

Prognostic impact of intravascular imaging in percutaneous coronary intervention according to procedural complexity



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ABSTRACT

BACKGROUND: Data regarding intravascular imaging (IVI) in complex percutaneous coronary intervention (PCI) remain scarce.

AIMS: In this study, we sought to assess the effects of IVI-guided PCI according to procedural complexity.

METHODS: This was a *post hoc* analysis of the RENOVATE-COMPLEX-PCI trial that compared IVI-guided PCI with angiography-guided PCI in patients with complex coronary artery lesions. The study population was stratified into three groups of low, moderate, and high risk, according to PCI procedural complexity, following the European Society of Cardiology criteria. The high-risk group included patients meeting at least one clinical risk criterion and at least one procedural risk criterion. The primary endpoint was target vessel failure (TVF), a composite of cardiac death, target vessel-related myocardial infarction, or clinically driven target vessel revascularisation.

RESULTS: At a median 2.1-year follow-up, TVF risk increased significantly in a stepwise manner from the low (reference) to moderate (adjusted hazard ratio [HR] 1.369, 95% confidence interval [CI]: 0.705-2.660; $p=0.353$) and high procedural complexity group (adjusted HR 1.619, 95% CI: 0.963-2.723; $p=0.069$). The benefit of IVI-guided PCI varied by procedural complexity, with significant risk reductions in the moderate-risk group (adjusted HR 0.374, 95% CI: 0.150-0.935; $p=0.035$) and the high-risk group (adjusted HR 0.633, 95% CI: 0.424-0.945; $p=0.025$) but not in the low-risk group (adjusted HR 0.735, 95% CI: 0.282-1.914; $p=0.528$). The interaction between the IVI effect and procedural complexity was statistically significant ($p_{\text{interaction}}=0.009$).

CONCLUSIONS: In patients undergoing complex PCI, an IVI-guided procedure significantly reduced adverse cardiac events, with a greater magnitude of benefit observed in procedures of high complexity.

KEYWORDS: coronary artery disease; intravascular imaging; percutaneous coronary intervention

Percutaneous coronary intervention (PCI) is becoming more complex, given the increasingly advanced age of the population and concomitant increases in morbidity indices and both atherosclerotic and non-atherosclerotic risk factors.¹⁻³ Complex PCI is typically associated with low rates of procedural success and high rates of recurrence or major adverse cardiac events.^{4,5} A careful diagnostic workup of the patient is key to successful complex PCI. In this context, the routine implementation of intravascular imaging (IVI) in complex coronary artery disease is a crucial part of preinterventional lesion assessment and postinterventional stent optimisation.

Recently, the Randomized Controlled Trial of Intravascular Imaging Guidance Versus Angiography-Guidance on Clinical Outcomes After Complex Percutaneous Coronary Intervention (RENOVATE-COMPLEX-PCI) showed that, among patients with complex coronary artery lesions, IVI-guided PCI led to a lower risk of a composite of death from cardiac causes, target vessel-related myocardial infarction (MI), or clinically driven target vessel revascularisation (TVR) than angiography-guided PCI.⁶ However, patients with complex lesion anatomy undergoing coronary stenting may experience different risks and outcomes according to procedural complexity. Given this context, patients undergoing complex PCI procedures may derive greater benefits from IVI guidance compared with those undergoing less complex PCI. In this study, we evaluated the effectiveness of IVI-guided versus angiography-guided complex PCI in improving clinical outcomes according to PCI procedural complexity.

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Methods

STUDY DESIGN

This study was a *post hoc* analysis of the RENOVATE-COMPLEX-PCI (ClinicalTrials.gov: NCT03381872), an investigator-initiated, randomised, open-label, multicentre, superiority trial conducted at 20 sites in the Republic of Korea. Briefly, patients aged ≥ 19 years who underwent PCI for complex coronary artery lesions were enrolled. Complex coronary artery lesions were defined as true bifurcation lesions with a side branch ≥ 2.5 mm in size, chronic total occlusions (CTOs), unprotected left main artery disease, long coronary lesions, multivessel PCI requiring multiple stents, in-stent restenosis, severe calcified lesions, or coronary ostial lesions. The key exclusion criteria were cardiogenic shock at presentation and known hypersensitivity to or contraindications for the use of aspirin, clopidogrel, prasugrel, ticagrelor, heparin, everolimus, or contrast media.⁶

This study was conducted in accordance with the principles of the Declaration of Helsinki. The institutional review board approved the trial protocol of each participating site. The authors confirm that patient consent forms were obtained for this article.

Impact on daily practice

PCI complexity is associated with an increased risk of adverse cardiac events. In our study, the benefit of imaging-guided PCI became more pronounced as PCI complexity increased, highlighting the potential value of risk-adapted imaging strategies.

RANDOMISATION AND TREATMENT

Patients with treatable complex coronary artery lesions were randomised in a 2:1 ratio to undergo IVI-guided or angiography-guided PCI. A standard PCI technique was used, and the choice of imaging modality and timing of its use were left to the discretion of the operators. Although IVI can be used at any stage of the PCI procedure (before, during, or after PCI), post-PCI imaging is required to ensure optimal stent deployment and adjustment of the treated segment. Protocols for IVI acquisition and procedural optimisation were established based on the latest expert consensus recommendations.⁷ After the index procedure, dual antiplatelet therapy was advised for a duration of at least 3-6 months in patients with stable ischaemic heart disease and for 6-12 months in patients with acute coronary syndrome (ACS). However, the choice of loading dose, maintenance dose, and overall duration of dual antiplatelet therapy was left to the discretion of the treating physician. Irrespective of the group assignment, the medical treatment of each patient followed the most up-to-date clinical guidelines.^{8,9}

ENDPOINTS AND DEFINITIONS

The primary endpoint was target vessel failure (TVF), defined as a composite of cardiac death, target vessel-related MI, or clinically driven TVR. The secondary endpoints included the individual components of the primary endpoint: cardiac death, target vessel-related MI, and TVR. Spontaneous MI was defined based on the Third Universal Definition,¹⁰ whereas procedure-related MI was defined based on the guidelines set by the Society for Cardiovascular Angiography and Interventions.¹¹ Deaths from unknown causes were categorised as cardiac deaths, with other endpoints defined in accordance with the Academic Research Consortium criteria.¹²

STRATIFICATION OF PROCEDURAL COMPLEXITY

In the current substudy, all patients enrolled in the RENOVATE-COMPLEX-PCI trial were stratified into three groups of low, moderate, and high risk, according to PCI procedural complexity (**Supplementary Figure 1**) as assessed by the criteria of the 2023 European Society of Cardiology (ESC) guidelines for ACS management (**Supplementary Figure 2**).¹³ The high-risk group consisted of patients

Abbreviations

ACS	acute coronary syndrome	ESC	European Society of Cardiology	PCI	percutaneous coronary intervention
CKD	chronic kidney disease	IVI	intravascular imaging	TVF	target vessel failure
CTO	chronic total occlusion	MI	myocardial infarction	TVR	target vessel revascularisation

who met at least one of the clinical risk criteria (diabetes mellitus; chronic kidney disease [CKD], which was defined as a glomerular filtration rate between 15 mL/min/1.73 m² and 60 mL/min/1.73 m²; prior MI; peripheral artery disease [PAD]; age <45 years; or multivessel coronary artery disease) and at least one of the angiographic risk criteria (≥ 3 stents implanted, ≥ 3 lesions treated, total stent length >60 mm, left main artery PCI, CTO, or bifurcation lesions treated with 2 stents). Patients in the moderate-risk group met at least one of the following clinical risk criteria: diabetes mellitus, CKD, prior MI, or PAD. The low-risk group included patients who did not fulfil the criteria for the high- or moderate-risk groups.

STATISTICAL ANALYSIS

All analyses were performed on an intention-to-treat basis. Categorical variables are reported as numbers and relative frequencies (%) and were compared using the χ^2 and Fisher's exact tests. Continuous variables are reported as mean $\pm$ standard deviation and were compared using the Student's t-test or Mann-Whitney U test. Kaplan-Meier analyses were performed for time-to-event outcomes, with intervention effects estimated using Cox proportional hazard regression models; the results are presented as hazard ratios (HRs) with 95% confidence intervals (CIs). Covariates that were either statistically significant in the univariate analysis ($p < 0.10$) or considered clinically important were included in the multivariate models. All probability values were two-sided, and $p < 0.05$ was considered statistically significant. Statistical analyses were performed using SPSS Statistics software, version 20.0 (IBM).

Results

BASELINE CHARACTERISTICS

The study population consisted of 1,639 patients, of whom 370 (22.6%), 232 (14.2%), and 1,037 (63.3%) were classified into the low-, moderate-, and high-risk groups, respectively (**Supplementary Figure 1**). The baseline clinical and procedural characteristics according to PCI complexity are shown in **Supplementary Table 1**. Some clinical and angiographic characteristics differed significantly across the three risk groups. The patients in the moderate- and high-risk groups were older, whereas hypertension and diabetes were more common in the high-risk group than in the other groups. CKD was more common in the moderate- and high-risk groups than in the low-risk group. The patients in the moderate- and high-risk groups more frequently had multivessel disease, left main artery involvement as the culprit lesion, true bifurcation lesions, and CTOs. Procedural metrics, including total stent length, total contrast volume, and procedural time, were significantly greater in the high-risk group than in the other groups. Procedural success rates were high in all groups but were slightly lower in the high-risk group than in the other groups. Medication use, including clopidogrel, prasugrel, and ticagrelor, varied significantly across the groups, with higher use of beta blockers and renin-angiotensin system inhibitors in the moderate- and high-risk groups than in the low-risk group. Finally, the duration of hospitalisation was significantly longer in the high-risk group than in the other groups.

COMPARISON OF CLINICAL OUTCOMES BASED ON PROCEDURAL COMPLEXITY

At a median follow-up of 2.1 years (interquartile range 1.4–3.0 years), the primary endpoint of cardiac death, target vessel-related MI, or clinically driven TVR occurred in 18 patients (4.9%) in the low-risk group, 19 (8.2%) in the moderate-risk group, and 99 (9.5%) in the high-risk group. The risk of the primary endpoint increased stepwise in the moderate-risk (adjusted HR 1.369, 95% CI: 0.705–2.660) and high-risk groups (adjusted HR 1.619, 95% CI: 0.963–2.723) compared with that in the low-risk group (**Figure 1**).

COMPARISON OF CLINICAL OUTCOMES IN IVI-GUIDED PCI VERSUS ANGIOGRAPHY-GUIDED PCI BY PROCEDURAL COMPLEXITY

In the angiography-guided PCI group, TVF occurred in 5.6%, 13.1%, and 12.4% of the patients in the low-, moderate-, and high-risk groups, respectively. In the IVI-guided PCI group, the rates of TVF were 4.5%, 5.4%, and 8.2% of the patients in the low-, moderate-, and high-risk groups, respectively. The unadjusted HRs for TVF showed a significant risk reduction in the moderate-risk (HR 0.389, 95% CI: 0.157–0.968; $p = 0.042$) and high-risk groups (HR 0.645, 95% CI: 0.433–0.960; $p = 0.031$) with IVI-guided PCI (**Table 1**). After adjustment, the HR remained significant in the moderate-risk (adjusted HR 0.374, 95% CI: 0.150–0.935; $p = 0.035$) and high-risk groups (adjusted HR 0.633, 95% CI: 0.424–0.945; $p = 0.025$). The effect of IVI-guided PCI varied according to PCI procedural complexity (adjusted p for interaction = 0.009), showing a significant benefit of using IVI in the patients in the moderate-risk and high-risk groups compared with those in the low-risk group (**Figure 2**).

Discussion

Among patients enrolled and randomised in the RENOVATE-COMPLEX-PCI trial, we found that those undergoing more complex PCI had a higher rate of subsequent ischaemic events compared with those undergoing standard PCI. The present study also found that the benefit of IVI-guided PCI increased additively with higher PCI procedural complexity (**Central illustration**).

Several hypotheses may explain these findings: (1) complex PCI is associated with higher risks of death, MI, and unplanned revascularisation.^{4,5} A careful diagnostic workup of the patient is the cornerstone for successful complex PCI procedures. In this respect, the routine assessment of IVI in complex coronary artery disease is pivotal for the diagnostic workup. Ultimately, for complex PCI, IVI should be a valuable adjunctive tool for preinterventional lesion assessment.^{14–16} (2) Stenting of complex lesions may increase the risks of stent malapposition, incomplete lesion coverage, and delayed endothelialisation, all of which, in turn, are involved in the enhancement of thrombotic propensity within the target vascular segment.¹⁷ In this context, routine assessment of IVI in complex coronary artery disease is essential for postinterventional stent optimisation. Recently, Witzenbichler et al showed that the benefits of intravascular ultrasound (IVUS) were especially evident in patients with ACS and complex lesions in ADAPT-DES.¹⁸ Bavishi et al also showed in their meta-analysis that IVUS-guided PCI led to significant reductions (by 36%) in the rates of major adverse

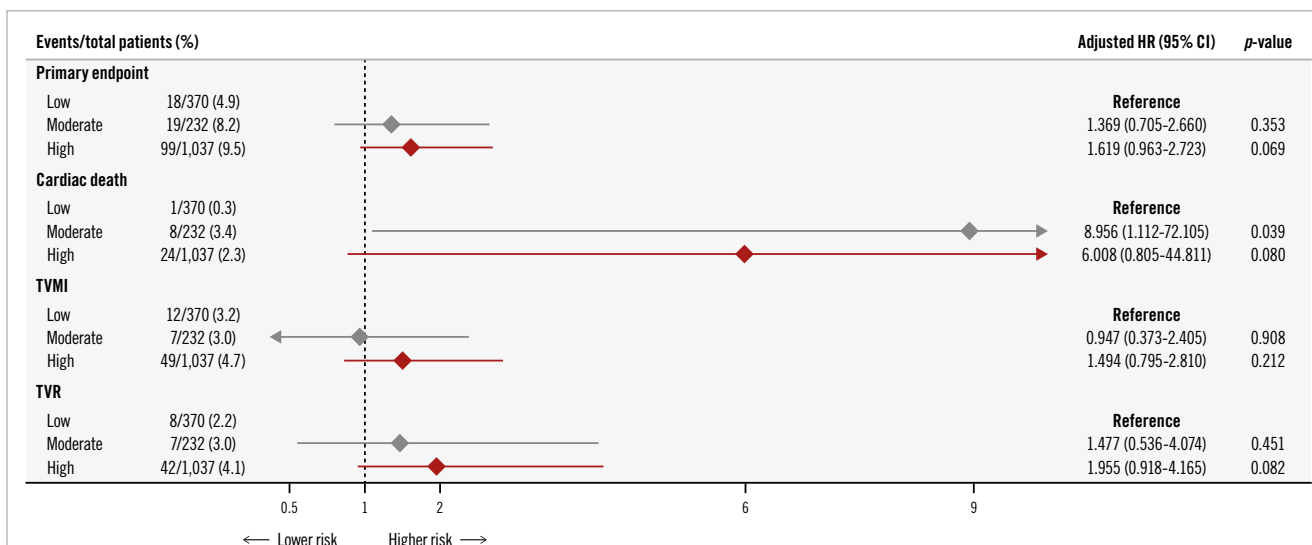


Figure 1. Adjusted risk of clinical outcomes by procedural complexity. The primary endpoint, TVF, was defined as a composite of cardiac death, TV-related MI, or clinically driven TVR. Event rates and adjusted HRs for TVF and its individual components are presented across the low-, moderate-, and high-risk groups, classified according to PCI procedural complexity. A stepwise increase in the adjusted risk of TVF was observed in the moderate-risk (HR 1.369, 95% CI: 0.705-2.660) and high-risk groups (HR 1.619, 95% CI: 0.963-2.723) compared with that in the low-risk group. CI: confidence interval; HR: hazard ratio; MI: myocardial infarction; PCI: percutaneous coronary intervention; TV: target vessel; TVMI: target vessel-related myocardial infarction; TVF: target vessel failure; TVR: target vessel revascularisation

Table 1. Comparison of clinical outcomes between IVI-guided PCI and angiography-guided PCI by procedural complexity.

ESC criteria/ randomisation	Low risk (n=370)	Moderate risk (n=232)	High risk (n=1,037)	Interaction p-value
Angiography-guided PCI	7/125 (5.6)	11/84 (13.1)	42/338 (12.4)	
Intravascular imaging-guided PCI	11/245 (4.5)	8/148 (5.4)	57/699 (8.2)	
Unadjusted HR for TVF (95% CI)	0.795 (0.308-2.052) p=0.636	0.389 (0.157-0.968) p=0.042	0.645 (0.433-0.960) p=0.031	0.013
Adjusted HR for TVF* (95% CI)	0.735 (0.282-1.914) p=0.528	0.374 (0.150-0.935) p=0.035	0.633 (0.424-0.945) p=0.025	0.009

Data are n/N (%) or HR (95% CI). *Adjusted for ACS, previous heart failure, ejection fraction, and randomised group (IVI-guided PCI versus angiography-guided PCI). ACS: acute coronary syndrome; CI: confidence interval; ESC: European Society of Cardiology; HR: hazard ratio; IVI: intravascular imaging; PCI: percutaneous coronary intervention; TVF: target vessel failure

cardiac events, in comparison with angiography guidance, with maximal benefit in patients with ACS, diabetes mellitus, and long lesions.¹⁹

In addition to lesion complexity, clinical factors play an important role in PCI outcomes. Conditions such as diabetes mellitus, CKD, or a history of MI are known to accelerate the progression of coronary artery disease and complicate treatment. The interplay between these clinical comorbidities and anatomical complexity has been reported to have a significant impact on procedural success and long-term outcomes.²⁰ Considering these points, in our study, we adopted the ESC criteria¹³ to quantify procedural complexity by incorporating both clinical and anatomical factors. This approach allowed us to categorise patients into low-, moderate-, and high-risk groups according to procedural complexity, thus offering a more comprehensive evaluation of the impact of IVI-guided PCI.

Major scientific cardiology societies have recommended the use of IVI to guide and optimise stent implantation in selected cases, including complex PCI. Previous consensus and guideline documents had assigned this a Class IIa recommendation.^{7,9,21} However, more recently, the 2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients With Acute Coronary Syndromes has upgraded the use of intravascular imaging to a Class I, Level of Evidence A recommendation in ACS patients with complex coronary lesions.²² Despite these recommendations, the overall adoption of IVI remains small, with current estimates indicating usage in <15% of all PCI procedures in the United States.¹⁵ Various explanations have been proposed for the underuse of IVI, including unfamiliarity with imaging equipment, knowledge gaps in image interpretation, recognition that increased procedure time adversely affects workflow efficiency, and a lack of adequate financial

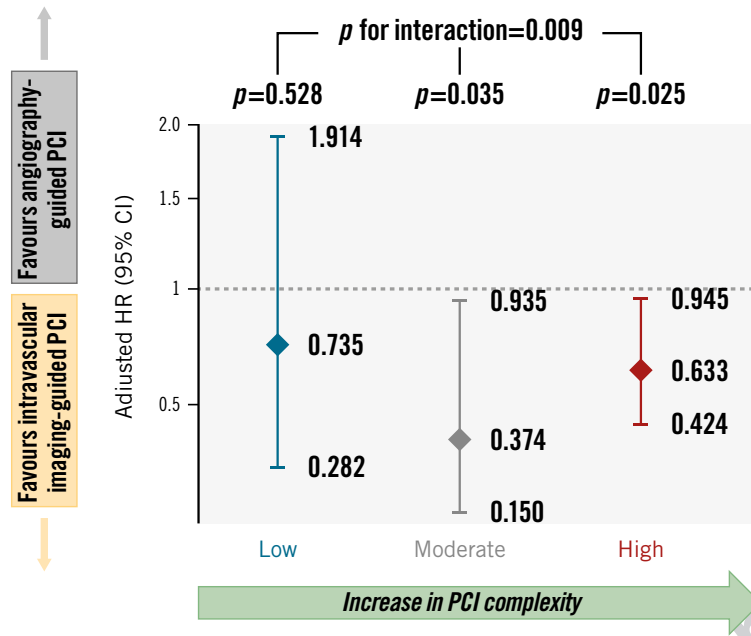
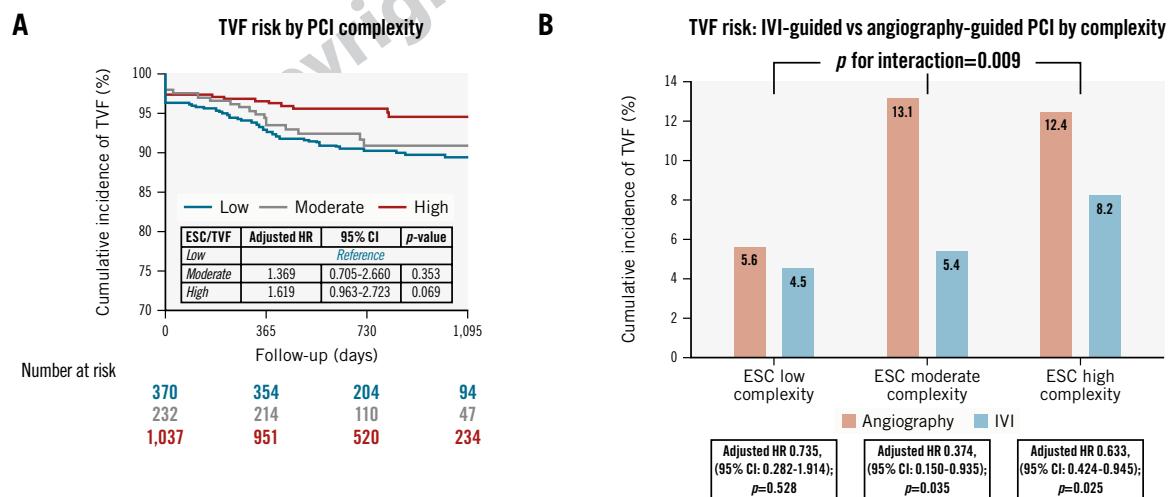


Figure 2. Adjusted risk of target vessel failure with IVI-guided versus angiography-guided PCI by procedural complexity. Adjusted hazard ratios for TVF comparing IVI-guided with angiography-guided PCI are shown across the low-, moderate-, and high-risk groups, classified according to PCI procedural complexity. The clinical benefit of IVI guidance became progressively more pronounced with increasing complexity (p for interaction=0.009), achieving statistical significance in the moderate- and high-risk groups. CI: confidence interval; HR: hazard ratio; IVI: intravascular imaging; PCI: percutaneous coronary intervention; TVF: target vessel failure

Clinical impact of IVI-guided PCI across procedural complexity.



This *post hoc* substudy of the RENOVATE-COMPLEX-PCI trial showed that patients undergoing more complex PCI experienced higher rates of ischaemic events. Importantly, the clinical benefit of IVI-guided PCI over angiography-guided PCI was more pronounced in the moderate- and high-complexity cases.

reimbursement.²³ In particular, in the setting of a complex procedure, hesitation in the use of the equipment may also be considered an important factor. Given the remaining difficulties in the widespread adoption of IVI, additional evidence to reinforce its benefits is needed. This finding may be helpful for decision-making in real-world clinical practice. Our comprehensive approach to assessing PCI complexity strengthens the conclusions of this study and provides a clearer understanding of the incremental benefits of IVI in different patient populations.

Two recent trials, OPTIMAL²⁴ and IVUS-CHIP,²⁵ yielded opposite results to the above findings. One of the randomised trials, OPTIMAL, showed no significant benefit of IVUS over angiography for guiding PCI in revascularisation of left main stenosis. The other, IVUS-CHIP, was a larger trial enrolling patients with a broader range of complex coronary artery lesions, and it too revealed no advantage of IVUS-guided PCI on the key endpoints. Although IVUS did not reduce the risk of events in these two trials, this conclusion should be restricted to procedures performed by expert IVUS operators. This is because IVUS experience improves the imaging skills of interventionalists, likely allowing experienced interventionalists to achieve good results with any type of imaging, whether with IVUS or angiography. However, the bottom line is that imaging is extremely valuable in developing an interventionalist's PCI practice.

Limitations

This study has some limitations. First, randomisation in the RENOVATE-COMPLEX-PCI trial was not stratified by procedural complexity, as this was a *post hoc* analysis of a randomised clinical trial. In addition, the sample size was small, especially in the moderate- and high-complexity subgroups. Consequently, the analysis may lack sufficient statistical power to detect differences in the primary endpoint between the study groups. In the same context, in the low procedural complexity subgroup, no significant difference in TVF was observed between IVI-guided and angiography-guided PCI. The small sample size and low event rate limit the reliability of this observation. Therefore, comparisons based on procedural complexity should be regarded as hypothesis-generating. Second, procedural complexity was defined using the ESC criteria in this substudy. However, the ESC criteria were developed to identify patients with ACS at moderate or high thrombotic risk, for whom extended treatment with a second antithrombotic agent might be considered after PCI;^{26,27} therefore, the ability of these criteria to define PCI procedural complexity has not been validated. Finally, the HRs are borderline significant with wide CIs.

Conclusions

Patients undergoing complex PCI procedures are at a substantially higher risk of ischaemic events, and this risk increases with PCI procedural complexity. Among patients who underwent complex PCI, IVI-guided PCI significantly reduced the risk of cardiac ischaemic events, compared with angiography-guided PCI, with an increased magnitude of benefit with greater procedural complexity. Our study suggests a potential benefit of using IVI in procedural high-risk PCI patients to reduce long-term adverse outcomes.

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Declaration of generative AI use

The authors did not use generative artificial intelligence (AI) or AI-assisted tools during the manuscript preparation process.

Conflict of interest statement

J.-Y. Hahn reports receiving grants from Abbott and Boston Scientific during the conduct of the study; and grants from the National Evidence-based Healthcare Collaborating Agency,

the Ministry of Health & Welfare, Republic of Korea, Biosensors, Biotronik, Daiichi Sankyo, Dong-A ST, Hanmi Pharmaceutical, and Medtronic, outside the submitted work. C.-W. Nam reports receiving grants from Abbott outside the submitted work. The other authors have no conflicts of interest to declare.

References

- Malik FT, Kalimuddin M, Ahmed N, et al. Assessing mortality rates and predictors of cardiac death in diabetic and non-diabetic patients after left main percutaneous coronary intervention with the Resolute zotarolimus-eluting stent in Bangladesh: a comprehensive analysis. *AsiaIntervention*. 2025;11:e119-28.
- Kaul U, Sudhir K, Bangalore S. Current status of percutaneous coronary interventions in diabetics with multivessel disease - is it time to challenge FREEDOM? *AsiaIntervention*. 2024;10:102-9.
- Alkhouli M, Alqahtani F, Kalra A, et al. Trends in Characteristics and Outcomes of Patients Undergoing Coronary Revascularization in the United States, 2003-2016. *JAMA Netw Open*. 2020;3:e191326.
- Mohamed MO, Polad J, Hildick-Smith D, et al. Impact of coronary lesion complexity in percutaneous coronary intervention: one-year outcomes from the large, multicentre e-Ultimaster registry. *EuroIntervention*. 2020;16:603-12.
- Chandrasekhar J, Baber U, Sartori S, et al. Associations Between Complex PCI and Prasugrel or Clopidogrel Use in Patients With Acute Coronary Syndrome Who Undergo PCI: From the PROMETHEUS Study. *Can J Cardiol*. 2018;34:319-29.
- Lee JM, Choi KH, Song YB, et al. Intravascular Imaging-Guided or Angiography-Guided Complex PCI. *N Engl J Med*. 2023;388:1668-79.
- Räber L, Mintz GS, Koskinas KC, et al. Clinical use of intracoronary imaging. Part 1: guidance and optimization of coronary interventions. An expert consensus document of the European Association of Percutaneous Cardiovascular Interventions. *Eur Heart J*. 2018;39:3281-300.
- Neumann FJ, Sousa-Uva M, Ahlsson A, et al. 2018 ESC/EACTS Guidelines on myocardial revascularization. *EuroIntervention*. 2019;14:1435-534.
- Writing Committee Members; Lawton JS, Tamis-Holland JE, Bangalore S, et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2022;79:e21-129.
- Thygesen K, Alpert JS, Jaffe AS, et al. Third universal definition of myocardial infarction. *Circulation*. 2012;126:2020-35.
- Moussa ID, Klein LW, Shah B, et al. Consideration of a new definition of clinically relevant myocardial infarction after coronary revascularization: an expert consensus document from the Society for Cardiovascular Angiography and Interventions (SCAI). *J Am Coll Cardiol*. 2013;62:1563-70.
- Cutlip DE, Windecker S, Mehran R, et al. Clinical end points in coronary stent trials: a case for standardized definitions. *Circulation*. 2007;115:2344-51.
- Byrne RA, Rossello X, Coughlan JJ, et al. 2023 ESC Guidelines for the management of acute coronary syndromes. *Eur Heart J*. 2023;44:3720-826.
- Hong SJ, Hong MK. Significance of verification of IVUS-guided stent optimisation. *AsiaIntervention*. 2018;4:7-9.
- Ugo F, Franzino M, Massaro G, et al. The Role of IVUS in Coronary Complications. *Catheter Cardiovasc Interv*. 2025;105:1171-82.
- Truesdell AG, Alasnag MA, Kaul P, et al. Intravascular Imaging During Percutaneous Coronary Intervention: JACC State-of-the-Art Review. *J Am Coll Cardiol*. 2023;81:590-605.
- Baber U, Kini AS, Sharma SK. Stenting of complex lesions: an overview. *Nat Rev Cardiol*. 2010;7:485-96.
- Witzenbichler B, Maehara A, Weisz G, et al. Relationship between intravascular ultrasound guidance and clinical outcomes after drug-eluting stents: the assessment of dual antiplatelet therapy with drug-eluting stents (ADAPT-DES) study. *Circulation*. 2014;129:463-70.
- Bavishi C, Sardar P, Chatterjee S, et al. Intravascular ultrasound-guided vs angiography-guided drug-eluting stent implantation in complex coronary lesions: Meta-analysis of randomized trials. *Am Heart J*. 2017;185:26-34.
- Généreux P, Giustino G, Redfors B, et al. Impact of percutaneous coronary intervention extent, complexity and platelet reactivity on outcomes after drug-eluting stent implantation. *Int J Cardiol*. 2018;268:61-7.
- Johnson TW, Räber L, di Mario C, et al. Clinical use of intracoronary imaging. Part 2: acute coronary syndromes, ambiguous coronary angiography findings, and guiding interventional decision-making: an expert consensus document of the European Association of Percutaneous Cardiovascular Interventions. *Eur Heart J*. 2019;40:2566-84.
- Rao SV, O'Donoghue ML, Ruel M, et al. 2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients With Acute Coronary Syndromes: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2025;151:e771-862.
- Hawranek M, Dziewierz A, Kaluzna-Oleksy M, et al. Temporal Trends in Coronary Physiology Testing and Intravascular Imaging Adoption in Poland (2014-2025). *Catheter Cardiovasc Interv*. 2026;107:969-76.
- Testa L, De la Torre Hernandez JM, De Maria GL, et al. IVUS-Guided versus Angiography-Guided PCI in Unprotected Left Main Coronary Disease. *N Engl J Med*. 2026;394:2189-99.
- Diletti R, Daemen J, Faurie B, et al. Intravascular Ultrasound-Guided or Angiography-Guided Complex High-Risk PCI. *N Engl J Med*. 2026;394:2200-11.
- Collet JP, Thiele H, Barbato E, et al. 2020 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. *Eur Heart J*. 2021;42:1289-367.
- Spirito A, Cao D, Sartori S, Sharma A, Smith KE, Vogel B, Kamaleldin K, Koshy AN, Feng Y, Power D, Baber U, Krishnamoorthy P, Dargas G, Kini A, Sharma SK, Mehran R. Predictive value of the thrombotic risk criteria proposed in the 2023 ESC guidelines for the management of ACS: insights from a large PCI registry. *Eur Heart J Cardiovasc Pharmacother*. 2024;10:11-9.

Supplementary data

Supplementary Table 1. Baseline clinical and procedural characteristics.

Supplementary Figure 1. Study flowchart.

Supplementary Figure 2. Risk criteria of the 2023 ESC guidelines for the management of ACS.

Data availability statement.

Author contributions.

The supplementary data are published online at:
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Supplementary data

Supplementary Table 1. Baseline clinical and procedural characteristics.

	Low risk (n = 370)				Moderate risk (n = 232)				High risk (n=1,037)				
	All	Angiographic (n = 125)	IVI (n = 245)	<i>p</i> value	All	Angiographic (n = 84)	IVI (n = 148)	<i>p</i> value	All	Angiographic (n = 338)	IVI (n = 699)	<i>p</i> value	Overall <i>p</i> value
†ESC high risk criteria													
Clinical feature	95 (25.7)	33 (26.4)	62 (25.3)	0.820	232 (100.0)	81 (100.0)	148	-	1,037	338 (100.0)	699	-	< 0.001
Angiographic feature	142 (38.4)	50 (40.0)	92 (37.6)	0.647	0 (0.0)	0 (0.0)	(100.0) 0 (0.0)	-	(100.0) 1,037 (100.0)	338 (100.0)	(100.0) 699 (100.0)	-	< 0.001
Baseline characteristics													
Sex				0.715				0.666				0.675	0.286
Female	75 (20.3)	24 (19.2)	51 (20.8)		57 (24.6)	22 (26.2)	35 (23.6)		207 (20.0)	70 (20.7)	137 (19.6)		
Male	295 (79.7)	101 (80.8)	194 (79.2)		175 (75.4)	62 (73.8)	113 (76.4)		830 (80.0)	268 (79.3)	562 (80.4)		
Age	64 (57–71)	65 (58-72)	63 (56-70)	0.318	68 (61–75)	67 (58-75)	69 (62-76)	0.173	66 (59-74)	67 (60-74)	66 (58-74)	0.106	<0.001
Body mass index, kg/m ²	24 (23–27)	24 (23-26)	25 (23-27)	0.892	24.6 (23–27)	25 (23-27)	25 (23-27)	0.643	25 (23–27)	25 (23-27)	25 (23-27)	0.671	0.350
Acute coronary syndrome	197 (53.2)	61 (48.8)	136 (55.5)	0.221	116 (50.0)	39 (46.4)	77 (52.0)	0.412	519 (50.0)	172 (50.9)	347 (49.6)	0.707	0.555
Diabetes mellitus	0 (0.0)	0 (0.0)	0 (0.0)	-	173 (74.6)	64 (76.2)	109 (73.6)	0.669	444 (42.8)	159 (47.0)	285 (40.8)	0.056	<0.001
Chronic kidney disease	0 (0.0)	0 (0.0)	0 (0.0)	-	78 (33.6)	27 (32.1)	51 (34.5)	0.720	218 (21.0)	66 (19.5)	152 (21.7)	0.411	<0.001
Hypertension	177 (47.8)	63 (50.4)	114 (46.5)	0.481	165 (71.1)	55 (65.5)	110 (74.3)	0.153	663 (63.9)	205 (60.7)	458 (65.5)	0.126	<0.001
Dyslipidemia	154 (41.6)	52 (41.6)	102 (41.6)	0.995	140 (60.3)	53 (63.1)	87 (58.8)	0.519	546 (52.7)	175 (51.8)	371 (53.1)	0.694	<0.001
Current smoker	70 (18.9)	19 (15.2)	51 (20.8)	0.192	33 (14.2)	8 (9.5)	25 (16.9)	0.123	204 (19.7)	68 (20.1)	136 (19.5)	0.802	0.157

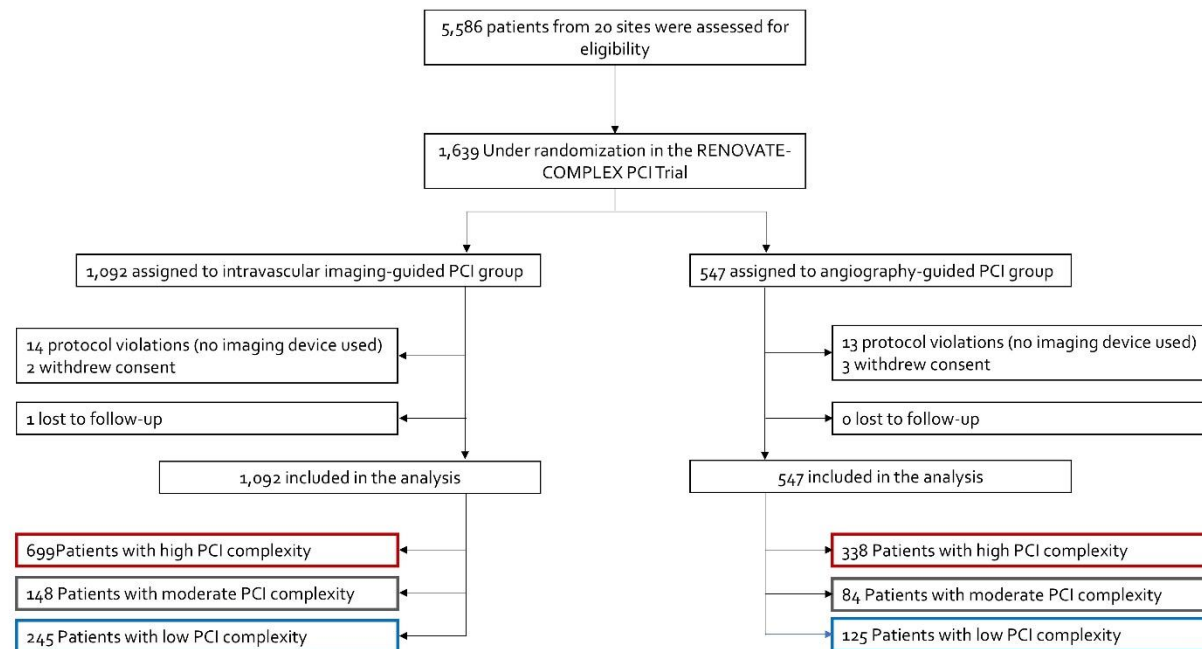
Previous PCI	70 (18.9)	23 (18.4)	47 (19.2)	0.856	110 (47.4)	38 (45.2)	72 (48.6)	0.617	215 (20.7)	66 (19.5)	149 (21.3)	0.505	<0.001
Previous MI	0 (0.0)	0 (0.0)	0 (0.0)	-	46 (19.8)	14 (16.7)	32 (21.6)	0.363	71 (6.8)	28 (8.3)	43 (6.2)	0.202	<0.001
Previous CABG	4 (1.1)	1 (0.8)	3 (1.2)	>0.99	6 (2.6)	3 (3.6)	3 (2.0)	0.670	30 (2.9)	10 (3.0)	20 (2.9)	0.930	0.151
Cerebrovascular accident	16 (4.3)	5 (4.0)	11 (4.5)	0.827	11 (4.7)	4 (4.8)	7 (4.7)	>0.99	85 (8.2)	33 (9.8)	52 (7.4)	0.201	0.016
Previous CHF	6 (1.6)	0 (0.0)	6 (2.4)	0.101	15 (6.5)	5 (6.0)	10 (6.8)	0.811	27 (2.6)	10 (3.0)	17 (2.4)	0.618	0.002
Peripheral vascular disease	0 (0.0)	0 (0.0)	0 (0.0)	-	7 (3.0)	2 (2.4)	5 (3.4)	>0.99	37 (3.6)	15 (4.4)	22 (3.1)	0.294	0.001
Previous Bleeding	7 (1.9)	3 (2.4)	4 (1.6)	0.692	6 (2.6)	3 (3.6)	3 (2.0)	0.670	30 (2.9)	16 (4.7)	14 (2.0)	0.014	0.585
LV ejection fraction (%)	63 (57–68)	62 (58-67)	62 (57-67)	0.935	60 (51–65)	61 (54-66)	60 (49-64)	0.098	61 (52–66)	61 (55-65)	61 (53-66)	0.290	<0.001
Discharge medications													
Clopidogrel	261 (70.5)	98 (78.4)	163 (66.5)	0.018	188 (81.0)	65 (77.4)	123 (83.1)	0.285	767 (74.0)	254 (75.1)	513 (73.4)	0.546	0.016
Prasugrel	54 (14.6)	14 (11.2)	40 (16.3)	0.186	22 (9.5)	10 (11.9)	12 (8.1)	0.343	102 (9.8)	34 (10.1)	68 (9.7)	0.867	0.032
Ticagrelor	44 (11.9)	10 (8.0)	34 (13.9)	0.099	17 (7.3)	6 (7.1)	11 (7.4)	0.935	148 (14.3)	45 (13.3)	103 (14.7)	0.540	0.014
Beta blocker	123 (33.2)	51 (40.8)	72 (29.4)	0.028	108 (46.6)	36 (42.9)	72 (48.6)	0.395	479 (46.2)	157 (46.4)	322 (46.1)	0.907	<0.001
ACE inhibitor or ARB	181 (48.9)	65 (52.0)	116 (47.3)	0.397	153 (65.9)	53 (63.1)	100 (67.6)	0.490	611 (58.9)	205 (60.7)	406 (58.1)	0.431	<0.001
Statin	362 (97.8)	122 (97.6)	240 (98.0)	>0.99	219 (94.4)	78 (92.9)	141 (95.3)	0.442	986 (95.1)	326 (96.4)	660 (94.4)	0.157	0.053
Number of disease vessels	281 (75.9)	96 (76.8)	185 (75.5)	0.716	122 (52.6)	50 (59.5)	72 (48.6)	0.270	123 (11.9)	38 (11.2)	85 (12.2)	0.910	<0.001
1-vessel disease	66 (17.8)	20 (16.0)	46 (18.8)		69 (29.7)	22 (26.2)	47 (31.8)		486 (46.9)	159 (47.0)	327 (46.8)		
2-vessel disease	23 (6.2)	9 (7.2)	14 (5.7)		41 (17.7)	12 (14.3)	29 (19.6)		428 (41.3)	141 (41.7)	287 (41.1)		
3-vessel disease													
Bifurcation	67 (18.1)	28 (22.4)	39 (15.9)	0.126	0 (0.0)	0 (0.0)	0 (0.0)	-	292 (28.2)	98 (29.0)	194 (27.8)	0.677	<0.001
Chronic total occlusion	46 (12.4)	15 (12.0)	31 (12.7)	0.857	0 (0.0)	0 (0.0)	0 (0.0)	-	273 (26.3)	84 (24.9)	189 (27.0)	0.454	<0.001

Unprotected left main	32 (8.6)	9 (7.2)	23 (9.4)	0.478	2 (0.9)	1 (1.2)	1 (0.7)	>0.99	158 (15.2)	44 (13.0)	114 (16.3)	0.167	<0.001
In-stent restenosis	45 (12.2)	17 (13.6)	28 (11.4)	0.546	88 (37.9)	32 (38.1)	56 (37.8)	0.969	103 (9.9)	29 (8.6)	74 (10.6)	0.311	<0.001
Severely calcified lesion	52 (14.1)	19 (15.2)	33 (13.5)	0.651	38 (16.4)	7 (8.3)	31 (20.9)	0.013	141 (13.6)	48 (14.2)	93 (13.3)	0.693	0.545
Ostial lesion	73 (19.7)	18 (14.4)	55 (22.4)	0.066	43 (18.5)	14 (16.7)	29 (19.6)	0.581	135 (13.0)	37 (10.9)	98 (14.0)	0.168	0.003
Total amount of contrast (mL)	170 (140–220)	160 (130-200)	170 (140-235)	0.415	150 (110–200)	140 (100-180)	160 (120-214)	0.040	210 (160–300)	200 (150-280)	220 (170-300)	0.008	<0.001
Procedural time (min)	52 (40–71)	45 (37-60)	56 (43-75)	<0.001	49 (39–72)	41 (33-61)	55 (42-74)	0.015	72 (54–98)	60 (45-82)	79 (60-105)	<0.001	<0.001
Total stent length (mm)	38 (24–52)	38 (24-51)	38 (28-52)	0.305	33 (23–46)	33 (24-38)	38 (23-48)	0.720	61 (38–84)	61 (38-85)	61 (38-84)	0.972	<0.001
Procedural success	367 (99.2)	125 (100.0)	242 (98.8)	0.554	232 (100)	84 (100.0)	148 (100.0)	-	1014 (97.8)	331 (97.9)	683 (97.7)	0.823	0.020
TVF	18 (4.9)	7 (5.6)	11 (4.5)	0.639	19 (8.2)	11 (13.1)	8 (5.4)	0.040	99 (9.5)	42 (12.4)	57 (8.2)	0.028	0.020

*Values are presented as either mean ± standard deviation, median (1st quartile, 3rd quartile), or numbers (%).

†The clinical risk criteria (diabetes mellitus; chronic kidney disease [CKD], which was defined as a glomerular filtration rate between 15 and 60 mL/min; prior MI; peripheral artery disease [PAD]; age <45 years; multivessel coronary artery disease) and at least one of the angiographic risk criteria (≥3 stents implanted, ≥3 lesions treated, total stent length >60 mm, left main artery PCI, CTO, and bifurcation lesions treated with two stents).

Abbreviations: ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; CABG, coronary artery bypass graft; CHF, congestive heart failure; IVI, intravascular imaging; LV, left ventricular; MI, myocardial infarction; PCI, percutaneous coronary intervention; TVF, target vessel failure



Supplementary Figure 1. Study flowchart.

PCI, percutaneous coronary intervention; RENOvATE-COMPLEX-PCI, Randomized Controlled Trial of Intravascular Imaging Guidance Vs Angiography-Guidance on Clinical Outcomes After Complex Percutaneous Coronary Intervention

Low risk	Moderate risk
Criteria for moderate or high risk not met	≥ 1 <i>clinical feature(s)</i>
	Diabetes mellitus
	Prior MI
	PAD (peripheral artery disease)
	CKD (chronic kidney disease)
High risk	
≥ 1 <i>clinical feature(s)</i>	≥ 1 <i>angiographic feature(s)</i>
Diabetes mellitus	≥ 3 stents
Prior MI	≥ 3 lesions treated
PAD	Total stent length > 60mm
CKD	Left main PCI (percutaneous coronary intervention)
Age < 45	CTO (chronic total occlusion)
Multivessel CAD (coronary artery disease)	Bifurcation with 2 stents

Supplementary Figure 2. Risk criteria of the 2023 ESC guidelines for the management of ACS. {13}

ACS, acute coronary syndrome; ESC, European Society of Cardiology

Data availability statement

The data underlying this article cannot be shared publicly due to privacy of the individual patient.

Author contributions

Drs Mijoo Kim, Joo-Yong Hahn, Jin-Ok Jeong, and Pil Sang Song had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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Acquisition, analysis, or interpretation of data: Mijoo Kim, Joo Myung Lee, Joo-Yong Hahn, Young Bin Song, Hyeon-Cheol Gwon, Jin-Ok Jeong, Pil Sang Song.

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