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Successful Coronary Interventions with the Ingenious Vector® Balloon in Chronic Total Occlusion (CTO): A Preliminary Study

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Authors' contributions

This work was carried out in collaboration among all authors. Author AUM designed the study and wrote the protocol. Author BSS wrote the first draft of the manuscript and managed the literature searches. Authors BSS and DK managed the analyses of the study. All authors read and approved the final manuscript.

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ABSTRACT

Aims: To assess the safety and plausibility of successful coronary interventions in Chronic Total Occlusion (CTO) with the innovative Vector® balloon through balloon-assisted crossing technique.
Study Design: Observational, prospective study.
Place and Duration of Study: Department of Cardiology, King Edward Memorial Hospital and Seth G. S. Medical College, Mumbai. The study was carried out between the months of March and June, 2024.
Methodology: A total of 20 patients were included in the study. All patients with chronic coronary syndrome were being planned for Percutaneous Coronary Intervention (PCI) for CTO. During PCI,

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the standard protocol of intervening CTO lesions was followed. When the operator was not able to cross the lesion with standard CTO guidewires, Vector® balloon-assisted crossing was planned. This technique was used in a total of seven (35%) patents. Success was defined as the possibility of advancing the guidewire further to the target lesion and being able to deploy a drug eluting stent. Safety was assessed as reporting complications like kinking or rupture of the balloon shaft, loss of balloon inside the guide or the coronary artery and the balloon burst rate after inflation exceeding the Rated Burst Pressure (RBP) according to the manufacturer's reference table.

Results: The mean age of the patients was 58.1 ± 3.6 years. The balloon-assisted crossing was successful in all seven patients. The most commonly used diameter of the balloon was 1.25 mm (42.85%).

Conclusion: The novel Vector® balloon catheter showed excellent result when deployed to treat the CTO after the usual strategy of guidewire escalation had failed. The proximal shaft with polytetrafluoroethylene (PTFE) coating brings the flexibility to navigate complex and tortuous vascular pathways with ease due to its laser welded core-wire. A study with a larger sample size and a comparator arm would rather clarify if such a balloon-assisted crossing technique in CTO would decrease the need of costly devices like double lumen microcatheters.

Keywords: Coronary angioplasty; balloon catheter; chronic total occlusion; balloon-assisted crossing.

1. INTRODUCTION

Despite the indication for intervening in Chronic Total Occlusion (CTO) in coronary arteries has been one of the most debated topics of interventional cardiology, there has been rapid development in the techniques used for CTO over the past decade, with success rate approaching more than 90% in experienced centers [1]. This is a result of innovations in devices as well as techniques. The available literature has constantly shown that the antegrade wiring (AW) is the most common strategy for crossing CTOs, particularly those of lower complexity [2,3]. There are a number of anatomical factors that need to be considered while planning for a CTO intervention. These include the proximal cap, the chronic total occlusion body, the distal cap, and the landing zone. Based on these anatomical factors, the devices to be used and the strategy are decided by the operator.

AW has traditionally been described as an escalation of wire tip load until the lesion is crossed. While this is an effective way of crossing some CTOs, it is more efficient to select the guidewire based on their suitability for a particular task within the procedure [2]. However, when the lesion could not be negotiated even after the routine escalation of the guidewires, other devices come into the action with modification of the initially selected strategy [4,5].

In such a complex intervention of a CTO, dedicated guidewires, over-the-wire (OTW) balloons, microcatheters are often needed. However, in resource-limited settings, these devices are rather more difficult to acquire due to their cost. Hence, the availability of a coronary angioplasty balloon which is designed with certain features to make difficult coronary procedures easier seems like a need of the hour [6-9]. With a view to assessing the safety and plausibility of successful coronary interventions in CTO with the innovative Vector® (SLTL, Gujarat, India) semi-compliant balloon through a balloon-assisted crossing technique, the present study was undertaken.

2. MATERIALS AND METHODS

2.1 Study Device

The Vector® (Sahajanand Laser Technology Limited, Gandhinagar, Gujarat, India) semi-compliant rapid-exchange balloon dilatation catheter has a 4 mm laser-bonded distal tip and an entry profile of 0.016". It is available with the diameters of 1.00 mm, 1.25 mm, and 1.50 mm. The smaller profile helps in negotiating the CTO microchannels leading to an easy, trauma-free lesion entrance. The polyamide copolymer balloon material creates a semi-compliant balloon with controlled expansion and ensures the precise vessel adaptation minimizing the risk of vessel damage.

The proximal shaft which is made of stainless steel with polytetrafluoroethylene (PTFE) coating brings the efficient flow, smaller profile, smooth transition, and offers flexibility to navigate complex and tortuous vascular pathways with ease due to its laser welded core-wire. This

advanced balloon catheter utilizing the cutting-edge laser bonding technology ensures a seamless and consistent attachment between the balloon and the catheter shaft which helps to eliminate bumps and irregularities at joints, reducing the risk of complications during its introduction as well as navigation through complex vascular pathways. Safety was assessed as reporting complications like kinking or rupture of the balloon shaft, loss of balloon inside the guide or the coronary artery, or the balloon burst rate after inflation exceeding the Rated Burst Pressure (RBP) according to the manufacturer's reference table.

Advanced pleating and folding technology ensure precise and consistent balloon wrapping which provides a low, uniform balloon profile improving the overall catheter performance.

2.2 Study Design and Patient Population

This was a prospective, observational, single-arm registry aimed to evaluate the performance of the novel Vector® balloon dilatation catheter for the treatment of CTO in an all-comers stable Chronic Coronary Syndrome (CCS) patient population. The objective of the registry was to test the safety and the plausibility of this new device leading to a successful intervention in CTO at a tertiary care teaching hospital.

The key inclusion criteria include:

1. Adult patients diagnosed with CCS with a positive functional test or indication for coronary intervention
2. Presence of a CTO according to the Euro CTO Club definition with planned antegrade approach[10]

The key exclusion criteria include:

1. Left main stem involvement
2. Balloon uncrossable calcified lesions
3. Acute coronary syndrome

2.3 Procedural Nuances

The percutaneous interventions for CTO were performed according to the standard guidelines. The choice of initial guidewire and the need for escalation were decided by the operator. The number of guidewires used was decided by the operator before using the balloon-assisted crossing technique. Use of semi-compliant balloons other than the Vector® balloon catheter was prohibited during the study. The Vector® balloon catheter was made available with the diameters of 1.00 mm, 1.25 mm, and 1.50 mm. The choice of the device diameter was left to the operator. The lesion was considered as successfully crossed if it was possible to advance the guidewire further to the target lesion and being able to deploy a drug eluting stent treating the target lesion. If the lesion could not be negotiated with the study device, the procedure was decided to be completed with other devices according to the operator preference.

The periprocedural protocols were followed as per the standard guidelines. Safety was assessed as reporting complications like kinking or rupture of the balloon shaft, loss of balloon inside the guide or the coronary artery and the balloon burst rate after inflation exceeding the Rated Burst Pressure (RBP) according to the manufacturer's reference table.

2.4 Endpoints and Clinical Follow-Up

The primary efficacy endpoint was the rate of successfully crossing the target lesion allowing the first lesion dilatation. Baseline, procedural, and clinical follow-up data were collected by the authors.

2.5 Statistical Analysis

The categorical data were presented as frequencies. Due to a small number of sample size, all the available data has been presented in a tabular form below. The tests for determining statistical significance were not applied due to a small sample size.

The study was approved by the local ethical committee, and each patient signed a written informed consent to be included in the study.

3. RESULTS AND DISCUSSION

3.1 Results

A total of 20 patients were included in the study between the months of March and June, 2024. All patients had undergone coronary angiogram previously which showed CTO and they were considered for an antegrade approach for coronary intervention. However, out of 20, seven (35%) were considered for balloon-assisted crossing of the lesion since the initial strategy of wire escalation was unsuccessful. The study device was utilised in these seven patients.

Table 1. Clinical and demographic characteristics of the study population

Demographic characteristics	Intervention strategy for CTO	
	Wire-escalation (n=13)	Balloon-assisted crossing (n=07)
Age (years)	52.7 ± 1.1	58.1 ± 3.6
Male gender	08 (61.53%)	04 (57.14%)
Tobacco consumer	05 (38.46%)	03 (42.85%)
Hypertension	11 (84.61%)	05 (71.42%)
Diabetes Mellitus	09 (69.23%)	06 (85.71%)
Dyslipidemia	04 (30.76%)	03 (42.85%)
eGFR < 30 ml/min/m^2	03 (23.07%)	02 (28.57%)
Baseline LVEF (%)	49.3 ± 5.4	46.1 ± 7.1

Table 2. Coronary interventional characteristics of the sturdy population

Interventional characteristics		Intervention strategy for CTO	
		Wire-escalation (n=13)	Balloon-assisted crossing (n=07)
Syntax Score		20.9 ± 7.9	24.1 ± 3.6
Guidewires used		3.1 ± 0.7	2.8 ± 0.4
Treated vessel	LAD	09 (69.23%)	05 (71.42%)
	LCx	01 (07.69%)	00 (00.00%)
	RCA	03 (23.07%)	02 (28.57%)
Lesion length (mm)		19.5 ± 4.1	25.9 ± 5.0
Blunt stump		05 (38.46%)	04 (57.14%)
Diameter of Vector® balloon used	1.00 mm	N/A	02 (28.57%)
	1.25 mm	N/A	02 (28.57%)
	1.50 mm	N/A	03 (42.85%)

The baseline patient characteristics and demographic data are represented in Table 1. The coronary intervention related data are represented in Table 2.

The mean age in the study population was 58.1 ± 3.6 years, 57.14% were males, 42.85% were tobacco consumers, 71.42% were hypertensives, 85.71% were diabetics. The mean Syntax score in the study population was 24.1 ± 3.6. On an average, 2.8 ± 0.4 guidewires were used in the balloon-assisted crossing group. LAD was the most commonly intervened vessel. The average lesion in length in the study population was 25.9 ± 5.0 mm. The blunt stump was evident on coronary angiogram in 57.14% of patients. The most commonly used Vector® balloon catheter had a diameter of 1.50 mm. The study device was highly effective in crossing the CTO leading to successful coronary interventions in all seven patients.

No patient of the study population had any adverse reaction during the hospital stay and were followed up after three months of the index procedure. Neither of the seven patients developed any long-term complications.

3.2 Discussion

This present study demonstrates the excellent safety and plausibility of a successful coronary interventions in CTO with the novel Vector® semi-compliant balloon dilatation catheter. The therapeutic options for patients with CTO have expanded immensely thanks to sophisticated pre-interventional planning. Because of the recent developments, the success rate of CTO PCI today exceeds 80-90%.[5] However, the recently developed innovative equipment are not always easily available in a resource-constraint setting. In such a scenario, the availability of a semi-compliant balloon with a smaller profile which would provide additional support to the guidewire, in addition to its function is a dilatation catheter, is indeed a welcome innovation. The study device Vector® dilatation catheter proved to be an excellent tool in such CTO interventions.

The Vector® semi-compliant rapid-exchange balloon dilatation catheter with its laser-bonded distal tip and an entry profile of 0.016” makes it easier to engage the lesions rather deeply. The smaller profile helps in negotiating the CTO

microchannels leading to an easy, trauma-free lesion entrance, also reducing the chance of dissection in the healthy proximal vessel. The proximal shaft with polytetrafluoroethylene (PTFE) coating brings the flexibility to navigate complex and tortuous vascular pathways with ease due to its laser welded core-wire. In addition, advanced pleating and folding technology ensure precise and consistent balloon wrapping. All these qualities of this catheter, makes it a favorable and cost-effective tool in CTO interventions, once the operator has exhausted the options of using different guidewires on the shelf.

This pilot study demonstrated the plausibility of using the Vector® balloon as workhorse first choice device to cross and begin dilatation of the CTO. It showed an excellent performance with a high rate of success in engaging and crossing the target lesions. Thus, this device which has excellent crossing profile, great pushability, and low cost would potentially replace the need of expensive microcatheters when it comes to antegrade CTO interventions. When it comes to the safety of the device, the authors did not come across any unwanted complications like kinking or rupture of the balloon shaft, loss of balloon inside the guide or the coronary artery, or the balloon burst rate after inflation exceeding the Rated Burst Pressure (RBP).

3.3 Limitations

The present study is a prospective registry without a randomized comparative arm, hence, the conclusion pertaining to advantage of using this balloon in CTO in comparison to other existing devices cannot be drawn from this study. Besides, a small sample size precludes any definite conclusions regarding the efficacy and safety beyond the perspective of a preliminary single-center feasibility study. Nonetheless, the observations made during the study reflects the promising results that this study device would provide while intervening the complex CTOs.

4. CONCLUSION

The ingenious Vector® semi-compliant balloon catheter demonstrated an excellent performance in approaching CTO through antegrade approach with balloon-assisted crossing technique in patients with chronic coronary syndrome. Besides, there are no safety concerns in this preliminary evaluation.

DISCLAIMER (ARTIFICIAL INTELLIGENCE)

Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during writing or editing of this manuscript.

CONSENT

All authors hereby declare that a signed informed consent was acquired from all the participants to participate in this study.

ETHICAL APPROVAL

As per international standards or university standards written ethical approval has been collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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