

Early Safety and Intraoperative Performance of An Intracoronary Shunt in Coronary Artery Bypass Grafting: A Multicenter Real-World Experience

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Abstract

Background: Intracoronary shunts are used during coronary artery bypass grafting (CABG) to maintain distal coronary perfusion and facilitate distal anastomosis. As the device is removed intraoperatively, evaluation is mainly limited to short-term safety and procedural performance. Therefore, this multicenter real-world study assessed the early safety and operational effectiveness of the NAUTICA™ intracoronary shunt during CABG.

Methods: A retrospective observational study consists of 211 patients, who received CABG or Off-pump coronary artery bypass grafting (OPCABG) or CABG with valve surgery at two medical facilities. The NAUTICA™ intracoronary shunt was used during distal coronary anastomosis. The primary endpoints of the study were major adverse cardiac and cerebrovascular events (MACCE) occurred within 30 days. While, length of hospital stay, hemodynamic stability, anastomosis time and device-related complications were secondary endpoints.

Results: The study consists of 211 patients (mean age 64.33 ± 9.54 years; 76.3% male) successful underwent shunt-assisted coronary anastomosis. The mean anastomosis time was 6.98 ± 1.41 minutes. Study reports no intraoperative myocardial infarctions, procedural failures, or shunt-associated complications. Hemodynamic was stable in all patients, with no ischemic changes on intraoperative electrocardiography. One in-hospital major adverse cardiac and cerebrovascular event (MACCE; 0.47%), corresponding to mortality due to acute congestive cardiac failure, was observed. No additional MACCE occurred during the 30-day follow-up.

Conclusion: The study shows a satisfactory intraoperative performance with stable hemodynamics of shunt during CABG. The outcomes of the study shows an acceptable short-term safety of shunt during coronary anastomosis.

Keywords: Intracoronary shunt, coronary artery bypass grafting, off-pump CABG, myocardial protection

Introduction

Coronary artery bypass grafting (CABG), including both traditional on-pump and off-pump approaches, remains to be pivotal in treating patients with severe coronary artery disease with multiple blocked arteries or to those who cannot receive percutaneous interventions. OPCABG remains as a beneficial alternative to traditional on-pump CABG, chiefly because it eliminates the need for cardiopulmonary bypass (CPB), and reduces risks associated with CPB such as systemic inflammation, coagulopathies, and neurological complications 1,2.

The earlier clinical studies have reported that OPCABG procedure produces lower perioperative complications, lower transfusion needs, reduced intensive care unit stays, and shorter hospital stays, primarily among patients at high risk 3,4. The primary technical challenges in OPCABG surgery are creating a precise coronary anastomosis, while keeping the heart continues to beat. Establishing a bloodless and stable operative field with distal myocardium perfusion remains to be a vital requirement during surgery 5.

Intracoronary shunts fulfil this requirement by enabling direct coronary blood flow during anastomosis procedures. The flexible tubes placed at arteriotomy sites provide myocardial blood flow while minimizing ischemic duration and enhancing visibility for suturing. Studies have indicated that these devices help decrease ischemic ECG changes, protect left ventricular function, and reduce postoperative cardiac enzyme levels 6,7.

The NAUTICA™ Intracoronary Shunt is a flexible, radiopaque, single-piece silicone device with a bulb-shaped tip, designed for atraumatic insertion and continuous distal blood flow during OPCABG. Despite positive intraoperative observations, systematic multicenter clinical data remain limited, making intraoperative handling and early postoperative outcomes the most appropriate evaluation endpoints. To address this evidence gap, we conducted a

retrospective, multicenter, observational study without a comparator group to assess the intraoperative performance and short-term safety outcomes (30 day follow-up) of the NAUTICA™ intracoronary shunt during CABG procedures.

Materials and Methods

Study Objective and Design

This retrospective, single-arm, multi-centre, observational, real-world clinical follow-up study was conducted to descriptively evaluate the safety and performance of the NAUTICA™ Intracoronary Shunt in routine clinical practice. Data were collected from the study populations from January 2024 to February 2025, which included patients aged 18 and above who underwent conventional CABG, combination CABG and valve operations, or OPCAB, and received the NAUTICA™ Intracoronary Shunt to maintain distal coronary bed blood flow. Patients who did not receive the NAUTICA™ Intracoronary Shunt during their procedure were excluded (Fig. 1). The treatment data from all qualified patients were extracted retrospectively through a standardised case report form (CRF) after taking institutional ethical approval.

The evaluation was restricted to intraoperative and short-term (30 day) postoperative outcomes, and no causal or comparative inferences were intended, as the device is removed immediately after completion of the anastomosis.

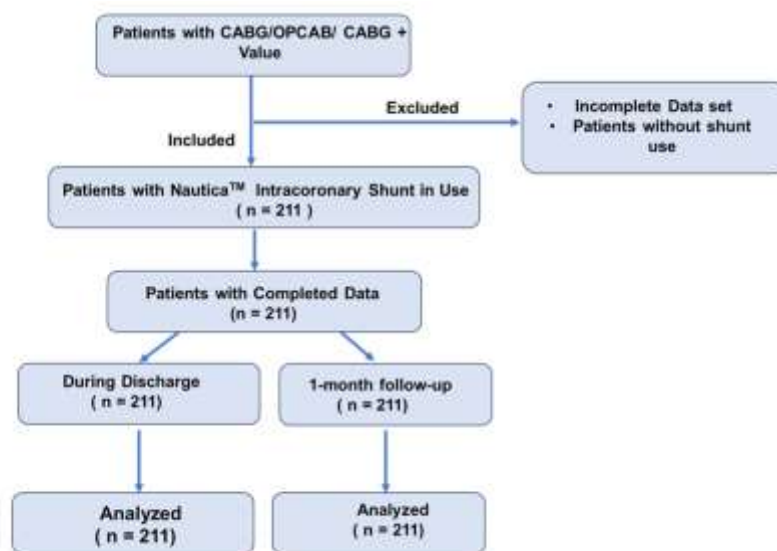


Figure 1. Study flowchart showing patient enrolment, discharge, follow-up, and analysis steps.

Device Description

The NAUTICA™ Intracoronary Shunt is a single use, radiopaque, fully integrated product made of medical grade silicone. The Shunt is a hollow tube that maintains distal coronary perfusion during an OPCABG and creates a bloodless anastomotic field. It is a bulb-tipped catheter that can be safely inserted into a coronary artery in a retrograde fashion. The Shunt has a range of external tip diameters from 1.25mm to 3.00mm, and corresponding internal lumen diameters of 0.5mm to 1.2mm. The product comes in a range of lengths from 19mm to 23mm and has a standardized effective length of 14mm. The mechanical properties of the bonds (shunt to itself and shunt to tag) have been tested to a failure of up to 2N and 5N respectively. In addition, the seal of the Shunt has been tested to a minimum of 364g. A radiopaque suture-secured marker enables easy identification of the Shunt intraoperatively. The marker also aids in the safe removal of the Shunt from the coronary artery. The NAUTICA™ Shunt was used in all of the cases that were enrolled in this study. Therefore, all of the Surgeons and their teams had

identical exposure to the shunt. Intraoperative experience with NAUTICA™ shunts was satisfactory.(fig.2).The device was used consistently across all enrolled cases, and no alternative intracoronary shunts were applied, ensuring uniformity of exposure in this cohort.

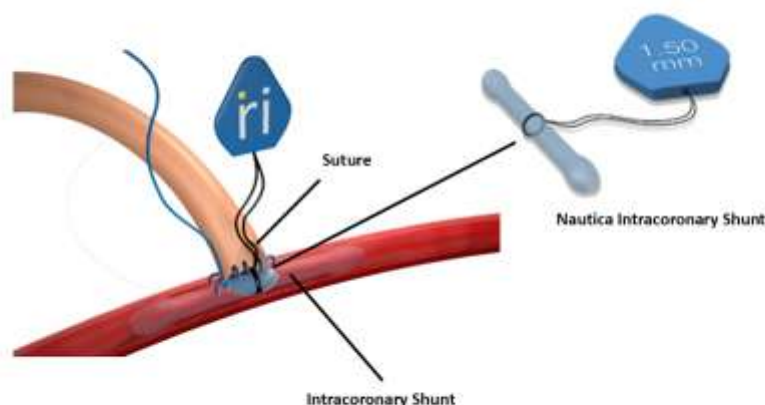


Figure 2. Illustration of NAUTICA™ intracoronary shunt use during CABG, showing insertion, perfusion maintenance, and during anastomosis. (Figure adopted and modified from manufacturer-provided material)

Study Endpoints

The primary endpoints mainly consist of the occurrence of major adverse cardiac and cerebrovascular events (MACCE). Death from any cause, including but not limited to acute myocardial infarction (MI), cardiac arrest with resuscitation, cardiogenic shock, stroke, renal failure, acute respiratory distress syndrome, coronary reintervention, and reoperation for bleeding were recorded as observational safety outcomes. Myocardial infarction (MI) was assessed based on the presence of new Q waves on ECG and/or new regional wall motion abnormalities on echocardiography. Neurological complications, such as stroke and transient ischemic attack (TIA), were evaluated through clinical approach and radiological imaging. The secondary endpoints consists of hyperdynamic shock, angina recurrence (Canadian Cardiovascular Society class II or higher), and postoperative myocardial infarction assessed using clinical, electrocardiographic, and echocardiographic criteria. The study monitored device-related complications, including bleeding, infection, renal and respiratory failure, duration of mechanical ventilation, and length of hospital stay. Endothelial irritation was defined intraoperatively as localized intimal erythema observed at the arteriotomy site without evidence of dissection, flow limitation, or requirement for additional surgical intervention.

Ethical approval

This study was conducted in accordance with the Declaration of Helsinki, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) - Good Clinical Practice (GCP), and ISO 14155:2020 GCP standards. The Institutional Ethics Committee (IEC Document approval letter; DMCH/DTEC/2025/1916) and College of Physiotherapy (IEC Document approval letter; DVVPF'S/COPT/IEC/- 650/A) approved the study prior to initiation. Due to the retrospective and observational nature of the study, there was no direct intervention and modification of the patient's treatment; therefore, the ethics committee waived the informed consent.

Statistical analysis

The study data analysis was conducted on eligible patients using R software version 4.3.2 or higher. The patient demographics are presented using descriptive statistics. The Kolmogorov-Smirnov test was used to check the normality of continuous variables, and the results are presented as mean $\pm$ standard deviation, while categorical variables are presented as frequencies and percentages. Given the single-arm, observational design of the study, no comparative or inferential statistical testing was performed. All outcomes were analysed descriptively. As the intracoronary shunt is a temporary intraoperative device removed at the end of distal anastomosis, pre–post intervention comparisons were not applicable in this study design. Statistical significance was determined at a 5% level only for descriptive consistency, where applicable, and no hypothesis testing or causal inference was intended.

Results

Baseline Demographics and Vital Signs

The study cohort enrolled 211 patients at two different centres. Most participants belonged to the 58–75 years age group with a mean age of 64.33 ± 9.54 years. Among the participants, 76.30% were male. All vital signs of participants showed an average heart rate of 79.70 bpm, systolic BP of 125.47 mmHg, and diastolic BP of 73.26 mmHg. The demographic characteristics of the study participants, along with their baseline clinical information, appear in Table 1.

Table 1. Demographic profile, vital signs, and baseline characteristics of study participants.

DEMOGRAPHIC	n (%)
Age, years, Mean $\pm$ SD	64.33 ± 9.54
Age Distribution Bifurcation	46 (21.80)
40-57	139 (65.88)
58-75	26 (12.32)
76-93	
Gender	161 (76.30)
Male	50 (23.70)
Female	
Height, cm, Mean $\pm$ SD	164.12 ± 8.48
Weight, kg, Mean $\pm$ SD	70.88 ± 8.94
BMI, kg/m ² , Mean $\pm$ SD	26.34 ± 2.93
Vital Signs, Mean $\pm$ SD	79.70 ± 12.53
Heart Rate (bpm)	125.47 ± 16.26
Systolic BP (mmHg)	73.26 ± 8.86
Diastolic BP (mmHg)	

Abbreviations: bpm: beats per minute; cm: centimetre; kilogram/m²: kilogram per meter square; mmHg: Millimeter of mercury; SD: Standard deviation

Comorbidities and Medical History

Table 2 shows the prevalence of diseases that patients already had, as well as their past medical history. Diabetes (45.50%) and hypertension (42.18%) were the two most common comorbid conditions, with coronary artery disease affecting 88.63% of patients. The incidence of less common conditions, including angina and hypothyroidism, and various isolated illnesses that included post-operative, orthopaedic, renal, and autoimmune diseases, was below 2%.

Table 2. Comorbidities and past medical history of patients undergoing NAUTICATM shunt-assisted procedures (N = 211).

MEDICAL HISTORY	n (%)
Hypertension	89 (42.18)
Diabetes	96 (45.50)
Angina	9 (4.27)
Coronary Artery Disease	187 (88.63)
Congestive Heart Failure	1 (0.47)
Myocardial Infarction	1 (0.47)
Social History	7 (3.32)
Smoking	
History of any other illness	1 (0.47)
Post-PTCA to LAD	2 (0.95)
Post PTCA to LCx	1 (0.47)
Post PTCA to OM	1 (0.47)
Post PTCA to RCA	2 (0.95)
Chronic kidney disease	4 (1.90)
- On hemodialysis	1 (0.47)
Acute Coronary Syndrome	2 (0.95)
Anal Fistula	1 (0.47)
Depressive illness	
Bilateral knee replacement	
Foot amputation	1 (0.47)
Hypothyroidism	9 (4.27)
Right Nephrolithiasis	1 (0.47)
Post Cholecystectomy	3 (1.42)
Old Anteroseptal myocardial infarction	1 (0.47)
Old Pulmonary Koch's	1 (0.47)
Peripheral artery disease	1 (0.47)
Post-Cataract Surgery	1 (0.47)
Post-Haemorrhoids Surgery	1 (0.47)
Psoriasis	1 (0.47)
Rheumatic Heart Disease	4 (1.90)
Cardiac Arrest	2 (0.95)
Post partial left nephrectomy	4 (1.90)
Breathlessness	3 (1.42)

Chest Pain Dyspnea Palpitation	
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Abbreviations: LAD: OM: Obtuse marginal artery; PTCA = Post Percutaneous Transluminal Coronary Angioplasty, RCA = Right Coronary Artery.

Procedural Characteristics and Device Specifications

The echocardiographic results showed normal Left Ventricular Ejection Fraction (LVEF) ($\geq 50\%$) in 41.71% of patients, but 32.23% had reduced LVEF below 40%. LAD received the highest number of interventions at 42.02%, followed by Left Circumflex Artery (LCx) with 25.45% and RCA with 24.44%. No intraoperative conversions or procedural failures occurred, and shunt placement was successful in all cases. No intraoperative major adverse cardiac and cerebrovascular events (MACCE) were observed. Minor device-related events included transient bradycardia and localized endothelial irritation, which were self-limiting and did not require additional intervention. The majority of patients underwent OPCAB as their primary procedure (49.76%) at the same rate as patients who received isolated CABG. Most patients presented with double (52.61%) and triple vessel disease (40.28%). The NAUTICA™ shunt procedure showed an average anastomotic time of 6.98 ± 1.41 minutes. This value reflects overall procedural performance during shunt-assisted anastomosis and was not intended as a comparative or superiority measure. The device provided uniform measurements in arterial segments with bulb outer diameters spanning from 1.36 mm Right Coronary Artery (RCA) to 1.50 mm Ramus intermedius artery (RAMUS). The study recorded zero MACCE during operations, and the only minor complications involved brief bradycardia and minimal endothelial irritation affecting between 0.47% and 0.95% of patients. The information about procedures, along with device-related specifications, is highlighted in Table 3.

Table 3. Procedural characteristics, anatomical locations, and device specifications during off-pump coronary interventions using the NAUTICA™ intracoronary shunt.

Procedure	n (%)
LVEF, Mean $\pm$ SD %	46.48 $\pm$ 12.52
LVEF Bifurcation	
Normal LVEF ($\geq 50\%$)	88 (41.71)
Mildly Reduced LVEF (40%-49%)	55 (26.07)
Reduced LVEF ($< 40\%$)	68 (32.23)
Coronary angiography performed, Total Locations	495
Location of Target Lesion	208 (42.02)
LAD	126 (25.45)
LCx	121 (24.44)
RCA	
Others	
RAMUS	40 (8.08)
Index Procedure	
Type of Procedure	105 (49.76)
OPCAB	1 (0.47)
Combined CABG and Valve Surgery	105 (49.76)

CABG	
Diseased Vessel	14 (6.64)
SVD	111 (52.61)
DVD	85 (40.28)
TVD	1 (0.47)
MVD	
Anastomotic time, min, Mean $\pm$ SD, n = 105	6.98 $\pm$ 1.41
Device specification, Mean $\pm$ SD	
LAD, n= 234	1.48 $\pm$ 0.12
Bulb Outer Diameter, mm	19.83 $\pm$ 0.38
Total Length, mm	
LCx, n= 134	1.38 $\pm$ 0.16
Bulb Outer Diameter, mm	19.43 $\pm$ 0.50
Total Length, mm	
RCA, n= 127	1.36 $\pm$ 0.21
Bulb Outer Diameter, mm	19.32 $\pm$ 0.56
Total Length, mm	
RAMUS, n= 40	1.50 $\pm$ 0.19
Bulb Outer Diameter, mm	19.78 $\pm$ 0.48
Total Length, mm	
Major Adverse Cardiac and Cerebrovascular Events	0 (0.00)
Device-related complications	2 (0.95)
Transient bradycardia	1 (0.47)
Mild vessel spasm	2 (0.95)
Localized endothelial irritation.	1 (0.47)
Minor localized endothelial irritation occurred due to a technical difficulty encountered.	

Abbreviations: DVD: Double Vessel Disease; MVD: Multiple Vessel Disease; SVD: Single Vessel Disease; TVD: Triple Vessel Disease

Intraoperative Device Handling

The NAUTICA™ intracoronary shunt had no trouble inserting the target coronary vessel through standard forceps. The combination of atraumatic tip design and low-profile construction made it possible to insert the device easily through calcified or small-calibre arteries. No device dislodgement, insertion-related trauma, or technical failure was observed during intraoperative use. The images in Fig. 3 A-C show the shunt placement during diagonal artery grafting and LAD and RCA grafting procedures.

The myocardial stabilizers maintained specific areas of cardiac stability while suction devices maintained an unobstructed surgical area. The shunt created a bloodless anastomotic site through continuous distal perfusion, which enabled precise suturing without causing any hemodynamic problems during surgery. The procedure revealed no instances of device dislodgement, insertion trauma, or technical failure.

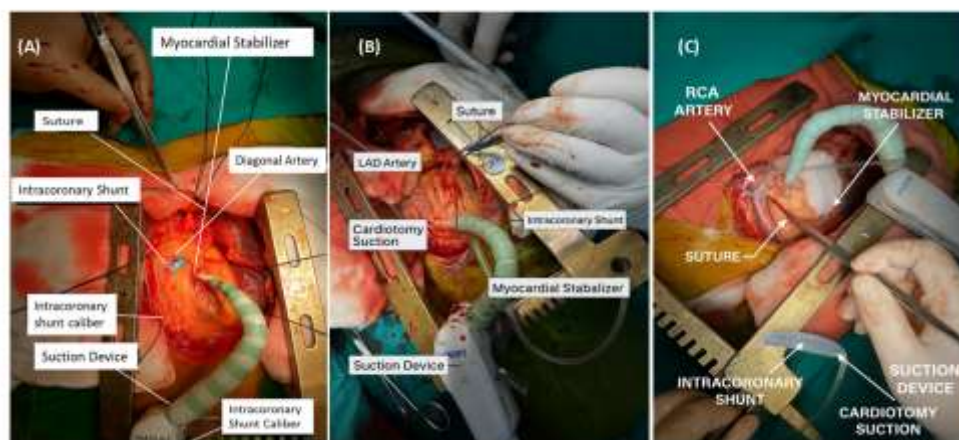


Figure 3 (A–C). Intraoperative placement of the NAUTICA™ intracoronary shunt during coronary artery bypass grafting, illustrated in off-pump settings: (A) diagonal artery, (B) left anterior descending (LAD), and (C) right coronary artery (RCA) anastomoses.

In-Hospital and Short-Term Clinical Outcomes

Among the 211 patients included, 210 were discharged, while one patient (0.47%) experienced in-hospital mortality due to acute congestive cardiac failure. The mean hospital stay was 11.34 ± 3.63 days. No cases of postoperative myocardial infarction, stroke, angina, or device-related complications were recorded. One in-hospital major adverse cardiac and cerebrovascular event (MACCE; 0.47%), corresponding to the reported mortality, was observed. Early in-hospital and 30-day clinical outcomes are summarized in Table 4. At 1-month, 210 discharged patients completed their follow-up, during which no new MACCE, myocardial infarctions, device-related complications, angina, or serious adverse events were reported.

Table 4. Early Clinical Outcomes During Hospitalization and at 30-Day Follow-Up

Outcome	In-Hospital (n = 211)	30-Day Follow-Up (n = 210)
All-cause mortality	1* (0.47%)	0
Major adverse cardiac and cerebrovascular events (MACCE)	1* (0.47%)	0
Acute myocardial infarction	0	0
Stroke	0	0
Repeat revascularization	0	0
Device-related complications	0	0
Diagnosis of hyperdynamic shock	0	0
Mechanical ventilation used	0	0
Angina experienced post-	0	0

operatively		
Muscle spasm (Chest cramp, ST depression, low magnesium)	2 (0.95 %)	
In-hospital adverse events/serious adverse events (AE/SAE)	1* (0.47%)	0
Length of hospital stay (days), mean $\pm$ SD	11.34 $\pm$ 3.63	—

*: The same patient. Abbreviation : AE/SAE : Adverse Event/ Serious Adverse Event

Note: The single in-hospital MACCE corresponded to death due to acute congestive cardiac failure in a patient with severe pre-existing left ventricular dysfunction. No additional MACCE or device-related adverse events were observed during the 30-day follow-up period.

Discussion

The present study demonstrates the surgical safety and early postoperative outcomes following use of the NAUTICATM intracoronary shunt during CABG intervention procedure. The study results shows an maintenance of myocardial perfusion and stable hemodynamics during intraoperative conditions on use of intracoronary shunting at CABG procedure. In our cohort of 211 patients, all anastomosis were completed successfully using the NAUTICATM shunt without any need for intraoperative conversion to cardiopulmonary bypass. The mean anastomosis time reached 6.98 ± 1.41 minutes, reflecting overall procedural performance during shunt-assisted anastomosis rather than device superiority, which exceeded the results from various previous studies.

Tüfekçi et al. in their study has reported a longer mean anastomosis times in shunt-assisted groups compared to non-shunt groups (7.7 ± 1.0 vs 6.8 ± 0.7 minutes; $p = 0.041$), indicating a mild delay due to the insertion and positioning of the shunt 9. The observed mean anastomosis time reflects procedural performance in this cohort and should not be interpreted as evidence of device-related efficiency or superiority.

Previous research has shown that intracoronary shunts successfully preserve blood flow to the distal coronary arteries during beating-heart grafting operations. Takami et al. in their study showed that shunt implementation maintained approximately 50% of typical coronary blood flow which protected the heart from ischemia 7. During the procedure in our study, stable hemodynamic parameters and the absence of ischemic changes on intraoperative ECG were observed, which indicates the NAUTICATM shunt's ability to maintain myocardial perfusion. The research results from our study confirmed the findings which Yeatman et al. reported in their investigation. where the stunt implementation decreased in cardiac index and stroke volume that occurs with conventional snaring 10. The observed outcomes from our intraoperative procedures matches the observations because all patients maintained stable blood pressure and heart rate without requiring any medication or intra-aortic balloon pump assistance.

Further, The study observed acceptable early safety outcomes within the limitations of a retrospective single-arm design. The study by Maile et al., supports our findings because they found in their study that no increased perioperative morbidity when using intracoronary shunts in OPCAB cases 11. The NAUTICA™ shunt was deployed across various vessel types in this cohort; however, consistent with previous reports such as Elsharkawy et al., its flexible tip and insertion profile may facilitate atraumatic placement. No direct causal inference regarding clinical benefit can be drawn from this observational study 12. Further, a study by Zhang et al., which included 4,889 redo CABG patients, demonstrated that off-pump techniques were associated with lower 30-day mortality rates and fewer complications than on-pump surgery, supporting the broader safety of OPCAB approaches 13. Although the absence of a comparator group is a limitation, the overall safety of shunt-assisted OPCAB was supported by a low incidence of early adverse events, with one in-hospital major adverse cardiac and cerebrovascular event (MACCE;

0.47%) corresponding to mortality in a high-risk patient, and no additional perioperative myocardial infarction or device-related complications. As the intracoronary shunt is a temporary intraoperative device removed at the completion of distal anastomosis, 30-day outcomes should not be interpreted as directly attributable to the device.

In our cohort, no additional complications were observed in patients with reduced LVEF; however, given the observational design, no direct causal relationship with shunt use can be established. Furthermore, our findings are in alignment with Srivastava et al., who demonstrated the safe and effective use of intracoronary shunts in 12% of totally endoscopic beating heart CABG procedures. Their use facilitated completion of anastomosis without time constraints and helped manage intraoperative ischemia, supporting the utility of shunts in complex off-pump revascularisation scenarios 14. While our findings affirm the short-term safety and technical feasibility of intracoronary shunting, long-term graft patency was beyond the scope of this study, as no angiographic or imaging-based follow-up was conducted.

Furthermore, the postoperative results demonstrate that the NAUTICA™ intracoronary shunt provides both intraoperative safety and technical reliability during surgical procedures. The absence of device-related complications and postoperative myocardial infarction or angina supports acceptable procedural safety across patient subgroups, without implying causality. Only one patient (0.47%), with pre-existing severe left ventricular dysfunction, experienced a major adverse cardiac event and subsequently died due to acute congestive cardiac failure, which was considered attributable to the patient's underlying cardiac condition rather than the intracoronary shunt or procedural factors. The two patients (0.95%) who experienced transient chest cramps with ECG changes had low serum magnesium levels but recovered without any lasting effects. In our cohort, no additional complications were observed in patients with reduced LVEF; however, given the observational design, no direct causal relationship with shunt use can be established.

Limitations

This is a retrospective single center, non-comparative, observational study. Thus, it does not allow to establish a causal relationship between the variables under study and any other variable. The study does not allow a direct comparison with other techniques. In addition, the absence of intraoperative flowmetry and of postoperative imaging of the graft does not allow an assessment of the graft patency.

Strengths

Despite these limitations, the multicentre real-world design strengthens the clinical applicability. Consistent use of the NAUTICA™ intracoronary shunt across OPCAB procedures demonstrates the procedural feasibility and performance consistency. With acceptable anastomosis time, along with the absence of device-related complications supports favourable short-term intraoperative performance and safety of the device

Conclusion

The NAUTICA™ intracoronary shunt demonstrated acceptable intraoperative performance in this retrospective observational cohort. The device enabled completion of distal anastomosis with stable hemodynamics and no intraoperative MACCE, while one in-hospital MACCE (0.47%) corresponding to mortality was observed, with no additional events during short-term follow-up. The findings represent descriptive real-world observations and should be interpreted within the limitations of a single-arm, non-comparative design. Further comparative studies with longer follow-up are required to better define the clinical role of intracoronary shunting.

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Author Contribution

Sarju Ralhan and Vinod Chinde contributed to conceptualization, methodology, formal analysis, investigation, data curation, supervision, project administration, and preparation of the original draft manuscript. Nirali Chauhan and Kiran Kumar Shetty contributed to editorial assistance, manuscript preparation support, and visualization. All authors participated in manuscript review and editing and approved the final version of the manuscript.

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