Left main stem stenosis angioplasty with intravascular ultrasound optimisation criteria guidance using a new generation everolimus drug-eluting stent

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ABSTRACT

Introduction: Intravascular ultrasound (IVUS) is recommended in the use of left main stem (LMS) percutaneous coronary intervention (PCI). Since the LMS diameter is usually larger than other coronary arteries, a new generation everolimus drug-eluting stent (DES), Synergy Megatron DES (Boston Scientific) has better axial and radial strength allowing more post implant overexpansion and consequently better suited for LMS lesions. We performed a study to evaluate the clinical outcomes of PCI using 1) an improved IVUS protocol with optimisation targets and 2) the use of Megatron stents.

Materials and Methods: This was a study involving LMS PCI coronary lesions using the Synergy Megatron DES. An IVUS protocol using predefined optimisation targets to evaluate for stent malapposition, longitudinal stent deformation, optimal stent expansion >90% of reference lumen and appropriate distal landing zone was used in all cases. The primary end-point was procedural success, defined by successful stent implantation with <30% residual stenosis. The secondary end-point was in-hospital and 30-day major adverse cardiovascular event (MACE).

Results: Eight patients with significant LMS stenosis were successfully treated with the Megatron stent. The primary end-point was achieved in all patients. There were no cases of stent malapposition or longitudinal stent deformation, one case did not have optimal LMS stent expansion and one case did not have an appropriate distal landing zone. IVUS optimisation criteria were met in 6 (75%) cases. There were no complications of coronary dissection, slow or no reflow, stent thrombosis or vessel perforation. None of the patients suffered in-hospital or 30-day MACE. The average LMS MLD at baseline was 2.1 ± 0.1mm and the post-PCI LMS MLD was 4.0 ± 0.5mm, with a significant acute luminal gain of 1.9 ± 0.7mm (p<0.01). A post-PCI MSA of 17 ± 3.9 mm2 was numerically superior compared to those documented in other LMS PCI trials.

Conclusion: This study demonstrates low rates of short-term major adverse cardiovascular events among patients with LMS PCI using the Megatron stents. It highlights the usefulness of IVUS-guided optimisation in LMS PCI. With the use of intravascular imaging, the new generation stent technology can improve the treatment of large proximal vessels and PCI of LMS lesions.

INTRODUCTION

Left main stem (LMS) stenosis is often regarded as clinically significant since the LMS bifurcates to the left anterior descending and left circumflex vessels, providing blood supply up to two-thirds of the left ventricle.[1] Due to the importance of good clinical outcomes following LMS angioplasty, current European guidelines recommend the use of intravascular ultrasound (IVUS) in patients undergoing LMS percutaneous coronary intervention(PCI).[2] When IVUS is used to evaluate plaque morphology, lumen characteristics and optimise stent sizing, clinical outcomes can be improved.[3] IVUS also provides better imaging of the LMS ostium and is often considered the first-line imaging method for LMS stenosis.[4] Better visualisation and assessment during PCI to the LMS helps to avoid complications such as inadequate stent expansion and malapposition of stent struts.[5] Both stent underexpansion and malapposition of stent struts have been shown to be predictors of acute stent thrombosis and early stent restenosis.[6] More recently, IVUS optimisation criteria has been used specifically for LMS intervention with good clinical outcomes, and we sought to implement the use of such criteria to guide LMS PCI in our cases.[7]

Current stent technology is limited by the capability of stents to expand beyond a certain limit, and since LMS diameter is often of large calibre, newer stent technology can provide improvements to clinical outcomes. Use of post-dilation balloons that exceed the recommended upper size limit may risk damage to the stent integrity and lead to long-term complications for PCI. The Synergy Megatron drug-eluting stent (DES) platform (Boston Scientific) is a new generation everolimus-coated stent, which offers improved over expansion capabilities.[8] This is a new stent technology, with little available data on clinical outcomes with the use of the stent.

This study has two objectives: the first is to evaluate the use of IVUS optimisation criteria and second is to evaluate clinical outcomes using a new generation stent technology in the PCI of LMS lesions.

MATERIALS AND METHODS

Patients and Study Design

This was a retrospective single-centre study. Patients with PCI to the LMS using the Synergy Megatron DES were included.

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Data were collected by medical record review. Patients gave informed consent for the publication of images. Baseline characteristics of patients, including age, cardiac risk factors and clinical presentation, left ventricular ejection fraction (LVEF) and baseline renal function (eGFR), were documented.

PCI and Intravascular Imaging
All patients were given dual-antiplatelet therapy and received intra-venous heparin during the PCI procedure. IVUS was performed in all cases. Measurements of baseline mean luminal diameter (MLD) and mean luminal area (MLA) were done. The angioplasty balloon size was selected based on vessel diameter measured by IVUS at a 1:1 ratio. Non-compliant (NC) balloons were used in all cases for post-dilation of the LMS stent. IVUS was used post-PCI to assess procedural success and document post-procedural complications. Post-PCI measurement of MLD and minimal stent area (MSA) were done. Following PCI, all patients were given dual antiplatelet therapy with either aspirin 100 mg, clopidogrel 75mg, or ticagrelor 180 mg/day for 12 months.

PCI results were evaluated according to an IVUS optimisation criteria which had been previously used for LMS intervention.[7] There were four areas used to define procedural success by IVUS assessment (Figure 1):

1) *Complete stent apposition* was defined by the absence of any IVUS evidence of malapposition (separation of ≥1 stent strut from the intimal surface of the arterial wall).[9]
2) *Absence of longitudinal stent deformation (LSD),* where multiple layers of stent struts are seen in any single cross-section within a single stent.[10]
3) *Optimal LMS stent expansion* is defined as follows: expansion >90% of the distal reference lumen in ostial and mid-LMS lesions, as well as expansion >90% of the proximal reference lumen in distal LMS lesions.
4) *Appropriate distal landing zone* was defined as distal stent edge with residual plaque burden <40% and absence of edge dissection.[11]

Endpoints
The primary end-point was defined as successful stent implantation with <30% residual stenosis. The secondary endpoints were in-hospital major adverse cardiovascular event (MACE), including cardiac death, myocardial infarction (MI), or target-vessel revascularization (TVR) and 30-day MACE.[12] Safety outcomes were procedural complications, defined as coronary dissection, slow or no reflow, stent thrombus or vessel perforation. A target MSA of the LMS post-PCI was 8 mm^2.[13]

Statistical Analysis
Statistics including mean and percentages were used. Categorical variables are presented as counts (%) and continuous variables are presented as mean ± standard deviation. The paired t-test was used for the comparison of MLD at baseline and MSA after PCI. A *p*-value of ≤ 0.05 was considered significant.

RESULTS

Baseline Clinical and Procedural Characteristics
Between October 2021 and October 2022, eight patients had LMS PCI using the Megatron stent. The baseline characteristics of the patients are shown in Table I.

Procedural Characteristics
Of the eight LMS lesions treated, 3 (37.5%) were distal LMS stenosis (Table II). Femoral vascular access was preferred in the majority of cases. The average stent diameter was 3.7 ± 0.3 mm, and stent length was 24 ± 5.6 mm. The average post dilatation non-compliant (NC) balloon diameter used was 5 ± 0.3 mm. Pre- and post-PCI coronary angiogram for two of the cases are shown in Figure 2.

Clinical Outcomes
The primary endpoint of successful stent implantation was achieved in all patients. There were noin-hospital MACE and 30-day MACE events (Table II). There were no cases of coronary artery dissection, slow flow or stent thrombosis. There were no cases of stent malapposition or longitudinal stent deformation, 1 (12.5%) case did not have optimal LMS stent expansion and 1 (12.5%) case did not have an appropriate distal landing zone (Table II). IVUS optimisation criteria were met in 6 (75%) of the cases. The average LMS MLD at baseline was 2.1 ± 0.1mm and the post-PCI LMS MLD was 4.0 ± 0.5mm, with significant acute luminal gain of 1.9 ± 0.7mm (p<0.01). The post-PCI MSA was 17 ± 3.9 mm^2. All cases achieved the LMS target MSA of > 8mm^2.

DISCUSSION

The main findings of our study are as follows: 1) IVUS optimisation criteria help to guide effective LMS PCI. 2) New generation stent technology can improve expansion capabilities with a low complication rate in LMS PCI.

IVUS optimisation criteria in LMS Angioplasty
Angiographic assessment of the LMS can be difficult. Due to the two-dimensional nature of coronary angiography, there is limited evaluation of the extent of disease and vessel-wall characteristics.[14] The latest European Society of Cardiology guidelines indicate a class IIa recommendation for the use of IVUS in LMS PCI to overcome these limitations.[15,16] IVUS provides information on accurate vessel dimensions to ensure optimal stent sizing and balloon sizing used for post- stent dilation (i.e., proximal optimisation technique [POT]).[17] Evaluation of post-PCI IVUS should include assessment for stent malapposition, stent underexpansion, exclusion of longitudinal stent deformation and stent-edge dissection.[18] Due to the complexity of various IVUS criteria, the use ofI VUS with predefined optimisation targets has been associated with improved clinical outcomes.[19,20] We have used these criteria successfully in our study to guide effective PCI.

Stent under expansion is the main predictor of stent failure and is associated with higher rates of target lesion revascularization (TLR) and stent thrombosis. IVUS criteria to achieve 90% MSA in the stented segment of the average reference cross-sectional area is frequently recommended.[21] We observed 1 case (12.5%) which did not achieve 90% MSA within the stent segment, although it did not directly predispose to any acute complication. This is in keeping with a previous registry where 12% of cases did not achieve > 90% stent expansion.[20] A previous study examined optimal IVUSMSA values for preventing in-stent restenosis in the LMS.[13] The recommended values were 5.0mm^2 for the left circumflex (LCX) ostium, 6.3 mm^2 for the left anterior descending (LAD) ostium, 7.2 mm^2 for the distal LMS and 8.2 mm^2 for the proximal LMS.[13] Subsequently, the "5-6-7-8 Rule"

Table I: Baseline Characteristics

Male, n (%)	86 (100)
Age (mean ± SD)	55 ± 12
Hypertension, n (%)	5 (63)
Hypercholesterolaemia, n (%)	4 (50)
Smoking, n (%)	2 (25)
Family history of cardiac disease, n (%)	2 (25)
Diabetes mellitus, n (%)	2 (25)
LVEF (mean ± SD %)	58 ± 4
eGFR (ml/min/1.73 m^2)	77 ± 27
Stable angina/positive stress test	4 (50)
Unstable angina	4 (50)

LVEF: Left Ventricular Ejection Fraction
eGFR: Estimated Glomerular Filtration Rate

Table II: Procedural characteristics and clinical outcomes

Left main stem disease, n (%)	
Ostial LMS	0%
Distal LMS	3%
Diffuse LMS	1%
Ostial LAD	4%
Procedural characteristics	
Procedural time (min ± SD)	103 ± 14
Fluroscopytime (min ± SD)	25 ± 9
Femoral vascular access, n (%)	5 (62.5)
Radial vascular access, n (%)	3 (37.5)
Stent parameters	
Stent diameter (mm ± SD)	3.7 ± 0.3
Stent length (mm ± SD)	24 ± 5.6
LMS post-dilatation NC balloon, mm (mean ± SD)	5 ± 0.3
IVUS characteristics	
Baseline LMS MLD	2.1 ± 0.1
Post-PCI LMS MLD (mean ± SD)	4.0 ± 0.5
Baseline LMS MLA (mean ± SD)	4.5 ± 0.5
Post-PCI LMS MSA (mean ± SD)	17 ± 3.9
Post-PCI LMS Luminal Gain (mean ± SD)	1.9 ± 0.7
Failure to Achieve LMS Target MSA > 8mm^2	0
Achievement of IVUS optimisation criteria	
Stent malapposition, n (%)	0 (0)
Longitudinal stent deformation, n (%)	0 (0)
Optimal LMS stent expansion, n (%)	7 (87.5)
Inappropriate distal landing zone, n (%)	1 (12.5)
Angiographic and clinical outcomes	
Procedure success with facilitated stent delivery	8 (100)
Perforation, dissection, slow flow, stent thrombosis	0 (0)
In-hospital MACE (MI/TVR/Death)	0 (0)
30-Day MACE (MI/TVR/Death)	0 (0)

LMS: Left main stem
LAD: Left anterior descending
PCI: Percutaneous coronary intervention
MLD: Minimal luminal diameter
MLA: Minimal luminal area
MSA: Minimal stent area
IVUS: Intravascular ultrasound
MACE: Major adverse cardiovascular events
MI: Myocardial infarction
TVR: Target vessel revascularization

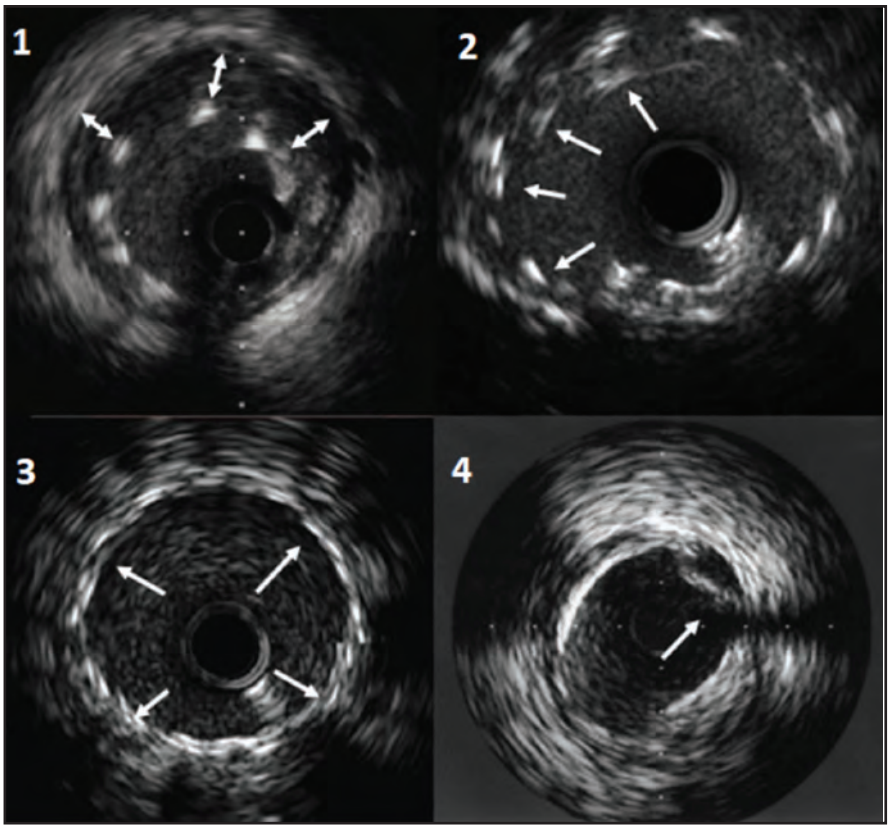

Fig. 1: Examples of IVUS images showing stent malapposition (1), longitudinal stent deformation (2),optimal LMS stent expansion (3), and stent edge dissection (4)

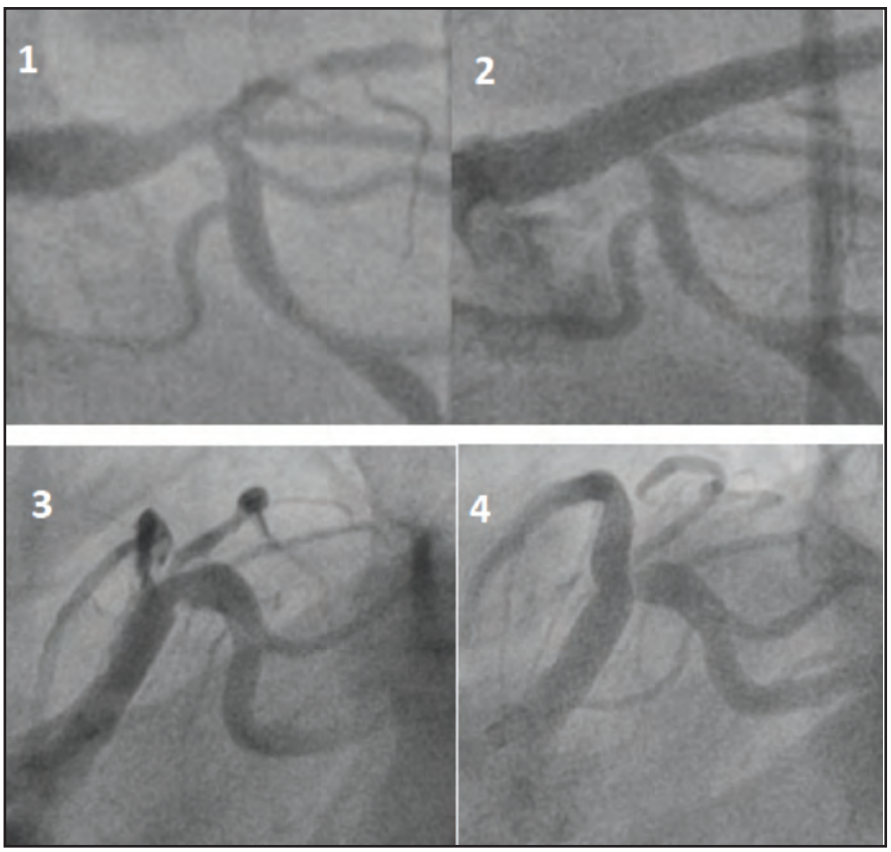

Fig. 2: Coronary angiogram of two cases. The first case shows severe distal LMS stenosis and proximal LAD stenosis (1). Post-PCI with the Megatron stent shows good results with no residual LMS or proximal LAD stenosis (2). The second case shows severe ostial LAD stenosis with a need to place the stent into the LMS (3). Post-PCI with the Megatron stent shows good results with no residual ostial LAD stenosis (4).

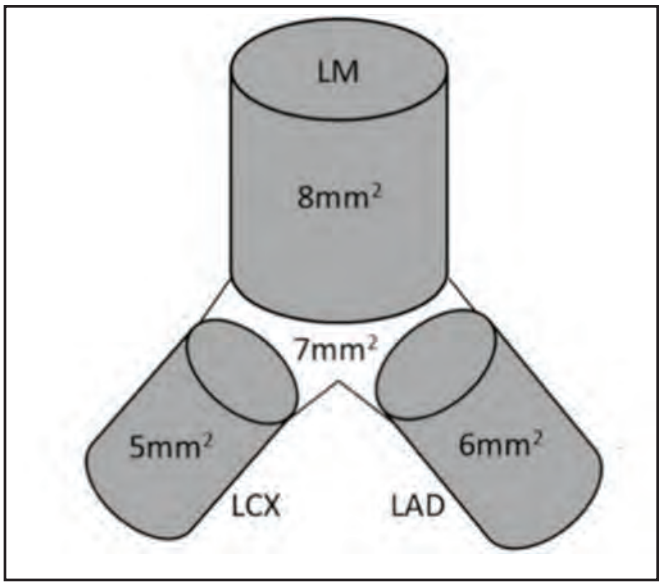

Fig. 3: Recommended MSA values for LMS, LAD and LCX arteries

was proposed on the basis of the minimum stent area (MSA) within each segment of the LMCA bifurcation (Figure 3). In our study, the recommended MSA value of > 8 mm^2 at the LMS above the polygon of confluence was achieved in all cases.

Stent malapposition is a lack of contact between at least one stent strut and the intimal surface of the artery. Significant malapposition often is seen on IVUS as stent struts floating in the lumen.[22] Stent edge dissection is also associated with increased complications of TLR[23] and early stent thrombosis.[24] Among our study cohort, there were no cases of stent malopposition or edge dissection. Appropriate distal landing zone with the stent landing on sites with plaque burden >40% appears increase the risk of subsequent stent edge restenosis.[25] In our cohort, 1 case (12.5%) did not achieve an appropriate distal landing zone as compared to a previous registry where 8% of the patient did not achieve this criteria.[20]

Longitudinal stent deformation occurs when multiple layers of stent struts are seen in any single cross-section image within a single stent. Acute deformation of second-generation DES has been seen in 8% of LMS PCIs. LSD of the stent is seen more frequently in LMS procedures.[26] The presence of stent deformation is associated with a significantly higher incidence of LMS-related acute coronary events and complications of TLR.[27]

Our study showed that it was frequently possible to meet IVUS optimisation targets using the Megatron DES stent technology for stent malapposition, stent expansion, appropriateness of landing zones, avoiding LSD and stent edge dissection.

A New-Generation Everolimus-Eluting Stent Platform

Previous experience with LMS PCI using older generation stents and infrequent use of intracoronary imaging guidance had demonstrated suboptimal outcomes for PCI when compared to CABG.[28] The majority of patients with LMS stenosis have a mean vessel diameter of >4 mm, suggesting the requirement for post-dilation beyond the nominal diameter of current generation DES devices in patients requiring LMS angioplasty.[29] Due to the large calibre of the left main artery, it may be difficult with older generation stents to achieve optimal MSA during LMS PCI. The Megatron DES stent provides a broader stent expansion range (3.5–6.0 mm) to overcome the issue of size mismatch between proximal and distal vessel diameters. Improved axial and radial strength allows for the successful treatment of heavily calcified, fibrotic and ostial lesions.[6] Long-term complications with TLR are reduced by both the performance of post-PCI IVUS with large MSA compared to small MSA.[7] Our study demonstrates the ability of the Synergy Megatron platform to produce a mean LMS MSA that is numerically superior to that seen in the well-known EXCEL[27] and NOBLE[30] trials which studied LMS PCI cases (17 ± 3.9 mm^2 vs 12.5 ± 3.0 mm^2 vs 9.9 ± 2.3 mm^2, respectively).

A previous study of 139 patients undergoing PCI using the Synergy Megatron DES had demonstrated a low rate of 0.7% of patients having short-term MACE events with no cases of acute/subacute stent thrombosis.[31] Our study demonstrates similarly low rates of MACE events and no acute complications post-LMS PCI with the Megatron DES.

LIMITATIONS

This study has limitations, given the retrospective nature of data analysed. In addition, there was no control group for comparison with other stent technology. The short follow-up period and relatively small number of patients in this study limit conclusions that can be drawn and mean that it is underpowered to detect events such as stent thrombosis.

CONCLUSION

This study demonstrates low rates of short-term major adverse cardiovascular events among patients with LMS PCI using the Megatron stents. It highlights the usefulness of IVUS-guided optimisation in LMS PCI. With the use of intravascular imaging, the new generation stent technology can improve the treatment of large proximal vessels and PCI of LMS lesions.

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