

# Coronary Drug Coated Ballon Used in De Novo and In-Stent Restenosis focus on Cardiovascular Event: A Retrospective Single Center Cohort Study

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## ABSTRACT

**Introduction:** Drug-Coated Balloon (DCB) is a semi-compliant angioplasty balloon coated with an antiproliferative drug, primarily used to treat in-stent restenosis (ISR). However, its use for de novo lesions, with the concept of "leaving nothing behind," has gained interest despite limited clinical evidence.

**Materials and Methods:** A retrospective single-center cohort study was conducted on 111 patients (ACS and non-ACS) treated with DCB at Mohammad Hoesin General Hospital Indonesia, between 2023 and 2024. Patients were followed up for 6 months via telecommunication to assess symptoms of Major Adverse Cardiac Events (MACE) and Non-Major Adverse Cardiac Events.

**Results:** Of the 111 patients, 63.1% had ACS and 36.9% were non-ACS. Most DCB use was for de novo lesions (78.4%). Among ACS patients, a significant relationship was found between DCB use in De Novo and cardiac arrest (18.3%,  $p = 0.017$ ), predominantly in patients with hypertension (38.5%,  $p = 0.003$ ) and Acute Kidney Injury (AKI) (30.8%,  $p = 0.045$ ). No significant relationships were observed between DCB use and other MACE (e.g., recurrent heart attack, stroke) or non-MACE outcomes (bleeding, heart failure) in both de novo and ISR lesions, across ACS and non-ACS groups.

**Conclusion:** No significant relationship were observed between ACS and non-ACS patients who used DCB with the incidence of MACE and non-MACE, except for cardiac arrest in ACS patients with uncontrolled hypertension and AKI.

**Keywords:** Drug-Coated Balloon, De Novo, In-Stent Restenosis, Major Adverse Cardiovascular Events

## Introduction

Coronary artery disease (CAD) remains a leading cause of morbidity and mortality worldwide, with percutaneous coronary intervention (PCI) playing a crucial role in its management [1]. Traditionally, drug-eluting stents (DES) have been the standard treatment for de novo coronary lesions and in-stent restenosis (ISR). However, despite advancements in stent technology, ISR remains a significant clinical challenge, often leading to recurrent ischemic events and the need for repeat revascularization [2].

Drug-coated balloons (DCB) have emerged as a promising alternative to DES, particularly in treating ISR and select de

novo lesions. By delivering antiproliferative drugs without the need for permanent metallic scaffolding, DCBs reduce the risk of late stent thrombosis and neoatherosclerosis while preserving vascular integrity. Based on ESC 2023 For many physicians, treatment of ISR remains the primary indication for angioplasty with DCB. At the same time, there is increased interest in the community in using DCB to treat de novo disease. The concept of "leaving nothing behind" is very appealing in certain lesions (i.e., vessels with diffuse disease, side branches in bifurcations and lesions in small vessels) and clinical settings (i.e., diabetes mellitus, multivessel disease, acute coronary syndromes, high bleeding risk patients). Clinical trial data for investigating DCB devices remains scarce. There remains a need for further real-world data to evaluate their long-term safety and effectiveness, particularly regarding major cardiovascular events [3,4].

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Table 1: Recommendations on repeat revascularization [5]

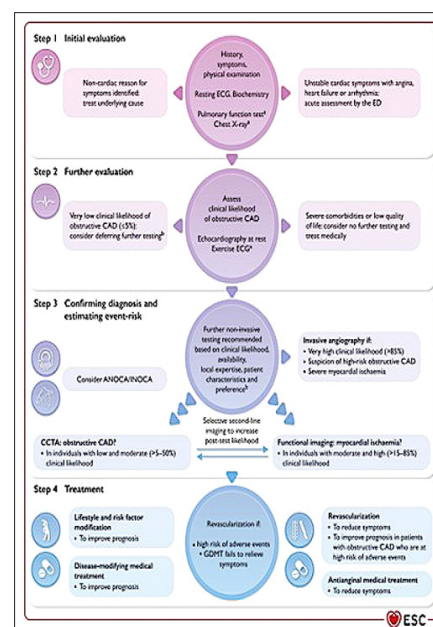
Recommendations on repeat revascularization		
Recommendations	Class <sup>a</sup>	Level <sup>b</sup>
<b>Early post-operative ischaemia and graft failure</b>		
Coronary angiography post-CABG is recommended for patients with: <ul style="list-style-type: none"> <li>● symptoms of ischaemia and/or abnormal biomarkers suggestive of perioperative MI</li> <li>● ischaemic ECG changes indicating large area of risk</li> <li>● new significant wall motion abnormalities</li> <li>● haemodynamic instability.</li> </ul>	I	C
It is recommended that either emergency reoperation or PCI is decided upon by <i>ad hoc</i> consultation in the Heart Team, based on the feasibility of revascularization, area at risk, comorbidities, and clinical status.	I	C
<b>Disease progression and late graft failure</b>		
Repeat revascularization is indicated in patients with a large area of ischaemia or severe symptoms despite medical therapy. <sup>84,334</sup>	I	B
If considered safe, PCI should be considered as first choice over CABG.	Ila	C
<b>Procedural aspects of the revascularization modalities</b>		
<b>CABG</b>		
IMA is the conduit of choice for redo CABG in patients in whom the IMA was not used previously. <sup>344</sup>	I	B
Redo CABG should be considered for patients without a patent IMA graft to the LAD. <sup>340,341,344</sup>	Ila	B
<b>PCI</b>		
Distal protection devices should be considered for PCI of SVG lesions. <sup>348,350,351</sup>	Ila	B
PCI of the bypassed native artery should be considered over PCI of the bypass graft.	Ila	C
<b>Restenosis</b>		
DES are recommended for the treatment of in-stent restenosis of BMS or DES. <sup>373,375,378,379</sup>	I	A
Drug-coated balloons are recommended for the treatment of in-stent restenosis of BMS or DES. <sup>373,375,378,379</sup>	I	A
In patients with recurrent episodes of diffuse in-stent restenosis, CABG should be considered by the Heart Team over a new PCI attempt.	Ila	C
IVUS and/or OCT should be considered to detect stent-related mechanical problems leading to restenosis.	Ila	C

BMS = bare-metal stent; CABG = coronary artery bypass grafting; DES = drug-eluting stent; ECG = electrocardiogram; IMA = internal mammary artery; IVUS = intravascular ultrasound; LAD = left anterior descending artery; MI = myocardial infarction; OCT = optical coherence tomography; PCI = percutaneous coronary intervention; SVG = saphenous vein graft.  
<sup>a</sup>Class of recommendation.  
<sup>b</sup>Level of evidence.

According to the European Society of Cardiology (ESC) 2018 Drug-coated balloons are recommended for the treatment of in-stent restenosis of BMS or DES. A single randomized trial of patients undergoing DCB for restenosis within DES showed superior angiographic outcomes in patients who underwent lesion preparation with scoring balloons vs. standard angioplasty balloons [5].

According to the ESC, categorize ACS into two main groups based on the electrocardiogram (ECG): ST-elevation myocardial infarction (STEMI) and non-ST-elevation acute coronary syndrome (NSTEMI), which includes unstable angina and non-STEMI [6].

The ESC provides guidelines for diagnosing and managing non-ACS (Acute Coronary Syndrome) diseases, focusing on Chronic Coronary Syndromes (CCS). CCS encompasses various conditions resulting from coronary artery disease, including stable angina and stable ischemic heart disease. The ESC recommends a stepwise approach to diagnosis, considering clinical pre-test probability and risk stratification [7]. For patients with low PTP, non-invasive testing may not be necessary, and clinicians can consider a conservative management approach. In contrast, an intermediate or high PTP, should lead to further diagnostic evaluation to confirm or exclude the presence of obstructive CAD (Figure 1) [8].



**Figure 1:** Stepwise approach to the initial evaluation and management of patients with suspected chronic coronary syndrome. a) In selected patients. b) Consider also coronary spasm or microvascular dysfunction. ANOCA: angina with non-obstructive coronary arteries; CAD: coronary artery disease; CCTA: coronary computed tomography angiography; ECG: electrocardiogram; ED: emergency department; GDMT: guideline-directed medical therapy; INOCA: ischaemia with non-obstructive coronary arteries [8].

Based on ESC, major adverse cardiovascular events (MACE) defined as the composite of cardiovascular mortality, myocardial infarction, stroke and revascularisation [9].

Heart failure and bleeding events are generally categorized as non-major adverse cardiovascular events (non-MACE) in clinical research and practice. MACE typically encompasses cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke. While heart failure and bleeding significantly impact patient outcomes, they are usually analyzed separately from MACE. In a systematic review by Bosco et al. (2021), it was noted that definitions of MACE in observational studies vary, but commonly include cardiovascular death, myocardial infarction, and stroke, with heart failure and bleeding often considered separate outcomes [10].

Similarly, bleeding events are frequently evaluated independently as safety endpoints. The Bleeding Academic Research Consortium (BARC) has established standardized bleeding definitions to facilitate consistent reporting in cardiovascular trials [11].

Type 0	No bleeding
Type 1	Bleeding that is not actionable and does not cause the patient to seek treatment
Type 2	Any clinically overt sign of hemorrhage that "is actionable" and requires diagnostic studies, hospitalization, or treatment by a health care professional
Type 3	a. Overt bleeding plus hemoglobin drop of 3 to <5 g/dL (provided hemoglobin drop is related to bleed); transfusion with overt bleeding b. Overt bleeding plus hemoglobin drop <5 g/dL (provided hemoglobin drop is related to bleed); cardiac tamponade; bleeding requiring surgical intervention for control; bleeding requiring IV vasoactive agents c. Intracranial hemorrhage confirmed by autopsy, imaging, or lumbar puncture; intraocular bleed compromising vision
Type 4	CABG-related bleeding within 48 h
Type 5	a. Probable fatal bleeding b. Definite fatal bleeding (overt or autopsy or imaging confirmation)

**Figure 2:** Bleeding Academic Research Consortium (BARC) Classification [10].

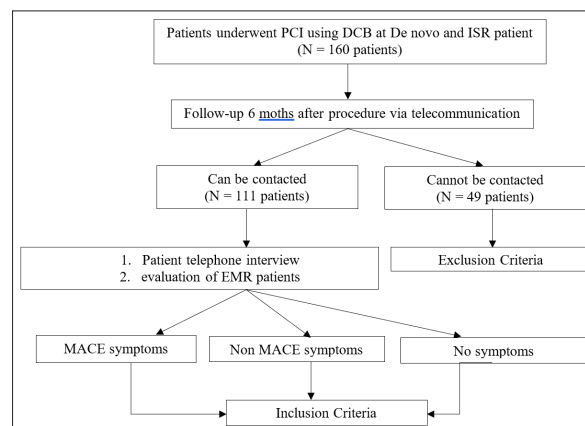
Therefore, while heart failure and bleeding are critical considerations in cardiovascular care, they are typically classified as non-MACE events and analyzed separately to provide a comprehensive understanding of patient risks and treatment outcomes.

This retrospective single-center cohort study aims to assess the outcomes of DCB use in both de novo lesions and ISR, focusing on cardiovascular events such as cardiac arrest, recurrent heart attacks, revascularization, bleeding, heart failure and stroke. By analyzing clinical and procedural data, this study seeks to provide insights into the efficacy and safety of DCBs in interventional cardiology practice.

## Methods

We designed this study as a retrospective cohort study. Therefore, we collect 111 data Acute Coronary Syndrome (ACS) and non-ACS patients who using DCB both de novo and in-stent restenosis from January 2023 to August 2024 at Mohammad Hoesin General Hospital Palembang. Follow-up was carried out via telecommunication and electronic medical record regarding symptoms both Major Adverse Cardiovascular Event and non-Major Adverse Cardiovascular Event that appeared after 6 months of coronary percutaneous intervention procedure. Data then analyzed using SPSS Statistics 23. Data were analyzed using bivariate analysis. Variables with p value <0.05 considered to have a significant relationship.

Patients with ACS and non-ACS criteria using DCB as de novo or in stent restenosis treatment who can be followed-up via telecommunication regarding symptoms both Major Adverse Cardiovascular Event (MACE) and non-Major Adverse Cardiovascular Event that appeared after 6 months of coronary percutaneous intervention procedure are included in the study. Patients who cannot be followed-up are exclude in the exclusion criteria. From 160 patients, we exclude 49 patients who cannot be contacted. In total 111 patients were enrolled in this study (Figure 2).



**Figure 3:** Inclusion and Exclusion Criteria

This study were approved by local ethics committee based on research protocol. The requirement of informed consent was waived by the committee.

## Results

This research was conducted retrospectively Acute Coronary Syndrome (ACS) and non-ACS patients who using DCB both de novo and in-stent restenosis that can be contacted from January 2023 to August 2024.

### Distribution of ISR and De Novo Lesions in ACS and Non-ACS Patients Receiving PCI with DCB

**Table 2: Distribution of MACE and Non-MACE in ACS and Non-ACS Patients Receiving PCI with DCB**

Categories	Samples n = 111	ISR N = 24 (21.6%)	De Novo N = 84 (75.7%)
Acute Coronary Syndrome	70 (63.1%)	10 (41.7%)	60 (69.0%)
Non- Acute Coronary Syndrome	41 (36.9%)	14 (58.3%)	27 (31.0%)
Total	111 (100%)	24 (21.6%)	87 ( 78.3%)

This data is processed using the SPSS statistics 23 using descriptive frequency analysis. From 111 patients, the proportion of ACS in this population is (n = 70, 63.1%) and non-ACS is (n = 41, 36.9%) from this data it is known that distribution of ISR in ACS patients (n = 10, 41.7 %) and ISR in Non-ACS patients (n = 24, 21.6%). De Novo in ACS patients (n = 60, 69.0%) and De Novo in Non-ACS patients (n = 27, 31.0%).

**Bivariate Analysis**

Bivariate analysis of patients who using DCB both De Novo and ISR. This data is processed using the SPSS statistics 23 using bivariate analysis to examine the relationship between two variables ISR and De-Novo with MACE dan non MACE (Table 3).

**Table 3: Bivariate analysis of ISR and De Novo lesions with MACE dan non MACE**

Variabel	Samples n = 111	In Stent Re- stenosis n = 24 (21.6%)	De Novo n = 87 (78.4%)	Nilai P	Odd Ratio (OR)	Confidential Interval 95%	
						Minimum	Maximum
<b>Major Adverse Cardiovascular events</b>							
Cardiac Arrest [n (%)]	13 (11.7%)	2 (8.3%)	11 (12.6%)	0.433	1.592	0.328	7.726
Recurrent Heart Attacks [n (%)]	5 (4.5%)	0 (0.0%)	5 (5.7%)	0.288	1.061	1.007	1.117
Revascularization [n (%)]	1 (0.9%)	1 (4.2%)	0 (0.0%)	0.216	0.958	0.882	1.042
Stroke [n (%)]	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-
<b>Non-Major Adverse Cardiovascular events</b>							
BARC Bleeds type 3 or 5 [n (%)]	2 (1.8%)	0 (0.0%)	2 (2.3%)	0.613	1.024	0.991	1.057
Heart Failure [n (%)]	5 (4.5%)	0 (0.0%)	5 (5.7%)	0.705	0.902	0.096	8.470

There are no significant relationship between uses of DCB in ISR lesions between MACE cardiac arrest (8.3%,  $p = 0.433$ ), recurrent heart attack (0%,  $p = 0.288$ ), revascularization (4.2%,  $p = 0.216$ ), stroke (0.0%), and non-MACE BARC bleeds type 3 or 5 (0.0%) and heart failure (0.0%).

There are no significant relationship between using DCB in De Novo lesions and MACE cardiac arrest (12.6%,  $p = 0.433$ ), recurrent heart attack (5.7%,  $p = 0.288$ ), revascularization (0.0%,  $p = 0.216$ ), stroke (0.0%), and non-MACE BARC bleeds type 3 or 5 (2.3%,  $p = 0.613$ ) and heart failure (5.7%,  $p = 0.705$ ).

**Sub-Analysis of DCB intervention in In Stent Restenosis lesions: ACS VS Non-ACS patients**

This sub-analysis is processed using the SPSS statistics 23 using bivariate analysis to examine the relationship between two variables ACS and non-ACS patients in ISR lesions with MACE dan non MACE (Table 4).

**Table 4: Sub-Analysis of DCB intervention in In Stent Restenosis lesions**

Variabel	Samples n = 111	In Stent Re-stenosis n = 24 (21.6%)		Nilai P	Odd Ratio (OR)	Confidential Interval 95%	
		ACS	Non-ACS			Minimum	Maximum
<b>Major Adverse Cardiovascular events</b>							
Cardiac Arrest [n (%)]	13 (11.7%)	2 (20.0%)	0 (0.0%)	0.331	2.045	0.385	10.879
Recurrent Heart Attacks [n (%)]	5 (4.5%)	0 (0.0%)	0 (0.0%)	0.618	0.906	0.852	0.963
Revascularization [n (%)]	1 (0.9%)	1 (10.0%)	0 (0.0%)	0.090	0.082	0.044	0.153
Stroke [n (%)]	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-
<b>Non-Major Adverse Cardiovascular events</b>							
BARC Bleeds type 3 or 5 [n (%)]	2 (1.8%)	0 (0.0%)	0 (0.0%)	0.827	0.908	0.856	0.964
Heart Failure [n (%)]	5 (4.5%)	0 (0.0%)	0 (0.0%)	0.618	0.906	0.852	0.963

There are no significant relationship between uses of DCB in ISR lesions at ACS patients between MACE cardiac arrest (20.0%,  $p = 0.331$ ), recurrent heart attack (0.0%,  $p = 0.618$ ), revascularization (10.0%,  $p = 0.090$ ) stroke (0.0%) and non-MACE BARC bleeds type 3 or 5 (0.0%,  $p = 0.827$ ), heart failure (0.0%,  $p = 0.618$ ).

There are no significant relationship between uses of DCB in ISR lesions at non-ACS patients and MACE cardiac arrest (0.0%,  $p = 0.331$ ), recurrent heart attack (0.0%,  $p = 0.618$ ), revascularization (0.0%,  $p = 0.090$ ) stroke (0.0%), and non-MACE BARC bleeds type 3 or 5 (0.0%,  $p = 0.827$ ), heart failure (0.0%,  $p = 0.618$ ).

**Sub-Analysis of DCB intervention in De Novo lesions: ACS VS Non-ACS patients**

This sub-analysis is processed using the SPSS statistics 23 using bivariate analysis to examine the relationship between two variables ACS and non-ACS patients in De Novo lesions with MACE dan non MACE (Table 5).



**Table 5: Sub-Analysis of DCB intervention in De Novo lesions**

Variabel	Samples n = 111	De Novo n = 87 (78.4%)		Nilai p	Odd Ratio (OR)	Confidential Interval 95%	
		ACS	Non-ACS			Minimum	Maximum
<b>Major Adverse Cardiovascular events</b>							
Cardiac Arrest [n (%)]	13 (11.7%)	11 (18.3%)	0 (0.0%)	0.017	5.500	1.158	26.116
Recurrent Heart Attacks [n (%)]	5 (4.5%)	5 (8.3%)	0 (0.0%)	0.061	0.519	0.432	0.623
Revascularization [n (%)]	1 (0.9%)	0 (0.0%)	0 (0.0%)	0.459	0.455	0.370	0.558
Stroke [n (%)]	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-
<b>Non-Major Adverse Cardiovascular events</b>							
BARC Bleeds type 3 or 5 [n (%)]	2 (1.8%)	2 (3.3%)	0 (0.0%)	0.499	0.532	0.446	0.635
Heart Failure [n (%)]	5 (4.5%)	2 (3.3%)	3 (10.7%)	0.705	1.108	0.118	10.406

There is a significant relationship between uses of DCB in De Novo lesions at ACS patients and MACE cardiac arrest (18.3%,  $p = 0.017$ ). Analysis showed that using DCB as PCI procedure at ACS patients had 5.500 times greater risk of cardiac arrest compared to non-ACS patients and was statistically significant (OR = 5.500; 95% CI: 1.158–26.116;  $p = 0.017$ ).

There are no significant relationship between uses of DCB in De Novo lesions at ACS patients between MACE recurrent heart attack (8.3%,  $p = 0.061$ ), revascularization (0.0%,  $p = 0.459$ ) stroke (0.0%) and non-MACE BARC bleeds type 3 or 5 (3.3%,  $p = 0.499$ ) and heart failure (3.3%,  $p = 0.705$ ).

There are no significant relationship between uses of DCB in in De Novo lesions at non-ACS patients between MACE cardiac arrest (0.0%), recurrent heart attack (0.0%,  $p = 0.061$ ), revascularization (0.0%,  $p = 0.459$ ) stroke (0.0%) and non-MACE BARC bleeds type 3 or 5 (0.0%,  $p = 0.499$ ), heart failure (10.7%,  $p = 0.705$ ).

**Table 6: Characteristics cause of death of MACE cardiac arrest in ACS patients**

Variabel	Samples n = 96	MACE Cardiac Arrest in ACS n = 13	Nilai p	Odd Ratio (OR)	Confidential Interval 95%	
					Minimum	Maximum
<b>Major Adverse Cardiovascular events</b>						
Cardiac Arrest [n (%)]	83 (86.5%)	5 (38.5%)	0.003	0.160	0.047	0.543
Recurrent Heart Attacks [n (%)]	13 (13.5%)	4 (30.8%)	0.045	4.395	1.125	17.172

After further analysis, a significant relationship between DCB uses in De Novo lesions and MACE cardiac arrest at ACS are influenced by hypertension (38.5%,  $P = 0.003$ ) and AKI (30.8%,  $p = 0.045$ ) as characteristics cause of death. compared to hypertension, AKI has a risk 4.395 times greater and statistically significant (OR = 4.395; 95% CI: 1.125–17.172;  $p = 0.045$ ).

### Discussion

The use of DCBs in the treatment of coronary artery disease, particularly for ISR and increasingly for de novo lesions, represents a significant advancement in PCI strategies. This study aimed to evaluate the cardiovascular events after used DCBs in both lesion types, with a focus on the incidence of MACE and non-MACE outcomes in ACS and non-ACS populations.

Our findings showed that most patients undergoing DCB intervention were from the ACS group (63.1%), and a majority of DCB applications were for de novo lesions (78.4%). Overall, there was no statistically significant association between DCB use and the incidence of MACE or non-MACE events. However, a notable exception was found in ACS patients with de novo lesions, where DCB use was significantly associated

with cardiac arrest (18.3%,  $p = 0.017$ ). Further analysis revealed that this risk was substantially higher among patients with hypertension (38.5%,  $p = 0.003$ ) and acute kidney injury (AKI) (30.8%,  $p = 0.045$ ).

These findings align with previous literature indicating that comorbid conditions such as uncontrolled hypertension and AKI are strong predictors of poor cardiovascular outcomes following PCI. The elevated risk of cardiac arrest in this subgroup suggests that special caution should be exercised when treating high-risk ACS patients with multiple comorbidities.

Importantly, no significant relationships were observed between DCB use and other adverse events such as recurrent myocardial infarction, revascularization, stroke, bleeding, or heart failure across both lesion types (de novo and ISR) and both patient populations (ACS and non-ACS). This suggests a generally favorable safety profile for DCBs, supporting their continued use in clinical practice, particularly when "leaving nothing behind" is desirable—such as in small vessels or patients at high bleeding risk.

Nonetheless, the retrospective nature of this study, the limited follow-up period (6 months), and the relatively small sample size highlight the need for further prospective, multicenter studies with longer follow-up may require additional caution.

### Conclusion

This retrospective single-center cohort study demonstrated that the use of drug-coated balloons (DCBs) in patients with both de novo coronary lesions and in-stent restenosis (ISR) showed no significant association with the incidence of major adverse cardiovascular events (MACE) or non-MACE, except for cardiac arrest in acute coronary syndrome (ACS) patients, which was significantly associated with uncontrolled hypertension and acute kidney injury (AKI). Other MACE components such as recurrent heart attacks, stroke, and revascularization, as well as non-MACE events like heart failure and bleeding, did not show statistically significant differences between ACS and non-ACS groups. These findings suggest that DCBs are generally safe in this population, although careful consideration is warranted for high-risk ACS patients with comorbid conditions like hypertension and AKI.

### Acknowledgements

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### Declarations

#### Ethical Approval and Consent to Participate

This study was approved by the Ethics Committee of Mohammad Hoesin General Hospital, Palembang, Indonesia.

### Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

### Authors' Contributions

SQ contributed to data collection, analysis, and manuscript writing. AM provided clinical oversight, interpretation of cardiology-related data, and manuscript review. KMAA contributed to study design, statistical analysis, and final manuscript approval. All authors read and approved the final manuscript.

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