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Clinical performance and safety of the Vector® percutaneous transluminal coronary angioplasty balloon catheter: A single-arm, multicenter, retrospective post-marketing clinical study

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Original Article

Abstract

BACKGROUND: The present post-marketing clinical study was conducted over a 12-month follow-up period to monitor the clinical outcomes of patients treated with the Vector® Percutaneous Transluminal Coronary Angioplasty (PTCA) Balloon Catheter for the dilatation of coronary lesions. The semi-compliant balloon improves balloon-to-vessel wall apposition and minimizes balloon slippage during PTCA, which could reduce complications and improve clinical outcomes. This investigation aimed to assess the safety and effectiveness of the Vector® PTCA Balloon Catheter in real-world settings.

METHODS: A retrospective study was conducted to investigate the safety and efficacy of the Vector® PTCA Balloon Catheter in 125 patients who underwent pre-dilatation and post-dilatation. The primary outcome of the study was major adverse cardiac events (MACE), a composite endpoint encompassing target-lesion revascularization (TLR), cardiac death, and myocardial infarction (MI).

RESULTS: The Vector® PTCA Balloon Catheter has shown promising results in a small group of patients undergoing dilatation of normal and intricate coronary artery lesions, reflecting a 100% procedural success rate. The successful delivery to the target lesion, deployment, and subsequent retrieval of the device during the index procedure led to a 100% device success rate without any technical issues. A total of 3.2% (4) patients experienced MACE during the 12-month follow-up, with 1.6% (2) MI, 1.6% (2) TLR, and no cardiovascular deaths..

CONCLUSION: This study demonstrated the favorable safety and reliability of the Vector® PTCA Balloon Catheter in patients with angina, MI, and a history of coronary artery disease in a real-world setting.

Keywords: Balloon Angioplasty; Coronary Stenosis; Dilatation; Major Adverse Cardiac Event; Percutaneous Coronary Intervention; Semi-Compliant Balloon

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Introduction

Percutaneous transluminal coronary angioplasty (PTCA), a minimally invasive endovascular procedure known as percutaneous coronary intervention (PCI), serves to restore unimpeded blood flow through blocked or narrowed coronary arteries. It was invented 40 years ago and has since paved the way for advancements in treating atherosclerosis. Atherosclerosis is the build-up of fat, cholesterol, and other substances on and within the walls of arteries. It significantly contributes to poor health, impairment, and mortality in the world's most industrialized and emerging nations[1-3]. Cardiovascular diseases continue to be the primary cause of mortality worldwide, with

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a staggering 80% of this burden borne by low- and middle-income nations, posing a significant concern in the healthcare sector as a multifactorial disease[4, 5]. The risk factors involve medical histories such as hypertension, hyperlipidemia, diabetes, obesity, and social histories like smoking, alcohol consumption, genetic causes, and some environmental factors[6]. Hence, advancements in understanding the etiology, diagnosis, and treatment have been possible through numerous discoveries in various fields of medical science and are still in progress, aiming for better restoration of obstructed blood flow in single, double, or triple diseased vessels[7]. These obstructions may present in the form of angina, myocardial infarctions (MI), and acute coronary syndrome (ACS), in which PTCA is advised along with its pharmacological therapies for higher chances of survival[8, 9]. Although PTCA has been widely practiced for decades, it can lead to major post-procedural complications such as cardiovascular death, vessel perforation, coronary artery dissection, excess bleeding that requires a transfusion, acute MI, target lesion failure (TLF), and target vessel revascularization (TVR)[10-12].

Angioplasty attempts to relieve distal ischemia by compressing the plaque with a balloon or stent and opening the stenosed artery[13, 14]. Pioneering the field of coronary interventions, balloon catheters continue to hold the position of the primary workhorse device, effectively serving both pre- and post-dilatation of atherosclerotic lesions[15]. Additionally, selecting appropriate balloon characteristics, such as lesion-crossing ability, vector force, or inflation pressure, is crucial for effective intervention, depending upon the lesion extension and density of the diseased vessel[16, 17]. The interventional cardiologist must carefully assess the patient's condition and lesion characteristics to select the most suitable balloon catheter. The advancement of balloon catheter systems has been driven by a consecutive stream of groundbreaking innovations, including the introduction of semi-compliant, non-compliant, and super high-pressure balloons, as well as cutting or scoring balloons and micro or miniature balloons, the development of steerable catheters, the refinement of catheter exchange techniques, and the integration of these advancements into comprehensive balloon catheter systems[15, 18]. SC balloons facilitate controlled and gradual arterial dilation, essential for gentle vessel expansion without excessive strain. By preconditioning the artery for stent implantation, these devices promote consistent and stable stent deployment. SC balloons optimize stent apposition to the vascular wall through arterial predilation, thereby reducing the risk of vessel trauma and complications such as dissection or perforation. The polyamide copolymer balloon material enables crossing profiles of 0.65 to 0.70 mm due to its low wrapping profile. The semi-compliant nature of the polyamide copolymer framework ensures precise vessel accommodation and controlled inflation, significantly mitigating the risk of vessel injury. Moreover, advanced folding and pleating technology guarantees accurate and reproducible balloon wrapping, enhancing overall catheter performance. The current post-market clinical study aimed to assess the safety and performance of the Vector® PTCA Balloon Catheter in real-world settings.

Materials and Methods

This study was conducted retrospectively, evaluating a single treatment group of patients at Maharaja Agrasen Hospital, Siliguri, West Bengal, India, and North Bengal Medical College and Hospital, Siliguri, West Bengal, India, over a 12-month period following the product's market release. The study was performed as per the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) - Good Clinical Practice (GCP), the International Organization for Standardization (ISO) 14155:2020, and local regulations. The clinical study was performed in compliance with the Declaration of Helsinki. The Om Institutional Ethics Committee, Ahmedabad, India, approved the study in its presented form. The patients who underwent PTCA catheterization with the Vector® PTCA Balloon Catheter for the expansion of balloon-expandable stents after implantation were allowed to participate in the study. The study included 125 patients who had been treated with the Vector® PTCA Balloon Catheter. However, 69 patients were excluded from the study due to screen failure. The demographic characteristics and medical history of the individuals subjected to the surgical intervention were recorded.

Study Device Description

The Vector® PTCA Balloon Catheter is a rapid

exchange PTCA dilatation catheter with semi-compliant properties, facilitating seamless catheter exchange using a standard-length guide wire. The proximal section of the rapid exchange catheter has a polytetrafluoroethylene (PTFE)-coated hypo tube equipped with a solitary luer port hub for balloon inflation and deflation to facilitate precise pressure control. The catheter's proximal shaft, constructed of stainless steel and coated with PTFE, exhibits exceptional pushability and trackability, enabling smooth advancement through the vessel. The outer lumen serves as the inflation pathway, and the inner lumen accommodates guide wires with a diameter of ≤ 0.014 inches (0.36 mm) to facilitate catheter navigation to and through the stenosis or stent for dilation. The specifically designed distal shaft allows frictionless trackability through the tortuous vasculature. This semi-compliant balloon (SCB) allows high-pressure dilatation of stenotic segments with controlled expansion size to offer an inflatable section with specified diameter, length, and optimal pressure levels. Radiopaque platinum-iridium marker bands on the catheter's balloon segment facilitate precise positioning under fluoroscopy. Balloons with 1.0 mm and 1.50 mm diameters carry one marker band, while all others have two radiopaque marker bands. Two marked segments on the proximal hypotube shaft indicate the catheter's location relative to the guiding catheter tip. A balloon protector maintains a low profile, and an internal mandrel preserves catheter patency. The tapered catheter tip eases advancement to and through the stenosis or stent. The catheter design lacks a distal lumen for dye injections or pressure measurements. The Vector® PTCA Balloon Catheter is available in diameters of 1.00, 1.25, 1.50, 2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, and 4.5 mm. The lengths available are 7, 10, 12, 14, 16, 18, 20, 25, 29, 34, 39, 43, and 45 mm. The Vector® PTCA Balloon Catheter is illustrated in Figure 1.

Study Procedure

Prior to the use of the Vector® PTCA Balloon Catheter, the patients were adequately hydrated. Medication reassessment was required, including anticoagulant discontinuation if possible. Common drugs, such as non-steroidal anti-inflammatory drugs (NSAIDs) or angiotensin-converting enzyme inhibitors (ACEIs), were also avoided to prevent increasing renal insufficiency. To avoid worsening renal failure and lactic acidosis, the diabetic medicine metformin was withheld before cardiac catheterization. The treatment was carried out under local anesthetic.

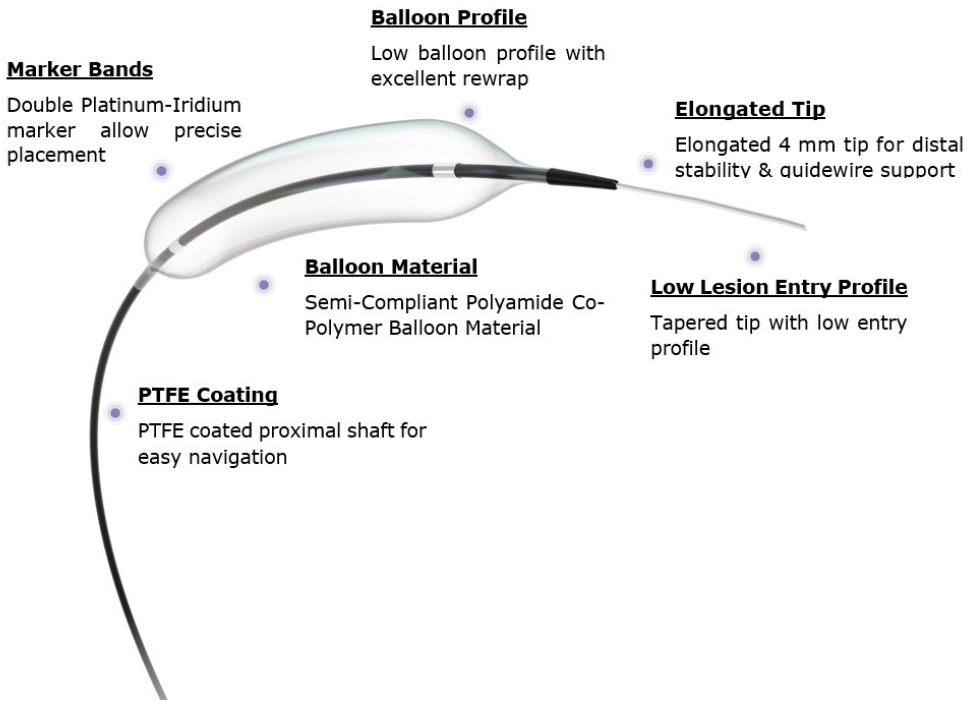

Figure 1. Eligibility Criteria

First, a needle was placed into the femoral/radial artery after the patient had been sedated with a localized injection of lidocaine (1.5 mg/kg) into the surface layers of the skin and tissues located just beneath the skin directly above the right femoral artery. Upon successful needle insertion, the needle was navigated into the blood vessel's lumen with the guidewire as a conduit. Subsequently, the needle was carefully retracted, leaving the guidewire securely positioned within the vascular lumen. Over the guidewire, an introducer-equipped sheath was inserted into the femoral artery. Following the guidewire's removal, the introducer was also carefully withdrawn, leaving only the sheath strategically positioned within the vascular lumen. This configuration facilitates seamless access to the femoral/radial artery lumen.

Subsequently, the "diagnostic catheter," a slender tube equipped with an internal guidewire, was meticulously advanced through the sheath. The diagnostic catheter was advanced retrograde into the femoral artery, iliac artery, descending aorta, aortic arch, and proximal ascending aorta. Subsequently, the guidewire was then withdrawn, keeping the diagnostic catheter tip in the ascending aorta. A syringe was used to connect the diagnostic catheter to the manifold. The manifold enables the injection of contrast, the measurement of inter-arterial pressure, and the administration of drugs. The diagnostic catheter was subsequently inserted into the ostium of the left or right major coronary artery. Contrast dye was injected, allowing for comprehensive visualization of both arteries through cine angiography. PTCA was performed if severe stenosis was detected in one of the arteries. The diagnostic catheter was subsequently withdrawn and replaced with a guiding catheter of similar caliber. Guiding catheters possess a larger luminal diameter to facilitate the passage of wires and balloons during angioplasty.

Following the insertion of the guiding catheter into the ostium of the affected artery, a PTCA guidewire was meticulously maneuvered through the catheter and across the stenotic lesion. Upon successful navigation of the stenosis, the PTCA guidewire was maintained until the procedure was completed. A Vector® PTCA Balloon Catheter wire was skillfully advanced over the PTCA guidewire until precisely positioned over the stenotic site. With precise control, the cardiologist directs and moves the PTCA guidewire and the balloon wire by rotating the external segment of these devices. Subsequently, the Vector® PTCA Balloon Catheter was continuously inflated and deflated until the artery was patent. The PTCA guidewire was then removed. Anticoagulation was used during the surgery to avoid clot formation. Depending on the technical complexities of the case, the complete procedure took from 30 minutes to 3 hours. Procedural success was defined as achieving less than 50% residual diameter stenosis with thrombolysis in myocardial infarction (TIMI) flow grade 3 and no in-hospital adverse events.

Study Endpoints and Definitions

The outcomes assessed during this long-term follow-up included cardiac death, myocardial infarction (MI), target lesion revascularization (TLR), target vessel revascularization (TVR), major adverse cardiac event (MACE), procedural success rate, and device success rate. Procedural success was defined as achieving <50% residual diameter stenosis with TIMI flow grade 3 and no in-hospital adverse events[19]. Device success was determined by the successful delivery, deployment, and retrieval of the study device at the site of stenosis during the interventional procedure[20].

MACE served as the primary endpoint of the clinical study, encompassing the combined incidence of cardiac death, target vessel MI, and TLR[21]. Cardiac death was attributed to cardiac causes unless overt non-cardiac causes could be established[22]. MI refers to tissue death resulting from ischemia, a condition characterized by insufficient oxygen delivery to myocardial tissue[23]. TLR was defined as any repeat intervention on the treated lesion, prompted by either a positive functional ischemia test (exercise stress testing, fractional flow reserve, or nuclear imaging) accompanied by ischemic symptoms, or a diameter stenosis of 70% or more in the angiographically relevant segment of the vessel without accompanying symptoms of ischemia or a positive functional study[21]. TVR was defined as any repeat intervention on the previously treated vessel involving either PCI or repeated coronary artery bypass grafting (CABG)[24].

Sample Size and Statistical Analysis

A 125-patient sample size was provided with a two-sided 95% confidence interval width of 0.067 (Wilson method) and a power of 85% with a reference

proportion of 14.6%. Descriptive statistics were employed to characterize the data set. For categorical variables, frequency distributions, including relative frequency and percentages, were generated, and the statistical analyses were conducted using SPSS v.20. For continuous variables, the outcomes were presented as mean ± standard deviation. In contrast, results were reported as numbers (%) for nominal variables. The Wilcoxon test was employed for ordinal variables to assess pre-post differences, and the paired t-test was utilized for continuous variables. For comparisons of frequency distributions, the chi-square test or Fisher's exact test was used, as required. The results were statistically significant, with a P-value lower than 0.05.

Results

Baseline and demographic characteristics

Table 1 outlines the baseline and demographic profiles of the selected study population. There were 83 (66.40%) males and 42 (33.60%) females, with a mean age of 59.33 ± 10.67 years. Out of 125 patients, 59 (47.20%) had a history of hypertension, 58 (46.4%) had diabetes, 49 (39.2%) were smokers, 11 (8.80%) had hyperlipidemia, and 9 (7.20%) had coronary artery disease. Moreover, 65 (52%) patients had stable angina, 30 (24%) patients had STEMI, 19 (15.2%) patients had NON-STEMI, and 11 (8.8%) patients had unstable angina. Lesions were categorized based on the American College of Cardiology (ACC)/American Heart Association (AHA) lesion morphology criteria detailed in Table 2[25].

Procedural Characteristics

Treatment was administered to 141 lesions using the Vector® PTCA Balloon Catheter in 125 patients. The majority of the patients, 110 (88.00%), had lesions in a single vessel, and 15 (12.00%) patients had double diseased vessels. The average stent measurements were 10.82 ± 2.24 mm in length and 2.15 ± 0.47 mm in diameter, respectively. The mean length of the identified lesions was 10.87 ± 1.68 mm. Table 2 summarizes the details of procedural characteristics. The locations of lesions are added in Table 2.

Table 3 incorporated information related to post-procedural and discharge-related characteristics.

Table 1. Baseline and Demographic Profiles

Baseline Characteristics	n = 125 patients
Age (year), Mean ± SD	59.33±10.67
Male, n (%)	83(66.40)
Female, n (%)	42(33.60)
Angiography, n (%)	125 (100)
Anticoagulant / antiplatelet therapy, n (%)	125 (100)
Single vessel, n (%)	110 (88)
Double vessel, n (%)	15 (12)
Baseline TIMI flow, n (%)	
1	116 (92.80)
2	09 (7.20)
% Occlusion at pre-procedure (%)	84.00
100% occlusion, n (%)	16 (1.07)
Heart Rate (bpm), Mean ± SD	81.78±10.95
Diastolic Blood Pressure Mean ± SD	80.69±12.60
Systolic Blood Pressure Mean ± SD	129.03±24.60
Medical history, n (%)	
Hyperlipidaemia	11(8.80)
Hypertension	59(47.20)
Smoking current	49 (39.20)
Diabetes Mellitus	58 (46.40)
Stable Angina	65 (52.00)
Acute coronary syndrome	60 (48.00)
STEMI	30 (50.00)
Non-STEMI	19 (32.00)
Unstable Angina	11 (18.00)
CAD	09 (7.20)

CAD- Coronary artery disease, SD-standard deviation, STEMI-Segment Elevation Myocardial Infarction, TIMI-thrombolysis in myocardial infarction

Procedural success and device success were achieved in 100% of patients. The results indicated that the device demonstrated satisfactory performance in usability, flexibility, crossability, trackability, and deliverability. The investigators did not experience difficulties during the balloon's inflation, deflation, or withdrawal. The incidence of cardiac events related to the utilization of the Vector® PTCA Balloon

Table 2. Procedural Characteristics

Clinical Characteristics	n = 125 Patients
Total no, of lesions (n)	141
Lesion length (mm) Mean ± SD	10.22±1.77
Study device details	
Balloon length (mm) Mean ± SD	10.99±1.77
Balloon diameter (mm) Mean ± SD	2.15±0.47
Balloon pressure pre-dilatation (atm.), Mean ± SD	11.04±1.21

atm.-Atmospheric pressure, SD-standard deviation

Table 3. Post-procedural and discharge-related characteristics

Questions	Yes (n%)	No (n%)
Was a final residual stenosis of less than 50% with TIMI 3 flow established?	125 (100.00)	00(00)
Did any procedure-related complication occur?	00(00)	125 (100)
Did any device-related complications occur?	00(00)	125 (100)
Achievement of successful access, deployment, and retrieval of the device at the target lesion during the first intervention.	125 (100)	00 (00)
Did the procedure result in vessel perforation, decrease in TIMI flow, or flow-limiting vessel dissection, compared to the initial measurements?	00	125 (100)
Did any In-Hospital AE/SAE occur?	29 (23.2)	96 (76.8)
Any medications	125 (100)	00
Did any cardiac death occur?	00	125 (100)
Myocardial Infarction (MI)	02 (1.6)	123 (98.4)
Target-Lesion Revascularization (TLR)	02 (1.6)	123 (98.4)
Procedural success [n (%)]	125 (100)	00 (00)
Device success [n (%)]	125 (00)	00(00

AE-adverse event, n-number of patients, SAE-severe adverse event, TIMI – Thrombolysis in Myocardial Infarction.

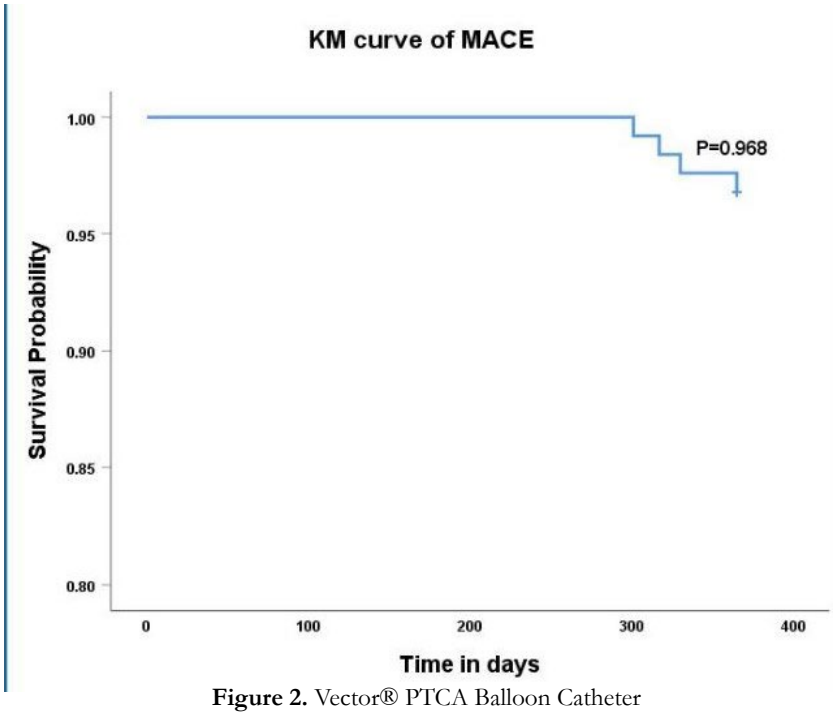

Figure 2. Vector® PTCA Balloon Catheter

Catheter at the 12-month follow-up reported 4 (3.2%) patients with MACE. At 12 months, 2 (1.6%) patients had TV-MI and TLR compositely. To express that, the Kaplan-Meier curves of the time-to-event ratio over up to 365 days (12 months) are shown in Figure 2.

Discussion

The present study was a retrospective, observational, multi-center, post-market surveillance of the Vector® PTCA Balloon Catheter, designed to facilitate challenging coronary procedures. The findings suggest that the Vector® PTCA Balloon Catheter offers several clinical benefits, particularly in navigating difficult lesions of arteries with reduced risk of vessel damage. The use of polyamide copolymer material in the balloon contributes to a low balloon crossing and wrapping profile, enhancing ease of catheter navigation. Additionally, the seamless attachment between the balloon and catheter shaft minimizes bumps and irregularities, reducing the likelihood of complications during insertion and while navigating complex vascular pathways. The study reported a high procedural success rate, with diameter stenosis reduced to less than 50% and no in-hospital adverse events. Importantly, no device-related or procedure-related complications, such as vessel perforation, decrease in TIMI flow, or flow-limiting vessel dissection, were observed. Among the 125 patients included in the study, only four experienced a major adverse cardiac event (MACE), supporting the device's favorable safety profile and clinical efficacy.

As inflation pressure rises, SCB systems initially enlarge in diameter in regions closer to or farther from the location of the most significant resistance, developing the recognizable dumbbell form as the pressure rises gradually. Due to challenges brought on by a limited ability to effectively treat severe aortic stenosis, using SCBs may result in prolonged periods of rapid pacing[26]. Kitani et al. demonstrated favorable long-term outcomes with DCB, with restenosis and TLR rates of 2.3% and 3.1%, respectively, at 12 months. Neither of the patients experienced side branch flow disturbance during the procedure, and the side branch TLR rate remained low among 129 patients[27]. Similarly, Lu et al. reported a low TLR rate in 92 individuals treated with DCB in de novo lesions, demonstrating non-inferiority compared to smaller vessels. The low rate of TLR observed in the clinical setting is likely due to the treatment of lesions located in larger vessels with an average RVD of 3.31 ± 0.44 mm and shorter lesion lengths. The total MACE rate was 4.3% in the patient population[28]. Hao et al. observed that out of 38 subjects in the SCB group, 11% reported MACE at 1-year follow-up[15]. A study by Cuculi et al. reported one patient with MI and one patient with TVR among 51 patients in the SCB group at 1-year follow-up[29]. Overall, the results obtained from previous research on balloon dilatation catheters are favorable and support the outcomes of the current study. In the present investigation, out of the 125 patients treated, two patients were observed to have TLR, and two patients had MI, with a cumulative MACE of 3.2% at 12-month follow-up. The noted AE/SAE were not related to the device implanted and the procedure performed on the patient, demonstrating the study device's significant safety and efficacy. Our findings support the continued use of this device in clinical practice and suggest that it may offer a valuable option for patients undergoing angioplasty procedures.

In real-world settings, coronary artery disease is frequently observed, and patients who are suitable for PCI may experience acute coronary syndrome that requires urgent treatment in the critical arteries. The outcomes of this study confirm the benefits of utilizing the study device for the patient population at risk and on a larger scale. These encouraging findings offer interventional cardiologists a valuable treatment modality for coronary ischemia patients to enhance myocardial perfusion.

Conclusion

It has been demonstrated that the Vector® PTCA Balloon Catheter was successfully utilized to treat patients for the dilatation of elementary and intricate lesions, evidencing coronary ischemia and improving the myocardial perfusion rate. The Vector® PTCA Balloon Catheter demonstrated efficacy in patients with angina, myocardial infarction, and a history of coronary artery disease, as evidenced by favorable procedural and device implant success rates in a real-world setting. This study reported the safe use of balloon catheters with very low incidences of

MACE. This leads to better outcomes for study devices in further clinical trials.

Limitation

There are several limitations to consider when interpreting the outcomes of the study. The investigation's retrospective design could affect the results' accuracy and reliability. Secondly, the absence of a control group hinders the direct evaluation of the device's efficacy and safety profile relative to other available options. The small sample size and limited follow-up period may also not provide sufficient statistical power. Another limitation of this study was that information about the angiography or coronary imaging was unavailable.

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Conflict of interests

The authors declare no conflict of interest.

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Author's Contributions

PV: Conception and design, analysis and interpretation of data. The drafting of the article, critical revision for important intellectual content. Final approval of the version to be published. AV: Conception and design. Critical revision for important intellectual content. Final approval of the version to be published. KA and KG: Critical revision for important intellectual content. Final approval of the version to be published.

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