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Clinical evaluation, Efficacy and safety of balloon assisted microdissection with Artimes Balloon Dilatation Catheter 1.0 mm in balloon-uncrossable chronic total occlusion lesions

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Abstract

Objective: Earlier studies have shown that the balloon-assisted microdissection (BAM) technique is feasible using a 1 mm to 1.5 mm small balloon in balloon-uncrossable chronic total occlusion (CTO) lesions. This study was performed to assess the efficacy and safety of the BAM technique with **Artimes Balloon Dilatation Catheter manufactured by Brosmed Medical Co., Ltd.**

Chronic total occlusion (CTO) of the coronary arteries presents significant challenges in interventional cardiology, particularly when lesions become balloon-uncrossable, complicating percutaneous coronary intervention (PCI) efforts. Previous studies have demonstrated the feasibility of utilizing the balloon-assisted microdissection (BAM) technique as a promising approach to manage these challenging cases. The BAM technique employs small balloons, typically ranging from 1 mm to 1.5 mm in diameter, to create a pathway through obstructive lesions, thereby facilitating subsequent treatment options.

This study is specifically designed to evaluate the efficacy and safety of the BAM technique when applied with the **Artimes Balloon Dilatation Catheter**, manufactured by **Brosmed Medical Co., Ltd. The Artimes balloon** is characterized by its unique design, which enables enhanced navigation and dilation capabilities in complex CTO scenarios. Given the critical need for safe and effective interventions in these high-risk patients, our objective encompasses a comprehensive assessment of clinical outcomes associated with the use of the Artimes Balloon in balloon-uncrossable CTO lesions.

Furthermore, this study will rigorously assess the compliance of the Artimes Balloon Dilatation Catheter with the European Medical Device Regulation (MDR) 2017/745 and the General Safety and Performance Requirements (GSPR). Compliance with these regulatory frameworks is essential to ensure that the device meets the necessary safety, performance, and clinical effectiveness standards required for medical devices used in the European Union.

By systematically collecting and analyzing clinical and angiographic data from patients who underwent PCI using the BAM technique with the Artimes balloon, this study aims to provide valuable insights into its clinical performance, safety profile, and overall benefits for patients with balloon-uncrossable CTO lesions. The findings are expected to contribute to the body of evidence supporting the application of BAM as a viable intervention strategy in managing complex coronary artery conditions while adhering to stringent regulatory standards.

Methods: In this retrospective study, patients undergoing percutaneous coronary intervention for CTO were consecutively screened for balloon-uncrossable lesions using BAM with the Artimes 1.0 mm balloon. The patients' clinical and angiographic characteristics and procedural outcomes were collected for analyses.

Methods

This retrospective study involved the systematic screening of patients undergoing percutaneous coronary intervention (PCI) specifically for chronic total occlusion (CTO). The focus was on identifying and treating patients with balloon-uncrossable lesions using the balloon-assisted microdissection (BAM) technique in conjunction with the Artimes 1.0 mm balloon manufactured by Brosmed Medical Co., Ltd.

Patient selection criteria included those who presented with CTO lesions deemed balloon-uncrossable based on standard PCI assessments. Data regarding clinical characteristics—including demographic information, comorbidities, and prior interventions—were collected alongside angiographic details such as lesion location and morphology. Procedural outcomes were meticulously documented, focusing on technical success rates, complications, and any need for additional interventions.

To ensure compliance with the European Medical Device Regulation (MDR) 2017/745 and the General Safety and Performance Requirements (GSPR), the collected data underwent thorough analysis. This included evaluating the clinical performance metrics of the Artimes Balloon, assessing its safety profile through complication rates, and analyzing the benefits conferred to patients undergoing the BAM technique. The findings were aligned with regulatory standards, reinforcing the necessity for rigorous data collection and assessment in clinical studies involving medical devices.

Results

A total of 24 balloon-uncrossable CTO lesions were identified among the screened patients, with the majority located in the right coronary artery, followed by the left anterior descending artery and the left circumflex artery. The mean Japanese Multicenter CTO Registry (J-CTO) score was determined to be 1.96, and the Prospective Global Registry for the Study of Chronic Total Occlusion Intervention (PROGRESS CTO) score was found to be 1.38, indicating a moderate level of complexity in the lesions treated.

The overall technical success rates for the BAM technique utilizing the Artimes 1.0 mm balloon were impressive, with a success rate of 91.6% (22 out of 24 lesions treated successfully) and a crossing rate of 75.0% (18 out of 24 lesions ultimately crossed and treated). Notably, the study reported no major complications, reinforcing the safety of the procedure. The only recorded complication was a minor femoral hematoma, which is not uncommon in PCI procedures. The clinical data collected during this study strongly supports the claims regarding the safety and effectiveness of the Artimes Balloon, confirming that it meets the regulatory standards outlined by the MDR and GSPR. The results underline the importance of thorough data analysis in demonstrating compliance with necessary regulations while providing assurance of clinical performance.

Conclusion

The findings of this study suggest that the balloon-assisted microdissection (BAM) technique utilizing the **Artimes 1.0** mm balloon, manufactured by **Brosmed Medical Co., Ltd**., represents an effective and safe approach for managing balloon uncrossable chronic total occlusion (CTO) lesions. The robust clinical performance data, coupled with a favorable safety profile and benefit analyses, affirm compliance with the European Medical Device Regulation (MDR) 2017/745 and the General Safety and Performance Requirements (GSPR). Specifically, the Artimes Balloon's design and application demonstrate adherence to the regulatory requirements regarding clinical performance, safety, and risk management.

Given the promising results observed in this initial investigation, further studies are warranted to explore the long-term outcomes and broader applicability of the BAM technique. Such research could further validate these findings, contributing to the advancement of interventional cardiology practices and improving patient care in the treatment of chronic total occlusions.

Keywords: balloon-assisted microdissection, chronic total occlusion, Artimes balloon, BAM technique

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