

EVINCI results could lead to 75% reduction of invasive procedures for patients with suspected coronary artery disease

Madrid, 26 June 2012: Preliminary findings from the EVINCI study show that the prevalence of “significant” coronary artery disease in patients with chest pain symptoms is lower than expected in Europe. In as much as 75% of this population an accurate non-invasive screening could avoid unnecessary and costly invasive procedures. The three year multicentre European trial will define the most cost effective strategy for diagnosing patients with suspected coronary artery disease.

The EVALuation of INtegrated Cardiac Imaging (EVINCI) study was completed on 15 June. Preliminary results were presented during the EVINCI Consortium’s final meeting at the University Hospital Ramón y Cajal in Madrid, Spain, on 26 June. EVINCI was designed by members of the European Society of Cardiology (ESC) Working Group on Nuclear Cardiology and Cardiac CT. www.escardio.org/evinci

The trend of increasing cardiovascular mortality in Europe has been reversed over the last 20 years mainly due to effective treatment of acute coronary syndromes and prevention of coronary artery diseases through tackling risk factors. The decrease in mortality has been accompanied by an increased prevalence of chronic coronary artery disease and heart failure. The net result is that health systems are seeing more patients with suspected coronary artery disease and an effective diagnosis and treatment are required.

In Europe and the US, most patients with suspected coronary disease undergo invasive procedures without first having preliminary effective non-invasive screening. But obstructive coronary disease is present in less than 40% of patients undergoing invasive coronary angiography, according to data from recent international registries. “It is thus obvious that we definitely need better selection of high risk patients by non-invasive means to avoid costly, risky and inappropriate invasive procedures,” says Dr Neglia.

There are numerous methods for diagnosing coronary artery disease but until now clinical studies have mainly focused on single modalities rather than comparing different integrated strategies. “We have a multiple array of methodologies that can be chosen according to guidelines and recommendations,” says EVINCI coordinator Dr Danilo Neglia (Pisa, Italy). “We do actually know the strengths and weaknesses of each technique but there is no clue as to which approach is the most cost effective to solve the diagnostic issue and define proper treatment in the single patient.”

The EVINCI study enrolled 695 patients with chronic chest pain and a 60% average probability of having coronary artery disease. Patients were aged 30-75 years and 38% were female. Patients were selected from 17 clinical centres in Europe and underwent integrated non-invasive diagnostic testing, largely based on cardiac imaging. After non-invasive screening, patients underwent heart catheterization (coronary angiography and functional measurements) when appropriate as a reference method to define the presence, extent and functional relevance of coronary disease (i.e. its effects in limiting coronary flow reserve). The different non-invasive strategies were compared for their diagnostic accuracy, and the costs and potential risks were monitored. This study design is in line with the push to perform comparative effectiveness research in Europe.

The major endpoint of EVINCI was to assess the ability of non-invasive multimodality imaging to diagnose the presence of coronary artery disease in the single patient, determine if it primarily involves the major coronary arteries or the microvessels, and whether the disease is causing ischaemia which needs aggressive treatment. This is relevant because knowing the extent and the functional relevance of the disease helps to determine whether treatment is likely to improve prognosis and quality of life. In this way unnecessary treatments can be avoided.

To this end, non-invasive imaging tests were chosen which would assess both coronary anatomic abnormalities and their functional effects. In each patient, coronary anatomy was assessed using multi-slice CT. Radionuclide imaging (either SPECT or PET) was used to measure myocardial perfusion at rest and during stress. The effects of myocardial ischaemia on ventricular function were assessed by either magnetic resonance imaging or echocardiography during stress. Patients were followed up for a maximum of three years.

Data collection concluded on 15 June. Preliminary analysis shows that in patients with stable angina or angina-like symptoms, the probability of significant coronary artery disease, based on clinical and stress electrocardiogram (ECG) evaluation, is currently largely overestimated. As a consequence many patients may receive unnecessary invasive procedures. The average estimated probability of disease in the EVINCI

population was 60% while the actual prevalence of significant coronary disease, confirmed at heart catheterization and deserving revascularization, was only 25%.

Once the final analysis is completed, the EVINCI study is expected to demonstrate that performing adequate non-invasive imaging screening of patients with suspected coronary artery disease could safely avoid invasive procedures in 75 out of 100 patients. Non-invasive cardiovascular imaging has a crucial role in identifying patients with significant coronary artery disease - ie an obstructive coronary stenosis able to cause ischemia and thus deserving revascularization - prior to invasive coronary angiography. This will reduce the use of inappropriate invasive procedures and related costs, reduce risks for patients, and enable patients who are truly at risk to be effectively treated. The EVINCI study will have sufficient power to answer the question of which is the most cost effective non-invasive imaging strategy to do the job. Final results on major endpoints are expected in a few weeks.

"The EVINCI results will probably show that a number of invasive coronary angiography procedures are unnecessary," says Dr Neglia. "In these patients a non-invasive diagnostic imaging test can be performed, which would save money and be safer for patients." Costs, potential risks of each procedure and patients' perception of health status are being evaluated in a health economic analysis comparing each diagnostic strategy. Some variability, particularly in costs, is expected among participating countries. Dr Neglia says: "The EVINCI study was intended to compare differences among procedures but it will also probably provide evidence for some variability in costs for the same procedure throughout Europe."

A huge European digital bank for multimodal cardiovascular imaging and biological bank for blood samples were created that will be relevant not only for the EVINCI study results but also for future studies and educational purposes. EVINCI received funding from the European Commission within the Seventh Framework Programme (FP7) for Research and Technological Development. This is the EU's main instrument for funding research in Europe and will run from 2007-2013. FP7 is also designed to respond to Europe's employment needs, competitiveness and quality of life.

EVINCI has been a collaborative effort by 20 partners – the 17 clinical centres, the ESC, the Italian National Research Council (CNR) and CF Consulting in Milan. A major output from the trial is eduCAD, a new web based tool for disseminating the design and approach of the EVINCI study and for training young cardiologists how to choose the best imaging test for diagnosing ischaemic heart disease. eduCAD is based on clinical cases selected from the EVINCI study and has the results of multiple non-invasive imaging tests and coronary angiography for each patient. It is available at www.escardio.org/educad

Cases are being validated by a commission of leading experts on each imaging modality from across Europe. Commission members were selected by the EVINCI Consortium and the ESC Working Group on Nuclear Cardiology and Cardiac CT.

eduCAD users are asked to choose the most appropriate imaging diagnostic pathway based on an initial clinical description of the patient and stress ECG. They do not have to be experts at interpreting the results of each test and can ask the experts for help if they wish. The user then makes a diagnosis and treatment plan. At the end, users compare their imaging diagnostic pathway, diagnosis and treatment plan with the commission's recommendations.

"This will help young cardiologists to understand which imaging strategy could have been chosen in that specific patient to maximise efficacy in performing the final diagnosis and addressing the right treatment," says Dr Neglia.

"Ultimately eduCAD should help cardiologists choose the most appropriate diagnostic test the first time round," he adds. "This will reduce the use of unnecessary tests, save money and provide a better experience for patients."

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Notes to editor

About the European Society of Cardiology (ESC) www.escardio.org

The European Society of Cardiology (ESC) represents more than 75,000 cardiology professionals across Europe and the Mediterranean. Its mission is to reduce the burden of cardiovascular disease in Europe.