Placement of a Single Axxess Stent as New Treatment Strategy for Medina 1,0,0 Left Main Stem Bifurcation Lesion

Eulogio García, MD, Leire Unzué Vallejo, MD, Francisco José Rodríguez-Rodrigo, PhD

ABSTRACT: A left main stem bifurcation lesion (Medina 1,0,0) treated with a single Axxess stent through radial access is presented. Although the use of this stent in left main stenosis is off label, in selected cases it may simplify the technique, avoiding the use of additional overlapping stents and ensuring the bifurcation coverage with minimal amount of metal at the carina.

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Despite progressive development of coronary intervention techniques, bifurcation lesions represent a challenge. Different strategies have been developed to solve this problem, directed to optimize the carina scaffolding, to ensure secondary branch access, or to facilitate a better adaptation of the stents to the bifurcation angle. The Axxess stent (Devax, Inc) is a self-expanding biolimus-A9 eluting stent designed to treat the problematic anatomy of bifurcation lesions. With a conical V shape, it provides an anatomically tailored treatment of the bifurcation, with maximum drug coverage and minimum overlap or deformation of the stent struts.

Case Report. A 73-year-old male with hypertension, hypercholesterolemia, and tobacco use was admitted at our center with positive stress test and inferior ischemia in an isotopic study. The left ventricle evaluated by transthoracic echocardiogram showed a normal systolic function.

Coronary angiography was performed via radial access and showed a well developed left main (LM) coronary artery with severe stenosis of the distal segment, and insignificant disease at the ostia of the left circumflex (LCX) artery, ramus intermedius, and left anterior descending (LAD) coronary artery, corresponding to a bifurcation lesion Medina 1,0,0 (Figures 1A and 1B). Given the lesion characteristics with a majority affectation of the main vessel and a bifurcation angle of 45°, immediate angioplasty with Axxess stent was decided. The LM was engaged with a 7 Fr Extra backup 3.5 guiding catheter (Medtronic, Inc) via radial access, advancing two 0.014” guiding wires (Abbott Vascular) to the LAD and the LCX. The lesion was predilated with a 3.5 x 10 mm non-compliant Hiryu balloon (Terumo Corporation) at 12 atm, and a 3.5 x 11 mm Axxess stent was implanted, adjusting the distal stent edge at the LM trifurcation (Figure 1C). The stent was positioned at the level of the carina and seated within the ostia of the branch vessels, to ensure complete coverage of the lesion. The wire was finally recrossed from the LCX to the ramus intermedius, and the procedure was concluded with kissing balloon at the bifurcation (3.5 x 10 mm Hiryu balloon at 10 atm at the LM-LAD and semicompliant 3 x 15 mm balloon at 10 atm at the ramus (Figure 1D). A good angiographic result was achieved (Figures 1E and 1F) with a procedure time of 65 minutes and total contrast dose of 190 cc Hexabrix (Guerbet, LLC).

The patient was discharged the day after the procedure on 10 mg/day prasugrel and 100 mg/day aspirin and remains asymptomatic 6 months after the intervention without a negative control stress test.

Discussion. The Axxess stent is a self-expanding, conically shaped nitinol stent specially designed to conform to the specific bifurcation anatomy, without creating a false carina, minimizing the amount of metal at the bifurcation. The self-expansion property of this stent facilitates the seating of the device within the ostia of the branch vessels, providing good lesion coverage and eventually avoiding the implantation of additional stents. The stent is coated with biolimus A9, a lipophilic, semi-synthetic sirolimus analog drug immersed into a biodegradable polymer, which is applied to the abluminal surface of the stent.

The current version of the Axxess system can accommodate vessels from 2.75 to 4.25 mm diameter, and is available in two different lengths (10 and 14 mm); however, the distal part of the stent can achieve an expansion of 6.5 mm according to the manufacturer. It requires a 7 Fr approach, and fits most bifurcations up to an angle of 70°. The stent has four highly visible radiopaque edges extending 2 mm outside the distal and proximal markers of the stent, with two additional central markers to guide a controlled liberation of the stent by the sheath retrieval. Further adjustment of the stent position remains possible as long as the cover sheath contains more than half the stent length (between the two central markers) (Figure 2).

The Axxess stent has been implanted under different study protocols in over 500 patients worldwide, with excellent success rates and good angiographic results and at mid-term follow-up.
Figure 1. Percutaneous treatment of left main stem with Axxess stent. Coronary angiography was performed via radial access and showed a well-developed LM with severe stenosis of the distal segment, and insignificant disease at the ostia of the LCX, ramus intermedius, and LAD, corresponding to a bifurcation lesion Medina 1,0,0 (A, B). The lesion was predilated with a 3.5 x 10 mm non-compliant Hiryu balloon (Terumo Corporation) at 12 atm, and a 3.5 x 11 mm Axxess stent was implanted, adjusting the distal stent edge at the LM trifurcation (C). The stent was positioned at the level of the carina and seated within the ostia of the branch vessels, to ensure complete coverage of the lesion. The wire was finally recrossed from the LCX to the ramus intermedius, and the procedure was concluded with kissing balloon at the bifurcation (3.5 x 10 mm Hiryu balloon at 10 atm at the LM-LAD and semicompliant 3 x 15 mm balloon at 10 atm at the ramus (D). A good angiographic result was achieved (E, F).
New Treatment for Medina 1,0,0 LM Stent Bifurcation Lesion

The Axxess Plus trial\(^2\) and the Diverge (Drug-Eluting Stent Intervention for Treating Side Branches Effectively) study\(^3,4\) showed a high procedural success rate, with a major adverse cardiac event (death, myocardial infarction and target lesion revascularization) rate of 10% and 7.7% at 6 and 9 months, respectively.

The use of this stent in LM disease has been reported in an “off-label” indication, while its implantation in these specific bifurcation lesions has not been specifically approved. A selective analysis of the Axxent trial\(^5\) evaluated 33 patients with LM disease treated with Axxess stent, obtaining good angiographic results and a clinical restenosis rate of 9% after the first 6 months. A special version of the Axxess stent designed for LM use is under development to allow larger diameters (up to 4.75 mm) and distinct bifurcation angles (flare-end diameters of 8 mm, 10 mm, and 12 mm).

This is the first report of an LM stem bifurcation lesion treated via radial access with implantation of a single Axxess stent. We consider this device to be especially useful in bifurcation lesions with a majority affectation of the main vessel (Medina 1,0,0) where the lesion can be attempted with the implantation of this unique stent, eventually avoiding the use of additional stents.

Conclusion. The use of the Axxess stent in LM bifurcation lesions may be considered as a good treatment option in selected cases, achieving good lesion coverage with minimal metal amount at the bifurcation.

References