Intravascular ultrasound-guided treatment of left main stem stenosis with a new-generation everolimus drug-eluting stent

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SUMMARY

Left main stem (LMS) percutaneous coronary intervention (PCI) can be complex and high risk. Since the LMS diameter is usually larger than other coronary arteries, intravascular imaging guided stent sizing and optimisation is especially important. The new-generation everolimus drug-eluting stent (DES), Synergy Megatron DES (Boston Scientific), has a platform that offers improved overexpansion capabilities as well as improved axial and radial strength, which may be more suitable for selected LMS lesions. We present a case where a LMS lesion was successfully treated with Intravascular ultrasound (IVUS)-guided PCI using the Megatron DES platform. This technology safely and effectively facilitates intravascular imaging optimised stent parameters for the improved treatment of large proximal vessels and PCI of LMS lesions.

INTRODUCTION

Left main stem (LMS) stenosis is regarded significant when compared to other coronary arteries since the LMS bifurcates to the left anterior descending and left circumflex vessels, providing blood supply to two-thirds of the left ventricle. Due to the importance of good clinical outcomes following LMS angioplasty, current European guidelines recommend that intravascular ultrasound (IVUS) should be considered in patients undergoing LMS percutaneous coronary intervention (PCI).[1] Since the LMS diameter is usually larger than other coronary arteries, when IVUS is used to evaluate plaque morphology and optimise stent sizing, clinical outcomes can be improved. Current stent technology is limited by the capability of stents to expand beyond a certain limit. Use of post-dilation balloons that exceed the recommended upper limit may pose risk of damage to the stent integrity and lead to long-term complications of PCI.

The Synergy Megatron drug-eluting stent (DES) platform (Boston Scientific) is a new-generation everolimus-coated DES, which offers improved overexpansion capabilities for the treatment of tapered proximal vessels and bifurcations. We present a case where a LMS lesion was successfully treated with IVUS-guided coronary PCI using the Megatron stent.

CASE REPORT

A 42-year-old male had presented with angina and shortness of breath on exertion for two months. He had a history of hypertension and diabetes mellitus and was on medication. Echocardiography showed good left ventricular systolic function with ejection fraction (EF) of 60%. ECG shows sinus rhythm, and blood tests showed normal full blood count and renal function. Cardiac enzymes including troponin were normal. In view of significant coronary risk factors and frequent angina, the patient consented for invasive coronary angiogram.

A coronary angiogram via femoral approach showed severe 60-70% stenosis of the distal LMS (Figure 1) and moderate stenosis at the mid- left anterior descending (LAD) artery, moderate stenosis at the left circumflex (LCX) artery (non-dominant and ectatic vessel), and mild mid-vessel stenosis of the right coronary artery (dominant vessel). SYNTAX scores were calculated to assess the risk of PCI as compared to coronary artery bypass grafting (CABG). The SYNTAX I score was 21 and SYNTAX II score was 14.5 estimating a 4-year mortality risk of 1.9% with PCI (risk of 1.5% with CABG). The decision was made to proceed to LMS PCI.

The left main coronary artery was engaged with a six French-sized guiding catheter (EBU) with a diameter of 3.5cm, and the LAD and LCX were crossed with 0.014 inch hydrophilic guidewires. Further evaluation was done with IVUS (Figure 2). The minimal lumen area (MLA) of the LMS vessel was 5.40mm^2, and the minimal luminal diameter was 2.5mm. The reference luminal area of the distal LMS vessel was 20.9mm^2, and the reference luminal diameter estimated by the external elastic membrane (EEM) was 5.5mm.

The distal LMS was predilated with a non-compliant (NC) 4.0×15mm balloon. A 4.0×15mm Synergy Megatron stent was deployed from the LMS into the proximal LAD. The stent was post-dilated with an NC of 5.5×8mm balloon with good results (Figure 1). Repeat IVUS post angioplasty showed improvement of the left main diameter to 5.5mm and stent cross sectional area of 20.60mm^2 at the distal LMS. The stent struts were well opposed to the LMS and LAD vessel wall (Figure 2).

The patient was hemodynamically stable post-procedure and was discharged after two days. He was put on dual anti-platelet treatment with aspirin and clopidogrel for one year. At follow-up in clinic after one month, the patient was stable with no further angina.

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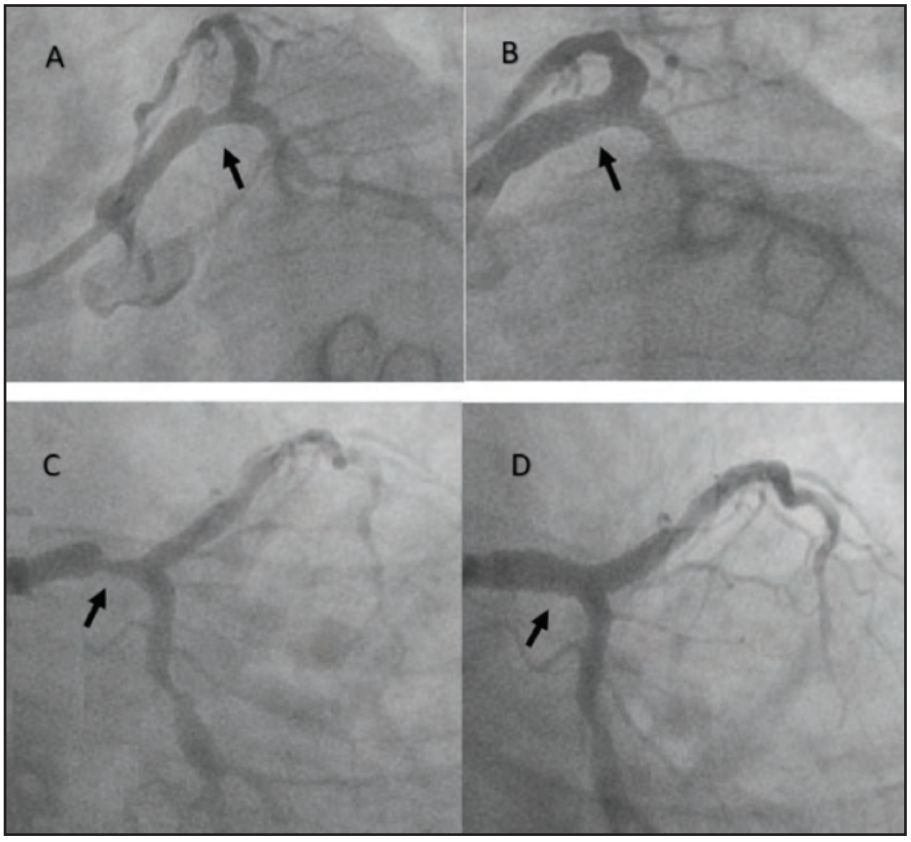

Fig. 1: Pre-procedure angiogram (A) in the spider view showing severe LMS stenosis (arrow) and corresponding post-procedure angiogram after PCI of the LMS (B) showing significant improvement in the stented LMS area (arrow). Pre-procedure angiogram (C) in the caudal view showing severe LMS stenosis (arrow) and corresponding post-procedure angiogram after PCI of the LMS (D) showing significant improvement in the stented LMS area (arrow).

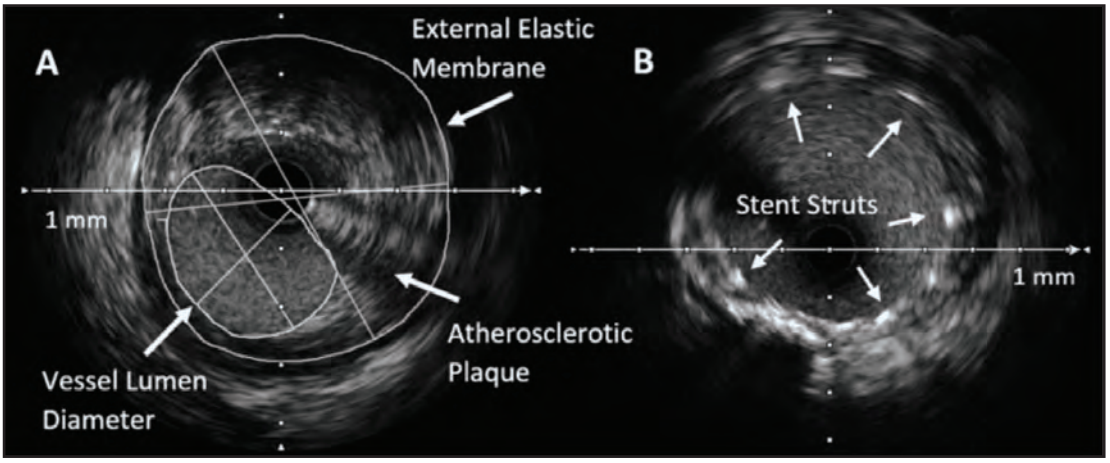

Fig. 2: Pre-procedure IVUS image (A) showing severe LMS stenosis with the inner circle showing vessel lumen, large areas of atherosclerotic plaque, and outer circle showing reference luminal diameter estimated by EEM. Post-procedure IVUS image (B) showing well-opposed LMS stent with arrows showing stent struts.

DISCUSSION

Coronary artery bypass grafting (CABG) currently remains the standard for treatment of LMS stenosis. Previous experience with PCI in treating LMS disease using older generation stents and infrequent use of intracoronary imaging guidance had demonstrated suboptimal outcomes for PCI when compared to CABG. However, newer-generation DES, consistent use of intravascular imaging guidance, and judicious selection of cases for PCI have allowed angioplasty to be a viable alternative to CABG in LMS stenosis.

Current ACC/AHA guidelines recommend calculation of a SYNTAX score for patients with LMS disease. The SYNTAX score estimates the risk of angioplasty based on features of

patient clinical risk profile and anatomical and morphological characteristics of the coronary lesion.[2] The decision for recommending PCI is guided by the calculated risk, and PCI is emerging as an alternative compared to CABG, especially in patients with low SYNTAX score (≤22).[3] In 2018, the European Society of Cardiology and European Association for Cardiothoracic Surgery (ESC/EACTS) jointly published the guidelines on myocardial revascularisation, in which LMS revascularisation with low SYNTAX score was considered class I level of evidence A for both PCI and CABG.[3]

Clinical Evidence for PCI in LMS Stenosis

PCI in LMS is usually considered when evaluation of IVUS shows an MLA <6mm.[2] The evidence comes from a multi-centre prospective study (LITRO study)[4] of intermediate LMS disease. In 354 patients, LMS intervention was deferred in 179 of 186 patients, and intervention was done in 152 of 168 patients based on the MLA cut-off value of 6 mm.[2] During 2-year follow-up, no difference was observed with regard to cardiac death or events. This demonstrated that an MLA of ≥ 6 mm[2] on IVUS is a safe value for deferring revascularisation for intermediate LMS disease.

The first large clinical comparison of PCI and CABG in LMS disease, the SYNTAX trial, randomised 1,800 patients to either the first-generation TAXUS DES (from Boston Scientific) or CABG for treatment.[5] Prior to randomisation, the SYNTAX score was used to quantify anatomical and lesion complexity. Cases were then divided into groups (SYNTAX score of 0–22, 23-32, and >32) based on the complexity of the lesions. It was found that CABG was superior in cases of high risk and complex coronary artery disease (i.e., SYNTAX score of >32).

The EXCEL trial was a non-inferiority study, in which 1,905 patients with LMS disease of low to intermediate complexity (SYNTAX score of <32) were randomised to either PCI using a second-generation everolimus coated DES (from Xience) or CABG.[6] At 3 years, the primary endpoint occurred in 15.4% of patients in the PCI group compared to 14.7% of patients in the CABG group (p=0.02 for non-inferiority), indicating that PCI was noninferior to CABG in the treatment of left main stenosis.

Conversely, the NOBLE trial involving 1,201 patients with LMS disease randomised to either PCI using DES (from BioMatrix) or CABG demonstrated inferiority in the PCI-treated group during a 5-year follow-up (p=0.0002).[7] There were higher MACCE (all-cause mortality, nonprocedural MI, repeat revascularisation, or stroke) rates in the PCI group (28.4% versus 19%).

New-Generation Everolimus-Eluting Stent Platform

The majority of patients with LMS stenosis have a mean vessel diameter of >4mm, suggesting the requirement for post-dilation beyond the nominal diameter of current-generation DES devices in patients requiring LMS angioplasty.[8] Since existing stent technology is limited by expansion capabilities, the use of NC post-dilatation balloons for stent expansion may pose risk of damage to stent structure and integrity. The Synergy Megatron DES platform confers improved overexpansion capabilities, which may be useful particularly for LMS angioplasty. A study of 139 patients undergoing PCI using the Synergy Megatron DES demonstrated very low rates of short-term major adverse cardiovascular events with no cases of acute/subacute stent thrombosis. The technology allows for IVUS-optimised stent parameters and improved treatment of large proximal vessels and bifurcations.[9]

Stent optimisation with larger sizing and optimal minimum stent area (MSA) is important in LMS PCI. Using IVUS optimisation, criteria to achieve 90% MSA in the stented segment of the average reference cross-sectional area are frequently recommended.[10] In the EXCEL trial, a small final LMS MSA was associated with higher major adverse cardiovascular events (small vs. large MSA tertiles; 19.4% vs 9.6%; p=0.01).[6] Similarly, the NOBLE trial demonstrated that long-term complications, such as target lesion revascularisation, were reduced by both the performance of post-PCI IVUS with large MSA compared to small MSA (5.1% vs. 11.6%; p=0.01).[7] It was shown that the Synergy Megatron DES had the capability to achieve a mean LMS MSA that is numerically superior to that in both the EXCEL and NOBLE trials (14.5±3.4 mm[2] vs. 12.5±3.0mm[2] vs. 9.9±2.3mm).[9] The Megatron DES stent also provided a broad overexpansion range (3.5-6.0mm) to overcome the issue of significant mismatch between proximal and distal vessel diameters.

CONCLUSION

PCI is emerging as an alternative to CABG for the treatment of LMS stenosis in patients with a low SYNTAX score. To further optimise the results for PCI in LMS, new-generation stent technology can provide overexpansion capabilities compared to current stents. This case demonstrates the successful use of a new-generation everolimus stent, the Synergy Megatron DES. This technology safely and effectively facilitates intravascular imaging optimised stent Figure 1 parameters for the improved treatment of large proximal vessels and PCI of LMS lesions.

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