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Impact of intravascular imaging on five-year mortality in patients undergoing unprotected left main coronary artery PCI: A propensity score matching analysis from the BIA-LM registry

Short title: Intravascular imaging in left main PCI

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INTRODUCTION

Intravascular imaging-guided percutaneous coronary intervention (PCI) was recently shown to reduce risk of cardiac death, target-vessel-related myocardial infarction (MI) and recurrent revascularization as compared to angiography-guided complex coronary angioplasties [1, 2]. Favourable results of RENOVATE-COMPLEX-PCI and OCTOBER randomized clinical trials (RCT) found reflection in the upgrade to Class I recommendation in latest 2024 European Society of Cardiology guidelines for the management of chronic coronary syndromes [3]. Although both studies permitted patients with unprotected left main coronary artery (LMCA) disease, this population is widely underrepresented in most of conducted RCTs, leaving a significant gap in evidence, especially in terms of all-cause mortality reduction.

Thus, the aim of the study was to assess impact of intravascular imaging-guided PCI on survival in patients undergoing LMCA angioplasty [4].

MATERIAL AND METHODS

Study population, design and procedures

The design and study population of the BIA-LM Registry (Bialystok Left Main Registry) was described before [4]. In brief, the registry included 998 patients undergoing LMCA PCI in years 2008–2022. For the needs of the current analysis, the population included 815 patients with unprotected LMCA who were divided into two groups based on the use of intravascular imaging. In the registry, the decision on the type, timing, and modality of used tools was left to the operator's discretion. Images were obtained using commercially available intravascular ultrasound (IVUS) or optical coherence tomography (OCT) devices. The decision on stent sizing, technique of angioplasty and eventual peri-procedural complication management was made by the operator, based on the experience and local protocols. Post-PCI antiplatelet regiment was prescribed in accordance to the pertinent European Society of Cardiology recommendations.

Analyzed endpoint was mortality at five-year observation, which was obtained for all of the patients from Centre for Information Technology, Minister of Digital Affairs, Poland (valid as for 13.06.2022).

Ethical considerations

The study was approved by the Bioethics Committee of the Medical University of Bialystok, Bialystok, Poland (approval no. APK.002.78.2022 obtained on 10.02.2022) and adheres to Helsinki Declaration as revised in 2013.

Statistical analysis

Summary statistics are presented as number (n) of occurrence and frequencies (%) for categorical variables and mean with standard deviation (SD) for continuous variables if normally distributed. Non-normal distributions of continuous variables are summarized as median and interquartile range (IQR). Differences between subgroups were assessed using Student's t-test or the Wilcoxon rank-sum test for continuous variables and using chi-square test or Fisher exact test (in cases when the expected count of variable was <5) for categorical variables.

Multivariable Cox proportional hazard regressions with variables identified with LASSO cross validation were used to determine mortality predictors. Then, model including variables identified in multivariable analysis for propensity score matching (PSM) was built [a

1 to 1 nearest neighbor matching was performed with replacement (caliper 0.2)] [5]. Finally, we assessed differences between subgroups and moderation effects in predefined groups.

Differences in survival were assessed using Cox proportional hazard regression models in the unmatched and matched cohorts. Results are presented as hazard ratio (HR) with 95% confidence interval (CI). For all analyses, the level of statistical significance was set at $P < 0.05$. All statistical analysis was performed using Stata Statistical Software (StataCorp, 2023, version 18, TX, US).

RESULTS AND DISCUSSION

Detailed information regarding baseline characteristics and outcomes before and after PSM are presented in Figure 1. Unadjusted analysis included 815 patients undergoing LMCA PCI (n = 322 with intravascular imaging). Propensity score matching resulted in final cohort of 278 balanced for clinical and procedural characteristics pairs. Median age was 69 years (IQR 59–77) and majority of patients were male (74%). Out of cohort of 278 patients, 262 patients had IVUS-guided procedure, 16 patients had OCT-only guidance and 2 patients had OCT and IVUS guided PCI. Median pre-procedural minimal lumen area was 5.8 (4.5–7.6) mm^2 and post-PCI minimal stent area 14.5 (11.6–16.8) mm^2. Total time at risk was 654,723 days, median follow-up was 3.6 years during which there were 114 (20.5%) deaths.

Intravascular imaging was associated with 68% (HR, 0.32; 95% CI, 0.24–0.44; $P < 0.001$) mortality reduction in unmatched population. After PSM, use of intravascular imaging was still associated with significant 34% (HR, 0.66; 95% CI, 0.45–0.97; $P = 0.03$) mortality reduction as compared to angiography-guided procedures. The subgroup analyses estimates were directionally consistent toward benefit of intravascular imaging, with significant differences and interaction in patients with chronic kidney disease ($P_{\text{difference}} = 0.007$, $P_{\text{interaction}} = 0.008$) and MI ($P_{\text{interaction}}$ and $P_{\text{difference}} < 0.001$).

Our findings align with trends reported in studies investigating impact of intravascular imaging among patients undergoing complex PCI and gives further insight into benefits in term of all-cause mortality reduction after LMCA angioplasty [1, 2, 4, 6]. In subgroup analysis there was mostly homogenous trend across subgroups for better survival with use of intravascular imaging. Significant interactions suggest that impact of additional tools may be different especially in patients with sustained renal function and those with MI.

When it comes to the overall impact of intravascular imaging, results from RCTs differ from observational studies [7]. While OCTOBER and RENOVATE-COMPLEX-PCI showed reduction in major adverse cardiovascular event (MACE) rates in population undergoing complex PCI, Bruno et al. [8] in their recent analysis of BIFURCAT-ULTRA registry found that IVUS-guided PCI was associated with reduction in MACE rates only in patients with LMCA lesions (HR, 0.62; 95% CI, 0.46–0.83), while such approach was not superior to angiography alone in non-LMCA bifurcations (HR, 1.12; 95% CI, 0.83–1.51; $P_{\text{interaction}} = 0.006$) [1, 2, 8]. Our investigation contributes to the real-world evidence, showing that intravascular imaging may not only be related with reduction in terms of MACE, but also in hard endpoint — all cause mortality [7].

Moreover, we tried to investigate subgroups that may benefit from intracoronary imaging. This is especially important when considering increasing burden of multimorbidity with the concurrent trend towards worse prognosis 30 days after procedure [6]. Better outcomes of intravascular imaging-guided PCI in population of patients with acute coronary syndrome (ACS) and complex coronary artery true bifurcation lesions was reported by Chen et al. [9]. In our analysis MI patients benefited more from intravascular imaging, which might be related with less frequent geographical miss and better stent expansion — both factors known to have negative impact in patients with ACS [9, 10]. We also found that intravascular imaging could be more suitable for patients without chronic kidney disease — whether this may be related with prolonged procedural times and more amount of used dye is yet to be elucidated.

Current study has several limitations apart from those described before [4]. Firstly, the BIA-LM Registry was conducted at an experienced invasive cardiology referral center within a large tertiary hospital. Consequently, one inherent limitation of single-center registries is the restricted generalizability of their outcomes. Secondly, subgroup analysis was conducted in relatively small populations and should be considered hypothesis-generating only. Despite the use of PSM and well-balanced baseline characteristics, significant differences were observed, particularly a higher rate of patients with isolated LMCA lesions in the intravascular imaging arm. Although larger number of patients with additional lesions might have influenced survival, we stress the fact that provided information regard moment of index procedure and analysed data did not include stepwise revascularization during follow-up, which is a standard procedure in our department.

In conclusion, use of intravascular imaging was related with lower rates of five-year mortality in overall and propensity-score matched population. Subgroup analysis revealed potential benefits especially in patients with MI and with sustained renal function. In order to elucidate optimal treatment strategy, future studies investigating differences in outcomes of intravascular-imaging guided PCI and coronary artery bypass grafting should be considered.

Article information

Abstract presentation: Preliminary results were presented at ESC Congress, August 30–September 2, 2024, London, United Kingdom and International Congress of the Polish Cardiac Society, September 19–21, 2024, Katowice, Poland.

Conflict of interest: None declared.

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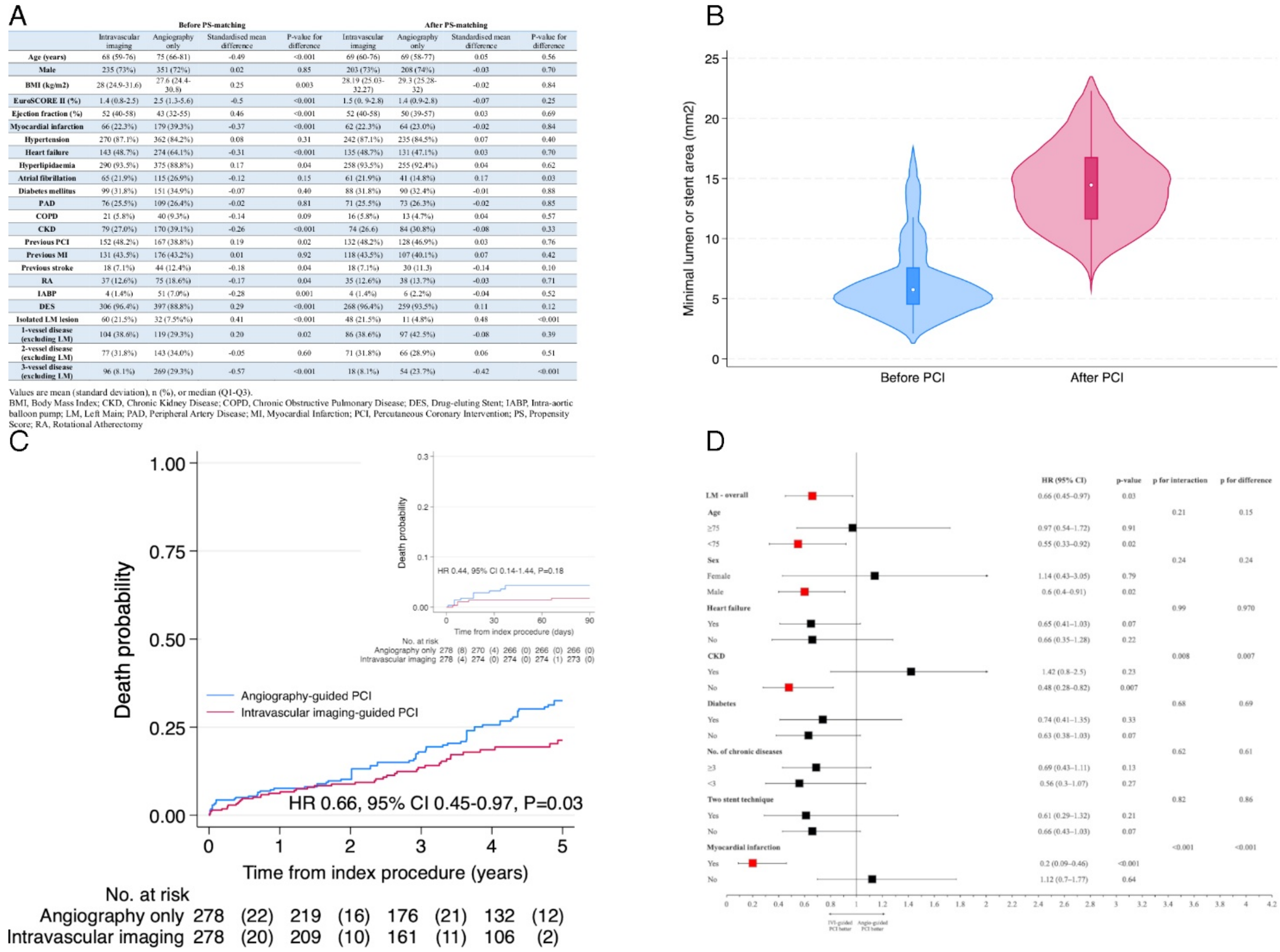
REFERENCES

1. Holm N, Andreasen L, Neghabat O, et al. OCT or Angiography Guidance for PCI in Complex Bifurcation Lesions. New England Journal of Medicine. 2023; 389(16): 1477–1487, doi: 10.1056/nejmoa2307770.
2. Lee SY, Choi KiH, Song YB, et al. RENOVATE-COMPLEX-PCI Investigators. Intravascular Imaging-Guided or Angiography-Guided Complex PCI. N Engl J Med. 2023; 388(18): 1668–1679, doi: 10.1056/NEJMoa2216607, indexed in Pubmed: 36876735.
3. Vrints C, Andreotti F, Koskinas KC, et al. ESC Scientific Document Group. 2024 ESC Guidelines for the management of chronic coronary syndromes. Eur Heart J. 2024; 45(36): 3415–3537, doi: 10.1093/eurheartj/ehae177, indexed in Pubmed: 39210710.
4. Dąbrowski EJ, Dobrzycki S, Kralisz P, et al. Percutaneous coronary intervention for left main coronary artery. Temporal trends and long-term outcomes from the all-comer BIA-LM registry. Pol Heart J. 2024; 82(12): 1247–1258, doi: 10.33963/v.phj.102774, indexed in Pubmed: 39377622.
5. Kowalewski M, Dąbrowski EJ, Kuźma Ł, et al. Tricuspid intervention for less-than-severe regurgitation simultaneously with minimally invasive mitral valve surgery in patients with atrial fibrillation. Kardiol Pol. 2023; 81(10): 990–997, doi: 10.33963/KP.a2023.0137, indexed in Pubmed: 37366255.

6. Dąbrowski EJ, Kożuch M, Dobrzycki S. Left Main Coronary Artery Disease-Current Management and Future Perspectives. J Clin Med. 2022; 11(19), doi: 10.3390/jcm11195745, indexed in Pubmed: 36233613.
7. Mrevlje B, McFadden E, de la Torre Hernández JM, et al. Intravascular ultrasound-guided versus angiography-guided percutaneous coronary intervention in unprotected left main coronary artery disease: A systematic review. Cardiovasc Revasc Med. 2024; 59: 99–108, doi: 10.1016/j.carrev.2023.08.006, indexed in Pubmed: 37657950.
8. Bruno F, Choi KiH, De Filippo O, et al. Impact of intravascular ultrasound for coronary bifurcations treated with last generations stents: insights from the BIFURCAT-ULTRA registry. Eur Heart J Qual Care Clin Outcomes. 2024 [Epub ahead of print], doi: 10.1093/ehjqcco/qcae091, indexed in Pubmed: 39567839.
9. Chen L, Xu T, Xue XJ, et al. Intravascular ultrasound-guided drug-eluting stent implantation is associated with improved clinical outcomes in patients with unstable angina and complex coronary artery true bifurcation lesions. Int J Cardiovasc Imaging. 2018; 34(11): 1685–1696, doi: 10.1007/s10554-018-1393-2, indexed in Pubmed: 29981016.
10. Calvert PA, Brown AJ, Hoole SP, et al. Geographical miss is associated with vulnerable plaque and increased major adverse cardiovascular events in patients with myocardial infarction. Catheter Cardiovasc Interv. 2016; 88(3): 340–347, doi: 10.1002/ccd.26275, indexed in Pubmed: 26527101.



A

	Before PS-matching				After PS-matching			
	Intravascular imaging	Angiography only	Standardised mean difference	P-value for difference	Intravascular imaging	Angiography only	Standardised mean difference	P-value for difference
Age (years)	68 (59-76)	75 (66-81)	-0.49	<0.001	69 (60-76)	69 (58-77)	0.05	0.56
Male	235 (73%)	351 (72%)	0.02	0.85	203 (73%)	208 (74%)	-0.03	0.70
BMI (kg/m2)	28 (24.9-31.6)	27.6 (24.4-30.8)	0.25	0.003	28.19 (25.03-32.27)	29.3 (25.28-32)	-0.02	0.84
EuroSCORE II (%)	1.4 (0.8-2.5)	2.5 (1.3-5.6)	-0.5	<0.001	1.5 (0. 9-2.8)	1.4 (0.9-2.8)	-0.07	0.25
Ejection fraction (%)	52 (40-58)	43 (32-55)	0.46	<0.001	52 (40-58)	50 (39-57)	0.03	0.69
Myocardial infarction	66 (22.3%)	179 (39.3%)	-0.37	<0.001	62 (22.3%)	64 (23.0%)	-0.02	0.84
Hypertension	270 (87.1%)	362 (84.2%)	0.08	0.31	242 (87.1%)	235 (84.5%)	0.07	0.40
Heart failure	143 (48.7%)	274 (64.1%)	-0.31	<0.001	135 (48.7%)	131 (47.1%)	0.03	0.70
Hyperlipidaemia	290 (93.5%)	375 (88.8%)	0.17	0.04	258 (93.5%)	255 (92.4%)	0.04	0.62
Atrial fibrillation	65 (21.9%)	115 (26.9%)	-0.12	0.15	61 (21.9%)	41 (14.8%)	0.17	0.03
Diabetes mellitus	99 (31.8%)	151 (34.9%)	-0.07	0.40	88 (31.8%)	90 (32.4%)	-0.01	0.88
PAD	76 (25.5%)	109 (26.4%)	-0.02	0.81	71 (25.5%)	73 (26.3%)	-0.02	0.85
COPD	21 (5.8%)	40 (9.3%)	-0.14	0.09	16 (5.8%)	13 (4.7%)	0.04	0.57
CKD	79 (27.0%)	170 (39.1%)	-0.26	<0.001	74 (26.6)	84 (30.8%)	-0.08	0.33
Previous PCI	152 (48.2%)	167 (38.8%)	0.19	0.02	132 (48.2%)	128 (46.9%)	0.03	0.76
Previous MI	131 (43.5%)	176 (43.2%)	0.01	0.92	118 (43.5%)	107 (40.1%)	0.07	0.42
Previous stroke	18 (7.1%)	44 (12.4%)	-0.18	0.04	18 (7.1%)	30 (11.3)	-0.14	0.10
RA	37 (12.6%)	75 (18.6%)	-0.17	0.04	35 (12.6%)	38 (13.7%)	-0.03	0.71
IABP	4 (1.4%)	51 (7.0%)	-0.28	0.001	4 (1.4%)	6 (2.2%)	-0.04	0.52
DES	306 (96.4%)	397 (88.8%)	0.29	<0.001	268 (96.4%)	259 (93.5%)	0.11	0.12
Isolated LM lesion	60 (21.5%)	32 (7.5%%)	0.41	<0.001	48 (21.5%)	11 (4.8%)	0.48	<0.001
1-vessel disease (excluding LM)	104 (38.6%)	119 (29.3%)	0.20	0.02	86 (38.6%)	97 (42.5%)	-0.08	0.39
2-vessel disease (excluding LM)	77 (31.8%)	143 (34.0%)	-0.05	0.60	71 (31.8%)	66 (28.9%)	0.06	0.51
3-vessel disease (excluding LM)	96 (8.1%)	269 (29.3%)	-0.57	<0.001	18 (8.1%)	54 (23.7%)	-0.42	<0.001

Values are mean (standard deviation), n (%), or median (Q1-Q3).
BMI, Body Mass Index; CKD, Chronic Kidney Disease; COPD, Chronic Obstructive Pulmonary Disease; DES, Drug-eluting Stent; IABP, Intra-aortic balloon pump; LM, Left Main; PAD, Peripheral Artery Disease; MI, Myocardial Infarction; PCI, Percutaneous Coronary Intervention; PS, Propensity Score; RA, Rotational Atherectomy

Figure 1. Study population baseline characteristics and outcomes. **A.** Baseline characteristics of the studied population before and after propensity score matching. **B.** Violin plot showing baseline minimal lumen area and minimal stent area in left main coronary artery after PCI. **C.** Kaplan–Meier curves showing differences in five-year survival after propensity score matching. Inner graph shows 90-days mortality. **D.** Forrest plot showing subgroup analysis after propensity score matching

Abbreviations: CI, confidence interval; CKD, chronic kidney disease; HR, hazard ratio; LM, left main coronary artery; PCI, percutaneous coronary intervention