Background Information on the Axxess™ Self-Expanding Bifurcation Drug-Eluting Stent

Bifurcation Lesions

Coronary bifurcation lesions are complex types of lesions that form at the intersection of two vessels. Such lesions are presented in approximately 15% to 20% of all patients undergoing percutaneous coronary interventions (PCI).1 Bifurcation lesions are generally associated with higher event rates than lesions involving just one vessel.

Treatment of Bifurcation Lesions

Prior to the introduction of Axxess™, the catheter-based treatment of coronary bifurcation lesions was sub-optimal. Compared with plain balloon angioplasty, bare metal stents (BMS) improve outcomes and reduce the risk of abrupt closure. However, the need for re-intervention remains high, even among stents specially designed to treat bifurcation lesions. Specifically, recurrences in the side branch constitute a major problem.2

The introduction of drug eluting stents (DES) has reduced the rates of restenosis: however, conventional designs are not always suitable in these lesions due to the anatomy of the bifurcation. Restenosis and stent thrombosis still occur more frequently than in lesions not involving a bifurcation. The problem is particularly acute in lesions of the left main coronary artery (LMCA), 95% of which are bifurcated. Current techniques such as conventional T-stenting often result in incomplete coverage of the origin of the side branch, which may impair outcome.

For this reason, dedicated bifurcation stents have been developed which are specially designed for treating bifurcation lesions. However, most of these dedicated stents are bare metal only. Of the four dedicated bifurcation DES available, two are balloon-expandable rather than self-expanding. Axxess is the only self-expanding dedicated bifurcation DES to use a limus drug, generally recognised as being the best class of drug to use on a stent.

The Axxess Self-Expanding Bifurcation DES

Axxess consists of a conical-shaped self-expanding nitinol (nickel/titanium) stent platform, specifically designed to conform to the shape of the bifurcation anatomy. It has been tailored to reconstruct the bifurcation without creating a false carina (the ridge where the two vessels join), lowering the risk of uncovered struts at the flow divider. The stent is coated with an abluminal-applied biodegradable poly-lactic acid (PLA) polymer that releases Biolimus A9™ (BA9™), an anti-restenotic drug designed by Biosensors specifically for use with DES. Both BA9 and the biodegradable polymer are vital components of the BioMatrix™ DES family, which has more published data to support its safety and efficacy than any other biodegradable polymer DES.

It has been estimated that around a third of all bifurcation lesions are suitable for treatment with Axxess due to their appropriate anatomy.

Axxess Clinical Data

The results from two long-term studies have confirmed the safety and efficacy of Axxess in over 400 patients with bifurcation lesions. They have demonstrated low cumulative rates of MACE and very few cases of definite very late stent thrombosis. Axxess is now the only dedicated bifurcation stent with a substantial body of supporting data out to five years.
AXXESS PLUS

AXXESS PLUS is a prospective, single-arm multi-center study involving 139 patients enrolled at 13 clinical sites in Europe, Brazil and New Zealand followed-up through five years. In addition to Axxess implantation in the proximal parent vessel, other stents could be implanted in the distal parent vessel and/or the side branch at the discretion of the operator. In over 76% of cases, the additional stent implanted was sirolimus-eluting.

Axxess implantation in the parent vessel achieved high levels of procedural and angiographic success (94.9% and 100% respectively). At five years post-procedure, the cumulative rate of MACE (a composite of cardiac death, MI, emergent cardiac artery bypass graft (CABG) and clinically-driven target lesion revascularization) was 17.3%. The occurrences of the individual components were 3.3% for cardiac death, 8.2% for MI, and 11.4% for clinically-driven TLR (there were no incidences of emergent CABG). There were no cases of ARC-defined definite very late stent thrombosis observed.3

DIVERGE

DIVERGE is a prospective, single-arm, multi-center study of 302 patients with de novo bifurcation lesions enrolled across 14 sites in Europe, Australia and New Zealand. Following implantation of Axxess, the distal parent and/or side branch vessels could be treated with a conventional sirolimus-eluting stent (SES) at the operators’ discretion. 12.3% of procedures involved Axxess only; 17.7% involved Axxess together with an SES in the distal parent vessel; 4.0% involved Axxess together with an SES in the side branch vessel; and 64.7% involved Axxess together with an SES in both of the vessels.

Primary endpoint data demonstrated low overall rates of MACE [a composite of death, MI and ischemia-driven target lesion revascularization] (7.6%); restenosis (0.7%); and late stent thrombosis (0.3%) at nine months in patients treated with Axxess.4

Five-year data from the DIVERGE trial was reported at EuroPCR in May 2013. 96.3% of patients originally enrolled in the study (291) were available for follow-up. The cumulative rate of MACE was 21.3% with the occurrences of the individual components being 6.5% for death, 8.6% for myocardial infarction and 12.4% for ischemia-driven TLR. Only five cases (1.7%) of very late definite stent thrombosis (VLST) were reported, all of which involved at least one SES. None of these very rare VLST events resulted in the death of a patient.5

AXXENT LMCA

AXXENT LMCA is a prospective, single-arm multicentre study designed to examine the effect of Axxess in treating bifurcation lesions of the LMCA. Six-month results from the pilot study involving 33 patients showed a device success of 90%, a lesion success rate of 97%, and a procedural success rate of 90%.6 IVUS ultrasound results at six months in 26 patients revealed a 12.4% increase in volume and significant neointimal suppression.7

Availability

Axxess is now available in most major markets worldwide.
References