A prospective, multicentre, randomised controlled trial evaluating the safety and efficacy of scoring balloon catheter for treating coronary artery disease

(NCT05509296)

Statistical Analysis Plan

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1. Study Overview

1.1. Study Objective

To evaluate the safety and efficacy of the scoring balloon catheter manufactured by Sino Medical Sciences Technology Inc. for the treatment of coronary artery stenotic lesions.

1.2. Indications

Scoring balloon catheter are employed to treat coronary artery stenosis, including in-stent restenosis and complex C-type lesions, thereby improving myocardial perfusion.

1.3. Study Design

This prospective, multicentre, randomised, parallel-group, non-inferiority trial design evaluated the safety and efficacy of the scoring balloon catheter. The trial planned to enrol 136 patients with coronary artery stenotic lesions. Following the signing of informed consent forms, all subjects underwent coronary angiography after investigators determined compliance with patient-related inclusion criteria and absence of patient-related exclusion criteria. If the angiographic findings met the inclusion criteria and excluded the exclusion criteria, subjects were randomly assigned to either the trial group or the control group (with a 50% probability of allocation to each group) for balloon dilatation of the lesion. Subjects in the trial group received balloon dilatation using the scoring balloon catheter developed by Sino Medical Sciences Technology Inc. Subjects in the control group received balloon dilatation using the NSE Coronary Dilatation Catheter (National Medical Device Import Registration No. 20163035067) developed by Goldman Co., Ltd.

Follow-up time points during this trial included pre-PCI, intra-procedural, and post-procedural follow-up until discharge. The primary endpoint was device success rate (by lesion level), with secondary endpoints comprising procedural success rate (by patient level). Concurrent safety endpoints comprised the composite target lesion failure (TLF) rate from procedure initiation to discharge and its constituent events, patient-oriented composite endpoints (PoCE) and its constituent event rates, alongside other procedure-related adverse events and serious adverse events (e.g., balloon rupture, vascular dissection, in-stent thrombosis), and device deficiency.

1.4. Trial flowchart

Item / Timepoint	Screening Period	Treatment Period	Follow-up Period
	Preoperative (D-14 to D-0)	Surgical Procedure (D 0)	Postoperative to Pre-Discharge
Signing of informed consent form	▲		
Demographic Data	▲		
Medical history	▲		
Vital Signs [1]	▲	▲	▲
Pregnancy Test [2]	▲		
Complete Blood Count, Blood Biochemistry [3]	▲		▲
Cardiac Enzyme Panel [4]	▲		▲ (within 48 hours post-procedure)
Electrocardiogram [5]	▲		▲ (Within 48 hours post-procedure)
Inclusion/Exclusion Criteria	▲		
Centralised randomisation	▲		
Clinical Evaluation		▲	
Coronary angiography [6]		▲	
Coagulation Function [7]	▲		
Cardiovascular adverse events [8]		▲	▲
Adverse events and serious adverse events		▲	▲
Device deficiency		▲	
Cardiovascular concomitant medications	▲	▲	▲

Notes:

1) Vital signs: systolic blood pressure, diastolic blood pressure, and heart rate.
2) Pregnancy test: Applicable only to women of childbearing age.
3) To safeguard the rights of trial participants, blood count and biochemical test results obtained within one month prior to operative shall be accepted (where multiple tests exist, the most recent result shall prevail): □ Blood count: White blood cell count (WBC), red blood cell count (RBC), platelet count (PLT), haemoglobin (HB); □ Renal function: Serum creatinine (SCr); □ Liver function: Alanine aminotransferase (ALT), Aspartate aminotransferase (AST); ④ Lipid profile: Triglycerides (TG), Total cholesterol (TC), High-density lipoprotein cholesterol (HDL-C), Low-density lipoprotein cholesterol (LDL-C).
4) Cardiac enzyme panel: Creatine kinase (CK), Creatine kinase MB isoenzyme (CK-MB), Cardiac troponin T (cTnT)/Cardiac troponin I (cTnI) (either one may be selected; both are not required). Note: Postoperative cardiac enzyme panel should be completed within 48 hours post-procedure. Should results be abnormal and clinically significant, repeat testing is required prior to discharge.
5) Postprocedure electrocardiogram (ECG) should be performed within 48 hours postprocedurally.
6) Coronary angiography shall be performed immediately postprocedurally at each centre and recorded onto optical disc.

Item / Timepoint	Screening Period	Treatment Period	Follow-up Period
	Preoperative (D-14 to D-0)	Surgical Procedure (D 0)	Postoperative to Pre-Discharge

7) Coagulation function includes prothrombin time (PT), activated partial thromboplastin time (APTT), thrombin time (TT), and fibrinogen (FIB). To safeguard subject rights, results from tests conducted within one month prior to procedure will be accepted.

8) Cardiovascular adverse events comprise major adverse cardiac events (MACE: including all-cause mortality, myocardial infarction [MI], and target lesion revascularisation [TLR]), target lesion failure (TLF, comprising cardiac death, target vessel myocardial infarction [TV-MI], and clinically-indicated target lesion revascularisation [CI-TLR]), and patient-oriented composite endpoints (PoCE, encompassing all-cause mortality, all myocardial infarctions, and all revascularisation events [target lesion revascularisation (TLR), target vessel non-target lesion revascularisation [TVR], and non-target vessel revascularisation).

Figure1 Trial flow chart

1.5. **Sample size**

Based on literature review, clinical experience, and results from studies evaluating scoring balloon catheters for coronary artery disease, it is hypothesised that the study group's Sino scoring balloon dilation catheter will demonstrate comparable efficacy to the control group's Goodman coronary NSE balloon catheter, with an anticipated device success rate of 96%. Considering factors such as operator skill variation, lesion complexity, and subject comorbidities and disease severity, the sponsor, clinical experts, investigators, and statisticians jointly determined a non-inferiority margin Δ of -10%, a one-sided test α of 0.025, and a test power (1-β) of 0.8. PASS software calculations yielded a total sample size of 122 subjects, with 61 subjects in each group. Accounting for a 10% dropout rate, the trial requires 136 subjects, distributed as 68 in each group. The sample size calculation formula is as follows:

$$n_T = n_C = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 [P_C(1-P_C) + P_T(1-P_T)]}{(|D| - \Delta)^2}$$

Where n_T and n_C denote the sample sizes for the treatment and control groups respectively, $Z_{1-\frac{\alpha}{2}}$ and $Z_{1-\beta}$ represent the quantiles of the standard normal distribution, P_T and P_C denote the expected event rates for the treatment and control groups respectively, $|D| = |P_T - P_C|$ denotes the absolute difference in expected rates between the two groups, and Δ denotes the non-inferiority margin, taken as a negative value.

This trial will be conducted concurrently across multiple clinical trial sites. In principle, enrolment numbers will be distributed as evenly as possible among centres to ensure adequate representativeness. However, considering feasibility and enrolment progress, adjustments to enrolment quotas for participating sites will be made based on actual circumstances, striving to maintain balanced enrolment scales across centres. The final enrolment size for any single centre shall not exceed 50% of the total number of cases.

2. Evaluation Criteria

2.1. Efficacy Evaluation

2.1.1. Primary efficacy endpoint

The primary efficacy endpoint of this clinical trial is the device procedural success rate (by lesion level).

Device usage success (by lesion level) requires simultaneous fulfilment of the following conditions:

a. The balloon must successfully complete the entire balloon dilatation procedure, including delivery, passage through the lesion, inflation, deflation, and withdrawal;

b. Immediate post-PCI residual stenosis at the target lesion ≤30% (post-PCI residual stenosis for ISR and drug-coated balloon restenosis lesions <50%).

2.1.2. Secondary efficacy endpoint

The secondary efficacy endpoint of this clinical trial is procedural success rate (by subject level).

Achieving procedural success (by the subject level) requires simultaneous fulfilment of the following conditions:

a. At least one target lesion demonstrates immediate post-PCI residual stenosis ≤30% (for ISR and drug-eluting balloon restenosis lesions, residual stenosis <50%);

b. Absence of major adverse cardiac events (MACE) during the postprocedure hospital stay: all-cause mortality, myocardial infarction (MI), and target lesion revascularisation (TLR).

2.2. **Safety Evaluation**

1) Target lesion failure composite endpoint (TLF) incidence

Any of the following events constituted a TLF:

a. Cardiovascular death (including cases where the cause of death is uncertain but considered cardiovascular in origin);

b. Target Vessel-Related Myocardial Infarction (TV-MI);

c. Clinically-indicated target lesion revascularisation (CI-TLR).

Evaluation method: The observation period spans from the commencement of procedure until discharge. For each subject, the incidence rates of individual events and the composite event rate are calculated.

2) Incidence of the patient-oriented composite endpoint (PoCE)

Any occurrence of the following events constituted a PoCE:

a. All-cause mortality;

b. All myocardial infarctions;

c. All recurrent revascularisation events, including target lesion revascularisation (TLR), target vessel non-target lesion revascularisation (TVR), and non-target vessel revascularisation.

Evaluation method: The observation period spans from the commencement of procedure until discharge. For each subject, the incidence rate of individual events and the composite event rate shall be separately calculated.

3) Incidence of Individual Adverse Events and Serious Adverse Events

Evaluation Method: The observation period spans from the commencement of procedure until discharge. Other potential adverse events include balloon rupture, vascular perforation, dissection, acute occlusion, vasospasm, thrombosis (including in-stent thrombosis), and arrhythmias requiring intervention. The incidence rate of each individual event shall be separately calculated.

4) Incidence of device deficiency

3. Analysis Data Set

Full Analysis Set (FAS): The population defined according to the intention-to-treat principle, comprising all subjects who were randomised and received the study product. For patients with missing primary efficacy endpoint data, worst observation carried forward (WOCF) was applied.

Per-protocol set (PPS): Subgroup of the completed trial population excluding major protocol deviations (e.g., subjects breaching inclusion or exclusion criteria).

Safety Set (SS): Refers to the dataset comprising subjects who used the investigational device and for whom safety endpoints were recorded.

Efficacy analyses will be conducted based on both the full analysis set and the per-protocol set. All baseline demographic analyses utilise data from the full analysis set, while safety evaluations employ the safety set.

4. Handling of missing data

For patients in the FAS who did not have an observation for the primary efficacy endpoint, worst observation carried forward was applied. For target lesions where device success could not be determined, imputation was performed as 'device failure'. No imputation was performed for secondary endpoints or efficacy endpoint in the PPS. Missing safety data were not imputed.

5. Statistical Analysis Methods

5.1. General Principles

Data description and analysis were performed using SAS software. All statistical tests employed two-sided significance testing (unless otherwise specified). Confidence intervals were calculated at the 95% confidence level.

1) Statistical Description: Quantitative indicators were described by calculating mean, standard deviation, median, minimum, maximum, lower quartile (Q1), and upper quartile (Q3). Categorical indicators were described by number and percentage of cases in each category. Grading indicators were described by number and percentage of cases in each grade.

2) Statistical inference: Comparisons between two groups will employ appropriate methods based on the nature of the indicator. For quantitative indicators, inter-group comparisons will utilise paired t-tests (assuming equal variance and normal distribution) or Wilcoxon signed-rank tests, depending on data distribution. Categorical indicators will be analysed using chi-square tests or exact probability methods (where chi-square is inappropriate). Ordinal data will be assessed via Wilcoxon signed-rank tests or the Mann-Whitney U test.

5.2. Subject Distribution and Trial Completion Status

Summarise screening, enrolment, and completion numbers per centre, listing dropout cases. Provide detailed tables comparing dataset sizes across groups, case distribution per centre, overall dropout rates, reasons for screening failure, and reasons for non-completion.

5.3. Demographic data and baseline analysis

Describe patient demographics (age, gender, etc.), relevant medical history, and treatment history. Compare characteristics such as age and gender between groups to assess comparability. Demographic analysis is based on the FAS analysis set.

5.4. Efficacy Analysis

5.4.1. Primary Efficacy Endpoints

Primary efficacy evaluation is based on the Full Analysis Set (FAS) and the Per-Protocol Set (PPS).

This trial employs a multicentre, randomised, parallel-group, non-inferiority design. The primary efficacy endpoint is device procedural success rate (by lesion level), with the following hypothesis testing:

$$H_0 : p_T - p_C \leq -\Delta$$
$$H_1 : p_T - p_C > -\Delta$$

In the formula, $P_{(T)}$ denotes the device usage success rate for the experimental group, P_C represents the device usage success rate for the control group, and -Δ signifies the non-inferiority margin, set at -10%.

At α=0.025 (one-sided test) and ß=0.2, the device procedural success rate (by lesion level) of the experimental group is compared with that of the control group. The difference in device procedural success rates (by lesion level) between the two groups is calculated, along with the 95% confidence interval for this difference. Based on the lower limit of the confidence interval, a judgement is made as to whether the non-inferiority criterion has been met. If the lower limit of the 95% confidence interval is not less than -10%, the conclusion of non-inferiority is established. Should centre effects require consideration, the CMH chi-square test shall be employed.

5.4.2. Secondary efficacy endpoints

Secondary efficacy assessments were based on the full analysis set (FAS) and the per-protocol set (PPS).

Surgical success rates at the subject level are statistically analysed according to categorical indicators and compared between groups.

5.5. **Safety analysis**

The composite endpoint of target lesion failure at the lesion level from procedure initiation to pre-discharge, along with the incidence rates of individual events, shall be statistically analysed as categorical variables and compared between groups.

Cardiovascular clinical composite endpoints at the subject level from the start of procedure until discharge, along with the incidence rates of various events, were statistically analysed according to classification criteria and compared between groups.

Calculate the number of events, incidence rates, and occurrence counts for all adverse events, related adverse events, and serious adverse events in both groups. Cases of study discontinuation due to adverse events and serious adverse events will be listed in a table. Conduct statistical analysis and intergroup comparisons for the incidence rates of individual adverse events and serious adverse events occurring from postprocedure to discharge.

Device deficiency were described using incidence rates.

The clinical significance of laboratory test results shall be presented in pre- and post-procedure cross-tabulation format, with a list of abnormalities deemed clinically significant.

6. Statistical analysis results

6.1. Subject distribution

Table 1 Case distribution across centres

Centre Code	Research Centre	Group	Screening	Screening Failure	Enrolment	Dropout Count	Dropout rate (%)	Number of exclusions	Exclusion rate (%)	Completed
01	Centre 1									
		Experimental Group								
		Control Group								
		Total								
02	Centre 2									
		Experimental group								
		Control group								
		Total								
03	Centre 3									
		Experimental group								
		Control group								
		Total								
……										
	Total									
		Experimental group								
		Control group								
		Total								

Note 1: Number of completions = Number enrolled - Number of dropouts.

Note 2: Exclusion refers to subjects who completed the trial but were not included in the PPS set.

Table 2 Subject Grouping by Centre

	FAS			PPS			SS		
Centre Name	Experimental Group	Control Group	Total	Experimental group	Control Group	Total	Experimental group	Control group	Total
01									

Centre Name	FAS			PPS			SS		
	Experimental Group	Control Group	Total	Experimental group	Control Group	Total	Experimental group	Control group	Total
02									
03									
……									
Total									

Table 3 Enrolled Cases and Safety/Efficacy Analysis Dataset

Item	Indicator	Experimental Group	Control Group	Total
Screening	Screening conducted			
	Screening Failure			
Randomisation status	Randomised allocation			
Trial completion status	Trial not completed			
	Completed trial			
Reasons for trial discontinuation	Subject declined to continue participation in the study for any reason			
	Withdrawal deemed necessary by the investigator for medical or safety reasons			
	Serious protocol deviation (as confirmed by the principal investigator)			
	Serious protocol deviation by the subject or alteration of the treatment regimen during the trial			
	Death			
	Other			
	Total			

6.2. **Demographics and Baseline Parameters (FAS)**

6.2.1. Demographic information

Table 4 Population Demographic Information

Item	Indicator	Experimental Group	Control Group	Total
Gender	Male n(%)			
	Female n(%)			
	Total (Missing)			
	Statistic			

Item	Indicator	Experimental Group	Control Group	Total
	P-value			
Age (years)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Weight (kg)	N (Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Height (cm)	N (Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
BMI (kg/m²)	N (Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			

Note: Age = (Date of informed consent signature - Date of birth) / 365.4375, rounded down.

6.2.2. Medical History

Table 5 Medical History

Item	Indicator	Experimental Group	Control Group	Total
Angina pectoris	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Type of angina pectoris	Stable n(%)			
	Unstable n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Myocardial infarction	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Type of myocardial infarction	Old myocardial infarction n(%)			
	Acute myocardial infarction n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			
Heart failure	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
NYHA classification	Class I n(%)			
	Class II n(%)			
	Grade III n(%)			
	Class IV n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Left ventricular ejection fraction (LVEF)	N (Missing)			
	Mean (SD)			
	Median			

Item	Indicator	Experimental Group	Control Group	Total
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Stroke	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Stroke type	Ischemic n(%)			
	Haemorrhagic n(%)			
	Mixed n(%)			
	Total (Missing)			
	Statistical Measure			
	P-value			
Type of haemorrhage in stroke	Intracerebral haemorrhage n(%)			
	Subarachnoid haemorrhage n(%)			
	Ventricle haemorrhage n(%)			
	Other n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			
History of active peptic ulcer	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
History of allergies	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Other diseases	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			

Item	Indicator	Experimental Group	Control Group	Total
	P-value			

6.2.3. Screening Period Examination

Table 6 Screening Period Vital Signs

Item	Indicator	Experimental group	Control Group	Total
Systolic Blood Pressure (mmHg)	N (Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P value			
Diastolic blood pressure (mmHg)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Heart rate (beats per minute)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			

Table 7 Screening Period Coagulation Function

Item	Indicator	Experimental group	Control Group	Total
Prothrombin Time (PT)	Normal Range n(%)			
	Abnormal without clinical significance n(%)			
	Clinically significant abnormality n(%)			
	Not tested n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Activated partial thromboplastin time	Normal range n(%)			
	Abnormal without clinical significance n(%)			

Item	Indicator	Experimental group	Control Group	Total
(APTT)	Clinically significant abnormality n(%)			
	Not determined n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			
Fibrinogen level (FIB)	Normal range n(%)			
	Abnormal without clinical significance n(%)			
	Clinically Significant Abnormal n(%)			
	Not determined n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			
Thrombin time (TT)	Normal range n(%)			
	Abnormal without clinical significance n(%)			
	Clinically significant abnormality n(%)			
	Not tested n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			

Table 8 Screening period pregnancy test

Item	Indicator	Experimental group	Control Group	Total
Pregnancy screening conducted	No n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			
Reason for non-performance	Following bilateral salpingectomy n(%)			
	Post-hysterectomy n(%)			
	Postmenopausal n(%)			
	Other n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Pregnancy Screening Item	Urinary pregnancy test n(%)			
	Blood pregnancy test n(%)			
	Total (Missing)			
	Statistical measure			

Item	Indicator	Experimental group	Control Group	Total
	P-value			
Pregnancy Qualitative Result	Negative n(%)			
	Positive n(%)			
	Total (Missing)			
	Statistic			
	P-value			

6.3. Protocol Deviation (SS)

Table 9 Protocol Deviation

Item	Indicator	Experimental Group	Control Group	Total
Protocol Deviation	No n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			

6.4. Combination therapy (SS)

Table 10 Combined Medication (Anticoagulants, Antiplatelet Agents and Statins)

Item	Indicator	Experimental group	Control Group	Total
Combination Therapy	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			

6.5. Procedure records (FAS)

Table 11 Number of target lesions

Item	Indicator	Experimental group	Control Group	Total
Number of Target Lesions	1 n(%)			
	2 lesions n(%)			
	……			
	Total (Missing)			
	Statistic			
	P-value			

Note: The number of target lesions is based on the target lesion sites recorded during the use of the test balloon in the procedure. The same applies below.

Table 12 Preprocedure target lesion coronary angiography (by lesion level)

Item	Indicator	Experimental Group	Control Group	Total
Target lesion length (mm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Reference Vessel Diameter (mm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Preprocedure target lesion stenosis (%)	N (Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Coronary artery lesion type*				
	n(%)			
	n(%)			
	n(%)			
	n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Restenotic Lesion	In-stent restenosis n(%)			
	Drug-eluting balloon restenosis lesions n(%)			
	Other n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			

Item	Indicator	Experimental Group	Control Group	Total
Calcified lesions	None/Mild n(%)			
	Moderate n(%)			
	Severe n(%)			
	None n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Distorted lesions	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistic			
	P-value			

*Note: Analysis of lesion types based on core laboratory data: XXX.

Table 13 Non-trial balloon pre-dilatation

Item	Indicator	Experimental group	Control Group	Total
Use of non-trial balloon pre-dilatation*	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			
Number of pre-expansion balloons*	1 n(%)			
	2 n(%)			
	3 n(%)			
	4 n(%)			
	5 n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Diameter (mm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			

Item	Indicator	Experimental group	Control Group	Total
Length (mm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Maximum expansion pressure (atm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min,Max			
	Statistic			
	P-value			
Expansion time (s)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			

Note: Analyses by device level, except for *use of non-trial balloon pre-dilatation and *number of pre-dilatation balloons at lesion level.

Table 14 Use of Study Balloons

Item	Indicator	Experimental group	Control Group	Total
Number of Balloons*	1 n(%)			
	2 n(%)			
	……n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Balloon size in experimental group	2.00*10 n (%)			
	2.00*15 n(%)			
	……n(%)			
	Total (Missing)			
	Statistic			

Item	Indicator	Experimental group	Control Group	Total
	P-value			
Control group balloon size	2.00*13 n (%)			
	2.25*13 n(%)			
	……n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			
Diameter (mm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Length (mm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Maximum expansion pressure (atm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min,Max			
	Statistic			
	P-value			
Expansion time (s)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			

Note: Except for the analysis of the number of balloons at the lesion level, all others are device-level analyses.

Table 15 Stent implantation status

Item	Indicator	Experimental group	Control Group	Total
Stent Implantation*	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Number of stents implanted*	1 n(%)			
	2 n(%)			
	3 n(%)			
	4 n(%)			
	5 n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Stent diameter (mm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Stent Length (mm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Maximum expansion pressure (atm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min,Max			
	Statistic			
	P-value			
Maximum expansion time (s)	N(Missing)			
	Mean (SD)			
	Median			

Item	Indicator	Experimental group	Control Group	Total
	Q1, Q3			
	Min,Max			
	Statistic			
	P-value			

Note: Analyses at the lesion level are indicated by * for stent implantation status and * for number of stents implanted; all others are device-level analyses.

Table 16 Drug-coated balloon usage status

Item	Indicator	Experimental group	Control Group	Total
Use of drug-coated balloon*	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			
Number of drug-coated balloons*	1 n(%)			
	2 n(%)			
	3 n(%)			
	4 n(%)			
	5 n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Diameter (mm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Length (mm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Maximum expansion pressure (atm)	N(Missing)			
	Mean (SD)			
	Median			

Item	Indicator	Experimental group	Control Group	Total
	Q1, Q3			
	Min,Max			
	Statistic			
	P-value			
Maximum expansion time (s)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min,Max			
	Statistic			
	P-value			

Note: Analyses at the lesion level exclude *use of drug-coated balloons and *number of drug-coated balloons; all others are at the device level.

Table 17 Balloon Post-dilation

Item	Indicator	Experimental group	Control group	Total
Use of post-balloon dilatation*	Yes n(%)			
	No n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			
Number of balloons*	1 n(%)			
	2 n(%)			
	3 n(%)			
	4 n(%)			
	5 n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Balloon type	Cutting balloon n(%)			
	Scoring balloon n(%)			
	Mammary balloon n(%)			
	Rotational atherectomy n(%)			
	Laser ablation n(%)			
	Other n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			

Item	Indicator	Experimental group	Control group	Total
Diameter (mm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Length (mm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Maximum expansion pressure (atm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min,Max			
	Statistic			
	P-value			
Expansion time (s)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			

Note: Analyses at the lesion level exclude *use of drug-coated balloons and *number of drug-coated balloons; all others are at the device level.

6.6. **Efficacy Endpoints (FAS、PPS)**

6.6.1. Primary Efficacy Endpoints

Table 18 Device procedural success (18)

Project	Indicator	FAS Experimental group	FAS Control Group	PPS Experimental Group	PPS Control Group
Device	Success n(%)				

Project	Indicator	FAS Experimental group	FAS Control Group	PPS Experimental Group	PPS Control Group
procedural Rate	Failure n(%)				
	Total (Missing)				
	Single-group success rate 95% CI				
	Statistic (CMH)				
	P-value				

Note 1: Device procedural success (by lesion level) requires simultaneous fulfilment of the following conditions: a. Successful completion of the entire balloon dilatation procedure, including delivery, lesion crossing, inflation, deflation, retraction, and withdrawal; b. Immediate post-PCI target lesion residual stenosis ≤30% (for in-stent restenosis and drug-coated balloon restenosis lesions, post-procedural residual stenosis <50%). a. Partial analysis presented in Table 20: Device Evaluation; b. Partial analysis presented in Table 21: Immediate Post-PCI Target Lesion Residual Stenosis.

Note 2: For patients in the FAS cohort where the primary efficacy endpoint was not observable, worst observation carried forward was applied; subjects where assessment was inconclusive were counted as failing device use success.

Table 19 Device Success Rate (Lesion Level) Hypothesis Test

Population	Parameter	Experimental group n(%)	Control Group n(%)	Difference in Rates Between Groups	Difference in rates between groups Two-sided 95% CI	Statistic	P value	Non-inferiority margin
FAS	Experimental group - Control group							-10%
PPS	Experimental group - Control group							-10%

Note 1: Rate difference = Experimental group - Control group. The non-inferiority margin is -10%. The 95% confidence interval for the rate difference was calculated using the XX method.

Note 2: The lower limit of the 95% confidence interval for the intergroup success rate difference exceeds -10%, establishing the non-inferiority hypothesis.

Table 20 Device Evaluation (Lesion Level)

Item	Indicator	FAS Experimental Group	FAS Control Group	PPS Experimental Group	PPS Control group
Device usage success	Yes n(%)				
	No n(%)				

Item	Indicator	FAS		PPS	
		Experimental Group	Control Group	Experimental Group	Control group
	Total (Missing)				
	Statistic				
	P-value				
Balloon successfully advanced to lesion	Yes n (%)				
	No n(%)				
	Total (Missing)				
	Statistic				
	P-value				
Balloon successful passage through lesion	Yes n (%)				
	No n(%)				
	Total (Missing)				
	Statistic				
	P-value				
Whether the balloon successfully covered the lesion	Yes n (%)				
	No n(%)				
	Total (Missing)				
	Statistic				
	P-value				
Balloon Retraction Success	Yes n (%)				
	No n(%)				
	Total (Missing)				
	Statistic				
	P-value				

Note: Device evaluation analysis is based on trial balloon performance assessments collected via EDC.

Table 21 Immediate postprocedure residual stenosis at target lesion (lesion level)

Item	Indicator	FAS		PPS	
		Experimental group	Control Group	Experimental Group	Control Group
De-nove lesion	N(Missing)				
	Mean (SD)				
	Median				
	Q1, Q3				
	Min, Max				

Item	Indicator	FAS		PPS	
		Experimental group	Control Group	Experimental Group	Control Group
	Statistic				
	P-value				
De-novo lesion - Postprocedure residual stenosis in target lesion ⩽30%	Yes n(%)				
	No n(%)				
	Total (Missing)				
	Statistical measure				
	P-value				
In-stent restenosis Restenotic lesion	N(Missing)				
	Mean (SD)				
	Median				
	Q1, Q3				
	Min, Max				
	Statistic				
	P-value				
In-stent restenosis Postprocedure residual stenosis degree of restenotic lesion <50%	Yes n(%)				
	No n(%)				
	Total (Missing)				
	Statistical measure				
	P-value				
Drug-eluting stent restenosis lesions	N(Missing)				
	Mean (SD)				
	Median				
	Q1, Q3				
	Min, Max				
	Statistic				
	P-value				
Postprocedure residual stenosis rate of drug-eluting balloon restenosis lesions <50%	Yes n(%)				
	No n(%)				
	Total (Missing)				
	Statistical measure				
	P-value				

Note 1: Primary lesion refers to a lesion with stenosis demonstrated by coronary angiography, excluding in-stent restenosis or drug-eluting balloon restenosis.

Note 2: Analysis of restenosis severity was based on core laboratory data: residual stenosis percentage in the post-procedural segment.

Table 22 Device Success Rates by Centre (Lesion Level)

Research Centre	Item	Indicator	FAS Experimental Group	FAS Control Group	PPS Experimental Group	PPS Control Group
01	Device usage success rate	Success n(%) Failure n(%) Total (Missing)				
02	Device Usage Success Rate	Success n(%) Failure n(%) Total (Missing)				
……	Success rate of instrument use	Success n(%) Failure n(%) Total (Missing)				

6.6.2. Secondary efficacy endpoint

Table 23 Procedure success rate (subject level)

Item	Indicator	FAS Experimental Group	FAS Control Group	PPS Experimental Group	PPS Control Group
Procedure success rate	Success n(%) Failure n(%) Total (Missing) Statistical measure P-value				

Note: Procedure success (subject level) requires simultaneous fulfilment of the following conditions: a. At least one target lesion residual stenosis ≤30% immediately after PCI (postprocedure residual stenosis <50% for ISR and drug-coated balloon restenosis lesions); No major adverse cardiac events (MACE) during postprocedure hospitalisation: all-cause mortality, myocardial infarction (MI), and target lesion revascularisation (TLR).

Table 24 Immediate postprocedure target lesion residual stenosis degree (subject level)

Item	Indicator	FAS Experimental group	FAS Control Group	PPS Experimental Group	PPS Control Group
Postprocedure Immediate Target Lesion Residual Stenosis Degree Meeting Criteria	Yes n(%) No n(%) Total (Missing) Statistical measure P-value				

Note: Target achievement denotes at least one target lesion with residual stenosis ≤30% immediately postoperatively (ISR and drug-eluting balloon restenosis lesions with residual stenosis <50% postoperatively). Analysis of target lesion residual stenosis is based on core laboratory data: residual stenosis within the postprocedure segment in XXX.

Table 25 Major Adverse Cardiac Events (MACE) During Postoperative Hospitalisation (Subject Level)

		FAS		PPS	
Item	Indicator	Experimental Group	Control Group	Experimental Group	Control Group
Incidence of MACE	Yes n(%)				
	No n(%)				
	Total (Missing)				
	Statistic				
	P-value				
All-cause mortality	Yes n (%)				
	No n(%)				
	Total (Missing)				
	Statistic				
	P-value				
Myocardial infarction (MI)	Yes n (%)				
	No n(%)				
	Total (Missing)				
	Statistic				
	P-value				
Target lesion revascularisation (TLR)	Yes n (%)				
	No n(%)				
	Total (Missing)				
	Statistic				
	P-value				

Note: Analyses for all-cause mortality, myocardial infarction (MI), and target lesion revascularisation (TLR) were based on death reports, myocardial infarction forms, and revascularisation forms.

Table 26 Major Adverse Cardiac Events (MACE) during Postprocedure Hospitalisation (Subject Level) - Primary Lesion

Table 27 Major Adverse Cardiac Events (MACE) During Postprocedure Hospitalisation (Subject Level) - Restenotic Lesion

6.7. **Safety Endpoints (SS)**

6.7.1. Target lesion failure (TLF) incidence

Table 28 Target lesion failure (subject level)

Item	Indicator	Experimental group	Control Group	Total
TLF Occurrence	No n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Cardiac death	No n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Occurrence of target vessel myocardial infarction	No n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Whether clinically driven target lesion revascularisation occurred	No n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			

Note: Any occurrence of the following events is considered a TLF (subject level): a. Cardiovascular death (if cause of death is uncertain, it is also considered cardiovascular death); b. Target Vessel-Related Myocardial Infarction (TV-MI); c. Clinically-Driven Target Lesion Revascularisation (CI-TLR). Analysis of cardiac death, target vessel-related myocardial infarction, and clinically-driven target lesion revascularisation was based on death reports, myocardial infarction reports, and revascularisation reports.

6.7.2. Incidence of the patient-oriented composite endpoints (PoCE)

Table 29 Patient-oriented composite endpoints (Subject level)

Item	Indicator	Experimental group	Control Group	Total
Occurrence of PoCE	No n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
All-cause mortality	No n(%)			

Item	Indicator	Experimental group	Control Group	Total
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Myocardial infarction	No n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Whether revascularisation occurred	No n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			

Note: Any occurrence of the following events was considered a PoCE: a. All-cause mortality; b. All myocardial infarctions; all revascularisation events, including target lesion revascularisation (TLR), target vessel revascularisation (TVR) and non-target vessel revascularisation. Analysis of all-cause mortality, myocardial infarction, and revascularisation was based on death reports, myocardial infarction reports, and revascularisation reports.

6.7.3. Procedure-related complications

Table 30 Procedure-related complications

Item	Indicator	Experimental group	Control Group	Total
Presence of procedure Complications	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistical measure			
	P-value			
Balloon rupture	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Puncture oedema	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Vascular perforation	None n(%)			
	Yes n(%)			
	Total (Missing)			

Item	Indicator	Experimental group	Control Group	Total
	Statistic			
	P-value			
Vascular dissection	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Acute occlusion	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Vasospasm	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Thrombosis	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			
Other	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			

6.7.4. Adverse events

Table 31 Summary of Adverse Events

	Experimental group (n=)			Control group (n=)			Total (n=)			
Item	Number of Occurrences	Incidence subjects	Rate (%)	Number Occurrence	Incidence of cases	Rate (%)	Number Occurrence	Incidence of cases	Rate (%)	P value
Adverse events										
Severity adverse events	Mild									
Moderate Adverse Events	Severity									

	Experimental group (n=)		Control group (n=)		Total (n=)		
Item	Number of Occurrences	Incidence subjects	Rate (%)	Number Occurrence of cases	Incidence Rate (%)	Number Occurrence of cases	Incidence Rate (%)	P value
Severe adverse events								
Adverse events related to the investigational device								
Adverse events related to surgery								
Adverse events leading to withdrawal								
Adverse events with a fatal outcome								

Note: Definition of adverse events related to the investigational device/procedure: Adverse events where the relationship to the investigational device/procedure is determined as "definitely related" or "possibly related".

Table 32 Event coding (SOC/PT)

	Experimental group (n=)		Control group (n=)		Total (n=)		
Indicator	Number of Occurrences	Incidence subjects	Rate (%)	Number Occurrence of cases	Incidence Rate (%)	Number Occurrence of cases	Incidence Rate (%)	P value
All adverse events								
SOC1								
PT1								
PT2								
……								

Table 33 Summary of Serious Adverse Events

	Experimental Group (n=)		Control Group (n=)		Total (n=)		
Item	Number of Occurrences	Incidence subjects	Rate (%)	Number Occurrence of cases	Incidence Rate (%)	Number Occurrence of cases	Incidence Rate (%)	P value
All serious adverse events								
Trial Device-Related SAE								

	Experimental Group (n=)		Control Group (n=)		Total (n=)		
Item	Number of Occurrences	Incidence subjects	Rate (%)	Number Occurrence	Incidence of cases	Rate (%)	P value
SAEs resulting in death							

Note: Definition of trial device-related serious adverse events: serious adverse events classified as "definitely related" or "possibly related" to the trial device.

Table 34 Serious Adverse Event Coding (SOC/PT)

	Experimental group (n=)		Control group (n=)		Total (n=)		
Indicator	Number of Occurrences	Incidence subjects	Rate (%)	Number Occurrence	Incidence of cases	Rate (%)	P value
All serious adverse events							
SOC1							
PT1							
PT2							
……							

6.7.5. Pre- and Postoperative Laboratory Tests Clinical Significance Cross-Tabulation

Table 35 Blood Count - Red Blood Cell Count

		Postoperative to discharge					
Group	Screening Period	Normal	Abnormal without clinical significance	Clinically Significant Abnormal	Not Detected	Missing	Total
Experimental group	Normal						
	Abnormal without clinical significance						
	Clinically significant abnormality						
	Not tested						
	Missing						
	Total						
Control group	Normal						

		Postoperative to discharge					
Group	Screening Period	Normal	Abnormal without clinical significance	Clinically Significant Abnormal	Not Detected	Missing	Total
	Abnormal without clinical significance						
	Clinically significant abnormality						
	Not tested						
	Missing						
	Total						

Table 36 Complete Blood Count - White Blood Cell Count

Table 37 Blood Count - Platelet Count

Table 38 Blood Routine - Haemoglobin

Table 39 Blood Biochemistry - Alanine Transaminase

		Postoperative to discharge					
Group	Screening Period	Normal	Abnormal without clinical significance	Clinically Significant Abnormal	Not Tested	Missing	Total
Experimental group	Normal						
	Abnormal without clinical significance						
	Clinically significant abnormality						
	Not tested						
	Missing						
	Total						
Control group	Normal						
	Abnormal Non-clinically significant						
	Clinically significant abnormality						
	Not tested						
	Missing						

		Postoperative to discharge					
Group	Screening Period	Normal	Abnormal without clinical significance	Clinically Significant Abnormal	Not Tested	Missing	Total
	Total						

Table 40 Blood Biochemistry - Aspartate Aminotransferase

Table 41 Blood Biochemistry - Serum Creatinine

Table 42 Blood Biochemistry - Total Cholesterol

Table 43 Blood Biochemistry - Triglycerides

Table 44 Blood Biochemistry - Low-Density Lipoprotein Cholesterol

Table 45 Blood Biochemistry - High-Density Lipoprotein Cholesterol

Table 46 Cardiac Enzymes Profile - Creatine Kinase

		48 hours post-operative					
Group	Screening Period	Normal	Abnormal without clinical significance	Clinically Significant Abnormal	Not Tested	Missing	Total
Experimental group	Normal						
	Abnormal without clinical significance						
	Clinically significant abnormality						
	Not tested						
	Missing						
	Total						
Control group	Normal						
	Abnormal without clinical significance						
	Clinically significant abnormality						
	Not tested						
	Missing						
	Total						

Table 47 Myocardial Enzyme Profile - Creatine Kinase Isoenzymes
Table 48 Cardiac Enzyme Profile - Troponin T
Table 49 Cardiac Enzyme Profile - Troponin I

Table 50 Twelve-lead electrocardiogram

		48 hours post-procedure					
Group	Screening Period	Normal	Abnormal without clinical significance	Clinically Significant Abnormality	Not Detected	Missing	Total
Experimental group	Normal						
	Abnormal without clinical significance						
	Clinically significant abnormality						
	Not tested						
	Missing						
	Total						
Control group	Normal						
	Abnormal without clinical significance						
	Clinically significant abnormality						
	Not tested						
	Missing						
	Total						

6.7.6. Device deficiency

Table 51 Device deficiency

Item	Indicator	Test group	Control Group	Total
Device deficiency	None n(%)			
	Yes n(%)			
	Total (Missing)			
	Statistic			
	P-value			

6.7.7. Intraoperative and Postoperative Vital Signs

Table 52 Vital signs during procedure

Table 53 Vital signs from post-procedure to discharge

6.8. **QCA data analysis (FAS)**

Table 54 Preprocedure QCA examination

Item	Indicator	Experimental Group	Control Group	Total
Preprocedure Reference Vessel Diameter (mm)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Preprocedure diameter stenosis (%)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Preprocedure lesion length (mm)	N (Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			

Table 55 Immediate QCA examination following scoring balloon angioplasty

Item	Indicator	Experimental Group	Control Group	Total
Intraballoon minimum lumen diameter (mm)	N (Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			

Item	Indicator	Experimental Group	Control Group	Total
	P-value			
Intraballoon	N(Missing)			
Reference	Mean (SD)			
vessel	Median			
diameter (mm)	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Intraballoon	N(Missing)			
residual	Mean (SD)			
stenosis (%)	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			

Table 56 Postprocedure QCA examination

Item	Indicator	Experimental group	Control Group	Total
Minimal	N(Missing)			
Lumen	Mean (SD)			
Diameter	Median			
(mm)	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Intra-device	N (Missing)			
reference	Mean (SD)			
lumen	Median			
diameter (mm)	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Instrumental	N (Missing)			
residual	Mean (SD)			
stenosis (%)	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P value			

Item	Indicator	Experimental group	Control Group	Total
Minimal Lumen Diameter within Segment (mm)	N (Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			
Intrasegmental - Reference Lumen Diameter (mm)	N (Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min,Max			
	Statistic			
	P-value			
Intrasegmental residual stenosis (%)	N(Missing)			
	Mean (SD)			
	Median			
	Q1, Q3			
	Min, Max			
	Statistic			
	P-value			

Table 57 Acute lumen gain

7. List

See the appendix for the full list.