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Clinical Effectiveness of IVUS-guided PCI vs Angiography-guided PCI: A Retrospective Two-Year Follow-Up Study from India

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ABSTRACT

Background: IVUS compared to angiography is associated with better vessel sizing, optimal stent selection and improved stent expansion, which has been associated with improved long-term outcomes, including reductions in mortality and target vessel failure (TVF). Despite these advantages, no long-term observational registries evaluating IVUS use have been reported from India or South Asia.

Methods: This was a retrospective observational cohort study conducted at a tertiary care centre in India. The institutional PCI registry was reviewed to identify all patients who underwent percutaneous coronary intervention between January 2022 and December 2023. A total of 809 patients were treated during this period, including 178 patients who received IVUS-guided PCI and 631 who received angiography-guided PCI. Of these, follow-up data were successfully obtained for 560 patients (69.2%), comprising 113 IVUS-guided and 447 angiography-guided cases. The remaining 249 patients (30.8%) were lost to follow-up. Clinical outcomes were assessed using standardized definitions. The primary outcome was major adverse cardiovascular events (MACE), defined as a composite of cardiac death, stent thrombosis, and in-stent restenosis. Secondary outcomes included symptom recurrence (angina and dyspnea). Relative risks (RR) and 95% confidence intervals (CI) were calculated, with statistical significance set at $p < 0.05$. Median follow-up duration was 2.6 years.

Results: Outcomes of 447 angiography-guided PCI and 113 IVUS-guided PCI patients were analyzed over a median follow-up of 2.6 years. IVUS-guided PCI was associated with a lower risk of major adverse cardiovascular events (MACE), showing a 23% relative risk reduction compared to the angiography group (RR = 0.77, 95% CI: 0.48–1.25, p = 0.27). There was a statistically significant reduction in stent thrombosis (RR = 0.40, 95% CI: 0.12–1.27, p = 0.05), and a 34% relative risk reduction in death was observed with IVUS-guided PCI (RR = 0.66, 95% CI: 0.23–1.86, p = 0.27).

Conclusion: IVUS-guided PCI was associated with numerically lower rates of stent thrombosis, mortality, and MACE compared with angiography-guided PCI; however, these differences did not reach statistical significance. These findings suggest a potential association but should be interpreted cautiously given the observational design and loss to follow-up.

Keywords: Intravascular Ultrasound (IVUS); Angiography; Percutaneous Coronary Intervention (PCI); Stent Thrombosis (ST); In-Stent Restenosis (ISR); Mortality; Clinical outcome, Major adverse cardiac events (MACE)

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INTRODUCTION

Globally, cardiovascular diseases (CVDs) were responsible for an estimated 19.8 million deaths in 2022, accounting for approximately 32% of all deaths worldwide [1-3]. India alone contributed 2,873,266 CVD deaths in 2021 [4], representing a substantial proportion of the global cardiovascular mortality

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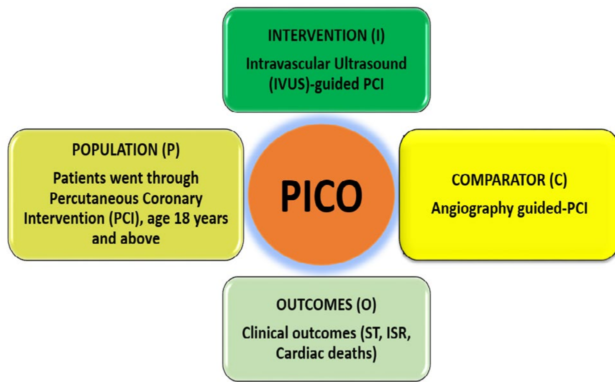

Figure 1: PICO

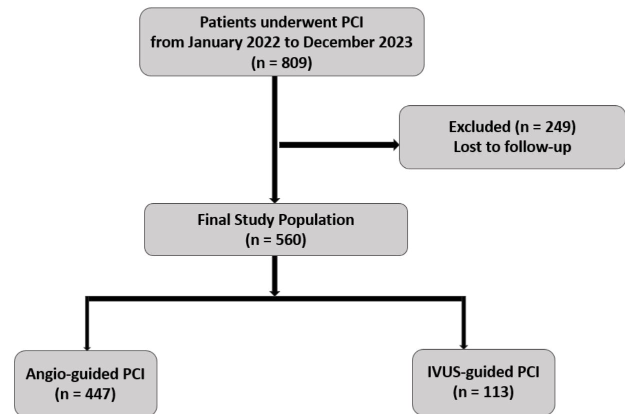

Figure 2: Flow chart of inclusion and exclusion of study population

burden and highlighting the critical public health impact of CVD in India.

Angiography provides only the outline of the vessel and stent sizing by visual estimate. However, IVUS provides a detailed cross-sectional view of the vessel [5,6]. These limitations can lead to suboptimal stent sizing, incomplete lesion coverage, or insufficient stent expansion, contributing to restenosis, stent thrombosis, and other adverse outcomes.

By providing high-resolution, cross-sectional visualization of the vessel lumen and arterial wall, IVUS enables precise assessment of plaque burden, lesion characteristics, and reference vessel dimensions [5-8]. This facilitates optimal stent sizing, accurate lesion preparation, and confirmation of adequate stent expansion and apposition. There is increasing global evidence that IVUS-guided PCI improves clinical outcomes compared to angiography-guided PCI alone [9-17]. Numerous studies have demonstrated that IVUS-guided PCI is associated with reduced rates of restenosis, repeat revascularization, and major adverse cardiovascular events compared with angiography-guided PCI [9-17]. Despite these benefits, the routine use of IVUS remains limited, especially in low- and middle-income countries like India. There is a complete paucity of studies of IVUS-guided PCI from South Asia. This study attempts to bridge this gap and is the first study of IVUS-guided PCI versus angio-guided PCI from India (Figure 1).

METHODS

Study design & population

The study was approved by the Technical Advisory Committee (TAC) of Health Technology Assessment (HTA), Department of Health Research (DHR), Ministry of Health and Family Welfare (MoHFW), India and allotted to the HTA center at AIIMS Rishikesh. IRB approval was not required as this was a retrospective study with encrypted patient identification. Telephonic hospital follow-up of patients who underwent PCI from January 2022 to December 2023 is included. All of the included patients are adults aged 18 years or older who had undergone PCI with drug eluting stent (DES). The use of IVUS was operator-dependent and may have been preferentially applied in more complex coronary lesions, introducing potential confounding by indication. This may influence observed differences between groups.

Data collection and definition

The study systematically collected comprehensive baseline characteristics of all patients undergoing PCI. Socio-demographic variables, including age and gender, were recorded to evaluate potential associations with clinical outcomes. Detailed information on comorbid conditions such as hypertension, hypotension, and non-insulin-dependent diabetes (NIDDM) was obtained. Lifestyle factors—including current alcohol consumption, smoking status, and tobacco use were assessed to understand their potential impact on cardiovascular risk. Additionally, a family history of cardiovascular disease was documented. Clinical outcomes were rigorously monitored and included major endpoints such as cardiac mortality, post-stent occurrence of angina and dyspnea, post-PCI stent thrombosis (ST), and post-PCI in-stent restenosis (ISR). These data provided a comprehensive framework to evaluate the safety and efficacy of IVUS-guided versus angiography-guided PCI (Figure 2). Approximately 30.8% of patients were lost to follow-up. No imputation was performed, and analyses assume that loss to follow-up was non-differential between groups.

Outcomes

The primary outcome of the study is the occurrence of major adverse cardiac events (MACE) within one year and beyond one-year post-PCI [18]. MACE is defined as a composite of cardiac death, stent thrombosis (ST), and in-stent restenosis (ISR). Cardiac death was defined according to standardized clinical criteria, including death due to myocardial infarction, arrhythmia, or other cardiovascular causes PCI.[19,20] The secondary outcomes are patient-reported symptomatic events, specifically post-PCI angina, assessed using the standardized Canadian Cardiovascular Society (CCS) grading of angina pectoris with only CCS-III & CCS-IV included [21], and post-PCI dyspnoea, evaluated using the New York Heart Association

Table 1: Baseline demographic data

Variables	*Angio-guided PCI (n=447, %)*	*IVUS-guided PCI (n=113, %)*	*p-value*
Age (Y)	58.2 ± 10.1	59.4 ± 10.4	0.26
Gender, n (%)			<0.01
Male	339 (75.8%)	87 (77.0%)	
Female	108 (24.2%)	26 (23.0%)	
Diabetes mellitus (NIDDM)	159 (35.6%)	39 (34.5%)	0.80
HTN	203 (45.4%)	59 (52.2%)	0.20
Current alcohol use	160 (36.0%)	42 (37.2%)	0.80
Current Smoker	264 (59.1%)	65 (57.5%)	0.76
Tobacco chewer	41 (9.2%)	12 (10.6%)	0.64
Family history of heart disease	60 (13.4%)	17 (15.0%)	0.65

(NYHA) classification, with only NYHA class III & IV included in this study.[11]

Statistical analysis

Statistical analyses were performed using IBM SPSS version 31. Normality of continuous variables assessed with the Kolmogorov–Smirnov test, and results are reported as mean ± standard deviation, based on distribution. Comparisons of normally distributed variables are made using the Student's *t*-test, while the Mann–Whitney U test was applied for non-normally distributed data. Categorical variables were summarized as frequencies or percentages and analyzed using the chi-square test or Fisher's exact *t*-test when appropriate. Relative risk (RR), 95% confidence intervals (95% CI) and *p*-values are reported as findings. A *p*-value less than 0.05 is considered statistically significant.

RESULTS

Follow-up patients

Year 2022

A total of 467 PCI procedures were performed in 2022, of which 90 (19.3%) were IVUS-guided and 377 (80.7%) were angiography-guided. Positive follow-up responses were obtained from 60 IVUS-guided patients (66%) and 287 angiography-guided patients (76.1%).

Year 2023

In 2023, 342 PCI procedures were recorded, comprising 88 IVUS-guided cases (25.7%) and 254 angiography-guided cases (74.3%). Positive responses were obtained from 53 IVUS-guided patients (60.2%) and 160 angiography-guided patients (62.9%).

Combined two years (2022–2023)

Across both years, a total of 178 IVUS-guided and 631 angiography-guided PCI procedures were identified. The overall positive response rates were 63.5% (113/178) for IVUS-guided patients and 70.8% (447/631) for angiography-guided patients.

Comparison of baseline clinical characteristics between angiography and IVUS groups

Table 1 and Figure 3 represent baseline demographic data of a total 560 patients to give a comparative evaluation of patients undergoing angiography-guided PCI (n = 447) and IVUS-guided PCI (n = 113). The mean age of patients is comparable between the two groups (59.4 ± 10.4 years for IVUS-guided PCI vs. 58.2 ± 10.1 years for angiography-guided PCI; *p* = 0.26. Female patients constituted a smaller proportion of both the angiography-guided and IVUS-guided PCI groups compared to male patients, and this gender-based distribution difference is statistically significant (p < 0.01), reflecting the known gender disparity in patients undergoing PCI [12,13]

The prevalence of comorbidities such as non-insulin-dependent diabetes mellitus (NIDDM) (35.6 vs. 34.5%; *p* = 0.80) and hypertension (45.4 vs. 52.2%; *p* = 0.20) is similar between the groups. Lifestyle factors, including current alcohol use (36.0 vs. 37.2%; *p* = 0.80), current smoking (59.1 vs. 57.5%; *p* = 0.76), and tobacco chewing (9.2 vs. 10.6%; *p* = 0.64) also showed no significant differences. Additionally, a family history of heart disease was comparable between angiography-guided and IVUS-guided PCI groups (13.4 vs. 15.0%; *p* = 0.65). Overall, the baseline demographic and clinical characteristics appeared broadly comparable between the angiography-guided and IVUS-guided PCI groups; however, residual confounding

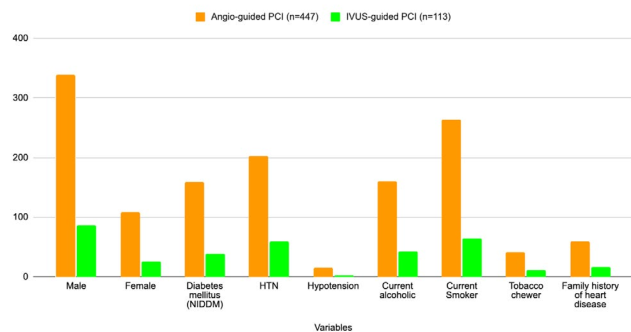

Figure 3: Bar chart baseline characteristics

Table 2: Relative risk (RR) for the year 2023 primary outcomes (ST, ISR, Cardiac death), p-value for two-tailed Fisher's exact test, * Significant value

Parameter (Year 2023)	*Risk (IVUS-guided PCI)*	*Risk (Angio-guided PCI)*	*Relative Risk (IVUS/Angio)*	*95% CI*	*Total Angio (n=160, %)*	*Total IVUS (n=53, %)*
RR of total ST	0.037	0.075	0.5	0.11-2.17	12 (7.5%)	2 (3.7%)
RR of total ISR	0.04	0.013	3.02	0.44-20.91	2 (1.25%)	2 (3.8%)
RR of total cardiac death	0.037	0.056	0.67	0.15-3.00	9 (5.6%)	2 (3.8%)

Table 3: Relative risk (RR) for the year 2022 primary outcomes (ST, ISR, Cardiac death), p-value for two-tailed Fisher's exact test, * Significant value

Parameter (Year 2022)	*Risk (IVUS-guided PCI)*	*Risk (Angio-guided PCI)*	*Relative Risk (IVUS/Angio)*	*95% CI*	*Total Angio (n=287, %)*	*Total IVUS (n=60,%)*
RR of total ST	0.016	0.062	0.27	0.04–1.95	18 (6.3%)	1 (1.67%)
RR of total ISR	0.016	0.017	0.96	0.11–8.04	5 (1.74%)	1 (1.67%)
RR of total cardiac death	0.033	0.052	0.64	0.15–2.71	15 (5.2%)	2 (3.3%)

Table 4(a): Relative Risk (RR) for the combined year (2022-2023) primary outcomes (ST, ISR, Cardiac death), p-value for two tailed Fisher's exact test, * Significant value

Variables	*Risk (IVUS-guided PCI)*	*Risk (Angio-guided PCI)*	*Relative Risk (IVUS/Angio)*	*95% CI*	*Total Angio (n=447, %)*	*Total IVUS (n=113, %)*	*p-value*
RR of Total ST	0.03	0.07	0.4	0.12-1.27	30 (6.7%)	3 (2.7%)	0.05*
RR of Total ISR	0.026	0.015	1.7	0.44-6.45	7 (1.6%)	3 (2.7%)	0.32
RR of Total Cardiac death	0.035	0.053	0.66	0.23-1.86	24 (5.4%)	4 (3.5%)	0.27

Table 4(b): Relative Risk (RR) for the combined year (2022-2023) secondary outcomes (Angina & Dyspnea), p-value for two-tailed Fisher's exact test, * Significant value

Variables	*Risk (IVUS-guided PCI)*	*Risk (Angio-guided PCI)*	*Relative Risk (IVUS/Angio)*	*95% CI*	*Total Angio/447*	*Total IVUS/113*
RR of Total Angina	0.04	0.02	1.8	0.64-5.07	11	5
RR of Angina (CCS-III)	0.04	0.02	2.19	0.75-6.43	9	5
RR of Angina (CCS-IV)	0.004	0.006	0.79	0.03-16.25	2	0
RR of Total Dyspnea	0.02	0.03	0.53	0.12-2.3	15	2
RR of Dyspnea (NYHA-III)	0.02	0.03	0.6	0.13-2.5	14	2
RR of Dyspnea (NYHA-IV)	0.004	0.003	1.31	0.05-31.95	1	0

cannot be excluded given the observational study design.

(a). Follow-up primary outcomes comparison between angiography and IVUS groups

Table 2, in the 2023 cohort, IVUS-guided PCI was associated with lower event rates and fewer complications compared with angiography-guided PCI. The incidence of total stent thrombosis is lower in the IVUS group (3.7 vs. 7.5%), corresponding to a relative risk (RR) of 0.50 (95% CI: 0.11–2.17). Although the IVUS-guided group showed a slightly higher rate of ISR (3.8% vs. 1.25%), this observation may be partially explained by the presence of diabetes, which is known to contribute to progressive in-stent restenosis[14,15]. Cardiac death is lower in the IVUS group (3.8 vs. 5.6%; RR 0.67, 95% CI: 0.15–3.00). Collectively, the outcomes are aligning well with existing literature demonstrating the benefit of intravascular imaging in reducing thrombotic events and

improving long-term clinical outcomes following PCI [9-17].

Table 3, in the 2022 cohort, IVUS-guided PCI is associated with a lower overall risk of stent thrombosis compared with angiography-guided PCI (1.67 vs. 6.3%; RR 0.27, 95% CI: 0.04–1.95). Rates of in-stent restenosis were comparable between groups (RR 0.96, 95% CI: 0.11–8.04). Cardiac deaths remained lower among IVUS-guided patients (RR 0.64, 95% CI: 0.15-2.71). Collectively, the 2022 data demonstrate that IVUS guidance provided a protective effect against stent thrombosis and cardiac death, with outcomes consistent with contemporary evidence supporting intravascular imaging–guided PCI [9-17].

Table. 4(a) and Figure 4, across the combined 2022–2023 cohort, IVUS-guided PCI suggested a favorable safety profile compared with angiography-guided PCI. The overall risk of stent thrombosis is lower in the IVUS group (3/113; 3%) than in the angiography group (30/447; 7%), corresponding to a relative risk of 0.40 (95% CI: 0.12–1.27, p=0.05). The incidence of in-stent restenosis (ISR) is numerically higher in the IVUS group (RR 1.70, 95% CI: 0.44–6.45, p=0.32) due to uncontrolled NIDDM[14,15]. Cardiac mortality is lower in the IVUS group (4/113; 3.5%) compared with the angiography group (24/447; 5.3%), with a relative risk of 0.66 (95% CI: 0.23–1.86, p = 0.27). Overall, the two-year cumulative data indicate that IVUS-guided PCI is associated with numerical reductions in primary outcomes such as thrombotic events and cardiac mortality compared with angiography-guided PCI.

(b). Follow-up secondary outcomes comparison between angiography and IVUS groups

Table 4(b) and Figure 5, the incidence of post-PCI angina was higher in the IVUS-guided group (5/113; 4%) compared with the angiography-guided group (11/447; 2%), yielding a relative risk of 1.80 (95% CI: 0.64–5.07, p = 0.21). Post-PCI dyspnea outcomes favored IVUS guidance, with a lower overall risk (2/113; 1.8%) compared to angiography-guided PCI (15/447; 3.4%), corresponding to a relative risk of 0.53 (95% CI: 0.12–2.30, p = 0.26). Similar reductions were observed for NYHA Class III dyspnea (RR 0.60, 95% CI: 0.13–2.50, p = 0.31), whereas NYHA Class IV symptoms were rare in both cohorts. These findings suggest that while angina symptoms were modestly more common in the IVUS group, IVUS-guided PCI was associated with reduced dyspnea severity.

DISCUSSION

This study represents the first retrospective observational analysis of IVUS-guided versus angiography-guided PCI conducted in South Asia, addressing an important evidence gap in the Indian context and providing complementary data for the subcontinental population over a median follow-up of 2.6 years.

In this retrospective analysis of 560 patients with coronary artery disease undergoing PCI with drug-eluting stents, IVUS-guided PCI showed trends toward improved clinical outcomes compared with angiography-guided PCI over median follow-up of 2.6 years. Baseline characteristics were well balanced between the two groups, suggesting minimal bias and supporting the validity of inter-group comparisons. Notably, the proportion of female patients undergoing PCI was significantly lower than males (p < 0.001), consistent with prior studies reporting underrepresentation of women in interventional cardiology cohorts[13,14]. Previous meta-analysis reports PCI for acute coronary syndrome (ACS) were significantly lower in women as compared to men (p=0.01) [13]. Analysis of clinical outcomes revealed that IVUS guidance was associated with favorable trends in both primary and secondary endpoints, including lower rates of stent thrombosis, reduced cardiac mortality, and improved post-procedural optimization through accurate stent sizing and expansion. These findings underscore the clinical utility of IVUS in enhancing procedural precision and improving long-term cardiovascular outcomes.

Previous global studies, including several meta-analyses, have consistently demonstrated that IVUS-guided PCI significantly reduces adverse clinical outcomes, including stent thrombosis, target lesion revascularization, and cardiac mortality [9-17]. However, to date, no similar studies have been conducted in South Asia, and we are reporting for the first time from this region, providing novel, region-specific evidence on the clinical benefits of IVUS-guided PCI.

Primary outcomes

(a). Stent Thrombosis

Our study indicates that IVUS-guided PCI was associated with a lower incidence of stent thrombosis with borderline statistical significance compared with angiography-guided PCI (2.7% vs 6.7%), corresponding to a relative risk of 0.40 (95% CI: 0.12-1.27, p=0.05), suggesting a potential clinical benefit of intravascular imaging in optimizing procedural outcomes. This finding aligns with global evidence from nine randomized and observational trials, which collectively reported that IVUS guidance significantly reduces the risk of stent thrombosis compared with angiography guidance (RR 0.48, 95% CI 0.29–0.81; p < 0.01)[16].

(b). In-stent Restenosis

In our study, the incidence of ISR was slightly higher in the IVUS-guided PCI group compared with the angiography-guided group (3/113, 2.7% vs. 7/447, 1.6%; RR 1.70, 95% CI: 0.44–6.45; p = 0.32). Although not statistically significant, this numerical increase is explained by the higher prevalence of diabetes among patients in the IVUS group. Diabetes has been consistently identified as a risk factor for restenosis due to mechanisms such as diffuse coronary disease, smaller vessel caliber, endothelial dysfunction, and increased neointimal proliferation[17]. A meta-analysis including 6,236 individuals reported higher restenosis rates among diabetic patients compared with non-diabetic patients (36.7% vs. 25.9%), with an unadjusted odds ratio of 1.61 (95% CI 1.21–2.14, p = 0.004)[18]

(c). Deaths

In our study, death was lower in the IVUS-guided PCI group (4/113; 3.5%) compared with the angiography-guided group (24/447; 5.3%), corresponding to a relative risk of 0.66 (95%

CI: 0.23–1.86, p=0.27). Although the reduction did not reach statistical significance due to modest sample size. A recent large-scale meta-analysis encompassing nine studies with 838,902 patients demonstrated that IVUS-guided PCI resulted in a 30% reduction in mortality among patients with acute myocardial infarction (RR 0.70, 95% CI: 0.59–0.82; $p < 0.01$)[19]. This robust global evidence reinforces the clinical relevance of the mortality trend observed in our study.

Secondary outcomes

With respect to secondary clinical outcomes, our study demonstrated that overall incidence of post-PCI angina was higher in the IVUS group (5/113; 4%) compared with the angiography group (11/447; 2%), yielding a relative risk of 1.80 (95% CI: 0.64–5.07). In the IVUS group, 40% (2/5) of patients who developed post-PCI angina were diabetic, while 27.3% (3/11) of those with post-PCI angina in the angiography-guided group were diabetic. The slightly higher proportion of patients presenting with angina in the IVUS-group may be explained by the underlying clinical profile of IVUS-group, the presence of extreme NIDDM serves as a major additional long-term risk factor and is associated with substantially higher rates of adverse clinical events[14,15,20]. Post-PCI dyspnea outcomes favored IVUS guidance, with a lower overall risk (2/113; 2%) compared to angiography-guided PCI (15/447; 3%), corresponding to a relative risk of 0.53 (95% CI: 0.12–2.30). These findings suggest that while angina symptoms were modestly more common in the IVUS group, IVUS-guided PCI was associated with reduced dyspnea severity.

LIMITATIONS

This study has several limitations. First, its retrospective single-center design limits generalizability and introduces potential selection bias. Second, approximately 30% of patients were lost to follow-up, which may introduce bias if outcomes differed systematically between those followed and those lost. Third, the use of IVUS was operator-dependent and may reflect confounding by indication. Finally, the relatively small sample size, particularly in the IVUS group, limits statistical power to detect differences in less frequent outcomes.

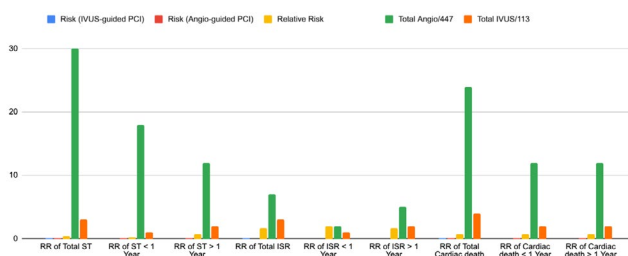

Figure 4: Bar chart to show the Relative risk Angio-guided vs IVUS-guided PCI

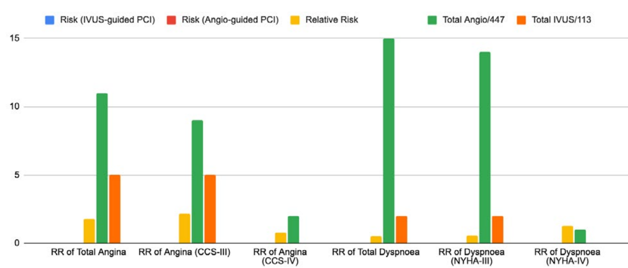

Figure 5: Bar chart to show the Relative risk Angio vs IVUS-guided PCI

CONCLUSION

In this real-world cohort, IVUS-guided PCI was associated with numerically lower rates of stent thrombosis, mortality, and major adverse cardiovascular events compared with angiography-guided PCI; however, most differences did not reach statistical significance. These findings suggest a potential benefit but should be interpreted cautiously given the observational design, loss to follow-up, and potential confounding by indication. Larger, adequately powered prospective studies are needed to confirm these findings and to better define the role of IVUS in routine clinical practice

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AUTHOR CONTRIBUTIONS

All authors actively participated in drafting and critically reviewing the manuscript. Each author has reviewed and given their approval for the final version to be submitted for publication. Dr. Amrita Kumari and Dr. Anuva Kapoor contributed equally as first author. Dr. Bhanu Duggal and Dr. Anuj Mubayi are the corresponding authors. Archana Negi contributed in data collection.

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