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Research Article

Preliminary Assessment of a Dedicated Bifurcation Stent Using a Modified Technique in True Coronary Bifurcation Lesions: A Dual-Centre Registry

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Abstract

Background/Aim: Bifurcation lesions present challenges in percutaneous coronary intervention (PCI), increasing the risk of side branch (SB) occlusion and restenosis. The Biomime Branch™, a sirolimus-eluting dedicated bifurcation stent with an ultra-thin strut design and Flexi Connector Technology, aims to optimize SB access and procedural outcomes.

Aim: To evaluate the feasibility, safety, and procedural success of the Biomime Branch™ stent using a modified implantation technique in a dual-center registry.

Materials and Methods: Eighty patients with Medina 1-1-1 bifurcation lesions underwent PCI with a sirolimus-eluting dedicated bifurcation stent with an ultra-thin strut design and Flexi Connector Technology between April 2023 and December 2024. The primary endpoint was procedural success, defined as ≤30% residual stenosis in both branches without major adverse cardiac events (MACE) at discharge.

Results: The mean age was 69.8 ± 11 years; 77.5% were male. Hypertension (68.7%) and dyslipidemia (70%) were common. The left anterior descending artery (LAD) was the most treated vessel (63.7%). Pre-dilatation and final kissing balloon inflation were performed in 98.7% of cases. Procedural success was 98.7%, with minimal complications.

Conclusions: The Biomime Branch™ stent demonstrated high procedural success and safety in true bifurcation lesions. Its novel design ensures SB access and vessel patency, providing a promising alternative to conventional two-stent techniques. Long-term follow-up is warranted.

Keywords: bifurcation pci; biomime branch™; dedicated bifurcation stent; coronary artery disease

Introduction

Bifurcation lesions accounting for approximately 15% to 20% of all lesions treated with PCI [1]. Despite significant advancements in stent technology, the treatment of bifurcation lesions remains a major challenge for interventional cardiologists. Procedural complexities contribute to an increased risk of periprocedural myocardial infarction (MI), stent thrombosis, long-term restenosis, and higher healthcare costs. [2] [3]

Over the years, various strategies have been proposed, to optimize bifurcation PCI. [4][7] The conservative (provisional) approach where the main branch (MB) is treated first, and the side branch (SB) is only intervened upon, if necessary, remains the current standard of care. [8] [2][3] [11][14] However, this strategy has several limitations, including the risk of SB ostial jailing by MB stent struts, which can complicate rewiring and the advancement of a balloon or stent into the SB. Additional concerns include the potential distortion of the MB stent during SB dilation, the inability to ensure complete SB ostial coverage, and the influence of operator expertise on procedural success.[7] Furthermore, previous studies assessing bifurcation PCI have been hindered by selection bias, small sample sizes, and heterogeneous techniques, limiting the ability to draw definitive conclusions.[2][21]

Dedicated bifurcation stents have emerged as a potential solution to overcome the challenges associated with the provisional approach. Recent

small non-randomised studies have reported promising initial outcomes with these devices. [15][19] Dedicated bifurcation stents can be broadly classified into two categories. [22] The first group comprises stents designed to maintain or facilitate SB access after MB stenting, eliminating the need for recrossing MB stent struts (e.g., Petal, former AST stent, Multi-link Frontier/Pathfinder, Invatec Twin-Rail, Nile Croco/Pax, Antares, Stentys . These devices allow for the placement of a second stent in the SB when required. The second group consists of stents that generally necessitate the deployment of an additional stent in the bifurcation (e.g., Axxess Plus, Sideguard, Tryton. The Tryton and Sideguard stents are implanted in the SB first, requiring recrossing into the SB after MB stenting for final kissing balloon inflation (FKBI).

A recent innovation in this field is the Biomime Branch™, a next-generation sirolimus-eluting coronary stent system featuring an ultra-thin 65 µm strut thickness and a novel hybrid design. These characteristics position Biomime Branch™ as a promising addition to the growing family of dedicated bifurcation stents, though further clinical trials are required to determine its long-term efficacy and safety.

To evaluate the feasibility, safety, and procedural success of implanting the dedicated bifurcation stent Biomime Branch™ using a modified technique. This modification, developed and refined by a single experienced operator, is assessed across two centres, one in Europe and one in America to determine its effectiveness in optimising stent deployment, improving procedural outcomes, and enhancing long-term vessel patency in complex bifurcation lesions.

Materials and Methods

Study Population

Patients were recruited from two different university hospital centres: one in the north of Spain (Lugo) and the other in central Mexico (Puebla), from April 2023 to December 2024. These patients were referred for diagnostic coronary angiography due to evidence of ischaemic heart disease diagnosed by non-invasive studies.

Following the diagnostic coronary angiography, coronary bifurcation lesions were identified. Patients with “true bifurcation” lesions classified as Medina 1-1-1, with MB ≥2.25 mm and ≤4.5 mm and SB of ≥ 2.25 mm, and for whom percutaneous coronary intervention (PCI) with a two-stent technique was planned, were included in the registry. The exclusion criteria was that the SB was not affected. The registry was approved by the ethics committee of both participating hospitals.

Study Device

The dedicated bifurcation stent Biomime Branch™ (Meril Lifesciences) consists of a proximal MB anchoring segment and a distal tapered SB segment with ultra-thin 65 µm strut thickness, connected by an advanced Flexi Connector Technology that ensures continuous SB access and protection. The Step-Up Balloon System allows for the simultaneous deployment of both segments, reducing procedural time and minimising the complexity associated with multiple hardware usage. Following Biomime Branch™ implantation, the MB segment can be stented as part of a standard PCI procedure, allowing seamless vessel integration [20]. All patients underwent bifurcation PCI using the Bio mime Branch™ dedicated bifurcation stent from Meril Lifesciences. The implantation technique was modified by the primary operator, incorporating two additional key steps essential for successful stent deployment. All procedures were performed by the same experienced operator at both participating centers. **Figure 1**.

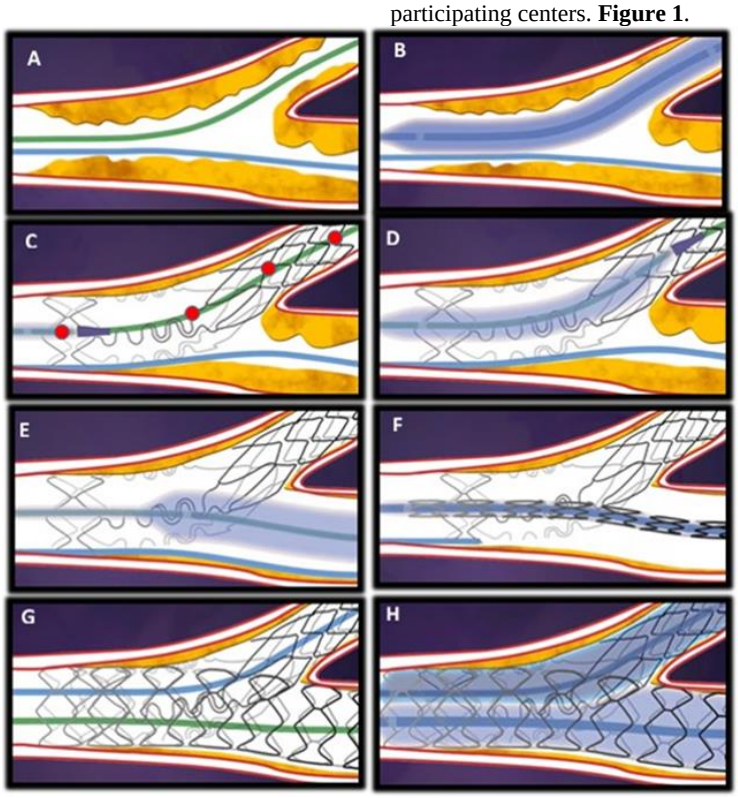

Figure 1: Step-by-step illustration of Biomime Branch™ stent implantation in a bifurcation lesion. Panels A–B: guidewire placement and lesion preparation.C: stent positioning using four radiopaque markers. D–E: modified technique with NC balloon inflation in the side branch to facilitate main vessel wiring.F–G: stent and wire recrossing. H: final kissing balloon inflation.

Endpoint And Definitions

The primary objective of this registry was to evaluate the feasibility and success rate of device implantation and the angiographic procedural success; defined as 30% residual diameter stenosis in both branches by quantitative coronary angiography [QCA] using the assigned device and without MACE at discharge. Statistical analysis was carried out using IBM SPSS Statistics, version 21 (IBM Corp., Armonk, NY, USA). Given

the retrospective and observational nature of the study, data are reported as absolute numbers and corresponding percentages. [20]

Results

Demographic and Clinical Characteristics

80 patients were included in the study, all presenting with Medina 1-1-1 bifurcation lesions ("true bifurcation"), and all undergoing PCI with complete revascularization. With a mean age of 69.8 ± 11 years. The majority of the population was male (77.5%), while females accounted for 22.5%.

Regarding clinical variables, hypertension was present in 68.7% of the patients, making it the most common comorbidity in this cohort. Dyslipidemia was also prevalent, affecting 70% of the patients. Diabetes mellitus was observed in 38.7%, reflecting a considerable burden of metabolic disease. Obesity was present in 35% of the patients, further indicating the presence of risk factors associated with cardiovascular disease. A history of smoking was reported in 51.2% of patients, highlighting a significant lifestyle-related risk factor.

Previous stroke and chronic obstructive pulmonary disease (COPD) were observed in 2.5% and 3.7% of cases, respectively, indicating a relatively low prevalence of cerebrovascular and pulmonary disease within the cohort. Chronic kidney failure was noted in 16.5% of patients, representing a relevant comorbidity that could influence procedural outcomes. Atrial fibrillation was present in 6.2% of patients, demonstrating a moderate prevalence of arrhythmic complications. Furthermore, 20% of patients had a history of ischemic heart disease, while 12.5% had undergone previous revascularization, indicating that a subset of the cohort had already undergone prior cardiovascular interventions.

Study Size and Inclusion Criteria

The study did not employ a formal sample size calculation, as it was based on a prospective registry. All consecutive patients who were referred for coronary angiography with a diagnosis of ischaemic heart disease and who were found to have Medina 1-1-1 bifurcation lesions during diagnostic coronary angiography were included. Patients meeting these criteria and undergoing percutaneous coronary intervention (PCI) with complete revascularisation were prospectively enrolled. The inclusion of patients followed a standardised institutional protocol and reflects real-world clinical practice.

Data Collection Methodology

No standardised questionnaire was used for data collection. Clinical and demographic parameters were obtained directly from electronic medical records and procedural reports. All data were extracted by trained personnel following a predefined data abstraction protocol to ensure consistency and accuracy across all cases. **Table 1**

AGE	69.8 ±11	
	Frequency	%
GENDER		
Female	18	22.5
Male	62	77.5
CLINICAL VARIABLES		
Hypertension	55	68.7
Dyslipidemia	56	70
Diabetes Mellitus	31	38.7
Obesity	28	35
Smoker	41	51.2
Previous Stroke	2	2.5
Previous COPD	3	3.7
Chronic Kidney Failure	13	16.5
Atrial Fibrillation	5	6.2
Previous Ischemic Heart Disease	16	20
Previous Revascularization	10	12.5

Table 1: Demographics and clinical variables, data are reported as absolute numbers and corresponding percentages.

Angiographic and Procedural Data

The most commonly affected main vessel was the left anterior descending artery (LAD) in 63.7% of cases, which is consistent with its dominant role in myocardial perfusion. The left main artery (LM) was affected in 21.3% of cases, indicating complex coronary pathology in a considerable number of patients. The circumflex artery (Cx) was involved in 13.8% of cases, while the right coronary artery (CD) was the least affected, with only 1.3% of cases.

Regarding side branches, the diagonal artery was the most frequently involved, with 61.3% of cases, followed by the circumflex artery (18.8%), LAD (6.3%), obtuse marginal (OM) (12.5%), and posterolateral (PL) (1.2%). This distribution highlights the frequent involvement of side branches in bifurcation lesions and the need for complex percutaneous coronary intervention (PCI) strategies.

Calcification was observed in 46.8% of patients, with 25.3% presenting severe calcification, 12.7% moderate, and 8.9% mild. The high prevalence of moderate to severe calcification suggests that many cases required advanced plaque modification techniques before stent implantation.

Vessel tortuosity was present in 31.6% of cases, with 11.4% being severe, 6.3% moderate, and 13.9% mild. The presence of tortuosity may pose technical challenges during PCI, necessitating careful guidewire and catheter manipulation. The Medina classification revealed that 91.3% of lesions were classified as 1-1-1, which is indicative of a high prevalence of true bifurcation lesions requiring complex interventional techniques. Less common classifications included 1-1-1 in 3.8%, 1-1-1 in 2.5%, and 1-1-1 and 1-1-1 in 1.3% each, reflecting some variability in lesion morphology.

Radial access was the predominant approach (82.5%), underscoring its widespread adoption due to its benefits in reducing bleeding complications and improving patient comfort. Other access sites included femoral (7.5%), cubital (8.8%), and humeral (1.3%), demonstrating alternative routes for arterial access when radial access was not feasible. Catheter extension was utilized in 12.5% of cases, indicating the need for additional support in complex lesion scenarios.

Pre-dilatation was performed in 98.7% of cases, underscoring the routine use of lesion preparation techniques before stent deployment. Similarly, final kissing balloon inflation was performed in 98.7% of patients, which is essential in bifurcation stenting to optimize stent expansion and reduce the risk of side branch occlusion. Atherectomy was used in 6.3% of cases, while lithotripsy was employed in 5%. A combination of both techniques was required in 2.5% of cases, highlighting the need for specialized plaque modification strategies in select patients with severe calcification.

No intraprocedural complications were observed in 98.7% of cases, demonstrating a high level of procedural safety. Procedural success was achieved in 98.7% of interventions, reflecting the effectiveness of the applied interventional strategies in this cohort. **Table 2**

	Item	No	%
Main Vessel	CD	1	1.3
	LAD	51	63.7
	Cx	11	13.8
	LM	17	21.3
Side Branch	Diagonal	49	61.3
	OM	10	12.5
	PL	1	1.2
	LAD	5	6.3
	Cx	15	18.8
Calcification	No	42	53.2
	Mild	7	8.9
	Moderate	10	12.7
	Severe	20	25.3
Tortuosity	No	54	68.4
	Mild	11	13.9
	Moderate	5	6.3
	Severe	9	11.4
Medina	1,0,0	1	1.3
	1,1,0	1	1.3
	1,1,1	73	91.3
	1,0,1	3	3.8
	0,1,1	2	2.5
Access	Femoral	6	7.5
	Radial	66	82.5
	Cubital	7	8.8
	Humeral	1	1.3
Use of Catheter Extension	Yes	10	12.5
Predilution	Yes	79	98.7
Final Kissing	Yes	79	98.7
Atherectomy	Yes	5	6.3
Lithotripsy	Yes	4	5
	Both	2	2.5
Intraprocedural Complications	No	79	98.7
Procedure Success	No	1	1.25
	Yes	79	98.7

Table 2: Angiographic and Procedural variables, data are reported as absolute numbers and corresponding percentages.

Discussion

The findings of this study reinforce the feasibility, safety, and efficacy of the Bio mime Branch™ dedicated bifurcation stent in the treatment of true bifurcation lesions. The modified implantation technique, systematically applied by a single experienced operator across two centers, resulted in a high procedural success rate (98.7%) with minimal intraprocedural complications. This underscores the potential of this next-generation stent system to simplify complex bifurcation PCI while maintaining excellent immediate angiographic outcomes.

Bifurcation lesions have long posed a significant challenge in interventional cardiology, given their inherent procedural complexities and the associated risks of side branch (SB) compromise, malposition, and restenosis. The conventional provisional approach, while widely adopted, has notable limitations, particularly in cases of Medina 1-1-1 lesions where SB protection is crucial. The present study demonstrates that the Bio mime Branch™ stent, with its ultra-thin 65 µm struts, hybrid design, and Flexi Connector Technology, offers an effective alternative by ensuring continuous SB access and facilitating optimal stent positioning.

A key advantage of the Bio mime Branch™ system is its Step-Up Balloon Technology, which allows for simultaneous deployment of both the main branch (MB) and SB segments, reducing the need for multiple recrossing attempts and minimizing procedural time. This feature is particularly relevant in complex anatomical scenarios, as it mitigates the risks of stent distortion, incomplete ostial coverage, and flow limitation in the SB. Additionally, the design of this stent facilitates the Culotte technique, a widely used approach for bifurcation PCI, by ensuring optimal SB access and deployment.

One particularly relevant aspect of this study is that a significant percentage of cases (21.3%) involved the left main (LM) artery. The LM

is a critical vessel supplying a large myocardial territory, and interventions in this location require precise technique to avoid compromising either the left anterior descending (LAD) or the circumflex (Cx) arteries. The successful application of the Bio mime Branch™ stent in LM bifurcation lesions adds further value to this study, demonstrating its feasibility in high-risk, complex coronary anatomy. [20]

The high prevalence of radial access (82.5%) in this cohort also reflects a contemporary PCI approach aimed at enhancing patient safety and comfort. Importantly, this study highlights the role of meticulous lesion preparation, with pre-dilatation performed in nearly all cases (98.7%) and final kissing balloon inflation (FKBI) systematically applied. These steps are critical for optimizing stent expansion and preventing SB occlusion, ultimately contributing to the excellent procedural success observed.

Notably, the one case of procedural failure observed in this study occurred during the early phase of implementation, before the refinements to the implantation technique were fully developed. This underscores the importance of technical evolution in complex PCI procedures. A key modification that contributed to subsequent success was the adoption of a more aggressive plaque modification strategy, which proved essential in optimizing stent expansion and improving procedural outcomes. Nonetheless, the present study provides compelling evidence that this novel device represents an excellent option for the treatment of true bifurcation lesions, offering a technically refined solution that enhances procedural efficiency while ensuring optimal vessel patency.

Conclusions

This study demonstrates that the Bio mime Branch™ dedicated bifurcation stent is a feasible and safe option for the treatment of true bifurcation lesions. The high procedural success rate (98.7%) and the absence of major complications highlight its potential to simplify complex bifurcation PCI while ensuring optimal angiographic outcomes. The innovative design of the stent, particularly the Flexi Connector Technology and Step-Up Balloon System, plays a crucial role in facilitating precise and efficient stent deployment.

Limitations

Although this study was conducted prospectively across two different centres, all procedures were performed by a single experienced operator. While this approach minimised variability and optimised the learning curve, it also introduces methodological bias, as the outcomes may be influenced by the individual operator's technique and expertise. This limits the generalisability of the results to the broader interventional cardiology community. Further studies involving multiple operators with varying levels of experience, as well as long-term follow-up, are warranted to better assess the durability and real-world applicability of this dedicated bifurcation stent system.

Tweet Summary:

"Multicenter study evaluates the clinical outcomes of the Biomime Branch™ bifurcation stent. Promising results in coronary interventions. #BranchStent #BifurcationPCI #InnovativeStent

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