Research Square

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Safety and Efficacy of a Novel Balloon Angiographic Catheter for Coronary Venography During Left Ventricular Lead Implantation: A Prospective Multicenter Single-arm Trial

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Research Article

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Abstract

Background

Cardiac resynchronization therapy (CRT) is a key treatment for heart failure with reduced ejection fraction, with optimal benefits depending on accurate placement of the left ventricular (LV) leads in ideal target veins. Complex coronary venous anatomy increases procedural difficulty. Conventional angiographic catheters may provide limited support and incomplete vessel visualization. This study aimed to evaluate the short-term efficacy and safety of a balloon angiographic catheter in standard CRT procedures.

Methods

This prospective, multicenter, single-arm, target-value clinical trial assessed a novel balloon angiographic catheter (LeesCa™) for coronary venography in patients undergoing LV pacing lead implantation via the coronary sinus. Ninety-seven eligible patients (73 men) were enrolled across four centers between October 28, 2024, and July 10, 2025. All patients met the indications for LV lead implantation via the coronary sinus. Coronary venography was performed using the LeesCa™ balloon angiographic catheter. The primary endpoint was the device success rate. Secondary endpoints included the immediate procedural success rate, LV lead implantation time, contrast medium volume, total fluoroscopy time, radiation dose, device performance, and safety outcomes. Patients were followed until hospital discharge or for 7 days post-procedure, whichever occurred first.

Results

Device success was achieved in all patients (97/97, 100%; 95% confidence interval: 96.27%–100%), which was significantly higher than the predefined target value of 93% ($P < 0.001$). The immediate procedural success rate was 98.97% (96/97). One patient failed to undergo trans-coronary sinus lead implantation because of small, tortuous target veins. The mean LV lead implantation time was 18.16 ± 12.14 min, the contrast volume was 29.65 ± 24.50 mL, the fluoroscopy time was 1113.00 ± 808.44 s, and the radiation dose was 368.92 ± 344.71 mGy. Three mild adverse events (puncture-site hematoma, contrast reaction, and vasovagal reflex) were documented, resulting in an overall adverse event rate of 3.09% (3/97). All device performance scores exceeded 3 points, satisfying the requirements for clinical application.

Conclusions

The LeesCa™ balloon angiographic catheter can safely and effectively complete coronary venous angiography during LV pacing lead implantation, providing satisfactory angiographic visualization and

stable performance.

Trial registration:

Chinese Clinical Trial Registry (registration number: ChiCTR2400089647; date of registration: September 12, 2024).

Background

Cardiac resynchronization therapy (CRT) is an important device-based therapy for patients with severe heart failure with reduced ejection fraction (HFrEF) [1]. Randomized controlled trials have demonstrated that CRT improves cardiac function and reduces heart failure-related hospitalization and all-cause mortality [2]. In patients with sinus rhythm, left bundle branch block (LBBB), left ventricular ejection fraction (LVEF) ≤ 35%, and a QRS duration ≥ 150 ms, CRT carries a New York Heart Association (NYHA) class IA recommendation [3, 4].

The benefit of CRT depends in part on whether the left ventricular pacing lead can be placed in an appropriate target vein [5–9]. Stable and complete coronary venous visualization is therefore essential for defining coronary venous anatomy, identifying the target vessel, and guiding left ventricular lead placement [10].

However, current coronary venography catheters often fail to achieve complete visualization of tortuous, small-caliber coronary venous branches in patients with routine heart failure indicated for CRT implantation [11]. Inadequate venous imaging prolongs lead positioning, increases fluoroscopy radiation exposure and contrast medium consumption, and elevates intraoperative procedural difficulty for the majority of patients with routine heart failure. Therefore, a catheter that improves venous opacification while providing guidewire support could address this practical procedural gap.

The novel LeesCa™ balloon angiographic catheter adopts balloon-occlusion retrograde imaging and a dual-lumen supportive design to address core clinical challenges in patients with routine heart failure, including poor opacification of slender, tortuous target veins, increased radiation exposure, and additional contrast medium use caused by repeated angiography. Previous single-center studies have demonstrated the preliminary feasibility and safety of the LeesCa™ balloon angiographic catheter; however, their findings are limited by single-institution experience and reproducibility could not be fully assessed across operators and clinical settings [12–14]. Therefore, evidence from prospective multicenter studies evaluating the feasibility, reproducibility, and short-term safety of the LeesCa™ balloon angiographic catheter across different centers and operators remains limited.

This prospective, multicenter trial aimed to systematically evaluate the short-term efficacy and safety of this balloon angiography catheter for standard CRT procedures, providing actionable intraoperative optimization evidence in routine heart failure management. Although a small number of patients with

prior tricuspid valve replacement (TVR) were enrolled, this trial primarily targeted routine CRT candidates requiring left ventricular lead implantation, and subgroup stratification was not implemented due to the insufficient sample size of patients with valve surgery.

Methods

Study Design

This prospective, multicenter clinical study used competitive enrollment across four tertiary hospitals, with Peking University People's Hospital serving as the leading center. This trial was reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The completed CONSORT 2025 checklist is provided in Additional file 1. Details regarding participating centers, ethics approvals, operator training, and procedural standardization are provided in Additional file 2. All participants provided written informed consent before enrollment. This study was registered with the Chinese Clinical Trial Registry (ChiCTR) under the registration number ChiCTR2400089647 on September 12, 2024.

Study Population

Between October 28, 2024, and July 10, 2025, consecutive patients at the four centers were screened. Eligible patients were aged ≥ 18 years and met the indications for CRT or left ventricular lead implantation. Indications included LVEF ≤ 35%, symptomatic heart failure despite optimized medical therapy (NYHA class II–IV), and a widened QRS duration according to published guidelines [4] (LBBB: QRS duration ≥ 130 ms; non-LBBB: QRS duration ≥ 150 ms).

Additional inclusion criteria included planned use of the LeesCa™ catheter for coronary venography and provision of written informed consent. Exclusion criteria included known severe allergy to contrast media, inability to establish venous access to the right atrium for interventional device placement, pregnancy or lactation, or investigator discretion that trial participation was inappropriate.

Sample Size Calculation

The sample size was calculated based on a single-arm target-value design. Previous studies have reported device success rates for coronary venography and left ventricular lead implantation during CRT ranging from 90% to 95% [15, 16]. The null success rate was set at 93%, and the expected success rate of the study device was set at 99%. A one-sided α of 0.025 and a statistical power (1 − β) of 80% were defined. Using the Inequality Tests for One Proportion module in PASS 15.0.5, the sample size was calculated via the exact binomial probability method, and a total of 97 participants were required. The target sample size of 97 participants included both patients with routine heart failure and a small

number of patients with special cardiac anatomical conditions. The statistical power for the primary endpoint was sufficient based on the entire cohort, regardless of the small number of TVR cases.

Study Device

The LeesCa™ balloon angiographic catheter (patent no. 201320413174.1) is a dual-lumen catheter reinforced with a steel-wire mesh. Compared with conventional single-lumen angiographic catheters, this dual-lumen device allows two guidewires to pass through simultaneously. A compliant balloon combined with a limited-volume injector enables controllable retrograde venography. Figures 1 and 2 show the structural diagram and physical appearance of the LeesCa™ balloon angiographic catheter.

Procedural Steps

Patients were placed in the supine position, routinely disinfected, draped, and administered local infiltration anesthesia with 1% lidocaine. After percutaneous venous puncture and sheath placement, the study device was advanced over a guidewire through the sheath into the coronary sinus ostium. A small amount of contrast medium was slowly injected into the coronary sinus ostium to visualize the course of the coronary sinus, and the catheter was advanced into the main coronary sinus branch. The balloon was inflated with 0.5 mL of air, and contrast medium was injected to evaluate the occlusion effect and optimize the balloon inflation status, followed by retrograde coronary venography to identify the target vein for lead implantation. One or two guidewires were advanced through the catheter into the target vein. The valve at the balloon-lumen port was opened, the limited-volume injector was withdrawn to completely deflate the balloon, the guidewire was retained, and the balloon angiographic catheter was removed. The left ventricular pacing lead was then implanted over the guidewire. Pacing thresholds and phrenic nerve stimulation were assessed after lead placement.

Preoperative clinical data, including demographic characteristics, medical history, preoperative diagnosis, standard 12-lead electrocardiography, and routine transthoracic echocardiographic findings, were collected from electronic medical records. During the procedure, the principal investigator or an authorized operator recorded vital signs, study device success, immediate procedural outcomes, left ventricular lead implantation time, contrast medium volume, total fluoroscopy time, total fluoroscopy dose, product performance scores, adverse events, serious adverse events, and device deficiencies. Postoperative follow-up continued until discharge or postoperative day 7, whichever occurred first. Follow-up assessments included vital signs, postoperative standard 12-lead electrocardiography, perioperative concomitant medications, and adverse or serious adverse events.

Study Endpoints

The primary endpoint was device success. Device success was defined as fulfillment of all the following criteria: (1) the balloon was inflated within the coronary sinus and achieved effective blood flow

occlusion; (2) successful retrograde coronary venography with visualization of at least one left ventricular lateral branch vein; and (3) the catheter was withdrawn without damage.

Secondary endpoints included immediate procedural success rate, left ventricular lead implantation time, total contrast medium volume, total fluoroscopy time, total fluoroscopy dose, adverse events, serious adverse events, and device deficiencies.

Device performance was additionally evaluated using a 5-point Likert scale (1 = very poor, 2 = poor, 3 = fair and meeting clinical needs; 4 = good; 5 = excellent). A score of ≥ 3 was regarded as clinically acceptable. Evaluation parameters included catheter maneuverability, catheter support, sheath compatibility, guidewire compatibility, balloon compliance, radiopacity, catheter integrity during withdrawal, and overall performance.

Subgroup analyses stratified by history of TVR were not performed because of the insufficient number of cases, and no subgroup-specific statistical analyses were reported.

Statistical Analysis

All statistical analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were tested for normality using the Shapiro–Wilk test. Normally distributed variables are presented as mean ± standard deviation, whereas non-normally distributed variables are presented as median (interquartile range: Q1, Q3). Categorical variables are presented as number (percentage). The primary endpoint was analyzed using a one-sided exact binomial test, and the 95% confidence interval (CI) was calculated using the Clopper–Pearson method. A P-value < 0.025 indicated that the success rate of the study device was significantly higher than the predefined target value. Secondary endpoint analyses were prespecified and interpreted descriptively, with no adjustment for multiple comparisons. Preoperative and postoperative QRS durations among patients with successful LV lead implantation and available paired electrocardiographic data were compared using the paired Wilcoxon signed-rank test because QRS duration was non-normally distributed.

Results

Baseline Characteristics

The final sample size met the prespecified requirement. Baseline demographic and clinical characteristics are summarized in Table 1. The mean age was 65.39 ± 11.92 years, and 73 patients (75.26%) were men. A total of 95 patients (97.94%) met the indications for CRT implantation, whereas two patients (2.06%) had a history of TVR. Dilated cardiomyopathy was the most common etiology (49 patients, 50.52%), followed by arrhythmia-related cardiomyopathy or pacing-induced cardiomyopathy (31 patients, 31.96%) and ischemic cardiomyopathy (16 patients, 16.49%). Some patients had multiple underlying etiologies. Owing to the limited sample size, no stratified comparative analyses were performed. All participants underwent preoperative 12-lead electrocardiography and transthoracic

echocardiography. The median QRS duration was 160.00 ms (147.50, 180.00), mean left ventricular end-diastolic diameter (LVEDD) was 63.54 ± 10.11 mm, and median LVEF was 34.29% (28.40, 41.00).

Table 1
Baseline characteristics

Variable	Value
Demographics	
Age, years	65.39 ± 11.92
Male, n (%)	73 (75.26)
Height, cm	167.67 ± 8.95
Weight, kg, median (Q1, Q3)	68.00 (60.00, 78.00)
BMI, kg/m^2, median (Q1, Q3)	24.62 (22.03, 26.45)
Comorbidities	
Hypertension, n (%)	36 (37.11)
Diabetes mellitus, n (%)	22 (22.68)
Coronary artery disease, n (%)	32 (32.99)
Hyperlipidemia, n (%)	21 (21.65)
Stroke, n (%)	14 (14.43)
Atrial fibrillation, n (%)	19 (19.59)
History of pacemaker implantation, n (%)	25 (25.77)
Etiology for heart failure	
Dilated cardiomyopathy, n (%)	49 (50.52%)
Arrhythmia-related cardiomyopathy or pacing induced cardiomyopathy, n (%)	31(31.96%)
Ischemic cardiomyopathy, n (%)	16(16.49%)
Electrocardiographic parameters	
Complete left bundle branch block, n (%)	55 (56.70)
Without complete left bundle branch block, n (%)	42 (43.30)
QRS duration, ms, median (Q1, Q3)	160.00 (147.50, 180.00)
Echocardiographic parameters	
Abbreviations: BMI, Body Mass Index; CRT, Cardiac Resynchronization Therapy; LVEDD, Left Ventricular End-Diastolic Diameter; LVEF, Left Ventricular Ejection Fraction	
Description of data: Supplementary Figure raw files: High-resolution (300 dpi) uncompressed original images of Figs. 1–5, provided in independent PNG/TIFF format per journal image submission requirements	

Variable	Value
LVEDD, mm	63.54 ± 10.11
LVEF, %, median (Q1, Q3)	34.29 (28.40, 41.00)
Abbreviations: BMI, Body Mass Index; CRT, Cardiac Resynchronization Therapy; LVEDD, Left Ventricular End-Diastolic Diameter; LVEF, Left Ventricular Ejection Fraction	
Description of data: Supplementary Figure raw files: High-resolution (300 dpi) uncompressed original images of Figs. 1–5, provided in independent PNG/TIFF format per journal image submission requirements	

[insert Table 1 here]

Primary and Secondary Endpoint Outcomes

All 97 participants completed coronary venography and the perioperative assessments (Fig. 3). Detailed endpoint results are presented in Table 2. The LeesCa™ balloon angiographic catheter successfully reached the target vessel within the coronary sinus in all 97 cases. Balloon occlusion of blood flow and retrograde coronary venography after contrast medium injection were achieved in all patients. The device success rate was 100% (97/97; 95% CI, 96.27%–100%), which was significantly higher than the prespecified target value of 93% ($P < 0.001$).

The immediate procedural success rate was 98.97% (96/97). Left ventricular lead implantation was successfully performed after coronary venography in 96 patients (Fig. 4). Implantation failed in one patient because of a small, tortuous target vessel, and left bundle branch pacing was adopted instead.

Table 2
Primary and secondary endpoints.

Endpoint category	Result
Primary endpoint	
Device success, n (%) (95% CI)	97 (100.00) (96.27%, 100.00%)
Secondary endpoints	
Immediate procedural success, n (%)	96 (98.97)
Left ventricular lead implantation time, min	18.16 ± 12.14
Contrast volume, mL	29.65 ± 24.50
Total fluoroscopy time, s	1113.00 ± 808.44
Total fluoroscopy dose, mGy	368.92 ± 344.71
Adverse events, n (%)	3 (3.09)
Serious adverse events, n (%)	0 (0.00)
Device deficiencies, n (%)	0 (0.00)
CI, confidence interval; CRT, cardiac resynchronization therapy	

The mean left ventricular lead implantation time was 18.16 ± 12.14 min, the mean contrast medium volume was 29.65 ± 24.50 mL, the mean total fluoroscopy time was 1113.00 ± 808.44 s, and the mean total fluoroscopy dose was 368.92 ± 344.71 mGy, as automatically recorded by the fluoroscopy system. Three mild adverse events occurred (3.09%): puncture-site hematoma, contrast-related reaction, and vasovagal reflex. None of these adverse events was attributable to the investigational catheter. The puncture-site hematoma was associated with the patient's anticoagulation regimen and postoperative immobilization compliance. One intraoperative lead displacement occurred as a procedural complication unrelated to the study device. All adverse events were successfully managed with conservative measures or intraoperative intervention, without permanent sequelae or trial withdrawal. No serious adverse events were reported.

All operator-assessed catheter performance scores were > 3 with a compliance rate of 100%. The median scores for maneuverability, support performance, sheath compatibility, guidewire compatibility, balloon compliance, radiopacity, and overall performance all exceeded 4.92. All catheters were withdrawn intact, yielding a 100% withdrawal integrity rate (Fig. 5). At the pre-discharge follow-up, among patients with successful left ventricular lead implantation, the postoperative QRS duration was shorter than the preoperative QRS duration. The median QRS duration decreased from 160.00 ms (147.50, 180.00) to 133.00 ms (128.00, 146.00) ($P < 0.001$, paired Wilcoxon test).

Discussion

This prospective, multicenter study demonstrated a device success rate of 100% with the use of the LeesCa™ balloon angiographic catheter for coronary venography during trans-coronary sinus left ventricular lead implantation; the success rate significantly exceeded the prespecified target value of 93%. Furthermore, the overall immediate procedural success rate reached 98.97%, with the single implantation failure attributable to inherent extreme venous tortuosity rather than device failure. Descriptively, this patient did not show a distinct comorbidity profile compared with patients who underwent successful LV lead implantation: this patient had diabetes and dilated cardiomyopathy but no hypertension, coronary heart disease, hyperlipidemia, stroke, atrial fibrillation, pulmonary hypertension, or prior pacemaker implantation. Compared with the successful implantation cohort, this patient had a longer preoperative QRS duration (210 ms vs. median 160 ms), larger LVEDD (71 mm vs. median 62.5 mm), and lower LVEF (20% vs. median 34.64%), suggesting more advanced baseline electrical dyssynchrony and ventricular remodeling. However, these values remained within the observed ranges of the successfully implanted cohort. The implantation failure was attributed to a small and tortuous target vessel rather than device malfunction. The LeesCa™ catheter successfully reached the coronary sinus and achieved balloon occlusion and retrograde coronary venography. No intraoperative adverse event, new adverse event on follow-up, or device deficiency was recorded in this patient. Notably, no serious device-related adverse events were observed throughout the 7-day perioperative follow-up, and all operators rated catheter handling above the predefined threshold. Collectively, this dual-lumen balloon occlusion catheter provided stable and complete coronary venous visualization and reliable intraoperative support for routine CRT procedures, representing a viable adjunctive tool for standard heart failure resynchronization procedures.

Conventional single-lumen coronary venography catheters have two inherent limitations widely observed in patients with routine heart failure indicated for CRT [17]. First, without balloon occlusion, contrast medium rapidly refluxes within the coronary sinus, resulting in suboptimal opacification of small and tortuous lateral veins, which are common in patients with dilated cardiomyopathy [18–20]. Incomplete venous visualization often necessitates repeated fluoroscopic angiography, inevitably elevating accumulated ionizing radiation for both patients and interventional staff, as well as contrast exposure, which increases the risk of contrast-induced nephropathy in older patients with heart failure and impaired renal function [21–24]. Second, single-lumen structures cannot simultaneously accommodate two guidewires; repeated catheter exchange prolongs the procedure duration and necessitates repeated contrast injections [25]. The LeesCa™ catheter addresses these limitations via a compliant balloon and a dual-lumen integrated design. Temporary balloon blockage eliminates contrast reflux and achieves full retrograde filling of small venous branches, while the dual channel permits dual guidewire placement without catheter repositioning. In addition, the device integrates three procedural steps—coronary sinus cannulation, coronary sinus venography, and guidewire delivery into the target vessel—which simplifies the procedure and shortens procedural time. In our cohort, the mean implantation time was only 18.16 min, and the mean contrast medium volume was 29.65 mL, potentially reducing the burdens of radiation exposure and contrast medium use during routine CRT implantation in general cardiology centers across China [12]. Although these values cannot be directly compared with those of conventional venography in

the absence of a randomized control group, they suggest that the catheter can be incorporated into the implantation workflow without increasing procedural burden. This advantage is particularly valuable for primary hospitals with limited high-end fluoroscopic shielding equipment and insufficient resources for monitoring renal function.

Previous single-center studies have demonstrated the preliminary feasibility and safety of the LeesCa™ balloon angiographic catheter; however, their findings were limited by single-institution experiences and they could not fully assess reproducibility across operators and clinical settings [13, 14]. In contrast, the present prospective multicenter trial enrolled 97 patients across four tertiary hospitals and used competitive enrollment, unified operator training, standardized procedural steps, and predefined endpoint assessment. Therefore, this study extends prior evidence by demonstrating consistent short-term device success, procedural feasibility, and safety across multiple centers. The 100% device success rate, 98.97% immediate procedural success rate, absence of serious device-related adverse events, and consistently favorable operator-rated performance extend prior evidence by demonstrating that the catheter can be used feasibly and safely across different centers and operators. Thus, the novelty of this study lies not only in its larger sample size but also in its demonstration of multicenter reproducibility and consistent device performance in routine CRT-related coronary venography. Because this was a single-arm study, these findings should be interpreted as multicenter feasibility and short-term safety evidence rather than proof of superiority over conventional angiographic catheters. The overall incidence of mild adverse events observed in this cohort was low (3.09%), and all adverse events were unrelated to the study catheter. No serious adverse events or device deficiencies were observed. Puncture-site hematoma, contrast allergy, and vasovagal reactions are common perioperative complications of cardiac interventional procedures rather than balloon occlusion venography. Notably, no balloon rupture, coronary sinus dissection, venous perforation, or catheter entrapment occurred, confirming the structural safety of the balloon and the hydrophilic coating under routine clinical inflation parameters. The absence of device deficiencies further proves stable mechanical performance during the full implantation and withdrawal procedures, minimizing intraoperative mechanical failure risks that may prolong surgery.

Only two patients with prior TVR were included in the overall cohort. Although both patients achieved successful coronary venography and lead implantation using the study catheter, the small sample size precludes robust conclusions regarding the applicability of this device in this subgroup. Large-scale targeted studies focusing on patients with prosthetic tricuspid valves are required to evaluate its applicability in complex anatomical scenarios.

From a clinical practice perspective, this balloon angiographic catheter delivers tangible intraoperative optimization for routine CRT procedures. For patients with heart failure in our cohort, improved venous visualization streamlined the surgical workflow, reduced the total fluoroscopy radiation dose, and reduced contrast consumption, yielding several clinical benefits. First, reduced radiation exposure may provide long-term occupational safety for operators performing large volumes of CRT surgeries [23]. Second, lower contrast dosage may reduce the risk of nephropathy in older patients with heart failure and combined chronic kidney disease, a common comorbidity among Chinese patients with HFrEF [26].

Third, simplified guidewire delivery may reduce procedural difficulty and shorten the learning curve for less experienced interventional cardiologists. Given the high prevalence of tortuous, slim coronary venous branches in patients with dilated cardiomyopathy in China, this device addresses an unmet need for standardized, high-quality coronary venography tools for routine CRT implantation [18].

This study evaluated only short-term (7-day) perioperative endpoints; therefore, long-term outcomes, including late lead dislodgement and sustained resynchronization response, remain unevaluated. Subsequent research directions should include, first, a long-term follow-up cohort tracking 6-month and 12-month cardiac function, adverse cardiovascular events, and device-related complications to verify sustained safety; and second, a head-to-head randomized controlled trial comparing this balloon catheter with conventional single-lumen angiographic catheters to quantify the magnitude of reduction in operative time, radiation exposure, and contrast use.

This study has some limitations. First, it was a single-arm, target-value study without a contemporaneous randomized control group; therefore, we could not directly compare the performance of the novel catheter with that of traditional angiographic catheters. Second, the sample size was relatively limited, and enrollment was primarily from experienced implantation centers, which may have introduced selection bias. Third, only short-term perioperative follow-up (within 7 days) was conducted, and long-term safety and efficacy outcomes were not collected. Finally, only two patients with prior TVR were included, and a subgroup analysis could not be performed, limiting the generalizability of the findings to patients with prosthetic tricuspid valves. Future large-sample randomized controlled studies and subgroup analyses of patients with complex coronary venous anatomy, including those with prior TVR, are needed to define the long-term clinical value of this device.

Conclusions

In this prospective, multicenter study, the LeesCa™ balloon angiographic catheter demonstrated a 100% device success rate for coronary venography among patients undergoing CRT or trans-coronary sinus left ventricular lead implantation, with acceptable procedural time, contrast volume, and fluoroscopy exposure. Given the absence of a comparator arm, these observations are limited to the present study cohort.

Abbreviations

BMI
Body Mass Index
CI
Confidence Interval
CRT
Cardiac Resynchronization Therapy
FAS

Full Analysis Set
HFrEF
Heart Failure with Reduced Ejection Fraction
LBBB
Left Bundle Branch Block
LV
Left Ventricle
LVEDD
Left Ventricular End-Diastolic Diameter
LVEF
Left Ventricular Ejection Fraction
NYHA
New York Heart Association
PPS
Per Protocol Set
SS
Safety Set
TVR
Tricuspid Valve Replacement

Declarations

Ethics approval and consent to participate

This prospective, multicenter clinical study was approved by the Ethics Committee of Peking University People's Hospital (approval no. 2024PHB306-001; approval date: August 19, 2024), the Medical Ethics Committee of Beijing Anzhen Hospital, Capital Medical University (approval no. KS2024086; approval date: August 19, 2024), the Ethics Committee of Guizhou Provincial People's Hospital (approval no. Lun-Shen [Scientific Research] 2024 – 158; approval date: November 12, 2024), and the Medical Scientific Research Ethics Committee of the First Hospital of China Medical University (approval no. Ke-Lun-Shen [2026] 780; approval date: June 30, 2026). The study was conducted in accordance with the Declaration of Helsinki and applicable institutional ethics requirements. All participants provided written informed consent before enrollment.

Consent for publication

All patients signed written consent permitting the publication of anonymized clinical data, procedural fluoroscopic images, and aggregated trial outcomes. No identifiable personal information is included in this manuscript.

Competing interests

The authors declare that they have no competing interests.

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Author Contribution

LX conceived the study and secured funding. ZJ developed the methodology, performed the formal analysis and data curation, and drafted the original manuscript. ZF, LD, HJ, WL, LF, YB, and YS conducted the investigation. WC reviewed and edited the manuscript and supervised project administration. LX and WC acquired funding for the study. All authors read and approved the final manuscript.

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Data Availability

Not applicable.

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Figures

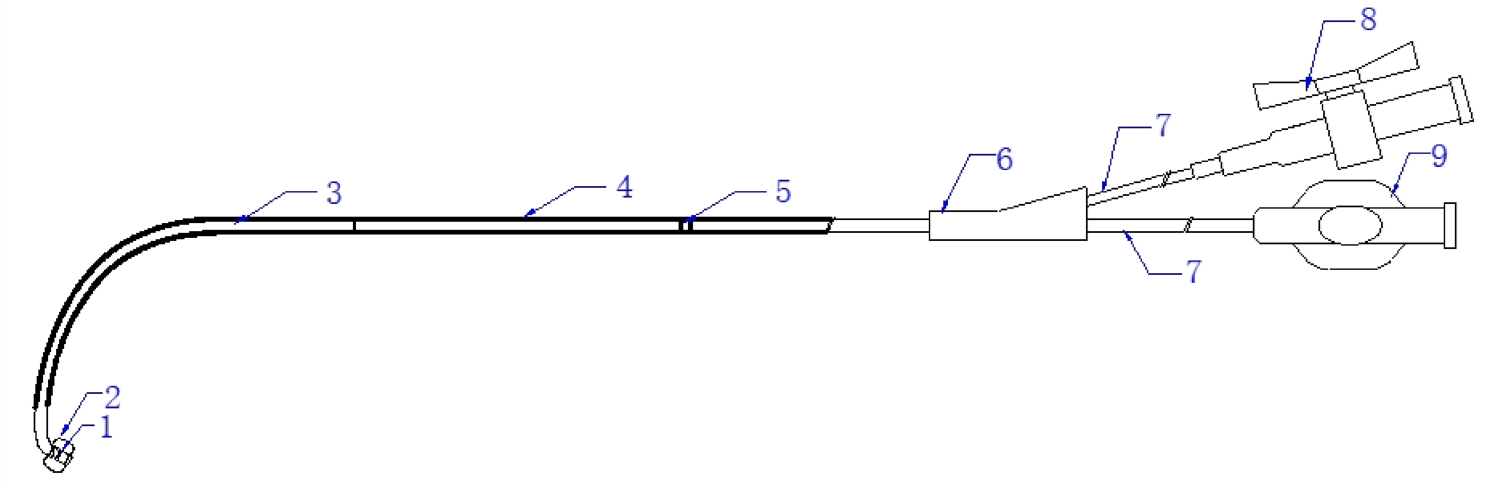


Figure 1

Structural schematic of the LeesCa™ balloon angiographic catheter.

1: Radiopaque marker; 2: Balloon; 3: Catheter body; 4: Hydrophilic coating; 5: Depth marker; 6: Strain relief; 7: Connecting tubing; 8: Luer connector; 9: Main hub.

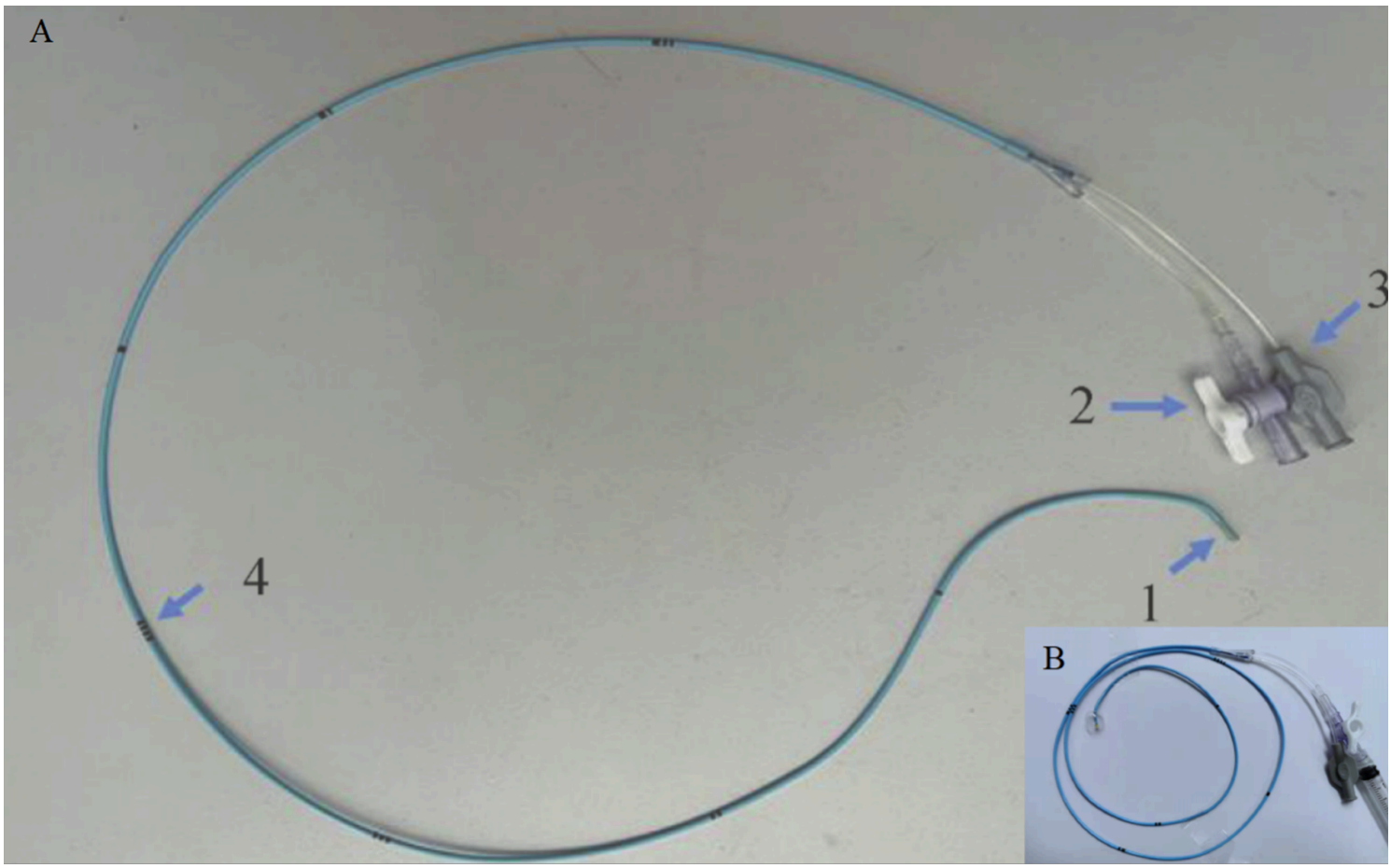


Figure 2

The LeesCa™ balloon angiography catheter.

(a) Structural overview of the catheter. 1: Balloon (non-inflated state); 2: Balloon inflation valve; 3: Central lumen (which accommodates both guidewire and contrast medium); 4: Radiopaque depth markers visible under fluoroscopy. (b) Photograph showing the balloon in its inflated configuration.

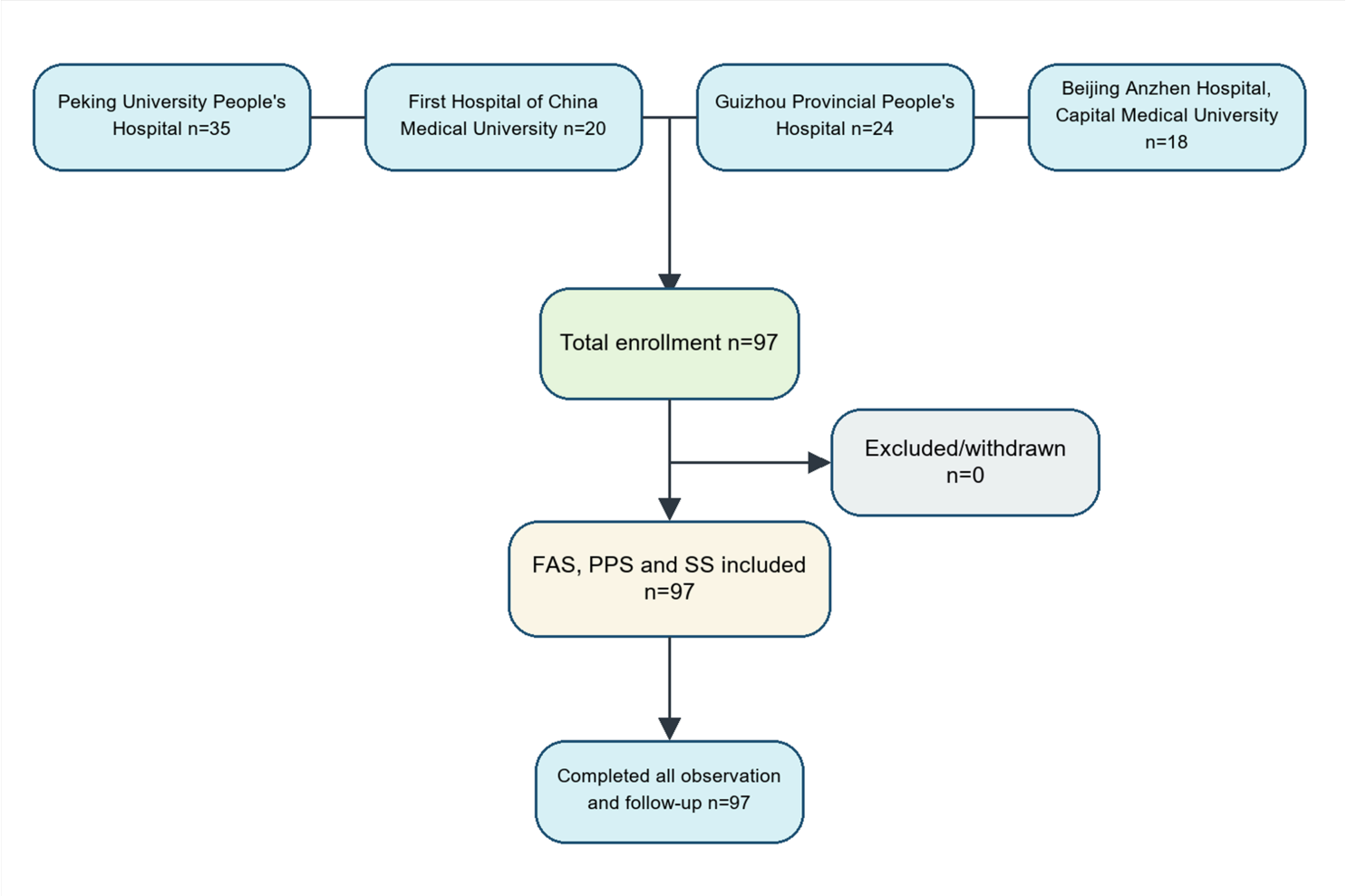


Figure 3

Study flowchart.

FAS, Full Analysis Set; PPS, Per Protocol Set; SS, Safety Population

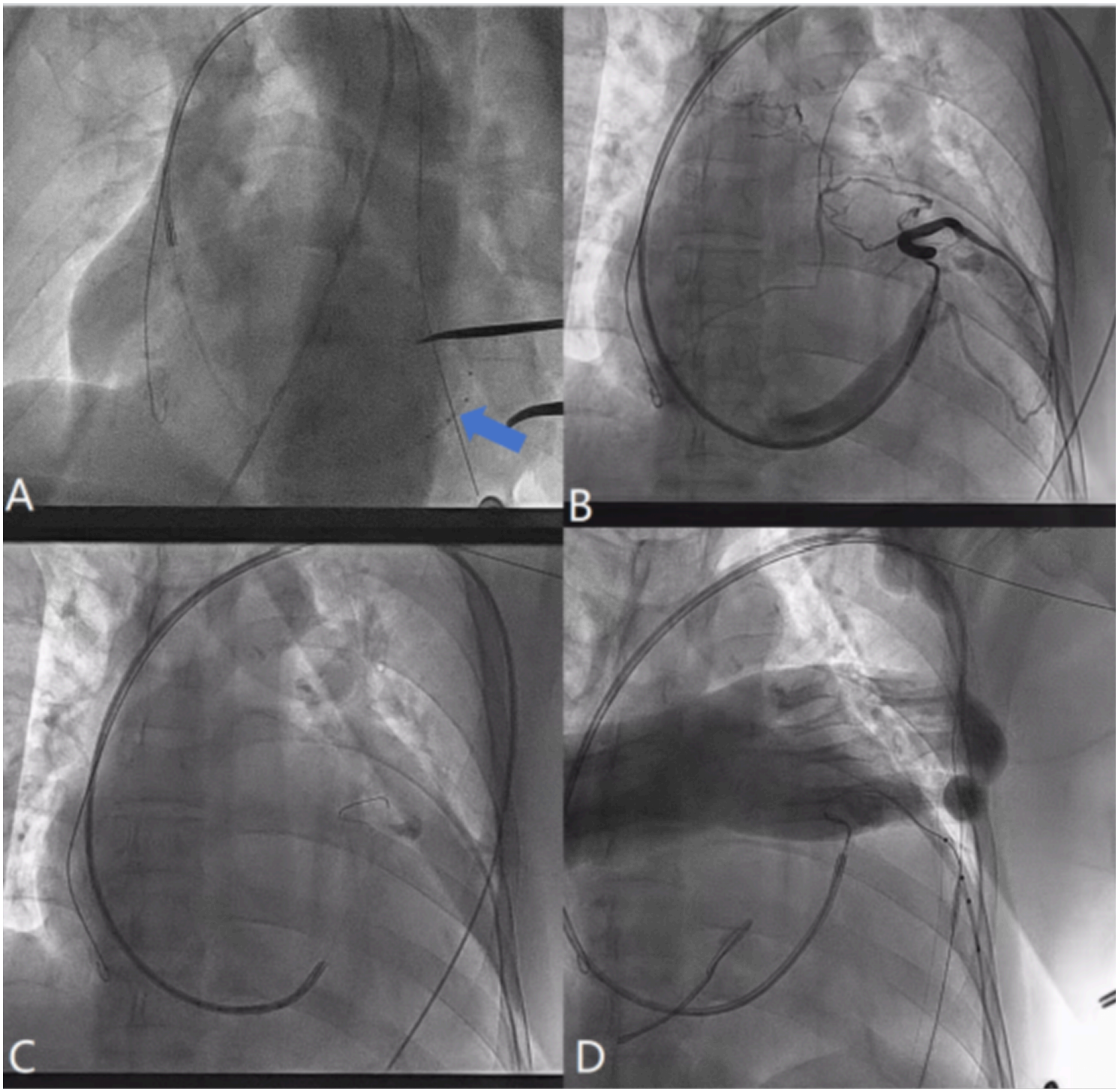


Figure 4

Left ventricular lead implantation using the LeesCa™ balloon angiographic catheter.

(a) The LeesCa™ balloon angiographic catheter advanced into the coronary sinus (blue arrow). (b) Retrograde coronary venography performed after balloon inflation. (c) Guidewire advancement into the target vessel through the catheter. (d) Advancement of the left ventricular lead over the guidewire.

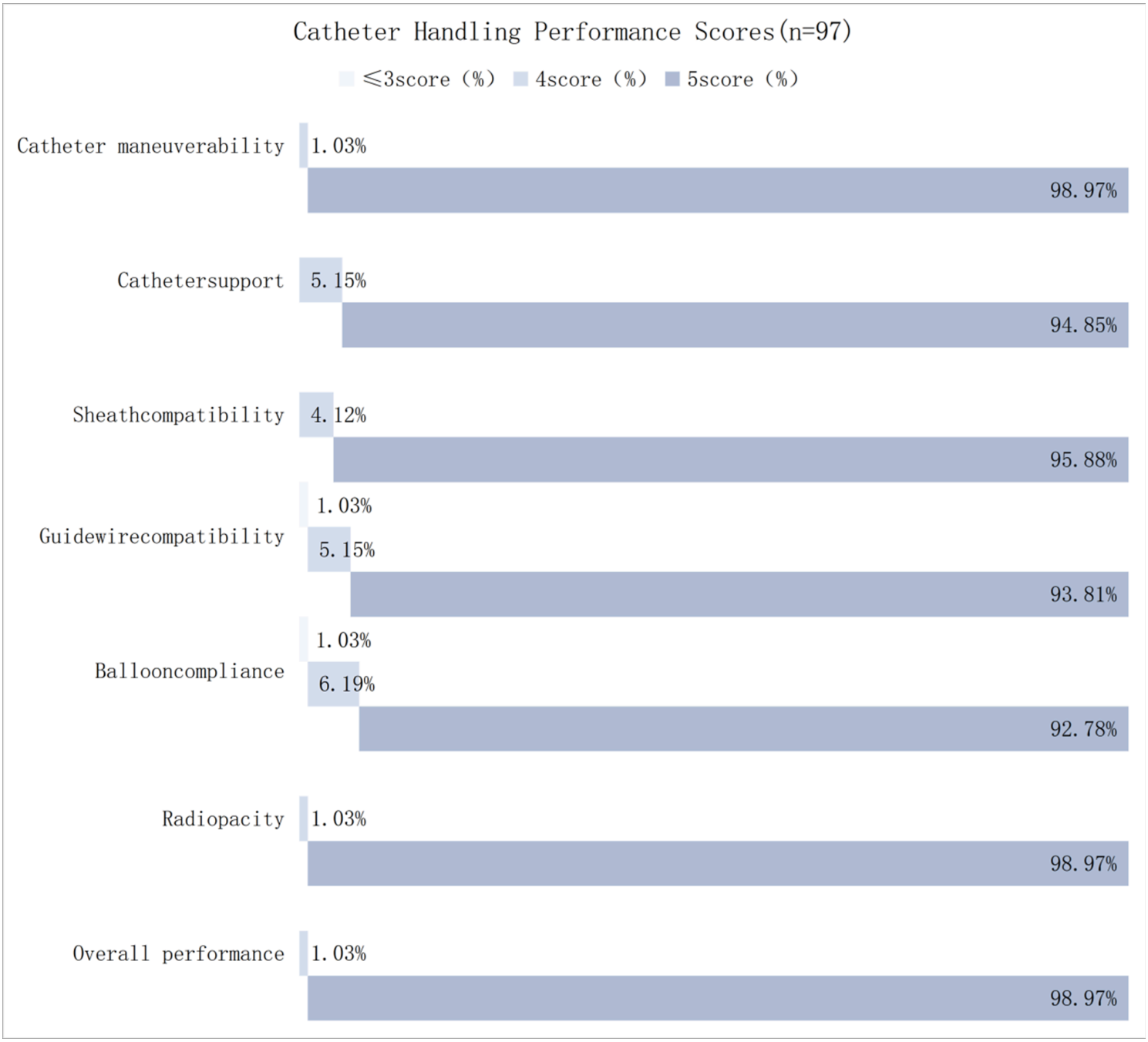


Figure 5

Operator-rated performance of the catheter across all evaluated parameters.

Supplementary Files

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- SupplementaryFile1CONSORTchecklist.docx
- SupplementaryFile2.docx