SIZING Registry – interim analysis results

Background

While treating a coronary lesion, difficulties are encountered when there is significant vessel diameter variance along the lesion length, large vessel diameter, or to assess final vessel diameter in thrombus containing lesions.

Conventional balloon expandable stents are tubular. The need to adapt them to the anatomy makes stent size selection difficult and adds the need for optimization techniques which may be aggressive for the vessel and the stent structure. Clinical risks may be associated with these extra steps or with malapposition.

To date there is a scarcity of data in the use of any coronary stents in these challenging lesions.

The Self-apposing Sirolimus-eluting stent Xposition S (Stentys, Paris, France) is delivered with a balloon-delivery system. We investigate the Xposition S stent in these challenging lesions in an everyday practice registry.

Methods

The worldwide prospective SIZING registry is designed to provide real world clinical data on STENTYS stents, in lesions with significant vessel diameter variance, large vessel diameter, or high thrombus load.

Patients selected by investigator to receive a STENTYS stent are enrolled (no exclusion criteria except requirement for patient written consent).

Primary endpoint is MACE at 12 months, defined as cardiac death, Target Vessel related Myocardial Infarction (TV-MI), Clinically-Indicated TLR (CI-TLR), emergent CABG.

Interim (exploratory) analysis is performed on all patients who received Xposition S stent, with a median follow-up of 12 months.

Results

Since March 2015, a total of 588 patients with Xposition S were enrolled in 19 sites. Median follow-up is 365 days (mean 294 days).

In this true all-comers population, high rates of STEMI (32%), previous CABG (16%), and class C lesions (45%) are found. Lesion anatomies highlight indications for self-apposing stents: 35.9% of lesions presented with significant vessel diameter variance (including aneurysmatic, ectatic, severely tapered vessels), 16.8% had significant thrombus load, 16.0% were bifurcations (including left main coronary), 7.5% were Saphenous Vein Grafts (SVG).

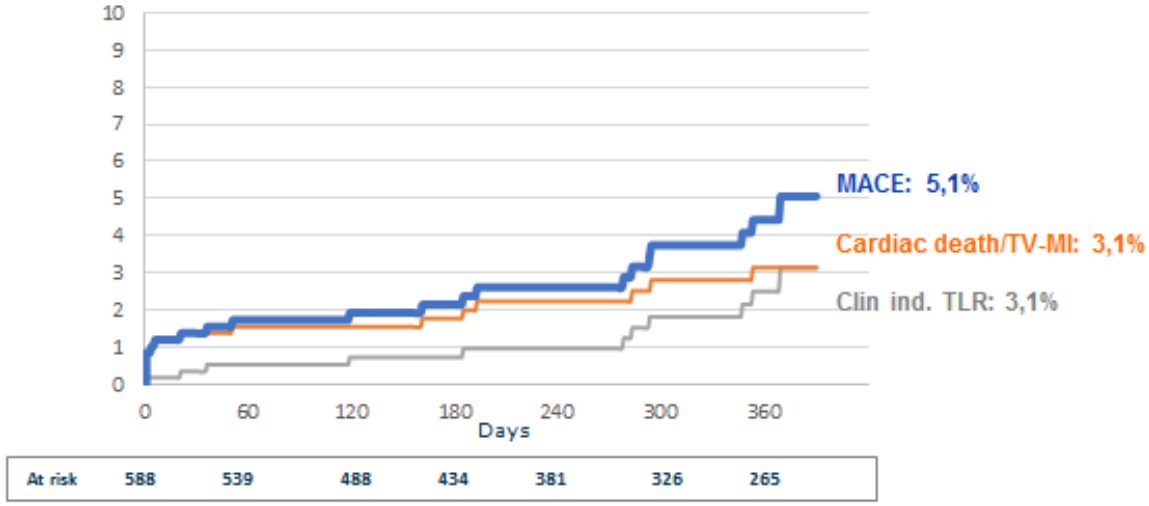

Figure 1: Kaplan-Meier estimate for clinical outcome at 12 months (n=588)

Despite the challenging anatomies treated, the MACE rate remains low, at 5.1% (Figure 1). Cardiac death occurred in 1.6% of patients, 2.1% for TV-MI and 3.1% for CI-TLR. Stent thrombosis rate (ARC def./prob.) is 0.7%.

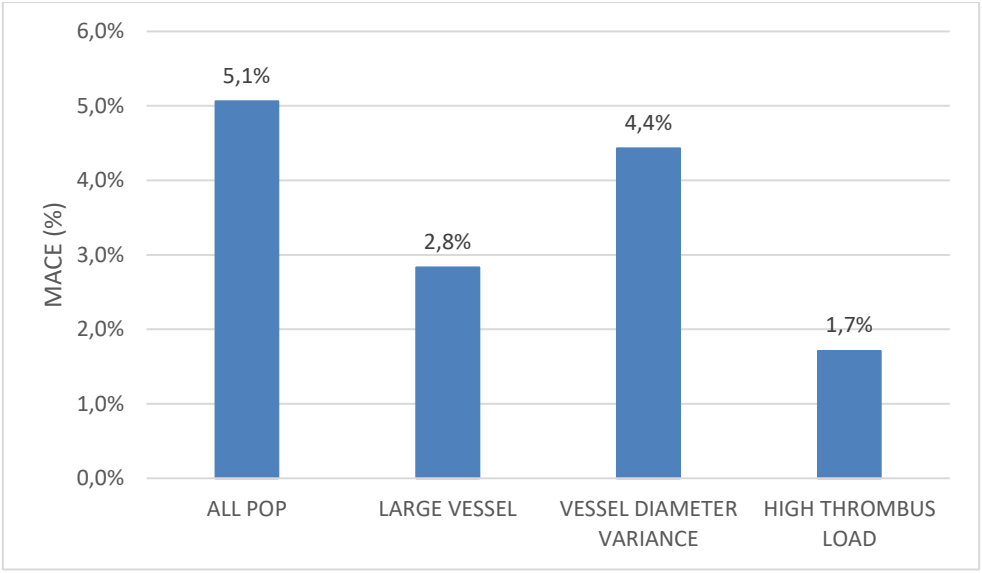

Figure 2: Subgroup analysis for MACE (Kaplan-Meier estimate): all population (n=588), large vessel subgroup (RVD ≥ 4,5mm) (n=125), significant vessel diameter variance subgroup (n=204) and hight thrombus load lesion subgroup (n=149).

The MACE rate was 2.8% in the large vessel subgroup, 4.4% in significant diameter variance, 1.7% in thrombotic lesions (Figure 2).

Conclusions

The results of this interim exploratory analysis - the first on the Xposition S stent in such a large all-comers population- highlight the type of challenging anatomies treated, as well as a low MACE rate at 1 year. These positive results will need to be confirmed with the final analysis.