groups were not statistically significant at early time points but reached significance at 3 years, with lower revascularization rates observed in the IVUS-guided arm.

- Target lesion failure (TLF) was significantly reduced in the IVUS group at 1, 2, and 3 years, again supporting a durable advantage for imaging guidance in reducing repeat revascularization events (Zhang et al. 2018, Gao et al. 2021).

- There were no significant differences at any time point in cardiac death, all-cause death, target vessel MI, or stroke in the all-comers population (Zhang et al. 2018, Gao et al. 2021, Gao et al. 2021).

ULTIMATE Subgroup: Patients with and without CKD

A prespecified subgroup analysis evaluated outcomes in patients with and without CKD. The ULTIMATE trial was not powered to detect differences in clinical outcomes within the CKD subgroup (Zhang et al. 2018, Gao et al. 2021, Gao et al. 2021). A total of

1,443 patients with coronary heart disease were enrolled in the study, including 349 (24.2%) patients in the CKD group and 1,094 patients in the non-CKD group. IVUS was used to guide stent implantation in 180 cases and angiography in 169 cases. The study focused on the primary endpoint of TVF.

Primary endpoint:

- In the CKD group, the incidence of TVF in patients who underwent IVUS-guided stent implantation was lower than that in angiography-guided stent implantation (8.3% [15/80] vs 16% [27/1690], *P*=0.03). There was no significant difference in the incidence of TVF between IVUS-guided stent implantation and angiography-guided stent implantation in the non-CKD group.

ULTIMATE provides important evidence that IVUS-guided PCI is associated with long-term reductions in repeat revascularization events in patients with complex CAD. These benefits become more evident over time.

IVUS-XPL

IVUS-XPL (Impact of Intravascular Ultrasound Guidance on the Outcomes of Xience Prime Stents in Long Lesions) was a randomized trial comparing IVUS-guided to angiography-guided DES implantation. Only the second-generation everolimus-eluting stent was used. This review identified a follow-up study reporting events occurring between years 1 and 5 (Hong et al. 2020).

A total of 1,400 patients with long coronary lesions were randomized to IVUS-guided (n=700) or angiography-guided (n=700) DES implantation. Five-year follow-up data were available in 1,183 patients (IVUS n=589 and angiography n=594). Full outcome data for the IVUS-XPL trial are reported in Table 20.

Primary endpoint:

- MACE at 5 years occurred in 36 patients (5.6%) receiving IVUS guidance and in 70 patients (10.7%) receiving angiography-guidance (HR: 0.50; 95% CI: 0.34 -0.75; *P*=0.007). The difference was primarily driven by lower rates of TLR.
- The landmark analysis showed that MACE events occurred in 17 (2.8%) patients who received IVUS guidance and 31 (5.2%) patients who received angiography guidance between 1 and 5 years (HR: 0.53; 95% CI: 0.29-0.95; *P*=0.031). These findings suggest a potential sustained benefit of IVUS beyond the first year.

Secondary endpoints:

- IVUS-guided PCI significantly reduced ischemia-driven TLR at ≤1 year (*P*=0.02) and at 5 years (*P*=0.007), but not between 1-5 years (*P*=0.15).
- Cardiac death and target lesion–related MI were lower in the IVUS group across time points, though differences were not statistically significant.

ULTIMATE and IVUS-XPL Pooled Analysis

The literature review identified 2 publications reporting pooled analyses of the ULTIMATE and IVUS-XPL trials. These included analyses of patients with long lesions (Hong et al. 2022) and patients undergoing post dilation following DES implantation (Lee et al. 2022). Full data from the ULTIMATE and IVUS-XPL pooled analyses are reported in Table 21.

ULTIMATE and IVUS-XPL Pooled Analysis: Patients with long lesions

This study aimed to combine individual participant data from the IVUS-XPL and ULTIMATE trials to enhance statistical power in assessing the long-term impact of IVUS guidance compared to angiography guidance on patient survival, specifically in those with long lesions. By focusing solely on patients with long lesions, the pooled analysis included a total of 2,577 individuals. 1,289 patients were randomized to IVUS guidance, and 1,288 patients were randomized to angiography guidance (Hong et al. 2022).

Primary endpoint:

- There was a statistically significant reduction in the primary endpoint of cardiac death for the IVUS-guided group versus the angiography-guided group (*P*=0.011).

Secondary endpoints:

- Target lesion related MI occurred less frequently in the IVUS-guided group (0.2%) compared to the angiography-guided group (0.7%), though this difference was not statistically significant (*P*=0.081).
- Stent thrombosis showed a similar pattern (0.2% vs 0.7%; *P*=0.082).
- Ischemia-driven TLR was significantly lower in the IVUS-guided group (3.8% vs 6.5%; *P*=0.002).

ULTIMATE and IVUS-XPL Pooled Analysis: Patients undergoing post dilation

Post dilation after DES implantation is commonly used to optimize stent expansion and reduce complications, but the clinical impact of angiography-guided versus IVUS-guided post dilation remains unclear. This study compared long-term outcomes of these 2 approaches, focusing on patients with long DES implantation, using pooled patient-level data from the IVUS-XPL and ULTIMATE trials. This post hoc analysis compared 1,037 patients with IVUS-guided post dilation to 905 patients with angiography-guided post dilation, and 383 patients with angiography-guided drug-eluting stent implantation with no post dilation (Lee et al. 2022).

Primary endpoint:

- The primary endpoint was composite of cardiac death, target lesion-related MI, or ischemia-driven TLR at 3 years, and was lower after IVUS guidance with post dilation versus angiography guidance without post dilation (*P* <0.001) and also after IVUS guidance with post dilation versus angiography guidance with post dilation (*P* <0.001).

These findings highlight the clinical benefits of IVUS guidance, particularly in high-risk groups such as patients with long lesions, and support its use in targeted patients.

RENOVATE-COMPLEX-PCI

RENOVATE-COMPLEX-PCI (Randomized Controlled Trial of Intravascular Imaging Guidance versus Angiography-Guidance on Clinical Outcomes after Complex Percutaneous Coronary Intervention) was a multicenter, prospective, randomized, open-label study of 1,639 patients with complex coronary lesions undergoing PCI in South Korea (Lee et al. 2023). The literature review identified the primary publication (Lee et al. 2023) and 4 prespecified subgroup analyses in patients with CKD (Kwon et al. 2023), ACS and CCS (Lee et al. 2024), diabetes (Choi et al. 2024), and by sex (Cha et al. 2024). Full data from the RENOVATE-COMPLEX-PCI trial are reported Table 22.

In the primary study, 1,092 patients were randomized to intravascular imaging (IVI)-guided PCI (IVUS- or OCT-guided PCI) and 547 patients were randomized to angiography-guided PCI. Median follow-up was 2.1 years (Lee et al. 2023).

Primary endpoint:

- TVF, defined as a composite of death from cardiac causes, target-vessel-related MI, or clinically driven TVR occurred in 7.7% (76 patients) with IVI-guidance compared to 12.3% (60 patients) with angiography guidance (HR 0.64; 95% CI: 0.45-0.89; *P*=0.008).

Secondary endpoints:

- Death from cardiac causes was lower in the intravascular imaging group (1.7%) compared to the angiography group (3.8%). Similarly, target vessel-related MI occurred less frequently in the intravascular imaging group (3.7% vs 5.6%), as did clinically driven target-vessel revascularization (3.4% vs 5.5%).

RENOVATE-COMPLEX-PCI Subgroups

Primary endpoint:

- Statistically significant reductions in TVF were observed in the CKD, non-CKD, CCS, non-diabetes, and female subgroups (Kwon et al. 2023, Lee et al. 2024).

Numerical reductions were seen in ACS, diabetes, and male populations, but these did not reach statistical significance.

Secondary endpoints:

- TLR was not significantly different overall, except in women, where IVI-guided PCI was associated with a significant reduction (Cha et al. 2024).
- Cardiac death was significantly lower in patients with ACS and patients without diabetes (Lee et al. 2024).
- There were no significant differences in all-cause death between groups.
- MI was significantly reduced in the CCS and the non-diabetic subgroup.

The RENOVATE-COMPLEX-PCI findings demonstrate that IVI-guided PCI provides meaningful clinical benefits over angiography-guided PCI, particularly in key subgroups such as patients with CKD, CCS, women, and non-diabetics. In these groups, IVI-guided PCI was associated with significant reductions in TVF, cardiac death, and MI. Further outcomes data for all-comers and subgroups are in Table 22.

Conclusion of Clinical Trial Outcomes

Across multiple large clinical trials, IVUS-guided PCI consistently demonstrated significant clinical benefits over angiography-only guided PCI in patients with complex CAD, particularly those with high-risk features. These benefits included reductions in TVF, MI, and TLR, and effects became more pronounced over longer-term follow-up.

Subgroup analyses highlighted meaningful advantages in populations with diabetes, CKD, ACS, and long lesions, and in women. Pooled analyses from the ULTIMATE and IVUS-XPL trials reinforced the durability of these effects across populations and settings.

Collectively, this evidence supports IVUS-guided PCI as a superior strategy in complex cases, with strong potential to improve outcomes and reduce repeat interventions. These results provide a solid foundation for value-based care decisions and cost-effectiveness modeling, particularly when targeting higher-risk subgroups.

Outcomes in Real-World Studies

Building on the findings from randomized clinical trials, real-world observational studies provide additional insight into the effectiveness of IVUS-guided PCI in routine clinical practice. These studies help assess whether the clinical benefits observed in trials translate into broader patient populations and real-world settings.

Thirteen observational studies comparing IVUS-guided PCI to angiography-only guided PCI were identified. Of these, 7 studies were retrospective, and 6 were prospective. Using a range of data sources, studies were conducted on patient data from the US, Europe, South Korea, Japan, and China. Sample sizes varied widely from 730 to over 2.4 million patients. PCI procedural types included DES in 5 studies, either bare metal stent (BMS) or DES in 2 studies, and was unspecified in 6. Follow-up duration ranged from 1 year to 11.9 years.

This section presents findings by clinical outcome including TLF, TLR, MACE, cardiac death, and MI in IVUS-guided cohorts compared to angiography-guided cohorts.

Target Lesion Failure

TLF, generally defined as a composite of cardiac death, target vessel MI and TLR, was reported in 3 real-world studies (Table 1). Across all studies, IVUS-guided PCI was associated with significant reductions in TLF compared with angiography-guided PCI, with HRs ranging from 0.37 to 0.59 (Cortese et al. 2022, Kim et al. 2022, Roh et al. 2023).

Table 1: Target lesion failure: Real-world observational studies

Study details	Time point	IVUS-guided n/N (%)	Angiography-guided n/N (%)	HR (95% CI)	*P* value
Prospective study in patients with acute MI at high ischemic risk undergoing PCI; KAMIR-NIH Registry, South Korea (Roh et al. 2023)	3 years	30/337 (8.9%)	218/1422 (15.3%)	0.55 (0.38-0.81)	0.002
Retrospective study in patients undergoing distal-left main coronary stenting; ROCK II study, Europe (Cortese et al. 2022)	1 year	6/100 (6.0%)	16/10 (16.0%)	0.37 (0.15-0.91)	0.03
Prospective study in patients undergoing PCI; KAMIR-NIH Registry, South Korea (Kim et al. 2022)	1099 days (median)	90/1887 (4.8%)	571/7120 (8.0%)	0.59 (0.47-0.73)	<0.001

Note: Target lesion failure definitions were consistent across studies and was defined as a composite of cardiac death, target vessel MI, and target lesion revascularization across studies. In the KAMIR-NIH studies, target lesion revascularization was ischemia driven (Kim et al. 2022, Roh et al. 2023).
Abbreviations: HR, hazard ratio; IVUS, intravascular ultrasound; MI, myocardial infarction; OCT, optical coherence tomography; PCI, percutaneous coronary intervention
Source: See table

Target Lesion Revascularization

Seven real-world studies reported on TLR, although definitions differed, making direct comparisons challenging (Table 2). Two studies reported statistically significant reductions in TLR with IVUS-guidance compared with the angiography-guided PCI, with HRs ranging from 0.51 to 0.79 (Maehara et al. 2018, Hong et al. 2020).

Four additional studies showed numerically lower rates of TLR, though in these the differences were not significantly significant (Chen et al. 2018, Cortese et al. 2022, Kim et al. 2022, Roh et al. 2023). One study reported no difference between the 2 groups (Joh et al. 2024).

Table 2: Target lesion revascularization: Real-world observational studies

Study details	Timepoint	IVUS-guided* n/N (%)	Angiography-guided n/N (%)	HR (95% CI)	*P* value
Prospective study in patients with acute MI and cardiogenic shock; Nationwide pooled registry of KAMIR-NIH and KAMIR-V, South Korea (Joh et al. 2024)	1 year (unmatched)	5/375 (1.7%)†	12/1458 (1.2%)	1.14 (0.38-3.39)	0.816
	1 year (matched)	4/330 (1.4%)†	6/621 (1.4%)	1.08 (0.1-7.99)	0.938
Prospective study in acute MI patients at high ischemic risk undergoing PCI; KAMIR-NIH Registry, South Korea (Roh et al. 2023)	3 years	7/337 (2.1%)	55/1422 3.9%)	0.51 (0.23-1.12)	0.09
Retrospective study in patients undergoing distal-left main coronary stenting; ROCK II study, Europe (Cortese et al. 2022)	NR	4/100 (4.0%)	9/100 (9.0%)	0.44 (0.14-1.39)	NR
Prospective study in patients undergoing PCI; KAMIR-NIH Registry, South Korea (Kim et al. 2022)	1099 days (median)	31/1887 (1.6%)	159/7120 2.2%)	0.72 (0.49-1.07)	0.101
Prospective study in patients with unstable angina and Medina 1,1,1 or 0,1,1 coronary bifurcation lesions undergoing PCI; DEFINITION Registry, China (Chen et al. 2018)	At 1 year	19/310 (6.1%)	46/620 (7.4%)	1.124 (0.711-2.071)‡	0.499
	End of follow-up	28/310 (9.0%)	62/620 (10.0%)	1.152 (0.737-1.800)‡	0.724
Prospective study in patients undergoing PCI with DES; ADAPT-DES, USA, Germany (Maehara et al. 2018)	2 years	161/3361 (5.0%)	314/5221 (6.5%)	0.79 (0.65-0.95)	0.01

Note: Definitions of TLR varied across studies. TLR was classified as clinically driven in (Maehara et al. 2018, Cortese et al. 2022) and ischemia driven in (Hong et al. 2020, Kim et al. 2022, Roh et al. 2023). Definitions were not reported in (Chen et al. 2018, Joh et al. 2024).

†IVI-guided PCI.

‡Direction of HR assumed to be reversed to be aligned with angiography as the intervention.

Abbreviations: DES, drug-eluting stent; HR, hazard ratio; IVI, intravascular imaging; IVUS, intravascular ultrasound; NR, not reported; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; TLR, target lesion revascularization

Major Adverse Cardiac Events

Eight studies reported on MACE, using varying definitions (Table 3). All studies reported HRs less than 1, indicating lower MACE rates with IVUS guidance compared to patients undergoing angiography guidance. Six of the 8 studies showed statistically significant reductions, with HRs ranging from 0.57 to 0.76 (Chen et al. 2018, Maehara et al. 2018, Hong et al. 2020, Kang et al. 2021, Kim et al. 2022, Roh et al. 2023, Joh et al. 2024). The 2 remaining studies showed no significant difference (Nakatsuma et al. 2016, Okura et al. 2019) , though both reported numerically lower MACE rates with IVUS guidance.

Table 3: MACE: Real-world observational studies

Study details	Timepoint	IVUS-guided* n/N (%)	Angiography-guided n/N (%)	HR (95% CI)	*P* value
Prospective study of patients with acute MI and cardiogenic shock; Nationwide pooled registry of KAMIR-NIH and KAMIR-V, South Korea (Joh et al. 2024)	1 year (unmatched)	68/375 (19.5%)†	399/1458 (28.2%)	0.59 (0.45-0.77)	<0.001
	1 year (matched)	61/330 (18.6%)†	161/621 (26.4%)	0.68 (0.46-0.99)	0.042
Prospective study of acute MI patients at high ischemic risk undergoing PCI; KAMIR-NIH Registry, South Korea (Roh et al. 2023)	3 years	68/337 (20.2%)	426/1422 (30.0%)	0.63 (0.49-0.82)	<0.001
Prospective study of patients undergoing PCI; KAMIR-NIH Registry, South Korea (Kim et al. 2022)	1099 days (median)	245/1887 (13.0%)	1200/7120 (16.9%)	0.76 (0.66-0.87)	<0.001
Retrospective study of patients undergoing unprotected left main coronary artery PCI; MAIN-COMPARE Registry, South Korea (Kang et al. 2021)	10 years	146/756 (19.2%)	72/219 (32.9%)	0.57 (0.44-0.73)	<0.001
Prospective study in acute MI patients undergoing PCI; J-MINUET study, Japan (Okura et al. 2019)	NR	354/1947 (18.2%)	133/689 (19.3%)	NR	0.096‡
Prospective study of patients with unstable angina and Medina 1,1,1 or 0,1,1 coronary bifurcation lesions undergoing PCI; DEFINITION Registry, China (Chen et al. 2018)	At 1 year	31/310 (10.0%)	93/620 (15.0%)	1.546 (1.029-2.321)§	0.04
	End of follow-up	47/310 (15.2%)	139/620 (22.4%)	1.546 (1.110-2.151) §	0.009
Prospective study in patients receiving DES; ADAPT-DES study, USA, Germany (Maehara et al. 2018)	0-30 days	54/3361 (1.6%)	108/5221 (2.1%)	0.78 (0.56-1.07)	0.12
	31 days-1 year	57/3361 (1.7%)	141/5221 (2.8%)	0.62 (0.46-0.84)	0.002
	1-2 years	58/3361 (1.9%)	140/5221 (3.0%)	0.64 (0.47-0.86)	0.003
	2 years	158/3361 (4.9%)	373/221 (7.5%)	0.65 (0.54-0.78)	<0.0001
Retrospective study in chronic coronary syndrome; CREDO-Kyoto AMI Registry, Japan (Nakatsuma et al. 2016)	5.1 years (median)	313/932 (34%)	813/2096 (40.0%)	1.12 (0.89-1.40)	0.33

Note: Definitions for MACE included the following across studies: Cardiac death, definite/probable ST, or any MI (Maehara et al. 2018); Cardiac death, definite/probable ST, any MI, or any revascularization by percutaneous or surgical methods (Joh et al. 2024); Any death, any MI, or any revascularization (Kim et al. 2022); Any death, Q-wave MI, or stroke (Kang et al. 2021); All death, cardiac

failure, ventricular tachycardia and/or ventricular fibrillation, or bleeding during hospitalization (Okura et al. 2019); All-cause death, any MI, or TVR (Nakatsuma et al. 2016); Cardiac death, any MI or target vessel revascularization (Chen et al. 2018); Not reported (Hong et al. 2020, Roh et al. 2023).
*Unless otherwise noted.
†IVI-guided PCI.
‡Comparison versus OCT-guided PCI and angiography-guided PCI.
§HR assumed to be reversed in direction, i.e. angiography versus IVUS.
Abbreviations: AMI, acute myocardial infarction; DES, drug-eluting stent; HR, hazard ratio; IVI, intravascular imaging; IVUS, intravascular ultrasound; MACE, major adverse cardiac events; NA, not applicable; NR, not reported; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; ST, stent thrombosis; TVR, target vessel revascularization
Source: See table

Cardiac Death

Cardiac death was reported in 6 studies; however, definitions varied (Table 4). In all studies, IVUS-guided PCI was associated with a lower numerical rate of cardiac death compared to angiography-guided PCI. Five studies demonstrated significant differences, with HRs ranging from 0.56 to 0.70 (Chen et al. 2018, Maehara et al. 2018, Kim et al. 2022, Roh et al. 2023, Joh et al. 2024).

Table 4: Cardiac death: Real-world observational studies

Study details	Timepoint	IVUS-guided* n/N (%)	Angiography-guided n/N (%)	HR (95% CI)	*P* value
Prospective study in patients with acute MI and cardiogenic shock; Nationwide pooled registry of KAMIR-NIH and KAMIR-V, South Korea (Joh et al. 2024)	1 year	48/330 (14.6%)†	130/621 (21.1%)	0.56 (0.35-0.89)	0.014
Prospective study in acute MI patients at high ischemic risk undergoing PCI; KAMIR-NIH Registry, South Korea (Roh et al. 2023)	3 years	23/337 (6.8%)	160/1422 (11.3%)	0.59 (0.38-0.91)	0.02
Retrospective study in patients undergoing distal-left main coronary stenting; ROCK II study, Europe (Cortese et al. 2022)	NR	2/100 (2.0%)	4/100 (4%)	NR	NR
Prospective study in patients undergoing PCI; KAMIR-NIH Registry, South Korea (Kim et al. 2022)	1099 days (median)	58/1887 (3.1%)	389/7120 (5.5%)	0.56 (0.42-0.73)	<0.001
Prospective study in patients receiving DES; ADAPT-DES study, USA, Germany (Maehara et al. 2018)	2 years	54/3361 (1.7%)	119/5221 (2.4%)	0.70 (0.51-0.96)	0.03
Prospective study in patients with unstable angina and Medina 1,1,1 or 0,1,1 coronary bifurcation lesions undergoing PCI; DEFINITION Registry, China (Chen et al. 2018)	1 year	2/310 (0.6%)	7/620 (1.1%)	0.238 (0.023-2.753)	0.726
	End of follow-up	4/310 (1.3%)	40/620 (6.5%)	5.132 (1.836-14.343)‡	0.001

Note: Definitions for cardiac death varied across studies: Death was considered cardiac death unless the exact non-cardiac cause of death could be identified (Chen et al. 2018, Hong et al. 2020, Roh et al. 2023); Cardiac death was defined as mortality from cardiac etiologies and any sudden death of unknown cause (Cortese et al. 2022); Not reported (Maehara et al. 2018, Kim et al. 2022, Joh et al. 2024).
*Unless otherwise noted.
†IVI-guided PCI.
‡HR assumed to be reversed in direction, i.e. angiography versus IVUS.

Abbreviations: DES, drug-eluting stent; HR, hazard ratio; IVUS, intravascular ultrasound; MI, myocardial infarction; NR, not reported; OCT, optical coherence tomography; PCI, percutaneous coronary intervention
Source: See table

All-Cause Death

Eleven real-world observational studies reported on all-cause mortality (Table 5). Definitions varied across studies, with some specifying in-hospital or medium-term death and others not providing a definition. In general, lower rates of all-cause death were observed in IVUS- or IVI-guided PCI cohorts compared to the angiography- or non-IVUS-guided cohorts.

Seven studies reported statistically significant reductions in all-cause death with IVUS-guidance, with HRs ranging from 0.52 to 0.78 (Maehara et al. 2018, Okura et al. 2019, Lemor et al. 2020, Kang et al. 2021, Kim et al. 2022, Roh et al. 2023, Joh et al. 2024). In the remaining 4 studies, rates of all-cause death were numerically lower but did not reach statistical significance (Nakatsuma et al. 2016, Hannan et al. 2022) or were not statistically evaluated (Ya'qoub et al. 2021, Cortese et al. 2022).

Table 5: All-cause death: Real-world observational studies

Study details	Timepoint	IVUS-guided* n/N (%)	Angiography-guided n/N (%)	HR (95% CI)	*P* value
Prospective study in patients with acute MI and cardiogenic shock; Nationwide pooled registry of KAMIR-NIH and KAMIR-V, South Korea (Joh et al. 2024)	1 year (unmatched)	57/375 (15.3%)†	396/1458 (27.5%)	0.52 (0.39-0.70)	<0.001
	1 year (matched)	54/330 (16.4%)†	148/621 (23.9%)	0.55 (0.35-0.84)	0.006
Prospective study in acute MI patients at high ischemic risk undergoing PCI; KAMIR-NIH Registry, South Korea; (Roh et al. 2023)	3 years	37/337 (11.0%)	259/1422 (18.2%)	0.58 (0.41-0.82)	0.002
Retrospective study in patients undergoing distal-left main coronary stenting; ROCK II study, Europe (Cortese et al. 2022)	NR	3/100 (3.0%)	6/100 (6.0%)	NR	NR
Retrospective study in patients with complex lesions undergoing PCI; New York's PCI Registry, USA; (Hannan et al. 2022)	3.7 years (median)	6170/6174 (7.39%)	6170/38,131 (8.57%)‡	0.88 (0.78-0.99)	0.496
Prospective study in patients undergoing PCI; KAMIR-NIH Registry, South Korea (Kim et al. 2022)	1099 days (median)	98/1887 (5.2%)	612/7120 (8.6%)	0.6 (0.48-0.74)	<0.001
Retrospective study in patients undergoing unprotected left main coronary artery PCI; MAIN-COMPARE Registry, South Korea (Kang et al. 2021)	10 years	125/219 (16.4%)	67/756 (31.0%)	0.54 (0.41-0.70)	<0.001
Retrospective study in hospitalized patients undergoing STEMI; Nationwide Readmissions Database, USA (Ya'qoub et al. 2021)	1 month	NR/33,616 (0.4%)	NR/33,616 (0.5%)‡	NR	NR
	3 months	NR/33,616 (0.7%)	NR/3,616 (0.7%)‡	NR	NR
	6 months	NR/33,616 (1.0%)	NR/33,616 (0.9%)‡	NR	NR
	11 months	NR/33,616	NR/33,616	NR	NR

		(0.7%)	(1.4%)‡		
	NR (matched cohort)	NR/33,616 (3.9%)	NR/33,616 (4.6%)‡	NR	NR
Retrospective study in patients undergoing PCI in the inpatient setting; Nationwide Inpatient Sample Database, USA (Lemor et al. 2020)	NR	NR/83,998 (1%)†	NR/3998 (1.5%)	OR: 0.67 (0.54-0.83)	<0.001
Prospective study in acute MI patients undergoing PCI; J-MINUET study, Japan (Okura et al. 2019)	NR	100/1947 (5.1%)	72/689 (10.4%)	NR	<0.0001
Prospective study in patients receiving DES; ADAPT-DES study, USA, Germany (Maehara et al. 2018)	2 years	106/361 (3.3%)	210/5221 (4.2%)	0.78 (0.62-0.98)	0.03
Retrospective study in chronic coronary syndrome; CREDO-Kyoto AMI Registry, Japan (Nakatsuma et al. 2016)	5.1 years (median)	112/932 (13.0%)	311/2096 (16.0%)	0.82 (0.57-1.19)	0.31

Note: Three studies defined all-cause death as in-hospital mortality: (Okura et al. 2019, Lemor et al. 2020, Ya'qoub et al. 2021); One study defined all-cause death as medium-term mortality: (Hannan et al. 2022); In 1 study, all-cause death was regarded as cardiac death unless a definite non-cardiac cause could be identified: (Kim et al. 2022); Six studies did not report definitions: (Nakatsuma et al. 2016, Maehara et al. 2018, Kang et al. 2021, Cortese et al. 2022, Roh et al. 2023, Joh et al. 2024).
*Unless otherwise noted.
†IVI-guided PCI.
‡Non-IVUS-guided PCI.
Abbreviations: DES, drug-eluting stent; HR, hazard ratio; IVUS, intravascular ultrasound; MI, myocardial infarction; NA, not applicable; NR, not reported; OCT, optical coherence tomography; OR, odds ratio; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction
Source: See table

Myocardial Infarction

Nine studies reported MI, yet definition varied from including any MI, Q-wave MI, and target vessel MI. Results were mixed (Table 6).

Two studies reported significantly lower rates of MI in IVUS-guided PCI cohorts compared to angiography-guided PCI, with HRs ranging from 0.62 to 3.802 (Chen et al. 2018, Maehara et al. 2018). Six studies reported numerically lower rates of any MI with IVUS-guided PCI compared with angiography-guided PCI (Nakatsuma et al. 2016, Ya'qoub et al. 2021, Cortese et al. 2022, Kim et al. 2022, Roh et al. 2023), However, these differences were either non-significant or the significance was not reported (Joh et al. 2024).

Table 6: MI: Real-world observational studies

Study details	Type of MI	Time point	IVUS-guided* n/N (%)	Angiography-guided n/N (%)	HR (95% CI)	*P* value
Prospective study in patients receiving DES; ADAPT-DES, USA, Germany (Maehara et al. 2018)	Any MI	2 years	112/3361 (3.5%)	279/5221 (5.6%)	0.62 (0.49-0.77)	<0.0001
	Periprocedural MI	2 years	44/3361 (1.3	84/5221 (1.6%)	0.81 (0.56-1.17)	0.26
	ST-related MI	2 years	17/3361 (0.5%)	46/5221 (0.9%)	0.57 (0.33-1.00)	0.05
	Spontaneous MI	2 years	52/3361 (1.7%)	151/5221 (3.1%)	0.53 (0.38-0.72)	<0.0001

	Target vessel-related MI	2 years	72/3361 (2.2%)	205/5221 (4.1%)	0.54 (0.41-0.71)	<0.0001
	Non–target vessel-related MI	2 years	37/3361 (1.2%)	75/5221 (1.6%)	0.76 (0.51-1.12)	0.17
Retrospective study in hospitalized patients undergoing STEMI; Nationwide Readmissions Database, USA (Ya'qoub et al. 2021)	Any MI	1 month	NR/33,616 (6.4%)	NR/33,616 (6.3%)‡	NR	NR
		3 months	NR/33,616 (7.9%)	NR/33,616 (8.0%)‡	NR	NR
		6 months	NR/33,616 (5.7%)	NR/33,616 (6.0%)‡	NR	NR
		11 months	NR/33,616 (5.1%)	NR/33,616 (6.5%)‡	NR	NR
Prospective study in patients with acute MI and cardiogenic shock; Nationwide pooled registry of KAMIR-NIH and KAMIR-V, South Korea (Joh et al. 2024)	Any MI (unmatched)	1 year	4/375 (1.2%)†	11/1458 (1.0%)	1.1 (0.29-4.15)	0.89
	Any MI (matched)	1 year	4/330 (1.3%)†	4/621 (0.8%)	0.51 (0.03-7.71)	0.625
Prospective study in patients undergoing PCI; KAMIR-NIH Registry, South Korea (Kim et al. 2022)	Any MI	1099 days (median)	45/1887 (2.4%)	210/7120 (2.9%)	0.79 (0.57-1.09)	0.158
Retrospective study in patients undergoing unprotected left main coronary artery PCI; MAIN-COMPARE Registry, South Korea (Kang et al. 2021)	Q-wave MI	10 years	18/756 (2.4%)	6/219 (2.7%)	0.74 (0.29-1.87)	0.53
Prospective study in acute MI patients at high ischemic risk undergoing PCI; KAMIR-NIH Registry, South Korea (Roh et al. 2023)	Any MI	3 years	10/337 (3.0%)	73/1422 (5.1%)	0.54 (0.28-1.05)	0.07
	Target vessel MI	3 years	3/337 (0.9%)	32/1422 (2.3%)	0.38 (0.12-1.24)	0.11
Retrospective study in chronic coronary syndrome; CREDO-Kyoto AMI Registry, Japan (Nakatsuma et al. 2016)	NR	5.1 years (median)	45/932 (5.2%)	123/2096 (6.6%)	0.81 (0.45-1.48)	0.5
Retrospective study in patients undergoing distal-left main coronary stenting; ROCK II study, Europe (Cortese et al. 2022)	NR	NR	1/100 (1.0%)	4/100 (4.0%)	NR	NR
Prospective study in patients with unstable angina and Medina 1,1,1 or 0,1,1 coronary bifurcation lesions undergoing PCI; DEFINITION Registry, China (Chen et al. 2018)	Any MI	At 1 year	4/310 (1.3%)	9/620 (1.5%)	1.126 (0.347-3.656)§	0.843
		End of follow-up	7/310 (2.3%)	52/620 (8.4%)	3.802 (1.727-8.369)§	<0.001

*Unless otherwise noted.
†IVI-guided PCI.
‡Non-IVUS-guided PCI.
§HR assumed to be reversed in direction, i.e. angiography versus IVUS.

Abbreviations: DES, drug-eluting stent; HR, hazard ratio; IVUS, intravascular ultrasound; MI, myocardial infarction; NA, not applicable; NR, not reported; OCT, optical coherence tomography; OR, odds ratio; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction
Source: See table

Stroke

Three studies reported stroke results (Table 7). Findings were mixed, and no statistically significant differences were observed. HRs ranged from 0.72 (95% CI: 0.16-3.35) to 1.95 (95% CI: 0.29-12.93), with wide confidence intervals, reflecting limited event numbers and high uncertainty (Maehara et al. 2018, Kang et al. 2021, Joh et al. 2024).

Table 7: Stroke: Real-world observational studies

Study details	Timepoint	IVUS-guided* n/N (%)	Angiography-guided n/N (%)	HR (95% CI)	*P* value
Prospective study in patients receiving DES; ADAPT-DES study, USA, Germany (Maehara et al. 2018)	2 years	32/3361 (1.0%)	50/5221 (1.0%)	0.99 (0.63-1.54)	0.96
Prospective study in patients with acute MI and cardiogenic shock; Nationwide pooled registry of KAMIR-NIH and KAMIR-V, South Korea (Joh et al. 2024)	1 year (unmatched)	3/375 (1%)†	12/1458 (1.2%)	0.72 (0.16-3.35)	0.677
	1 year (matched)	3/330 (1.1%)†	3/621 (0.6%)	1.95 (0.29-12.93)	0.491
Retrospective study in patients undergoing unprotected left main coronary artery PCI; MAIN-COMPARE Registry, South Korea (Kang et al. 2021)	10 years	21/56 (2.8%)	7/219 (3.2%)	0.74 (0.31-1.74)	0.49

Note: Stroke was defined by Kang et al. 2021 as detected by neurological deficits, was confirmed by a neurologist, and on imaging modalities (Kang et al. 2021). It was not defined in Maehara et al. 2018 (Maehara et al. 2018) or Joh et al. 2024 (Joh et al. 2024).
*Unless otherwise noted.
†IVI-guided PCI.
Abbreviations: DES, drug-eluting stent; HR, hazard ratio; IVUS, intravascular ultrasound; MI, myocardial infarction; PCI, percutaneous coronary intervention

Conclusion

Real-world evidence from multiple international studies demonstrates that IVUS-guided PCI is consistently associated with improved clinical outcomes compared to angiography-alone guided PCI. Significant reductions were observed in TLF, TLR, MACE, cardiac death, and all-cause mortality across a range of populations and follow-up durations.

While results for MI and stroke were more variable and did not consistently reach statistical significance, the overall trend supports a clinical benefit with IVUS guidance. Collectively, these findings reinforce the role of IVUS as an important adjunct to angiography, with the potential to enhance procedural outcomes and reduce long-term cardiovascular risk in real-world practice.

Outcomes in Economic Studies

Economic analyses were identified in the targeted review, including CEA and BIMs.

Cost-Effectiveness Analyses

Ten cost-effectiveness evaluations (across 13 publications, abstracts, and reports) compared IVUS-guided (or IVI-guided) PCI with angiography-guided PCI in patients with complex CAD undergoing PCI. One model included both IVUS and OCT under the IVI-guided PCI category. Model analyses were conducted across several countries including South Korea, Bulgaria, the UK, Italy, Germany, Australia, and China. Analyses were performed in all-comers populations and specific subgroups. Time horizons varied. Markov models were the most commonly used approach. Model inputs and assumptions varied widely across analyses.

Across all models, IVUS-guided PCI was found to be cost-effective at commonly accepted willingness-to-pay (WTP) thresholds. Incremental cost-effectiveness ratios (ICERs), expressed as cost per quality-adjusted life-year (QALY) gained, ranged from dominant (more effective and less costly) to USD 140,622 (2023 adjusted). These favorable results were primarily driven by reduced risks of MI, revascularization, and mortality with IVUS or IVI compared to angiography.

The individual evaluations are summarized in the following pages.

Sharp et al. 2024 (United Kingdom)

A UK-based cost-effectiveness analysis evaluated IVUS-guided versus angiography-guided PCI from the National Health Service (NHS) and Personal Social Services (PSS) perspective over a lifetime horizon (42 years) (Sharp et al. 2024). The model included 2 distinct cohorts: patients with ST-elevation myocardial infarction (STEMI) and those with unstable angina (UA) or non-ST-elevation myocardial infarction (NSTEMI).

Baseline event risks were derived from real-world UK populations treated with angiography-guided PCI. Repeat PCI rates were informed by the EXAMINATION trial, while the relative effect of IVUS was based on outcomes from the ULTIMATE trial. Intervention effects were assumed to apply during the first year only.

IVUS was found to be cost-effective in both patient groups, with ICERs well below the commonly accepted UK WTP threshold of Great British pound (GBP) 20,000 per QALY. The ICER was GBP 3,649 (US dollars [USD] 6,284) per QALY gained in STEMI patients and GBP 5,706 (USD 9,826) per QALY gained in UA/NSTEMI patients (Table 8) (Sharp et al. 2024).

Table 8: ICER for IVUS-guided PCI versus angiography-guided PCI in subgroups of patients with ACS

Analysis	ICER (GBP)	ICER (USD, 2023)
STEMI	GBP 3,649/QALY gained	USD 6,284/QALY gained
UA/NSTEMI	GBP 5,706/QALY gained	USD 9,826/QALY gained

Note: The original currency units were reported in 2019-2020 GBP. Costs were converted to 2023 USD after adjusting for purchasing power parity and inflation.
Abbreviations: ICER, incremental cost-effectiveness ratio; GBP, Great British pounds; NSTEMI, non-ST-elevation myocardial infarction; QALY, quality-adjusted life-year; STEMI, ST-elevation myocardial infarction; UA, uncontrolled angina; USD, United States dollars
Source: (Sharp et al. 2024)

Hong et al. 2024 and Lee Joo et al. 2023 (South Korea)

The review identified 2 publications reporting the same cost-effectiveness evaluation, an abstract (Lee Joo et al. 2023) (Lee Joo et al. 2023) and paper (Hong et al. 2024) (Hong et al. 2024). This analysis assessed IVI-guided versus angiography-guided PCI in patients with complex coronary artery lesions, from the South Korean healthcare sector perspective. Analyses were conducted using both a 3-year within-trial horizon and a lifetime simulation (Lee Joo et al. 2023, Hong et al. 2024).

Transition probabilities were derived from the intention-to-treat population of the RENOVATE-COMPLEX-PCI trial and supplemented with data from a meta-analysis of 20 randomized controlled trials, including RENOVATE-COMPLEX-PCI. In the base case, treatment effects were held constant over time.

In the 3-year analysis, IVI-guided PCI resulted in an ICER of USD 57,040 per QALY gained, which was above the author-stated WTP threshold of USD 35,000 per QALY gained (Table 9). in both lifetime simulation scenarios (using trial-based and meta-analytic transition probabilities), IVI was dominant—producing better outcomes at lower overall costs (Lee Joo et al. 2023, Hong et al. 2024).

Table 9: ICER for IVI-guided PCI versus angiography-guided PCI in patients with complex coronary artery lesions

Analysis	ICER
Within trial (3 years)	USD 57,040/QALY gained
Lifetime simulation (transition probability from trial)	Dominant
Lifetime simulation (transition probability from meta-analysis)	Dominant

Note: The original currency units were reported in USD without stating a currency year.
Abbreviations: ICER, incremental cost-effectiveness ratio; IVI, intravascular imaging; PCI, percutaneous coronary artery intervention; QALY, quality-adjusted life-year; USD, United States dollars
Source: (Lee Joo et al. 2023, Hong et al. 2024)

Dacheva et al. 2023 (Bulgaria)

A cost-effectiveness model from the Bulgarian National Health Insurance Fundpayer perspective evaluated IVUS-guided versus angiography-guided PCI in patients with

CAD, for both STEMI and UA/NSTEMI populations, over a lifetime horizon (Dacheva et al. 2023).

Clinical sources and IVUS assumptions were not reported. The ICER for IVUS versus angiography guidance was considered cost-effective at a WTP threshold of Bulgarian lev (BGN) 60,636/QALY. The ICERs were for BGN 8,757.12/QALY gained for STEMI patients and BGN 16,238.27/QALY gained UA/STEMI (Table 10) (Dacheva et al. 2023).

Table 10: ICER for IVUS-guided PCI versus angiography-guided PCI in subgroups of patients with CAD

	ICER (BGN)	ICER (USD, 2023)
STEMI patients	BGN 8,757.12/QALY gained	USD 21,893/QALY gained
UA/NSTEMI patients	BGN 16,238.27/QALY gained	USD 40,596/QALY gained

Note: The original currency units were reported in BGN without stating a currency year; the original currency year was assumed to be 2023 to estimate the values in 2023 USD. Costs were converted to 2023 USD after adjusting for purchasing power parity.
Abbreviations: BGN, Bulgarian lev; CAD, coronary artery disease; ICER, incremental cost-effectiveness ratio; IVUS, intravascular ultrasound; NSTEMI, non-ST-elevation myocardial infarction; PCI, percutaneous coronary artery intervention; QALY, quality-adjusted life-year; STEMI, ST-elevation myocardial infarction; UA, uncontrolled angina; USD, United States dollars
Source: (Dacheva et al. 2023)

Lao et al 2022a and Lao et al. 2022b (China)

A lifetime cost-effectiveness analysis from the Chinese healthcare payer perspective evaluated IVUS-guided versus angiography-guided PCI in patients with CAD (Lao et al. 2022, Lao et al. 2022). Clinical inputs were derived from a meta-analysis of results from the ULTIMATE trial and Ahn et al. (Ahn et al. 2014).

When IVUS benefits were assumed to persist over a patient's lifetime, IVUS was dominant, producing better outcomes at lower cost (Table 11). In a scenario where IVUS benefits were limited to the first year after PCI, the ICER was CNY 133,001 per QALY gained (USD 140,622). This remained below the threshold of 2 times China's 2019 per capita GDP of CNY 70,892 (Lao et al. 2022, Lao et al. 2022).

Table 11: ICER for IVUS-guided PCI versus angiography-guided PCI in patients with CAD

	ICER (CNY)	ICER (USD, 2023)
Benefits of IVUS last for life	CNY −176,678/QALY gained	USD 51,889/QALY gained
Benefits of IVUS limited to first year after PCI	CNY 133,001/QALY gained	USD 140,622/QALY gained

Note: Costs were converted from 2019 CNY to 2023 USD after adjusting for purchasing power parity and inflation.
Abbreviations: CAD, coronary artery disease; CNY, Chinese yuan, ICER, incremental cost-effectiveness ratio; IVUS, intravascular ultrasound; PCI, percutaneous coronary artery intervention; QALY, quality-adjusted life-year; USD, United States dollars
Source: (Lao et al. 2022, Lao et al. 2022)

Zhou et al. 2020 and Zhou et al. 2021 (Australia)

A cost-effectiveness analysis from the Australian healthcare system perspective evaluated IVUS-guided versus angiography-guided PCI in all-comers undergoing DES

implantation. The model used 2-year, 5-year, and lifetime horizons (Zhou et al. 2020, Zhou et al. 2021).

Event rates for the angiography-only arm were drawn from Australian PCI registry data where available, supplemented by pooled trial data when necessary. A meta-analysis of 10 randomized controlled trials comparing IVUS- and angiography-guided DES implantation was used to estimate the relative risk reductions associated with IVUS. The benefit of IVUS was assumed to extend over the first 2 years post-procedure.

ICERs decreased substantially with longer time horizons. At 2 years, IVUS was associated with an ICER of Australian dollars (AUD) 148,864 per QALY gained, while at 5 years the ICER declined to AUD 64,371. Over a lifetime horizon, IVUS was considered cost-effective at AUD 17,539 per QALY gained, below Australia's commonly cited WTP threshold of AUD 50,000 per QALY (Table 12).

Table 12: ICER for IVUS-guided PCI versus angiography-guided PCI in all-comers undergoing DES implantation

Analysis	ICER (AUD)	ICER (USD, 2023)
2 years after index procedure	AUD 148,864/QALY gained	USD 123,695/QALY gained
5 years after index procedure	AUD 64,371/QALY gained	USD 53,488/QALY gained
Lifetime horizon	AUD 17,539/QALY gained	USD 14,574/QALY gained

Note: Original costs were reported in 2019 AUD and were converted to 2023 USD after adjusting for purchasing power parity and inflation.
Abbreviations: AUD, Australian dollars; DES, drug-eluting stent; ICER, incremental cost-effectiveness ratio; IVUS, intravascular ultrasound; PCI, percutaneous coronary artery intervention; QALY, quality-adjusted life-year; USD, United States dollars
Source: (Zhou et al. 2020, Zhou et al. 2021)

Boston Scientific in 2021 (Australia)

A cost-effectiveness model from the Australian healthcare system perspective evaluated IVUS-guided versus angiography-guided PCI in all-comers and patients with complex anatomical characteristics, including left main lesions or long lesions ≥28mm. Analyses were conducted over both a 5-year and lifetime (33 years) horizon (Boston Scientific 2021).

Clinical inputs were drawn from several sources: the ULTIMATE trial for general coronary lesions; the IVUS-XPL trial and Kim et al. (2013) for long lesions; Tan et al. (2015), Liu et al. (2019), and IVUS-XPL for left main lesions. The model assumed MI and TLR rates were equal between arms beyond 5 years, based on stabilization of event rates in the angiography group (Boston Scientific 2021).

Over a lifetime horizon, ICERs ranged from AUD 1,506 to AUD 27,284 per QALY gained, depending on subgroup, and was cost-effective versus angiography all-comers (Table 13). In the 5-year horizon analysis, cost-effectiveness varied more widely, with ICERs ranging from AUD 7,694 in patients with left main lesions to AUD 115,557 per QALY in

patients with long lesions (Boston Scientific 2021). No explicit WTP threshold was stated in the publication.

Table 13: ICER for IVUS-guided PCI versus angiography-guided PCI

Analysis	Population	ICER (AUD)	ICER (USD, 2023)
Lifetime horizon	All-comers	AUD 16,317/QALY gained	USD 13,070/QALY gained
	Patients with left main lesions	AUD 1,506/QALY gained	USD 1,206/QALY gained
	Patients with long lesions ≥28mm	AUD 27,284/QALY gained	USD 21,854/QALY gained
	Patients with complex anatomical characteristics (left main lesions or long lesions ≥28mm)	AUD 17,873/QALY gained	USD 14,316/QALY gained
5-year time horizon based on latest follow-up time point	All-comers to PCI	AUD 83,332/QALY gained	USD 66,749/QALY gained
	Patients with left main lesions	AUD 7,694/QALY gained	USD 6,163/QALY gained
	Patients with long lesions ≥28mm	AUD 115,557/QALY gained	USD 92,561/QALY gained

Note: Currency converted from 2021 AUD to 2023 USD after adjusting for purchasing power parity and inflation.
Abbreviations: AUD, Australian dollars; ICER, incremental cost-effectiveness ratio; IVUS, intravascular ultrasound; PCI, percutaneous coronary artery intervention; QALY, quality-adjusted life-year; USD, United States dollars
Source: (Boston Scientific 2021)

Ahn et al. 2020 (South Korea)

A cost-effectiveness model from the South Korean healthcare system perspective evaluated IVUS-guided versus angiography-guided PCI in all-comers over 5-year and lifetime horizons (Ahn et al. 2020).

Clinical inputs were drawn from several sources including the COMPARE trial and other published literature, although specific details were not provided. Assumptions regarding the duration or magnitude of the IVUS benefit were not reported.

The 5-year ICER was South Korean won (KRW) 30,268,580 per QALY gained, while the lifetime ICER was substantially lower at KRW 610,660/QALY gained. Both ICERs were considered cost-effective by the authors, though no specific WTP threshold was provided (Table 14) (Ahn et al. 2020).

Table 14: ICER for IVUS-guided PCI versus angiography-guided PCI in all-comers

Analysis	ICER KRW	ICER (USD, 2023)
5-year horizon	KRW 30,268,580/QALY gained	USD 40,985/QALY gained
Lifetime horizon	KRW 610,660/QALY gained	USD 827/QALY gained

Note: Costs were originally reported in KRW (assumed 2020) and were converted to 2023 USD after adjusting for purchasing power parity and inflation.
Abbreviations: ICER, incremental cost-effectiveness ratio; IVUS, intravascular ultrasound; KRW, South Korean won; PCI, percutaneous coronary artery intervention; QALY, quality-adjusted life-year
Source: (Ahn et al. 2020)

Alberti et al. 2016 (Italy)

A lifetime cost-effectiveness model from the Italian healthcare payer perspective evaluated IVUS-guided versus angiography-guided PCI in patients with CAD (Alberti et al. 2016).

Event probabilities for MI and revascularization in the angiography arm were based on the COMPARE trial and a meta-analysis by Ahn et al. 2014. Relative treatment effects for the IVUS arm were applied as risk ratios to these baseline probabilities. Subgroup-specific HRs for patients with diabetes, renal insufficiency, and ACS were sourced from the ADAPT-DES trial. The base case assumed that IVUS benefits would persist long term. A scenario analysis was also conducted in which the benefits of IVUS were limited to the first year post PCI.

Across all scenarios and subgroups—including patients with diabetes, renal insufficiency, ACS, and those treated with everolimus-eluting stents—IVUS was dominant, meaning it was both more effective and less costly than angiography-guided PCI. These results held even when IVUS benefits were restricted to the first year (

Table 15).

Table 15: ICER for IVUS-guided PCI versus angiography-guided PCI with DES in patients with CAD across multiple subgroup analyses

Analysis	ICER (EUR)	ICER (USD, 2023)
All-comers	EUR -3,430/QALY gained	USD -6,883/QALY gained
Diabetes mellitus	EUR -3,493/QALY gained	USD -7,010/QALY gained
Renal insufficiency	EUR -3,491/QALY gained	USD -7,006/QALY gained
ACS	EUR -3,492/QALY gained	USD -7,008/QALY gained
Everolimus-eluting stents only	EUR -2,288/QALY gained	USD -4,592/QALY gained
All-comers: IVUS benefit limited to first year	EUR -9,624/QALY gained	USD -19,314/QALY gained

Note: Costs were converted from 2013 EUR to 2023 USD after adjusting for purchasing power parity and inflation.
Abbreviations: ACS, acute coronary syndrome; CAD, coronary artery disease; DES, drug-eluting stent; EUR, euros; ICER, incremental cost-effectiveness ratio; IVUS, intravascular ultrasound; PCI, percutaneous coronary artery intervention; QALY, quality-adjusted life-year; USD, United States dollars
Source: (Alberti et al. 2016)

Mueller et al. 2003 (Germany)

This cost-effectiveness analysis evaluated IVUS-guided versus angiography-guided PCI in patients undergoing percutaneous transluminal coronary angioplasty (PTCA) or stenting, from a German societal perspective over a 2-year time horizon (Mueller et al. 2003).

The model used a cost per MACE-free survival framework, defined as:
(Cost IVUS – Cost Angiography) / (MACE-free IVUS – MACE-free Angiography).
MACE included death, nonfatal MI, and clinically driven TVR. Model inputs were based on a prospective clinical study reported in the same publication.

In the base case, IVUS was dominant, yielding both improved outcomes and lower overall costs. The reported cost per MACE-free survivor gained with IVUS was USD -1,417. (USD, 1996). This equates to -USD 2,752 in 2023, adjusted using purchasing power parity and exchange rates.

Berry et al. 2000 (United Kingdom)

A cost-effectiveness analysis from the UK healthcare provider perspective evaluated IVUS-guided versus angiography-guided PCI over 6-month and 5-year time horizons in an all-comer population (Berry et al. 2000).

Clinical inputs for angiographic restenosis and MACE rates were derived from a meta-analysis of observational studies. The model did not specify assumptions regarding the duration of IVUS benefit.

For long-term outcomes, IVUS-guided PCI was associated with an ICER of GBP 6,439 per QALY gained in all-comers, which was considered cost-effective at a WTP threshold of GBP 10,000 per QALY. After adjustments for purchasing power parity and inflation, the ICER equates to approximately USD 18,676 per QALY in 2023 USD. The currency

year was not stated in the original publication but was assumed to be 2000 for conversion purposes.

Budget Impact Evaluations

Budget impact analyses comparing IVUS-guided and angiography-guided PCI were identified in 2 studies (across 3 publications). Both were conducted in patients with CAD and alongside cost-effectiveness models presented earlier.

In China, a model estimated that replacing angiography with IVUS would increase per patient costs by CNY 9,200 at baseline (Lao et al. 2022, Lao et al. 2022). However, due to the associated reduction in MI and revascularization events, cumulative healthcare costs decreased over time. Over a 37-year horizon, IVUS use was projected to generate net savings of CNY 14,884 per patient for the medical insurance payer.

In Australia, a budget impact analysis estimated the total Medicare Benefits Schedule cost of IVUS adoption for all-comers receiving PCI with DES at AUD 606,905 in 2022, increasing to AUD 3.5 million by 2026 (Boston Scientific 2021). For patients with complex anatomical characteristics (left main lesions or long lesions ≥28 mm), projected costs were lower: AUD 305,880 in 2022, rising to AUD 454,022 in 2026.

Conclusion

Evidence from multiple countries and healthcare systems consistently demonstrates that IVUS-guided PCI is a cost-effective—and often dominant—strategy compared to angiography-guided PCI. Across diverse models evaluating STEMI, UA/NSTEMI, and complex CAD populations, IVUS consistently delivered favorable economic value despite variations in healthcare costs, input assumptions, time horizons, and WTP thresholds. Cost-effectiveness was primarily driven by reductions in myocardial infarction and revascularization events, with long-term models showing increasing value over time. Budget impact analyses further suggest that while upfront costs may be higher, IVUS can lead to downstream savings through avoidance of costly complications. These findings support the broader adoption of IVUS to enhance both patient outcomes and health system efficiency.

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Appendices

Appendix 1: Targeted Literature Review Methods

Objectives and Research Questions

The objective of this targeted literature review was to identify both clinical and economic evidence on the IVUS system for PCIs. The evidence identified was used to develop a report providing a comprehensive overview of the clinical efficacy, safety and economic impact of the use of the IVUS system in this indication.

Clinical objective - What are the safety and effectiveness outcomes of IVUS-guided PCI as reported in clinical trials and real-world studies?

Economic objective - What are the outcomes of economic evaluations—including cost-effectiveness and budget impact models—of IVUS-guided PCI?

Search Methodology

Eligibility criteria were applied following the population-intervention-comparators-outcomes-study design (PICOS) framework, in line with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance (Table 16).

Eligible studies included peer-reviewed clinical trials, real-world studies, cost-effectiveness analyses, and budget impact models. Publicly available cost-effectiveness reports were also considered.

Table 16: PICO search strategy (Databases: Embase, MEDLINE)

Set#	Searched for	Results
S1	AB,TI((coronary stent) OR (percutaneous coronary intervention) OR (PTCA) OR (Percutaneous transluminal coronary angioplasty) OR (coronary artery recanalization) OR (saphenous vein graft) OR (heart muscle revascularization))	222033*
S2	TI,AB,IF((pci) OR (pcta) OR (pcicto) OR (ctopci) OR (ctoptca) OR (ptacacto) OR (postpci) OR (postptca))	120011*
S3	(TI,AB,IF((coronary OR intracoronary OR myocard* OR "myo card*") NEAR/5 (stent* OR angioplas* OR intervention* OR "angio plast*" OR balloon* OR percutaneous OR intervent* OR transluminal)))	243512*
S4	(TI,IF((heartmuscle OR "heart muscle") NEAR/2 (revascularization OR revascularisation OR "re vascularisation" OR "re vascularization")))	7°
S5	S1 OR S2 OR S3 OR S4	314900*
S6	IF((intravascular imaging) OR (intravascular ultrasound) OR (intravascular ultrasound catheter))	6339*
S7	AB,TI,IF((IVUS) OR (IVUSguided))	17466*
S8	(AB,TI,IF((intravascular OR "intra vascular" OR intracoronary OR "intra coronary") NEAR/3 (ultrasound* OR ultrasonog* OR "ultra sound*" OR "ultra sonogr*" OR imaging)))	31002*
S9	S6 OR S7 OR S8	33939*
S10	(Clinical effectiveness) OR (efficacy) OR (treatment success) OR (Survival rate) OR (mortality) OR (Restenosis) OR (restenosis rate) OR (recurrent coronary artery disease) OR (Stent thrombosis) OR (stent failure) OR (Complications) OR (adverse	20430736*

Set#	Searched for	Results
	events) OR (major adverse cardiac events) OR (MACE) OR (Procedure success) OR (procedural complication rate) OR (Follow-up) OR (long-term outcomes) OR (patient outcomes) OR (Coronary artery patency) OR (vessel patency) OR (quality of life) OR (symptom relief)	
S11	S5 AND S9 AND S10	11196*
S12	TI,AB(case NEAR/1 (stud* OR report)) OR EMB.EXACT("Case study") OR EMB.EXACT("Abstract report" OR "Letter") OR RTYPE("Case reports") OR RTYPE("Letter") OR RTYPE("Historical article") OR PSTYPE("Conference proceedings") OR RTYPE("Conference abstract") OR RTYPE("Editorial") OR RTYPE("Note") OR DTYPE("Conference abstract")	14806657*
S13	S11 NOT S12	6775*
S14	(S13 AND PD(>2015))	1756°
S15	(Cost-effectiveness) OR (cost-effectiveness analysis) OR (economic evaluation) OR (Cost-benefit) OR (cost-utility) OR (incremental cost-effectiveness ratio) OR (ICER) OR (Health economics) OR (economic burden) OR (cost-saving) OR (Quality adjusted life years) OR (QALYs) OR (QALY) OR (life years) OR (life-years) OR (LYS)	3255127*
S16	S5 AND S14 AND S15	74°
S17	S43 NOT S44	6775

Search date 29 January 2025.
* Duplicates are removed from the search but included in the result count.
° Duplicates are removed from the search and from the result count.

The following additional criteria were applied:

- All studies with n <300 in the IVUS arm were excluded
- Only those studies comparing IVUS/IVI to angiography alone were included
- Single-center studies were excluded
- Studies using IVUS during PCIs with another procedure were excluded

Literature Sources

PubMed, MEDLINE, and Embase were searched (via ProQuest) for full studies published over the past 10 years and conference abstracts for the past 2 years. Search strings are reported in Table 16.

Boston Scientific provided the 2021 MSAC Assessment report for IVUS-guided coronary stent insertion, and an internal clinical evaluation report for review prior to the search.

The Tufts Cost-Effectiveness Analysis Registry, INAHTA, and ISPOR website were searched for additional economic models.

The reference lists of any recent and relevant systematic literature reviews and network meta-analyses were checked for relevant sources. Clinical guidelines were not explicitly identified from the searches, and those included in the report were sourced internally by Boston Scientific.

Screening and Extraction

Screening and full-text selection were conducted by a primary reviewer and checked by a senior researcher. Each study was extracted by 1 researcher and reconciled for accuracy against random spot checks of the extractions.

Appendix 2: Identified Studies

A total of 40 studies were identified. Of these, clinical outcomes were provided in 27 clinical and/or real-world studies, and economic outcomes were provided in 13 records.

Table 17: List of studies included

Study name or data source (references)	NCT number	Study type	Study country	Patient populations studied	Total sample size
RENOVATE-COMPLEX-PCI (Choi et al. 2024)	NCT03381872	Clinical	South Korea	Coronary artery disease requiring PCI	1639
RENOVATE-COMPLEX-PCI (Lee et al. 2024)	NCT03381872	Clinical	South Korea	Patients undergoing PCI for complex coronary artery lesions	1639
RENOVATE-COMPLEX-PCI (Cha et al. 2024)	NCT03381872	Clinical	South Korea	NR	1639
RENOVATE-COMPLEX-PCI (Lee et al. 2023)	NCT03381872	Clinical	South Korea	Patients undergoing PCI for complex coronary artery lesions	1639
RENOVATE-COMPLEX-PCI (Kwon et al. 2023)	NCT03381872	Clinical	South Korea	Coronary artery disease requiring PCI	1639
IVUS-ACS (Gao et al. 2025)	NCT03971500	Clinical	China, Italy, Pakistan, United Kingdom	Acute coronary syndrome	1105
ULTIMATE (Gao et al. 2021)	NCT02215915	Clinical	China	Silent ischemia, stable or unstable angina, or myocardial infarction (MI)	1448
IVUS-XPL and ULTIMATE (Lee et al. 2022)	NCT01308281; NCT02215915	Clinical	IVUS-XPL: South Korea; ULTIMATE: China	Patients undergoing DES implantation for long lesions	2325
ULTIMATE (Zhang et al. 2018)	NCT02215915	Clinical	China	Silent ischemia, stable or unstable angina, or myocardial infarction (MI)	1448
IVUS-XPL and ULTIMATE (Hong et al. 2022)	NCT01308281; NCT02215915	Clinical	IVUS-XPL: South Korea; ULTIMATE: China	IVUS-XPL: Patients with typical chest pain or evidence of myocardial ischemia ULTIMATE: Silent ischemia, stable or	2577

				unstable angina, or myocardial infarction	
ULTIMATE (Gao et al. 2021)	NCT02215915	Clinical	China	Asymptomatic myocardial ischemia, stable angina pectoris, unstable angina pectoris, or acute myocardial infarction	1443
IVUS-ACS (Li et al. 2024)	NCT03971500	Clinical	China, Italy, Pakistan, United Kingdom	Acute coronary syndrome	3505
IVUS-XPL (long-term follow-up) (Hong et al. 2020)	NCT03866486	Clinical	South Korea	Patients with typical chest pain or evidence of myocardial ischemia indicated for everolimus-eluting stent implantation	1400
KAMIR-NIH and KAMIR-V Registry (Joh et al. 2024)	NA	Real-world	South Korea	AMI patients with cardiogenic shock	1833
Nationwide Inpatient Sample Database (Lemor et al. 2020)	NA	Real-world	USA	Patients with ST-segment elevation myocardial infarction (STEMI)	2425036
J-MINUET Registry (Okura et al. 2019)	NA	Real-world	Japan	Acute myocardial infarction	2788
KAMIR-NIH Registry (Kim et al. 2022)	NA	Real-world	South Korea	Patients who underwent PCI with second-generation DES implantation	9007
CREDO-Kyoto AMI Registry (Nakatsuma et al. 2016)	NA	Real-world	Japan	AMI patients who underwent coronary revascularization	3028
New York's PCI Registry (Hannan et al. 2022)	NA	Real-world	USA	Patients with complex lesions undergoing PCI	44305
Medicare claims data (Bergmark et al. 2023)	NA	Real-world	USA	Patients who underwent PCI in the inpatient setting	502821
KAMIR-NIH Registry (Roh et al. 2023)	NA	Real-world	South Korea	Acute myocardial infarction	1759
Nationwide Readmissions Database (NRD)	NA	Real-world	USA	Patients who underwent PCI during the hospitalizations for STEMI	809332

(Ya'qoub et al. 2021)					
ROCK II (Cortese et al. 2022)	NA	Real-world	Europe	Patients undergoing distal LM angioplasty with one or more of the latest generation DES	730
DEFINITION Registry (Chen et al. 2018)	NA	Real-world	China	Patients with Medina 1,1,1 or Medina 0,1,1 true bifurcation lesions and an SB diameter≥2.5 mm	1465
ADAPT-DES (Maehara et al. 2018)	NCT00638794	Real-world	USA, Germany	Patients undergoing PCI with DES	8582
MAIN-COMPARE Registry (Kang et al. 2021)	NCT02791412	Real-world	South Korea	Unprotected LMCA disease who underwent PCI or coronary artery bypass grafting	995
(Lao et al. 2022)	NA	Economic	China	Patients with CAD receiving PCI	NA
(Hong et al. 2024)	NA	Economic	South Korea	Patients with complex coronary artery lesions receiving PCI	NA
(Sharp et al. 2024)	NA	Economic	United Kingdom	STEMI patients with ACS receiving PCI	NA
(Mueller et al. 2003)	NA	Economic	Germany	Patients undergoing PTCA or stenting	NA
(Zhou et al. 2021)	NA	Economic	Australia	All-comers undergoing DES implantation	NA
(Berry et al. 2000)	NA	Economic	United Kingdon	Patients receiving PCI	NA
(Zhou et al. 2020)	NA	Economic	Australia	Patients undergoing DES implantation	NA
(Ahn et al. 2020)	NA	Economic	South Korea	All-comers to PCI	NA
(Dacheva et al. 2023)	NA	Economic	Bulgaria	STEMI and UA/NSTEMI patients with CAD undergoing PCI	NA
(Lee Joo et al. 2023)	NA	Economic	NR (Assumed South Korea)	Patients with CAD receiving PCI	NA
(Lao et al. 2022)	NA	Economic	China	Patients with CAD receiving PCI	NA
(Boston Scientific 2021)	NA	Economic	Australia	Patients receiving PCI with DES - All-comers - With left main lesions - With long lesions ≥28mm - With complex anatomical characteristics	NA

(Alberti et al. 2016)	NA	Economic	Italy	CAD patients undergoing PCI with DES – - General patient population - Diabetes mellitus - Renal insufficiency - ACS	NA

Appendix 3: Data Tables for Outcomes in Clinical Studies

Table 18: IVUS-ACS clinical outcome data

Study details	Timepoint	IVUS-guided* n (%)	Angiography-guided n (%)	HR	(95% CI)	*P* value
Patients with ACS						
TVF*	1 year	70 (4)	128 (7.3)	0.55	0.41-0.74	0.0001
Target vessel failure without procedural MI	1 year	38 (2.2)	90 (5.1)	0.45	0.30-0.66	<0.0001
Clinically driven TLR	1 year	22 (1.3)	44 (2.5)	0.52	0.31-0.88	0.014
Cardiac death†	1 year	9 (0.5)	20 (1.1)	0.56	0.24-1.29	0.17
All-cause death	1 year	14 (0.8)	26 (1.5)	0.64	0.32-1.27	0.2
Target vessel MI‡	1 year	44 (2.5)	67 (3.8)	0.63	0.43-0.92	0.018
Procedural MI	1 year	34 (1.9)	42 (2.4)	0.78	0.50-1.22	0.28
Non-procedural MI§	1 year	11 (0.6)	26 (1.5)	0.41	0.20-0.84	0.014
Patients with diabetes						
TVF*	1 year	20 (3.6)	46 (8.3)	0.46	0.27-0.81	0.007
Target vessel failure without procedural MI	1 year	11 (2)	37 (6.7)	0.29	0.15-0.57	<0.001
TLR	1 year	5 (0.9)	15 (2.7)	0.32	0.12-0.89	0.029
Cardiac death†	1 year	3 (0.5)	10 (1.8)	0.3	0.09-1.07	0.065
All-cause death	1 year	4 (0.7)	13 (2.4)	0.3	0.10-0.93	0.037
Target vessel MI‡	1 year	13 (2.3)	18 (3.3)	0.71	0.35-1.45	0.355
Procedural MI	1 year	9 (1.6)	10 (1.8)	0.89	0.36-2.19	0.807
Non-procedural MI§	1 year	4 (0.7)	8 (1.5)	0.49	0.15-1.63	0.246

Abbreviations: ACS, acute coronary syndrome; HR, hazard ratio; IVUS, intravascular ultrasound; MI, myocardial infarction; PCI, percutaneous coronary intervention

*Target vessel failure; composite of cardiac death, target vessel MI, or clinically driven target vessel revascularization.

†Cardiac death related to the acute coronary syndrome culprit lesion; Cardiac death was defined as any death due to a proximate cardiac cause (e.g., MI, low-output failure, or fatal arrhythmia), unwitnessed death and death of unknown cause, and all procedure-related deaths including those related to concomitant treatment.

‡Target vessel MI consisted of procedural and spontaneous MI.

§Nonprocedural MI (beyond 48 hours after the index procedure) was defined according to the third universal definition of MI.

Source: Patients with ACS (Li et al. 2024); Patients with diabetes (Gao et al. 2025)

Table 19: ULTIMATE clinical outcome data

Outcome (Population)	Reference	Timepoint	IVUS-guided PCI n (%)	Angiography-guided PCI n (%)	HR	95% CI	*P* value
TVF* (All-comers)	(Gao et al. 2021a, Zhang et al. 2018)	1 year	21 (2.9)	39 (5.4)	0.53	0.31-0.90	0.02
	(Gao et al. 2021a)	2 years	43 (6)	65 (9)	0.65	0.44-0.95	0.03
	(Gao et al. 2021a)	3 years	47 (6.6)	76 (10.7)	0.6	0.42-0.87	0.01
TLR (All-comers)	(Zhang et al. 2018)	30 days	0 (0)	2 (0.3)	-	-	0.16
	(Zhang et al. 2018, Gao et al. 2021)	1 year	9 (1.2)	12 (2.6)	0.47	0.21-1.03	0.05
	(Gao et al. 2021)	2 years	26 (3.6)	40 (5.6)	0.63	0.39-1.04	0.07
	(Gao et al. 2021)	3 years	27 (3.8)	45 (6.3)	0.59	0.36-0.94	0.03
TLF (All-comers)	(Zhang et al. 2018)	30 days	6 (0.8)	14 (1.9)	0.427	0.164-1.111	0.08

	(Zhang et al. 2018, Gao et al. 2021)	1 year	20 (2.8)	37 (5.1)	0.53	0.31-0.92	0.02
	(Gao et al. 2021)	2 years	38 (5.3)	63 (8.8)	0.59	0.39-0.88	0.01
	(Gao et al. 2021)	3 years	42 (5.9)	72 (10.2)	0.57	0.39-0.83	0.003
TLF (CKD)	(Gao et al. 2021)	3 years	15 (8.3)	25 (14.8)	-	-	0.05
TLF (No CKD)	(Gao et al. 2021)	3 years	27 (5)	47 (8.5)	-	-	0.02
Cardiac death** (All-comers)	(Zhang et al. 2018)	30 days	1 (0.1)	3 (0.4)	0.332	0.164-1.111	0.08
	(Zhang et al. 2018, Gao et al. 2021)	1 year	5 (0.7)	10 (1.4)	0.5	0.17-1.45	0.19
	(Gao et al. 2021)	2 years	9(1.3)	16 (2.2)	0.56	0.25-1.26	0.16
	(Gao et al. 2021)	3 years	13 (1.8)	19 (2.7)	0.68	0.34-1.38	0.28
Cardiac death** (CKD)	(Gao et al. 2021)	3 years	6 (3.3)	10 (5.9)	-	-	0.25
Cardiac death** (No CKD)	(Gao et al. 2021)	3 years	7(1.3)	9 (1.6)	-	-	0.63
All-cause death (All-comers)	(Zhang et al. 2018)	30 days	1 (0.1)	5 (0.7)	0.199	0.023-1.707	0.1
	(Zhang et al. 2018, Gao et al. 2021)	1 year	10 (1.4)	17 (2.3)	0.58	0.27-1.28	0.17
	(Gao et al. 2021)	2 years	24 (3.3)	27 (3.8)	0.88	0.51-1.53	0.65
	(Gao et al. 2021)	3 years	31 (4.3)	31 (4.4)	0.99	0.60-1.63	0.98
All-cause death CKD	(Gao et al. 2021)	3 years	15 (8.3)	16 (9.5)	-	-	0.69
All-cause death No CKD	(Gao et al. 2021)	3 years	16 (2.9)	15 (2.7)	-	-	0.83
Target vessel MI*** (all-comers)	(Gao et al. 2021)	1 year	7 (1)	11 (1.5)	0.63	0.25-1.64	0.34
	(Gao et al. 2021)	2 years	7 (1)	14 (1.9)	0.5	0.20-1.23	0.12
	(Gao et al. 2021)	3 years	7 (1)	15 (2.1)	0.46	0.19-1.14	0.46
Stroke (all-comers)	(Zhang et al. 2018)	30 days	1 (0.1)	2 (0.3)	0.499	0.045-5.499	0.56
	(Zhang et al. 2018)	1 year	5 (0.7)	4 (0.6)	1.241	0.333-4.620	0.75

*TVF was defined as cardiac death, target vessel MI, or clinically driven target vessel revascularization. ** All deaths were considered to be cardiac deaths unless there was a clear noncardiac cause. ***Target vessel MI was defined as any MI without clear evidence of a nontarget vessel.
Abbreviations: CKD, chronic kidney disease; HR, hazard ratio; IVUS, intravascular ultrasound; MI, myocardial infarction; PCI, percutaneous coronary intervention; TLR, target lesion revascularization; TVF, target vessel failure
Sources: See table

Table 20: IVUS-XPL clinical outcome data

Time point	IVUS-guided everolimus-eluting stent implantation		Angiography-guided everolimus-eluting stent implantation		HR	95% CI	*P* value
	n	%	n	%			
At 5 years							
MACE*	36	5.6	70	10.7	0.50	0.34-0.75	0.001

Cardiac death	6	0.9	14	2.2	0.43	0.17-1.12	0.074
Target lesion-related MI	4	0.6	6	0.9	0.67	0.19-2.36	0.525
Ischemia-driven TLR	31	4.8	55	8.4	0.54	0.33-0.89	0.007
Definite of probable stent thrombosis	2	0.3	2	0.3	1.00	0.14-7.10	1.000
Landmark analyses							
MACE							0.817
≤1 yr	19	2.9	39	5.8	0.48	0.28-0.83	
1-5 years	17	2.8	31	5.2	0.53	0.29-0.95	
Cardiac death							0.550
≤1 yr	3	0.4	5	0.7	0.60	0.14-2.52	
1-5 years	3	0.5	9	1.4	0.33	0.90-1.23	
Target lesion-related MI							-
≤1 yr	0	0.0	1	0.1	-	-	
1-5 years	4	0.6	5	0.8	0.80	0.21-2.97	
Ischemia driven TLR							0.675
≤1 yr	17	2.5	33	5.0	0.51	0.28-0.91	
1-5 years	14	2.3	22	3.7	0.61	0.31-1.20	
Definite of probably stent thrombosis							-
≤1 yr	2	0.3	2	0.3	1.00	0.14-7.10	
1-5 years	0	0.0	0	0.0	-	-	

*Major adverse cardiac events was a composite of cardiac death, target lesion-related myocardial infarction, or ischemia-driven TLR. Source: (Hong et al. 2020).
Abbreviations: IVUS, intravascular ultrasound; MACE, major adverse cardiac event; MI, myocardial infarction; TLR, target lesion revascularization

Table 21: ULTIMATE and IVUS XPL pooled analysis: Clinical outcome data

Outcome† (population)	Reference	Intervention group	n(%)	Comparator group	N (%)	HR	95% CI	*P* value
TLF	(Lee et al. 2022)	IVUS-guided PCI with post-dilation	45 (4.5%)	Angio-only PCI without post-dilation	36 (9.8%)	0.35	0.22-0.56	<0.001
	(Lee et al. 2022)	Angio-only PCI with post-dilation	75 (8.6%)	Angio-only PCI without post-dilation	36 (9.8%)	0.76	0.50-1.15	0.194
TLR*	(Lee et al. 2022)	IVUS-guided PCI with post-dilation	37 (3.7%)	Angio-guided PCI without post-dilation	30 (8.2%)	0.36	0.21-0.60	<0.001
	(Lee et al. 2022)	Angio-guided PCI with post-dilation	50 (5.8%)	Angio-guided PCI without post-dilation	30 (8.2%)	0.70	0.44-1.14	0.15
Cardiac death** (long-lesions)	(Hong et al. 2022)	IVUS-guided PCI	12 (1%)	Angio-guided PCI	28 (2.2%)	0.43	0.22-0.84	0.011
Cardiac death**	(Lee et al. 2022)	IVUS-guided PCI with post-dilation	9 (0.9%)	Angio-guided PCI without post-dilation	5 (1.4%)	0.43	0.13-1.40	0.163
	(Lee et al. 2022)	Angio-guided PCI	23 (2.6%)	Angio-guided PCI without	5 (1.4%)	1.27	0.46-3.47	0.645

		with post-dilation		post-dilation				
All-cause death	(Hong et al. 2022)	IVUS-guided PCI	38 (3%)	Angio-guided PCI	48 (3.8%)	0.79	0.51-1.20	0.268
Target Lesion–Related MI***	(Hong et al. 2022)	IVUS-guided PCI	3 (0.2%)	Angio-guided PCI	9 (0.7%)	0.33	0.09-1.22	0.081
	(Lee et al. 2022)	IVUS-guided PCI with post-dilation	1 (0.1%)	Angio-guided PCI without post-dilation	2 (0.5%)	0.06	0.00-0.96	0.047
	(Lee et al. 2022)	Angio-guided PCI with post-dilation	7 (0.8%)	Angio-guided PCI without post-dilation	2 (0.5%)	0.97	0.19-5.06	0.973

*Ischemia-driven target lesion revascularization was defined as ischemia or angina referable to the target lesion that required repeat percutaneous intervention or bypass surgery, ** All deaths were considered cardiac deaths unless a definite noncardiac cause could be established; this definition of cardiac death was used in both trials. ***Target lesion–related MI was defined as the presence of clinical symptoms, electrocardiographic changes, or abnormal imaging findings with evidence of myocardial necrosis corresponding to the territory supplied by the coronary artery containing the lesion stented during the index procedure.
† All outcomes are at a median follow-up of 3 years
Abbreviations: DES, drug-eluting stent; HR, hazard ratio; IVUS, intravascular ultrasound; MI, myocardial infarction; NR, not reported; PCI, percutaneous coronary intervention; TLF, target lesion failure; TLR, target lesion revascularization
Source: See table

Table 22: RENOVATE-COMPLEX-PCI: Clinical outcomes

Outcome†	Population (Reference)	IVI-guided PCI†† n (%)	Angiography-guided PCI n (%)	HR	95% CI	*P* value
TVF*	All-comers (Lee, 2023)	76 (7.7%)	60 (12.3%)	0.64	0.45-0.89	0.008
	IVUS (Lee, 2023)	59 (8.0%)	60 (12.3%)	0.66	0.46-0.95	NR
	CKD (Kwon, 2023)	22 (13.3%)	19 (23.3%)	0.53	0.28-0.99	0.03
	Non-CKD (Kwon, 2023)	54 (6.4%)	41 (9.9%)	0.65	0.43-0.99	0.05
	ACS (Lee, 2024)	51 (10.4%)	33 (14.6%)	0.74	0.48-1.15	0.18
	CCS (Lee, 2024)	25 (5.0%)	27 (10.4%)	0.46	0.27-0.80	0.006
	Diabetes (Choi, 2024)	45 (12.9%)	26 (12.3%)	0.97	0.60-1.57	0.90
	No diabetes (Choi, 2024)	31 (4.7%)	34 (12.2%)	0.41	0.25-0.67	<0.001
	Men (Cha, 2024)	66 (8.3%)	46 (11.7%)	0.72	0.49-1.05	0.09
	Women (Cha, 2024)	10 (5.2%)	14 (14.5%)	0.34	0.15-0.78	0.01
TLR	All-comers (Lee, 2023)	24 (2.6%)	20 (4.4%)	0.66	0.36-1.22	NR
	CKD (Kwon, 2023)	7 (4.3%)	2 (2.3%)	1.65	0.32-8.59	NR
	Non-CKD (Kwon, 2023)	17 (2.2%)	18 (4.8%)	0.48	0.25-0.94	NR
	ACS (Lee, 2024)	15 (3.5%)	11 (5.0%)	0.64	0.30-1.40	0.27
	CCS (Lee, 2024)	9 (1.8%)	9 (3.7%)	0.51	0.20-1.28	0.15
	Diabetes (Choi, 2024)	15 (4.6%)	11 (5.2%)	0.75	0.34-1.63	0.47
	No diabetes (Choi, 2024)	9 (1.5%)	9 (3.7%)	0.46	0.18-1.15	0.10
	Men (Cha, 2024)	20 (2.8%)	16 (4.5%)	0.63	0.33-1.22	0.17
	Women (Cha, 2024)	4 (1.9%)	7 (7.4%)	0.24	0.07-0.81	0.02
Cardiac death**	All-comers (Lee, 2023)	16 (1.7%)	17 (3.8%)	0.47	0.24-0.93	NR
	CKD (Kwon, 2023)	9 (5.8%)	9 (12.0%)	0.51	0.19-1.34	NR

	Non-CKD (Kwon, 2023)	7 (0.8%)	8 (1.9%)	0.40	0.14-1.13	NR
	ACS (Lee, 2024)	8 (1.9%)	11 (5.9%)	0.35	0.14-0.86	0.02
	CCS (Lee, 2024)	8 (1.7%)	6 (2.2%)	0.68	0.24-1.97	0.48
	Diabetes (Choi, 2024)	13 (4.1%)	9 (4.2%)	0.81	0.35-1.90	0.63
	No diabetes (Choi, 2024)	3 (0.4%)	8 (3.4%)	0.17	0.05-0.65	0.01
	Men (Cha, 2024)	14 (1.7%)	13 (3.5%)	0.58	0.27-1.24	0.16
	Women (Cha, 2024)	2 (1.6%)	4 (4.8%)	0.26	0.05-1.44	0.12
All-cause death	All-comers (Lee, 2023)	42 (5.3%)	28 (6.4%)	0.71	0.44-1.15	NR
	CKD (Kwon, 2023)	22 (15.5%)	12 (15.4%)	0.94	0.45-1.97	NR
	Non-CKD (Kwon, 2023)	20 (2.8%)	16 (4.4%)	0.61	0.31-1.19	NR
	ACS (Lee, 2024)	17 (4.5%)	16 (7.9%)	0.51	0.26-1.00	0.05
	CCS (Lee, 2024)	25 (6.0%)	12 (5.2%)	1.06	0.53-2.12	0.86
	Diabetes (Choi, 2024)	25 (8.0%)	15 (7.4%)	0.93	0.49-1.76	0.83
	No diabetes (Choi, 2024)	17 (3.7%)	13 (5.8%)	0.60	0.29-1.23	0.16
	Men (Cha, 2024)	36 (5.7%)	22 (6.3%)	0.84	0.49-1.43	0.52
	Women (Cha, 2024)	6 (3.4%)	6 (6.9%)	0.53	0.17-1.67	0.28
MI***	All-comers (Lee, 2023)	43 (4.4)	32 (6.2)	0.78	0.48-1.25	NR
	CKD (Kwon, 2023)	10 (6.9)	11 (12.8)	0.45	0.19-1.09	NR
	Non-CKD (Kwon, 2023)	33 (3.9)	21 (4.9)	0.77	0.44-1.34	NR
	ACS (Lee, 2024)	34 (7)	15 (6.2)	1.1	0.60-2.01	0.77
	CCS (Lee, 2024)	9 (1.9)	17 (6.4)	0.27	0.12-0.60	0.001
	Diabetes (Choi, 2024)	24 (7.1)	15 (7.2)	0.9	0.47-1.72	0.76
	No diabetes (Choi, 2024)	19 (3)	17 (5.6)	0.51	0.27-0.99	0.04
	Men (Cha, 2024)	36 (4.7)	27 (6.7)	0.67	0.40-1.10	0.11
	Women (Cha, 2024)	7 (3.6)	5 (5.0)	0.71	0.23-2.26	0.57
Stroke	Men (Cha, 2024)	7 (0.9)	4 (1.1)	0.96	0.28-3.30	0.95
	Women (Cha, 2024)	5 (2.5)	4 (5)	0.6	0.16-2.24	NR

*Target vessel failure defined as composite of cardiac death, target vessel–related myocardial infarction (MI), and target vessel revascularization. ** Any death due to a proximate cardiac cause (e.g., myocardial infarction, low output failure, fatal arrhythmia), unwitnessed death and death of unknown cause, and all procedure-related deaths, including those related to concomitant treatment, was classified as cardiac death. *** The definition used in this trial was based on the Third Universal Definition of Myocardial Infarction for spontaneous myocardial infarction, and the Society for Cardiovascular Angiography & Interventions definition for procedure-related MI.

† All outcomes are at a median follow-up of 2.1 years

††The IVI-guided group included those receiving intravascular IVUS or OCT

Abbreviations: ACS, acute coronary syndrome; CCS, chronic coronary syndrome; CKD, chronic kidney disease; HR, hazard ratio; IVI, intravascular imaging; IVUS, intravascular ultrasound; NR, not reported; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; TVF, target vessel failure