

20th European **Cardiology** Conference

October 16-18, 2017 | Budapest, Hungary

Feasibility of myocardial hybrid revascularization versus coronary artery bypass grafting for complex triple-vessel disease; randomized clinical trial: Pilot phase

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Background: The best treatment for coronary artery disease (CAD) in patients with multi vessel disease is still subject of debate. The hybrid coronary revascularization (HCR) is a procedure that combines both the advantages of conventional coronary artery bypass surgery (CABG), with the revascularization of the left anterior descending artery (LAD) using the left internal mammary artery (LIMA) graft, without the use of cardiopulmonary bypass (CPB), with minimally invasive benefits of percutaneous treatment of remaining affect arteries.

Objective: To assess, in a pilot study, feasibility and safety of HCR I patients with multi vessel CAD and to compare early results (within 30 days) of this approach to conventional surgery.

Methods: Prospective clinical study, aiming to include 60 patients, randomized in a 2:1 ratio for hybrid treatment (HCR group, n=40) or conventional CABG (CABG group, n=20). Patients must have three-vessel disease, with an intermediate or high Syntax Score (>22), in which, after exclusion of LAD lesion, the remaining Syntax Score become low (>22). The primary endpoint of the study is the feasibility of HCR in the absence of major adverse events (a compound of overall mortality, acute myocardial infarction (MI), stroke or unplanned revascularization).

Results: Between August 2014 and April 2017, 46 patients were included in the study (HCR=32 and CABG =14). The primary endpoint was observed in 3 patients (8%), all belonging to HCR group (12%), however, without statistical significance ($p=0.54$). There was no statistical difference between the groups (HCR vs. CABG, respectively) in terms of mortality (3.2% vs. 0%), unplanned revascularization (7% vs. 0%), MI (7% vs. 0%), or any of the secondary outcomes evaluated. Patients who presented with any of the complications (12 patients 26%) had a tendency (not statistically significant) to be older (62 vs. 59 years; $p=NS$) and to present with higher risk scores (Euro SCORE 1.40 vs. 0.70; $p=0.19$) than patients without complications.

Conclusions: HCR is a feasible and safe technique when compared to conventional surgery, with similar complications rates. However, the study is underpowered due to the low number of patients included.

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