An update on ongoing contemporary trials in interventional cardiology

There are a multitude of ongoing clinical trials in interventional cardiology at any given time. *Confluence* has identified three important trials that will provide key evidence to guide clinical decision making.

IN.PACT Global Registry

The IN.PACT Global superficial femoral artery (SFA) clinical study is the largest controlled, independently adjudicated all-comers trial in SFA intervention. This international, prospective, multicenter study will assess the safety and efficacy of Medtonic's In.Pact Admiral paclitaxel-eluting balloon for the treatment of atherosclerotic disease in the SFA and/or popliteal arteries. The registry will enrol up to 1500 patients with any lesion length in a 'real world' setting, across 80 sites in Europe, Middle East, Latin America and Asia. The study involves thorough clinical and functional assessment (EQ-5D™, 6-minute walk test and walking impairment questionnaire). The study, initiated in April 2012, will follow patients for five years.

CvLPRIT

The Complete Versus Lesion-only PRimary PCI Pilot (CvLPRIT) trial is an open-label,multi-centre randomized controlled trial in patients with acute ST-segment elevation myocardial infarction in whom multi-vessel coronary artery disease is identified at the time of primary percutaneous coronary intervention (PCI). In this clinical trial, 300 patients will be randomized on a 1:1 basis to culprit-only PCI or in-patient complete multivessel PCI. The study will assess cumulative all-cause mortality, recurrent myocardial infarction, heart failure, and need for revascularization with either PCI or coronary artery bypass grafting (CABG), at 12 months. It is hoped that this study will shed light on the optimal revascularization strategy for patients with multi-vessel disease, including insights into the consequences of intervention in non-culprit lesions undertaken during the peri-infarct period. In the interim, the PRAMI group have published a very similar trial which demonstrates a significant (64%) benefit from treating all lesions during the index admission. Alone, this trial is unlikely to change the guidelines, particularly in view of some criticisms regarding blinding and demographics. Therefore, a second trial with nested nuclear scans to help direct treatment in addition to PRAMI results will be valuable.

EXCEL

EXCEL (Evaluation of Xience Prime versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization) will compare PCI with the Xience drug-eluting stent (Abbott Vascular) with the standard treatment, CABG or surgery, in select patients with unprotected left main coronary artery disease. The EXCEL trial will enrol more than 2,600 patients at up to 165 medical centres in 18 countries from regions including the US, Europe, Asia Pacific, Canada and Latin America. The primary endpoint of the study is the composite measure of all-cause mortality, myocardial infarction, or stroke at a median follow-up duration of three years, with all randomized patients having reached a minimum of two years' follow-up. This study will help to elucidate whether drug-eluting stents provide a viable treatment option in this patient group.