

Comparative Efficacy of Drug-Coated Balloon and Drug-Eluting Stent in Patients with Hemodynamically Stable Acute Coronary Syndrome: A Retrospective Cohort Study Focusing on Long-Term Vascular Structure and Function

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Abstract: *Objective:* To compare the differences in long-term vascular structure and function after treatment with drug-coated balloons (DCB) versus drug-eluting stents (DES) in patients with hemodynamically stable acute coronary syndrome (ACS). *Methods:* This was a single-center retrospective cohort study. Patients admitted for ACS between November 2022 and June 2025, with Killip class 1–2, who underwent percutaneous coronary intervention (PCI) and completed 6–12 months of angiographic follow-up were consecutively enrolled. Patients with cardiac arrest, those requiring mechanical ventilation, or those with severe non-cardiovascular comorbidities were excluded. Based on the final interventional technique, patients were divided into the DES group (n = 62) and the DCB group (n = 42). The primary endpoint was late lumen loss (LLL) measured by quantitative coronary angiography (QCA). Secondary endpoints included coronary slow flow phenomenon (CSFP), coronary restenosis, and repeat revascularization during follow-up. Multivariable rank regression was used to adjust for confounding factors such as left ventricular ejection fraction (LVEF) and acute myocardial infarction (AMI) status. *Results:* After multivariable adjustment, the extent of LLL was significantly lower in the DCB group than in the DES group ($\beta = 21.90, p < 0.001$). Subgroup analysis demonstrated that this advantage persisted across different LVEF levels. Importantly, the incidence of CSFP was significantly lower in the DCB group than in the DES group (2.4% vs. 17.7%, $p = 0.016$). No statistically significant differences were observed between the two groups in terms of restenosis rate and repeat revascularization rate. *Conclusion:* In patients with hemodynamically stable ACS, the DCB interventional strategy demonstrates significant advantages over DES in suppressing LLL and preventing CSFP.

Keywords: Acute coronary syndrome (ACS); Drug-coated balloon (DCB); Drug-eluting stent (DES); Late lumen loss (LLL); Coronary slow flow phenomenon (CSFP)

Online publication: March 3, 2026

1. Introduction

Acute coronary syndrome (ACS) is a clinical emergency, with acute myocardial infarction (AMI) being a leading cause of clinical mortality and heart failure. Timely percutaneous coronary intervention (PCI) is the preferred method for improving prognosis. Drug-eluting stents (DES), capable of providing immediate mechanical support to rapidly restore blood flow, have become the primary choice for PCI^[1,2]. However, DES also introduces long-term risks, including acute, subacute, and late stent thrombosis, intimal hyperplasia, and impaired vasomotor function, leading to a decline in long-term efficacy, with limited research on outcomes beyond 10 years. These issues may be associated with persistent local inflammation and endothelial dysfunction^[3]. In recent years, drug-coated balloons (DCB) have emerged as an “intervention without implantation” strategy, delivering short-term drug administration without leaving permanent implants, thereby allowing the vessel to more closely resemble its native physiological state. The mechanism still involves inhibiting excessive intimal hyperplasia and promoting physiological vascular healing^[4,5]. However, their application in AMI remains controversial, as DCB has not yet been incorporated into guidelines for AMI treatment and is mostly used for relatively stable lesions^[6]. The efficacy of PCI depends not only on maintaining lumen patency but also on microcirculatory function. Late lumen loss (LLL) is an imaging indicator used to assess the degree of intimal hyperplasia, while coronary slow flow phenomenon (CSFP) is a clinical condition observed during angiography that is associated with microvascular dysfunction and independently linked to adverse cardiovascular outcomes^[7]. This study focuses on patients with hemodynamically stable ACS, employing multivariate statistical methods to adjust for known confounding factors, aiming to further investigate whether differences exist between DCB and DES in terms of LLL and CSFP, as well as to explore the relationship between LLL and CSFP.

2. Methods

2.1. Study design and population

This study was a single-center retrospective cohort study that screened patients admitted for ACS and undergoing PCI between November 2022 and June 2025.

The inclusion criteria are as follows:

- (1) Hemodynamically stable with a Killip class of 1 or 2 at admission;
- (2) Successful PCI and completion of coronary angiography follow-up at 6–12 months (180–360 days) post-procedure.

The exclusion criteria are as follows:

- (1) Killip class 3 or 4;
- (2) Successful resuscitation from cardiac arrest;
- (3) Respiratory failure requiring intubation and mechanical ventilation;
- (4) Severe non-cardiovascular comorbidities (e.g., advanced malignancy, end-stage liver or renal failure);
- (5) Incomplete clinical or imaging follow-up data.

Patients were ultimately divided into the DES group and the DCB group based on the final management of the culprit lesion.

2.2. Interventional strategy and procedures

All PCI procedures were performed by experienced interventional cardiologists. The treatment strategy (DES or DCB) was determined based on a comprehensive assessment of lesion characteristics (thrombus burden, vessel

size, presence of dissection) during the procedure.

For DES (minimally invasive rapamycin-eluting cobalt-chromium alloy stent) group, adequate pre-dilation was performed before stent implantation to achieve a residual stenosis of < 50%, followed by standard-pressure dilation for 10 seconds and subsequent non-compliant balloon dilation for 10 seconds to restore TIMI grade 3 blood flow.

For DCB (lepu paclitaxel-eluting drug-coated balloon, dose 3.0 µg/mm², drug matrix: urea) group, strict adherence to the following operational standards:

- (1) If no thrombus was present, adequate pre-dilation was performed first; if residual stenosis was > 30%, a cutting balloon was used for dilation at standard pressure for 10 seconds, referencing the distal lesion diameter (1:1), to ensure residual stenosis of < 30%;
- (2) If thrombus was present, thrombus aspiration was performed first, followed by repetition of step (1);
- (3) No intimal dissection of type C or above and TIMI grade 3 blood flow;
- (4) DCB selection was based on the distal lesion diameter (1:1 ratio) with standard-pressure dilation for 60 seconds. If vessel diameter rebound was < 30% after drug release, the procedure was considered successful; otherwise, DES was used.

2.3. Endpoint definitions and assessments primary endpoint: Late lumen loss

Measurements were obtained by two independent technicians using QCA software, and the average value was used for analysis. LLL was defined as the post-procedure minimal lumen diameter (MLD) minus the follow-up MLD^[8]. The secondary endpoints are as listed.

2.3.1. CSFP during follow-up

CSFP was quantitatively assessed using the standard TIMI frame count method. The criteria for slow flow were based on the established and widely validated method described by Gibson *et al.*^[7]. Coronary slow flow was defined as a corrected TIMI frame count (cTFC) exceeding the normal upper limit for the respective vessel. The specific diagnostic cutoffs were as follows:

- (1) cTFC > 40 frames for the left anterior descending artery (LAD);
- (2) cTFC > 27 frames for the left circumflex artery (LCX);
- (3) cTFC > 26 frames for the right coronary artery (RCA)^[7].

In addition, slow flow was also defined qualitatively as a TIMI flow grade ≤ 2.

2.3.2. Restenosis

Restenosis was defined as ≥ 50% diameter stenosis of the target lesion vessel segment at follow-up^[9].

2.3.3. Repeat intervention

Repeat intervention was defined as any revascularization performed during the follow-up period due to ischemia-related symptoms or objective evidence related to the target lesion, with QCA-confirmed stenosis of ≥ 70%^[10].

2.4. Statistical analysis

Jamovi 2.6.4 software was used. Continuous variables were described as median [interquartile range] or mean ± standard deviation, and group comparisons were performed using the Mann-Whitney U test or independent samples *t*-test based on Shapiro-Wilk test results. Categorical variables were described as frequencies (%), and

group comparisons were made using the chi-square test or Fisher’s exact test. Given the severely right-skewed distribution of the primary endpoint LLL, rank transformation (RANK_LLL) was used for multivariate analysis to enhance robustness. Multiple linear regression models were constructed: Model 1: Adjusted for interventional method + left ventricular ejection fraction (LVEF). Model 2: Model 1 + acute myocardial infarction (AMI) status. Model 3 (Full model): Model 2 + low-density lipoprotein cholesterol (LDL-C) + history of diabetes. Additionally, subgroup analysis was performed based on the median LVEF. All tests were two-sided, and $P < 0.05$ was considered statistically significant.

3. Results

3.1. Baseline characteristics

The cohort attributes of the stable ACS population underwent rigorous screening, resulting in a total of 104 patients who met all inclusion criteria being included in the final analysis, with 62 patients in the DES group and 42 patients in the DCB group. Given the inclusion criteria of this study (excluding Killip class III-IV patients), the entire study cohort exhibited a relatively favorable baseline cardiac function status, with a median left ventricular ejection fraction (LVEF) of 62%, indicating that the overall myocardial injury in the enrolled patients was relatively limited and hemodynamically stable. However, significant clinical treatment selection bias still existed. As shown in **Table 1**, the baseline risk characteristics of the DES group were notably higher than those of the DCB group: The proportion of patients with acute myocardial infarction (AMI, including STEMI and NSTEMI) in the DES group was as high as 80.6% (50/62), while it was only 54.8% (23/42) in the DCB group, with a highly statistically significant difference between the two groups ($p = 0.005$). Meanwhile, the mean LVEF in the DES group was $59.3\% \pm 9.0\%$, which was lower than that in the DCB group ($62.6\% \pm 5.4\%$) ($p = 0.039$). There were no statistically significant differences between the two groups in terms of other traditional cardiovascular risk factors, such as age, gender composition, low-density lipoprotein cholesterol (LDL-C) levels, and diabetes prevalence ($p > 0.05$).

Table 1. Baseline characteristics of patients

Characteristic	DES group (n = 62)	DCB group (n = 42)	p-value
Age (years)	53.6 ± 12.5	50.7 ± 10.7	0.223
Male, n(%)	53 (85.5%)	37 (88.1%)	0.706
AMI, n(%)	50 (80.6%)	23 (54.8%)	0.005
LVEF, %	59.3 ± 9.0	62.6 ± 5.4	0.039
LDL-C, mmol/L	3.53 ± 1.56	3.03 ± 1.07	0.076
Diabetes, n(%)	15 (24.2%)	6 (14.3%)	0.217
Current smoker, n(%)	26 (41.9%)	17 (40.5%)	0.882
Hypertension, n(%)	27 (43.5%)	23 (54.8%)	0.261
Renal insufficiency, n(%)	2 (3.2%)	0 (0.0%)	1.000

Note: Data are presented as mean ± standard deviation or frequency (percentage). AMI: Acute myocardial infarction; LVEF: Left ventricular ejection fraction; LDL-C: Low-density lipoprotein cholesterol. *P*-values are derived from independent samples *t*-tests or chi-square tests.

3.2. Primary endpoint: Late lumen loss

Postoperative LLL is a critical indicator for evaluating the long-term efficacy of interventional therapy. In this study, the overall distribution of LLL among the 104 patients exhibited a right-skewed pattern (Shapiro-Wilk test, $p < 0.001$). The median LLL (0.270 mm) was used for descriptive purposes, and nonparametric methods were employed for analysis. Univariate analysis revealed that patients treated with DCB had a lower median LLL compared to those treated with drug-eluting stents (DES) (0.150 mm [0.112, 0.241] vs. 0.340 mm [0.262, 0.488], Mann-Whitney U = 580, $p < 0.001$), with a large effect size (rank-biserial correlation coefficient = -0.555), indicating a statistically significant difference. Baseline characteristics between the two groups were imbalanced in terms of the proportion of acute myocardial infarction (AMI) and left ventricular ejection fraction (LVEF), among other factors (**Table 1**), which may have influenced the intergroup comparison results for LLL. To address this, multivariate linear regression analysis was employed.

As shown in **Table 2**, in Model 1, after adjusting solely for LVEF, the interventional approach (DES vs. DCB) emerged as an independent factor influencing LLL ranking ($\beta = 26.94$, $p < 0.001$). In Model 2, after simultaneously adjusting for LVEF and AMI status, the effect size of the interventional approach decreased, but its strong association with a lower LLL ranking persisted ($\beta = 23.82$, $p < 0.001$), with the difference remaining statistically significant. Additionally, AMI status itself was identified as an independent risk factor for increased LLL ($\beta = 14.41$, $p = 0.017$). In Model 3, which incorporated LDL-C and diabetes history into the regression analysis, the difference between DCB and DES in reducing LLL remained statistically significant and stable ($\beta = 21.90$, $p < 0.001$). The consistency of results across multiple regression analyses indicates that, after adjusting for key clinical confounders, the DCB strategy remains significantly superior to DES in reducing LLL.

Table 2. Multivariate linear regression analysis of late lumen loss (after rank transformation)

Variable	Model 1 ($R^2 = 0.246$)		Model 2 ($R^2 = 0.288$)		Model 3 ($R^2 = 0.285$)	
	β (95%CI)	P value	β (95%CI)	P value	β (95%CI)	P value
Interventional device (DES vs. DCB)	26.94(16.23, 37.65)	< 0.001	23.82(13.06, 34.58)	< 0.001	21.90(10.97,32.83)	< 0.001
LVEF (per 1% increase)	-0.59(-1.26, 0.08)	0.083	-0.40(-1.07, 0.27)	0.239	-0.33 (-1.02, 0.36)	0.348
AMI (Yes vs. No)	--		14.41(2.66, 26.16)	0.017	11.65(-0.87,24.16)	0.068
LDL-C (per 1 mmol/L increase)	--		--		1.40 (-2.58, 5.38)	0.488
Diabetes Mellitus (Yes vs. No)	--		--		9.16 (-3.58, 21.90)	0.157
Constant	72.21	0.001	52.45	0.022	44.17	0.071

Note: β value represents the regression coefficient, reflecting the extent of the impact of the independent variable on the rank (percentile) of late lumen loss (LLL); the 95% CI denotes the confidence interval; a P -value < 0.05 indicates statistical significance. Model 1 is adjusted for the interventional method and left ventricular ejection fraction (LVEF); Model 2 incorporates acute myocardial infarction (AMI) status in addition to the variables in Model 1; Model 3 is the full model, including all variables.

3.3. Subgroup analysis

Results were stratified by left ventricular ejection fraction (LVEF) to evaluate whether the efficacy of DCB is consistent across patients with different baseline cardiac function status, this study conducted a subgroup analysis

using the median LVEF (62%) as the cutoff point.

The advantage of DCB in reducing LLL persisted across patients with varying levels of cardiac function. In the high LVEF subgroup (LVEF \geq 62%), patients treated with DCB had a lower median LLL compared to those treated with DES (0.150 mm [0.115, 0.210] vs. 0.340 mm [0.270, 0.490], $P < 0.001$), with the difference being statistically significant. In the low LVEF subgroup (LVEF $<$ 62%), although the absolute values of LLL in both groups were higher than those in the high LVEF subgroup, the advantage of DCB over DES remained clear and statistically significant (0.120 mm [0.110, 0.285] vs. 0.360 mm [0.260, 0.480], $P = 0.006$), as shown in **Table 3**.

Table 3. Comparison of LLL in subgroups stratified by left ventricular ejection fraction (LVEF)

LVEF subgroup	Treatment group	n	Median LLL [IQR] (mm)	Mann-Whitney U Test	P value
High LVEF group (LVEF \geq 62%)	DES	31	0.340 [0.270, 0.490]	U = 180	< 0.001
	DCB	28	0.150 [0.115, 0.210]		
Low LVEF group (LVEF $<$ 62%)	DES	31	0.360 [0.260, 0.480]	U = 95	0.006
	DCB	14	0.120 [0.110, 0.285]		

Note: IQR stands for interquartile range; LLL stands for late lumen loss. P -values are derived from the Mann-Whitney U test.

3.4. Secondary endpoint analysis

CSFP represents one of the most enlightening findings of our study. As shown in **Table 4**, during the 6 to 12-month angiographic follow-up, only one patient in the DCB group (1/42, 2.4%) developed CSFP. In contrast, 11 patients in the DES group (11/62, 17.7%) experienced CSFP, with an incidence rate more than seven times higher than that in the DCB group. The difference between the two groups was statistically significant ($P = 0.016$, Fisher's exact test). This result strongly suggests that DES implantation may be associated with an increased risk of medium to long-term coronary microvascular dysfunction following the procedure, whereas the DCB strategy may offer unique advantages in protecting microcirculatory function.

Table 4. Comparison of the incidence of coronary slow flow phenomenon during follow-up

Group	Total cases (n)	Slow flow cases (n)	Incidence rate (%)	Statistical test and P value
DES group	62	11	17.7	Fisher's exact test, $P = 0.016$
DCB group	42	1	2.4	
Total	104	12	11.5	

Note: Coronary slow flow phenomenon (CSFP) is defined as a corrected TIMI frame count exceeding the normal upper limit for the vessel and a TIMI flow grade of ≤ 2 . P -values are derived from Fisher's exact test.

3.5. Restenosis and repeat intervention

During the 6–12 month follow-up period, the incidence of restenosis was 17.7% (11/62) in the DES group and 9.5% (4/42) in the DCB group. Although the restenosis rate was numerically lower in the DCB group, the difference between the two groups was not statistically significant ($\chi^2 = 1.37$, $P = 0.242$). There was also no significant difference in the rate of repeat intervention between the two groups (11.3% in the DES group vs. 9.5% in the DCB group, $\chi^2 = 0.083$, $P = 0.774$). This suggests that at the mid-term follow-up point of this study, the structural advantage of DCB in inhibiting intimal hyperplasia (as evidenced by lower LLL) has not yet fully translated into

a significant reduction in the traditionally defined “restenosis” rate, possibly due to the limited sample size and relatively short follow-up duration, as shown in **Table 5**.

Table 5. Comparison of restenosis and repeat intervention

Group	DES group (n = 62)		DCB group (n = 42)		P value
	Cases (n)	Incidence (%)	Cases (n)	Incidence (%)	
Angiographic restenosis	11	17.7	4	11	17.7
Repeat intervention	4	11.3	4	4	11.3

3.6. Further exploration

3.6.1. The relationship between slow coronary flow and restenosis

We conducted a more detailed analysis of patients who developed CSFP within the DES group to investigate whether CSFP is directly associated with restenosis. Among the 11 patients in the DES group who developed CSFP, 2 exhibited angiographic restenosis, accounting for 18.2% of CSFP patients and 3.2% of the entire DES group. In contrast, among the 51 patients in the DES group who did not develop CSFP, 9 still experienced restenosis, representing 17.6% of non-CSFP patients and 14.5% of the entire DES group. These findings are noteworthy: patients with CSFP do not necessarily exhibit significant luminal stenosis (> 50%). Conversely, patients with restenosis do not always present with slow blood flow. This suggests that the mechanism underlying CSFP after DES implantation may be independent of, or at least partially independent of, mechanical luminal stenosis in large vessels caused by intimal hyperplasia. One possible explanation is that, even without meeting traditional restenosis criteria, endothelial function may be impaired after DES implantation, leading to increased microcirculatory resistance and functional blood flow abnormalities. Another anatomical consideration is that the percentage of diameter stenosis assessed by two-dimensional angiography may not fully reflect the loss of vascular cross-sectional area (a 50% reduction in diameter corresponds to a 75% reduction in area) or may fail to identify complex, irregular luminal geometries caused by stent strut embedding, malposition, etc., all of which can affect blood flow without necessarily manifesting as significant “stenosis.”

4. Discussion

This study is the first to systematically evaluate, through multivariate adjustment, the long-term effects of DCB versus DES on LLL and CSFP in patients with hemodynamically stable ACS.

Two key findings emerged. After adjusting for differences in baseline cardiac function and acute event status, the DCB strategy demonstrated independent and significant superiority over DES in inhibiting LLL. Additionally, during long-term follow-up angiography, the DCB group exhibited a significantly lower risk of new-onset CSFP. These results collectively suggest that for this specific patient population, the “intervention without implantation” DCB strategy may offer greater advantages in promoting favorable long-term vascular structural and functional healing.

The notable treatment selection bias observed in this study, DES being more frequently used in patients with acute myocardial infarction (AMI), reflects the current clinical practice of prioritizing mechanical support for unstable lesions^[11]. However, this bias could severely mislead direct comparisons of outcomes between the two groups. Our study addressed this through statistical correction using multivariate regression models, demonstrating

that even after balancing baseline risk differences attributable to AMI status, the advantage of DCB in reducing intimal hyperplasia (as measured by LLL) persisted. This aligns with the fundamental concept of DCB: the absence of foreign material after delivering antiproliferative drugs may provide a healing environment with less inflammatory stimulation and more favorable physiological repair for the vascular endothelium ^[12]. Previous studies have suggested that the permanent polymer coating and metal struts of DES may induce persistent local inflammatory responses, delaying complete endothelial healing ^[3]. The higher LLL observed in the DES group during long-term follow-up in our study may partially reflect this unfavorable healing pattern for complete endothelialization.

This study highlights that CSFP is an important angiographic manifestation of coronary microvascular dysfunction, associated with angina symptoms and adverse prognosis in patients ^[13]. Our study found that the incidence of CSFP during follow-up was 17.7% in the DES group versus only 2.4% in the DCB group, a clinically significant difference warranting attention. Prior research on vascular functional status beyond six months post-procedure has been scarce, and the absence of restenosis does not equate to optimal blood supply. This discrepancy is unlikely due to perioperative embolization and more likely reflects microvascular functional status. We hypothesize that the underlying mechanism may relate to persistent physical stimulation and inflammation caused by DES permanent implants on the vessel wall, which could impair endothelium-dependent vasodilation and increase microvascular resistance ^[14,15]. Conversely, the DCB strategy, by avoiding permanent implantation, may better preserve the vessel's native vasomotor function and microcirculatory regulatory capacity ^[16]. Whether DES implantation exerts compressive or destructive effects on even smaller, angiographically invisible vessels warrants further investigation. This finding extends the benefits of DCB beyond traditional "lumenographic" endpoints to potential "functional" domains, which may hold significant implications for improving patients' long-term quality of life. Particular attention should be paid to patients with clinical angina symptoms but no stenosis on coronary CTA, who should not be indiscriminately attributed to non-cardiac pain or cardiovascular neurosis.

Notably, despite DCB's significant advantages in LLL and slow flow phenomenon, these did not translate into statistically significant reductions in restenosis or repeat revascularization rates during the mid-term follow-up period of this study. Specifically, the slow flow rate among patients with clinically defined restenosis (luminal diameter reduction > 50%) was 2/11 (18.2%), compared to 9/51 (17.6%) in those without restenosis, a strikingly similar incidence despite the expectation of better TIMI flow in the absence of restenosis. This phenomenon may stem from the limitation of two-dimensional imaging in accurately reflecting the true three-dimensional intravascular conditions. Vessels are circular conduits, and the luminal shape at lesion sites is often irregular. Even with metal stent implantation, the lumen may not achieve a near-circular shape, as confirmed by intravascular ultrasound (IVUS) and optical coherence tomography (OCT) in clinical practice. Even assuming a near-circular stenotic lumen, a 50% reduction in luminal diameter implies a 75% reduction in luminal area, suggesting that defining restenosis by a 50% diameter reduction may underestimate true hemodynamic consequences. This study proposes that defining restenosis by a 50% area reduction may be more appropriate. In fact, clinical interventionalists routinely use QCA-derived % stenosis (percent area stenosis) in their work. Another, and likely primary, reason is that DES, as a foreign body within the vessel, contributes to CSFP development, whereas DCB, leaving no residual foreign material, results in an extremely low CSFP incidence. Studies indicate that 10–30% of patients with clinical angina symptoms have no coronary stenosis, with CSFP being a potential primary cause ^[14,15].

This study has several limitations as follows:

- (1) Its retrospective observational design, despite multivariate adjustment, cannot fully exclude the influence

- of unmeasured confounders;
- (2) The study population explicitly excluded critically ill patients with Killip class 3–4, limiting conclusions to hemodynamically stable ACS patients and precluding generalization to high-risk populations requiring circulatory or respiratory support;
 - (3) The sample size was relatively small, and the findings represent single-center experience;
 - (4) The lack of simultaneous assessment with intravascular imaging (e.g., IVUS, OCT) and coronary functional indices (e.g., coronary flow reserve [CFR], fractional flow reserve [FFR]) prevented in-depth exploration of microscopic differences in intimal coverage quality and microvascular resistance.

5. Conclusion

In conclusion, our study suggests that for patients with hemodynamically stable ACS, DCB treatment may yield superior long-term vascular repair outcomes compared to DES, manifested as less LLL and a lower incidence of CSFP. These findings provide new evidence supporting individualized adoption of an “intervention without implantation” strategy in this patient population. Future large-scale, prospective, randomized controlled trials incorporating intravascular imaging and functional assessments are warranted to further validate the potential of DCB in improving long-term clinical outcomes and vascular function in ACS patients.

Funding

Social Development Science and Technology Project of Dongguan Science and Technology Bureau (Project No.: 20221800905302; Issuing Document No.: DGKT (2022) No. 61)

Disclosure statement

The authors declare no conflict of interest.

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