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The SV stent study: a prospective, multicentre, angiographic evaluation of the BiodivYsio phosphorylcholine coated small vessel stent in small coronary vessels ☆

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Abstract

Objective: To evaluate the use of the phosphorylcholine (PC) coated BiodivYsio small vessel (SV) stent in native coronary vessels of small calibre.
Design and setting: Prospective, multi-centre, multi-national registry with 6-month clinical and core-lab angiographic follow-up. Adverse events were adjudicated by a Clinical Events Committee (CEC) and included peri-procedural analysis of cardiac enzymes.
Patients: Patients with signs or symptoms of ischaemia with an identified target lesion in an epicardial vessel with reference diameter 2.0–2.75 mm were enrolled. Intervention in other epicardial territories in the same patient was permitted.
Results: Recruitment of 150 consecutive lesions (in 143 patients) was completed in 19 centres in Europe and Israel. The stent was deployed successfully in all but one lesion. At 6 months, 1 patient (1%) had experienced sudden cardiac death, 4 further patients (3%) had a non-Q wave MI, and a further 24 patients (17%) had repeat revascularisation of a study target vessel. The mean reference vessel diameter prior to stenting was 2.2 mm (S.D. 0.4). Mean minimal luminal diameters at pre-procedure, post procedure and follow-up were 0.6 mm (S.D. 0.3), 2.0 mm (S.D. 0.4) and 1.2 mm (S.D. 0.6), respectively. The late lumen loss index was 0.55 (S.D. 0.53) with a binary restenosis rate of 32%.
Conclusions: In stenting of selected lesions in small vessels, the BiodivYsio SV™ stent demonstrated high rates of implant success. The rates of major adverse cardiac events (MACE), angiographic restenosis and repeat revascularisation are similar to those reported in other small vessel bare metal stent studies.

Keywords: Small vessel; Stent; Coated; Phosphorylcholine; Quantitative coronary angiography; Registry; Percutaneous coronary intervention

1. Introduction

The advantage of coronary stent implantation over simple balloon angioplasty has been established in a number of clinical settings. From the initial landmark trials [1,2] much of the evidence supporting more widespread stent use has been derived from studies addressing lesions in vessels of reference diameter ≥3 mm. Despite this,

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registries and trials report that over a third of percutaneous intervention procedures are performed in vessels of small calibre (<3 mm). In this setting, the rates of angiographic restenosis and repeat revascularisation remain high and present a continuing challenge for the interventional cardiologist [3–8].

The BiodivYsio™ small vessel stent (SV Stent) from Biocompatibles has been designed for small vessel application. The stent is laser-cut from a 1 mm tube of 316L stainless steel and provides a 15% metal to artery surface coverage ratio in a 2.0 mm diameter vessel. The stent is coated with a phosphorylcholine (PC) layer, which is a synthetic copy of the predominant phospholipid in the outer layer of an erythrocyte [9,10]. This layer can be used as a polymer subsequently for drug elution studies with agents that inhibit restenosis. In a retrospective sub-group analysis of a previous registry (using an earlier PC coated stent design) the angiographic restenosis rate in vessels 1.25–2.66 mm in diameter (n=45) was 20% at 6 months [11]. This favourable observation suggested the need for a prospective evaluation of the SV device in vessels of small calibre.

2. Methods

2.1. Patients and angiographic eligibility criteria

Patients were considered eligible for recruitment if they were aged 18 or over and had either symptoms of angina pectoris or evidence of myocardial ischaemia. Patients were excluded if a coronary intervention was planned within 48 h of an acute myocardial infarction event or within 24 h of an acute coronary syndrome manifest as pain at rest or on minimal exertion associated with ECG changes of ischemia.

Study target lesions were identified as de novo stenoses in native vessels with a reference vessel diameter between 2.0 and 2.75 mm. Lesion length had to be less than 16 mm and the stenosis had to reduce the luminal diameter by more than 50% when compared to the adjacent reference vessel. All measurements were made by visual estimate following the introduction of intra-coronary nitrate. Lesions situated in the left main coronary artery or the ostium of the right coronary were excluded. Other lesion exclusion criteria included visible calcium or thrombus, the involvement of side branches with a diameter of >2.0 mm or severe angulation in the proximal vessel or at the site of the lesion. A proposed study lesion had to be the sole intervention target in that epicardial territory. This allowed for a potential maximum of three study target lesions per patient. Non-study related intervention was permitted in epicardial vessels remote from an identified study target.

2.2. Ethical issues

The study was conducted according to the principles of the Declaration of Helsinki and to the standards of ICH-GCP and EN540. National, regional or local review boards for each participating centre granted ethical approval. Patients confirmed their informed consent in writing after discussions with local staff and having read a patient information sheet, presented in the local language and approved by the local ethical committee.

2.3. Stent devices, procedures, and anti-thrombotic treatment

Study SV stent devices were available in lengths of 10 and 18 mm, pre-mounted on either a 2.0 or 2.5 mm delivery balloon. Specific, trial related consignment stock was supplied to participating centres. To ensure an 'intention to treat' analysis, the use of any trial stent device had to be supported with case record form documentation. A patient was enrolled when a study stent was opened.

Stent placement and balloon angioplasty procedures were performed according to standard methods. Interventionists performing the procedures were all experienced operators at recognised high-volume centres. The study protocol recommended the achievement of a final diameter stenosis of <20% by visual estimate at the end of procedures. The use of additional non-study stents was allowed in the event of dissections or threatened closure. The use of aspirin, heparin, ticlopidine, clopidogrel and glycoprotein IIb/IIIa receptor blockers prior, during and after the procedure were left to the discretion of the investigator.

Routine screening for cardiac enzyme (CK or CKMB) release was performed with a blood sample drawn 12–24 h post procedure. This was analysed in local laboratories and the results described in terms of the elevation of the observed value above the upper limit of the local reference range.

Follow-up angiography was scheduled at 6 months for all patients, unless the target vessel had already been assessed as part of an adverse event episode.

2.4. Angiographic evaluation

Digital or cine angiogram records were analysed in a central angiographic core laboratory using an automated edge detection system—CMS (Medis Medical Imaging Systems). Investigators were required to record paired orthogonal images of target lesion segments before and after the intervention and at scheduled follow-up. Each angiographic sequence was preceded by an intra-coronary injection of nitrate. The core laboratory performed calibration from the guide catheter and recorded the minimal lumen diameter (MLD), reference diameter, lesion length and percentage stenosis, calculated from the mean of two views where available. Lumen gain was derived as the difference between MLD at baseline and the end of the intervention and at the 6-month follow-up. Late loss index