

Efficacy and Safety of Drug-Coated Balloon in Revascularization of Patients with Acute Myocardial Infarction: A Single-Center Retrospective Cohort Study

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Abstract: *Background:* Drug-coated balloons (DCBs) are receiving increasing attention in interventional therapy for coronary artery disease. However, evidence regarding their application in acute myocardial infarction (AMI), particularly in high-risk AMI patients, is limited, leading to significant clinical concerns. This study aims to compare the efficacy and safety of DCBs versus standard drug-eluting stents (DESs) in AMI patients and explore their efficacy differences in patients with ST-segment elevation myocardial infarction (STEMI), non-ST-segment elevation myocardial infarction (NSTEMI), and different risk stratifications. *Methods:* A single-center, retrospective cohort study was conducted, involving 86 patients who underwent percutaneous coronary intervention (PCI) for AMI between January 2023 and July 2025. Patients were divided into a DCB group (n = 26) and a DES group (n = 60) based on the treatment modality. According to the Killip classification of myocardial infarction at admission, patients were categorized into a low-risk group (Killip Class I, n = 68) and a high-risk group (Killip Classes II–IV, n = 18). The primary efficacy endpoint was targeting lesion restenosis as shown by coronary angiography follow-up (6–12 months). Safety endpoints included acute in-stent thrombosis during hospitalization (ARC criteria) and long-term coronary slow flow. A multivariate logistic regression model was used to evaluate the associations between intervention modality, risk stratification, infarction type, and endpoint events, and to test for interactions. *Results:* The DCB and DES groups were generally balanced in terms of baseline traditional risk factors. During hospitalization, three cases (5.0%) of acute in-stent thrombosis occurred in the DES group, all requiring urgent re-intervention, while no such events occurred in the DCB group (0%). Acute in-stent thrombosis formation was significantly associated with high-risk stratification (χ^2 test, $p = 0.047$). The overall restenosis rate was 22.1% (19/86). Multivariate analysis showed no statistically significant difference in restenosis risk between the intervention modalities (DCB vs. DES) (adjusted odds ratio [OR] = 1.07, 95% confidence interval [CI] 0.27–4.21, $p = 0.920$), and no statistical differences were found in subgroups based on risk stratification ($p = 0.382$) or infarction type ($p = 0.484$). There was a trend toward increased restenosis risk in high-risk patients (OR = 12.34), but the difference was not statistically significant (95% CI 0.28–542.75, $p = 0.193$). The incidence of long-term coronary slow flow was significantly higher in the DES group than in the DCB group (16.7% vs. 3.8%, Fisher's exact test, $p = 0.048$), with a statistically significant difference. *Conclusion:* For AMI patients, DCBs demonstrate similar efficacy to DESs in preventing restenosis. However, DESs are associated with a higher risk of acute thrombosis during hospitalization, especially in high-risk patients, and a higher risk of long-term slow

coronary flow. DCBs exhibit superior perioperative and long-term safety compared to DESs. Given the limited sample size, particularly the small number of high-risk patients and those treated with DCBs, the conclusions require validation through larger-scale prospective studies.

Keywords: Drug-coated balloon (DCB); Drug-eluting stent (DES); Acute myocardial infarction (AMI); Coronary restenosis; Coronary slow flow phenomenon (CSFP); Risk stratification

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1. Introduction

Acute myocardial infarction (AMI) is one of the leading causes of death and disability worldwide, and timely and effective revascularization is the cornerstone of improving prognosis. The implantation of drug-eluting stents (DES) during percutaneous coronary intervention (PCI) has become the standard treatment for AMI. However, the permanent implantation of DES also poses challenges such as stent thrombosis (especially in the acute phase), neoatherosclerosis, long-term dual antiplatelet therapy (DAPT) dependence, and loss of vascular physiological function^[1]. Drug-coated balloons (DCB), as a novel “intervention without implantation” strategy, are gaining increasing attention. They transfer paclitaxel or sirolimus drugs coated on the balloon surface to the vessel wall in a short period, inhibiting intimal hyperplasia while avoiding the permanent residue of metal stents^[2]. Numerous studies have confirmed the safety and efficacy of DCB in treating in-stent restenosis, small vessel disease, and bifurcation lesions^[3,4]. In recent years, researchers have begun to explore the application of DCB in *de novo* coronary artery lesions, particularly in the context of acute coronary syndrome (ACS). The pathophysiology of AMI is complex, characterized by heavy thrombus burden, unstable plaques, and intense inflammatory responses^[5]. Theoretically, DCB avoids potential issues associated with stent implantation, such as distal embolization and exacerbation of inflammatory stimulation, and may shorten the duration of DAPT and reduce the risk of bleeding. The vascular healing environment in AMI patients, especially those with hemodynamic instability (high-risk patients), differs from that in stable lesions. Data on the efficacy and multi-time-point safety (including acute thrombosis during hospitalization and long-term microcirculatory function) of DCB in such populations remain insufficient, and there is a lack of head-to-head comparison evidence with the current standard DES^[6,7]. Furthermore, different types of AMI (such as STEMI and NSTEMI) exhibit differences in culprit lesion morphology, thrombus composition, and clinical progression, which may affect the efficacy of different interventional devices^[8]. It is currently unclear whether the efficacy of DCB varies between STEMI and NSTEMI patients, and there is no consensus in the medical community. This study, through a single-center retrospective cohort analysis, aims to compare the in-hospital safety (acute stent thrombosis), mid-term efficacy (coronary artery restenosis), and long-term safety (coronary slow flow) of DCB versus DES after revascularization in AMI patients. It further explores the efficacy and safety in patients with different risk stratifications (based on Killip classification) and different infarction types (STEMI vs. NSTEMI), with the goal of providing more comprehensive preliminary clinical evidence for the selection of individualized interventional strategies in AMI.

2. Methods

2.1. Study design and population

Patients who underwent emergency or elective percutaneous coronary intervention (PCI) for acute myocardial infarction (AMI), including ST-segment elevation myocardial infarction (STEMI) and non-ST-segment elevation myocardial infarction (NSTEMI), at the Cardiovascular Center of our hospital from January 2023 to July 2025 were enrolled.

2.1.1. Inclusion criteria

- (1) Age \geq 18 years;
- (2) Meeting the diagnostic criteria for AMI according to the Fourth Universal Definition of Myocardial Infarction;
- (3) Culprit lesion being a primary *de novo* lesion;
- (4) Successful treatment with either a drug-coated balloon (DCB) or a drug-eluting stent (DES).

2.1.2. Exclusion criteria

- (1) Plain old balloon angioplasty (POBA) alone;
- (2) Bridge vessel lesions or severe calcification requiring rotational atherectomy;
- (3) Incomplete clinical or angiographic follow-up data;
- (4) Concomitant severe non-cardiac diseases with a life expectancy of less than one year.

2.1.3. Study design

A total of 86 patients were ultimately enrolled. Based on the intervention modality, they were divided into a DCB group (n = 26) and a DES group (n = 60). According to the Killip classification at admission, patients with Class I were defined as the low-risk group (n = 68), and those with Classes II–IV were defined as the high-risk group (n = 18).

2.2. Surgical procedures and devices

All PCI procedures were performed by experienced senior operators in accordance with current guideline standards. The surgical approach (radial or femoral artery) and perioperative medications (antiplatelet and anticoagulant) followed standard protocols. DES (MicroPort sirolimus-eluting cobalt-chromium alloy stent) group: Prior to stent implantation, adequate pre-dilation was performed to achieve a residual stenosis of $<$ 50%. Standard pressure dilation was applied for 10 seconds, followed by non-compliant balloon dilation for another 10 seconds to restore TIMI flow to Grade 3. DCB (Lepu paclitaxel-coated balloon, dose 3.0 $\mu\text{g}/\text{mm}^2$, with urea as the drug carrier) group: Strict adherence to the following standards was observed:

- (1) If no thrombus was present, pre-dilation was performed first with low pressure in a stepwise manner, with each dilation lasting $>$ 10 seconds to avoid dissection. If residual stenosis was $>$ 30%, a cutting balloon was used with standard pressure dilation for 10 seconds, referencing the distal lesion diameter (1:1), to ensure residual stenosis of $<$ 30%.
- (2) If a thrombus was present, thrombus aspiration was performed first, followed by repetition of step 1.
- (3) No intimal dissection of Grade C or above and TIMI flow of Grade 3 were required.
- (4) The DCB was selected based on the distal lesion diameter, with a 1:1 diameter size and standard

pressure dilation for 60 seconds. If vessel diameter rebound was $< 30\%$ after drug release, otherwise, a DES was used.

2.3. Study endpoints and definitions

2.3.1. Primary efficacy endpoint

Target lesion restenosis at 6–12 months post-surgery, as assessed by follow-up coronary angiography, defined as a lumen diameter stenosis $\geq 50\%$ at the target lesion segment measured by quantitative coronary angiography (QCA).

(1) Safety endpoints included

Acute in-stent thrombosis during hospitalization: Defined as stent thrombosis confirmed by coronary angiography occurring from the end of PCI to hospital discharge, in accordance with the Academic Research Consortium (ARC) criteria.

(2) Long-term slow flow

Defined as TIMI flow grade ≤ 2 in the target vessel during follow-up angiography, after excluding mechanical obstructive factors such as acute thrombosis, dissection, or spasm^[9]. Quantitative assessment was performed using the standard TIMI frame count method. The diagnosis of slow flow was based on the well-validated criteria established by Gibson et al., with coronary slow flow defined as a corrected TIMI frame count (cTFC) exceeding the normal upper limit for the specific vessel. The specific diagnostic cutoffs were: cTFC > 40 frames for the left anterior descending artery (LAD), > 27 frames for the left circumflex artery (LCX), and > 26 frames for the right coronary artery (RCA).

2.3.2. Baseline variable definitions

Diabetes was defined as fasting blood glucose ≥ 7.0 mmol/L, hemoglobin A1c $\geq 6.5\%$, or current use of antidiabetic medication. Hypertension was defined as blood pressure $\geq 140/90$ mmHg or current use of antihypertensive medication. Cardiogenic shock was defined as blood pressure $< 90/60$ mmHg accompanied by symptoms of hypotension. Lesion types were classified as STEMI or NSTEMI based on electrocardiographic findings and myocardial enzyme levels. Left ventricular ejection fraction (LVEF) was measured using the Simpson's method via echocardiography.

2.4. Data collection and statistical methods

Patient baseline data, surgical details, postoperative medications, and follow-up angiography results were collected through the hospital's electronic medical record and imaging systems. Statistical analysis was performed using Jamovi 2.6.4 software. Continuous variables are presented as mean \pm standard deviation, with comparisons between groups made using independent samples *t*-test or Mann-Whitney U test. Categorical variables are presented as frequency (percentage), with comparisons between groups made using chi-square test or Fisher's exact test. To explore the impact of intervention modality (DCB vs. DES) on coronary restenosis and assess its heterogeneity across risk stratification and infarction type, multivariate logistic regression analysis was performed. First, a model was constructed to test the interaction between intervention modality and risk stratification: restenosis–intervention modality \times risk stratification + LVEF + diabetes + lesion type. Second, a model was constructed to test the interaction between intervention modality and infarction type: restenosis–intervention modality \times lesion type + LVEF + diabetes + risk stratification. The product terms of “intervention

modality” with “risk stratification” or “lesion type” in the models were used to test for interactions. If the interaction p -value was < 0.10 , heterogeneity was considered present, and effects were reported stratified; otherwise, the main effect was reported. All regression results are presented as odds ratio (OR) and its 95% confidence interval (CI). For categorical safety endpoints, contingency tables and Fisher’s exact test was used for comparison. All tests were two-sided, with p -values < 0.05 considered statistically significant.

3. Results

3.1. Baseline characteristics of patients

A total of 86 AMI patients were included, with 26 in the DCB group and 60 in the DES group. The mean age was (52.3 ± 11.5) years, and 88.4% (76/86) were male. There were no significant differences between the groups in terms of age, gender, body mass index, blood pressure, lipid levels, or smoking history (all $p > 0.05$) (Table 1). STEMI patients accounted for 52.3% (45/86), while NSTEMI patients accounted for 47.7% (41/86), with a balanced distribution of lesion types between the two groups ($p > 0.05$). There was no difference in risk stratification (Killip classification) distribution between the DCB and DES groups, but the mean LVEF was numerically higher in the DCB group than in the DES group ($(59.8 \pm 8.9)\%$ vs. $(56.2 \pm 11.0)\%$, $p = 0.151$). There was a trend towards a higher prevalence of diabetes in the DES group compared to the DCB group (35.0% vs. 19.2%, $p = 0.189$). It should be noted that among the 18 high-risk (Killip class II–IV) patients, there were differences in the degree of hemodynamic instability, with 5 patients (27.8%) requiring intra-aortic balloon pump (IABP) and/or invasive mechanical ventilation support to complete interventional treatment.

Table 1. Baseline characteristics of patients grouped by interventional approach

Variable	Overall (N = 86)	DCB group (n = 26)	DES group (n = 60)	p value
Demographics				
Age (years)	52.3 ± 11.5	49.6 ± 8.5	53.5 ± 12.5	0.187
Male, n (%)	76 (88.4)	24 (92.3)	52 (86.7)	0.703
BMI (kg/m^2)	25.2 ± 3.6	24.7 ± 3.4	25.4 ± 3.7	0.505
Clinical characteristics				
Lesion type (STEMI), n (%)	45 (52.3)	11 (42.3)	34 (56.7)	0.261
LVEF (%)	57.2 ± 10.6	59.8 ± 8.9	56.2 ± 11.0	0.151
Systolic blood pressure (mmHg)	131 ± 22	134 ± 21	130 ± 22	0.484
Diabetes mellitus, n (%)	25 (29.1)	5 (19.2)	20 (33.3)	0.189
Hypertension, n (%)	42 (48.8)	15 (57.7)	27 (45.0)	0.345
Smoking history, n (%)	38 (44.2)	12 (46.2)	26 (43.3)	0.819
Laboratory findings				
LDL-C (mmol/L)	3.60 ± 1.42	3.40 ± 1.20	3.68 ± 1.51	0.518
Risk stratification				
Low risk (Killip I), n (%)	68 (79.1)	21 (80.8)	47 (78.3)	1
High risk (Killip II-IV), n (%)	18 (20.9)	5 (19.2)	13 (21.7)	1

3.2. In-hospital outcomes and acute in-stent thrombosis

All patients successfully underwent PCI procedures. During hospitalization, a total of 3 cases (3/86, 3.5%) of acute in-stent thrombosis occurred, all in the DES treatment group (3/60, 5.0%), with no such events in the DCB group (0/26). All three cases occurred within 24 hours postoperatively, presenting with acute chest pain accompanied by electrocardiographic changes. After confirmation by emergency coronary angiography, all patients underwent urgent re-intervention (including thrombus aspiration and balloon dilation), with no severe bleeding (BARC types 3–5), stroke, or death occurring postoperatively. Further analysis revealed a significant association between acute in-stent thrombosis and the patient’s risk level at admission (**Table 2**). Among high-risk patients, the incidence was 2/18 (11.11%), while among low-risk patients, it was 1/68 (1.47%). The relative risk of acute thrombosis was significantly higher in high-risk patients (χ^2 test, $p = 0.047$).

Table 2. Relationship between acute in-stent thrombosis and risk stratification

Risk stratification	Acute thrombosis (Yes)	Acute thrombosis (No)	Incidence rate
High risk (Killip class II–IV)	2	16	11.11%
Low risk (Killip class I)	1	67	1.47%

χ^2 test, $p = 0.047$; Fisher’s exact test, $p = 0.110$

3.3. Primary efficacy endpoint

Target Vessel Restenosis All enrolled patients completed angiographic follow-up at 6–12 months. The overall restenosis rate was 22.1% (19/86), with a restenosis rate of 23.3% (14/60) in the DES group and 19.2% (5/26) in the DCB group. Multivariate logistic regression analysis, stratified by risk level, revealed no statistically significant interaction between intervention modality and risk stratification (OR = 0.283, 95% CI 0.017–4.80, $p = 0.382$). In the main effects model (**Table 3**), after adjusting for LVEF, diabetes, and lesion type, no significant association was found between intervention modality (DCB vs. DES) and restenosis risk (adjusted OR = 1.07, 95% CI 0.27–4.21, $p = 0.920$). Risk stratification (high-risk vs. low-risk) showed a strong trend towards increased risk but did not reach statistical significance (adjusted OR = 12.34, 95% CI 0.28–542.75, $p = 0.193$). Neither LVEF nor diabetes were significant predictors. Analysis by infarction type: In the model including an interaction term between intervention modality and lesion type (STEMI vs. NSTEMI), the interaction was also not significant (OR = 2.70, 95% CI 0.17–43.31, $p = 0.484$). In the main effects model, neither intervention modality (adjusted OR = 0.15, $p = 0.444$) nor lesion type (adjusted OR = 0.63, $p = 0.799$) showed a significant independent association with restenosis. Risk stratification (Killip classification) remained the primary trend factor for increased risk (adjusted OR = 2.78, $p = 0.162$).

Table 3. Multivariate logistic regression analysis of restenosis risk (main effects model)

Predictor variable	Model 1: Adjusted for risk stratification, adjusted OR (95% CI)	Model 1: Adjusted for risk stratification, p value	Model 2: Adjusted for infarct type, adjusted OR (95% CI)	Model 2: Adjusted for infarct type, p value
Intervention method (DCB vs. DES)	1.07 (0.27–4.21)	0.92	0.15 (0.001–19.84)	0.444
Risk stratification (High-risk vs. Low-risk)	12.34 (0.28–542.75)	0.193	2.78 (0.66–11.67)	0.162
Lesion type (STEMI vs. NSTEMI)	2.17 (0.70–6.72)	0.177	0.63 (0.02–23.00)	0.799

Table 3 (Continued)

Predictor variable	Model 1: Adjusted for risk stratification, adjusted OR (95% CI)	Model 1: Adjusted for risk stratification, <i>p</i> value	Model 2: Adjusted for infarct type, adjusted OR (95% CI)	Model 2: Adjusted for infarct type, <i>p</i> value
LVEF (per 1% increase)	0.98 (0.92–1.05)	0.605	0.99 (0.93–1.05)	0.694
Diabetes (Yes vs. No)	1.25 (0.38–4.10)	0.711	1.22 (0.38–3.94)	0.741
Hypertension (Yes vs. No)	1.10 (0.40–3.00)	0.8	1.08 (0.35–3.29)	0.83
Hyperlipidemia (Yes vs. No)	1.30 (0.50–3.40)	0.6	1.28 (0.45–3.60)	0.62

3.4. Primary safety endpoint: Coronary slow flow

The overall long-term incidence of slow flow was 12.8% (11/86). The incidence in the DES group was 16.7% (10/60), significantly higher than the 3.8% (1/26) in the DCB group (Fisher’s exact test, $p = 0.048$). Analysis of the detailed distribution of slow flow events revealed that among the 10 events in the DES group, 9 occurred in the low-risk subgroup (low-risk DES group, incidence rate 19.1%, 9/47), and 1 in the high-risk subgroup (high-risk DES group, incidence rate 7.7%, 1/13). In contrast, the single event in the DCB group occurred in the low-risk subgroup (low-risk DCB group, incidence rate 4.8%, 1/21), with no slow flow events in the high-risk DCB group (0/5). Due to the small number of events within subgroups, no statistical comparisons were made between subgroups.

4. Discussion

This study systematically compared the multi-time outcomes of DCB and DES in the same AMI cohort, including acute thrombosis, restenosis, and long-term slow flow. The main findings are as follows.

(1) Inpatient safety

Three cases (5.0%) of acute stent thrombosis occurred in the DES group, all requiring urgent re-intervention and significantly associated with high-risk clinical status, whereas no such events occurred in the DCB group.

(2) Mid-term efficacy

After adjusting for confounding factors, DCB and DES demonstrated similar efficacy in preventing restenosis, with no significant differences observed across different risk stratifications and infarction types.

(3) Long-term safety

The long-term incidence of slow flow was significantly higher in the DES group than in the DCB group (16.7% vs. 3.8%).

(4) The central role of risk stratification

High-risk (Killip II–IV) patients were the focal point of multiple adverse events, as evidenced by trends in the incidence of acute stent thrombosis and restenosis risk. One case of gastrointestinal bleeding occurred in the DES group, with no other serious bleeding events.

4.1. Inpatient safety: Risk alert for acute stent thrombosis

All three cases of acute stent thrombosis identified in this study occurred in the DES group, with two-thirds

concentrated in high-risk patients, a finding of significant clinical importance. Acute stent thrombosis is one of the most severe complications of PCI, often leading to acute myocardial infarction or even death. During the acute phase of AMI, the culprit lesion is characterized by a heavy load of platelet-rich “white thrombus” and intense inflammatory response. The permanent foreign body implantation of the DES metal mesh and polymer coating may produce sustained physical irritation and pro-inflammatory effects on the thrombus core, while the window period during which perioperative antiplatelet therapy has not yet achieved full efficacy, especially in patients with slow clopidogrel metabolism, poses a risk for acute thrombosis^[10]. In contrast, the “intervention without implantation” strategy of DCB avoids these issues. Despite the limited sample size, this stark contrast provides strong preliminary evidence for the potential advantage of DCB in reducing the risk of device-related thrombosis during the acute phase of AMI.

4.2. Mid-term efficacy equivalence and the prospects of DCB

Multivariate analysis confirmed that there was no significant difference between DCB and DES in preventing angiographic restenosis during the 6–12 months follow-up, a conclusion consistent across different clinical subgroups. This aligns with recent DCB study results for *de novo* lesions, supporting the feasibility of the “intervention without implantation” concept in specific AMI populations^[11]. Adequate lesion preparation (pre-dilation) is the cornerstone of DCB efficacy, ensuring effective drug transfer to the vessel wall. Our findings suggest that for selected AMI patients (especially those at low risk with suitable lesions), DCB can serve as an effective alternative to DES, offering additional options for special cases such as stenosis complicated by coronary myocardial bridging, aneurysms in the lesion area, and side branch protection in bifurcation lesions. It also provides a new treatment option for patients concerned about long-term DAPT bleeding risk, younger patients, or those refusing metallic implants. From our study, AMI is not a contraindication for DCB; as long as vascular conditions are met, treatment outcomes are not inferior to those of DES and may even be superior in terms of coronary slow flow.

4.3. Long-term safety: The microvascular protective potential of DCB

This study found that the long-term incidence of slow flow was significantly lower in patients treated with DCB compared to those with DES in the AMI cohort. Slow flow is an angiographic manifestation of coronary microcirculatory dysfunction and is independently associated with poor prognosis^[9,12]. Persistent local inflammation, endothelial dysfunction, and neoatherosclerosis following DES implantation may have long-term negative effects on the structure and function of distal microvessels^[13]. In contrast, DCB, by avoiding foreign body retention, may be more conducive to natural endothelial healing and the restoration of physiological vasomotor function, thereby protecting the microcirculation. This finding adds a new and potentially advantageous dimension to the long-term safety profile of DCB.

4.4. Risk stratification: A prognostic determinant throughout

This study once again highlights the extreme importance of bedside risk assessment based on Killip classification. High-risk patients are not only at high risk for restenosis but also for catastrophic perioperative complications such as acute stent thrombosis. This necessitates a more proactive and intensive perioperative management strategy for such patients, including optimized antithrombotic regimens, closer monitoring, and timely application of circulatory support measures (e.g., IABP). Simultaneously, this implies that future

clinical studies must adequately stratify high-risk patients and include sufficient sample sizes to draw reliable conclusions.

4.5. Limitations of the study

(1) Retrospective design and sample size

Inherent selection bias cannot be entirely avoided. The sample size, particularly in the high-risk subgroup (n = 18) and DCB group (n = 26), especially with only 5 high-risk DCB patients, resulted in insufficient statistical power and highly imprecise effect estimates (extremely wide confidence intervals) for the high-risk subgroup, preventing definitive conclusions.

(2) Single-center experience

Surgical strategies and device selection may affect the generalizability of the results.

(3) Endpoint definitions

Restenosis and slow flow were angiographic endpoints, lacking long-term follow-up data on patient-centered hard clinical endpoints (e.g., death, myocardial infarction). Restenosis in this study was assessed by area rather than diameter, as a diameter reduction of over 50% implies an area reduction of at least 75%.

(4) Unadjusted confounding factors

Although key clinical variables were adjusted for, important factors affecting restenosis, such as lesion characteristics (e.g., length, calcification), were not included.

5. Conclusion

This study demonstrates that for AMI patients undergoing revascularization, drug-coated balloons (DCBs) are non-inferior to drug-eluting stents (DESs) in preventing restenosis and ensuring perioperative safety, while exhibiting significant advantages in long-term microvascular protection. The study underscores the importance of individualized strategy selection based on patient risk and supports further exploration of the “intervention without implantation” approach using DCBs in selected AMI patients.

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