TCT-83

Risk Model for Estimating the One-Year Risk of Deferred Lesion Intervention Following Deferred Revascularization after Fractional Flow Reserve Assessment

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Background: Lesions deferred revascularization following fractional flow reserve (FFR) assessment have a low risk of adverse cardiac events. The variability in risk for deferred lesion intervention (DLI) has not been evaluated previously. The aim was to develop a prediction model to estimate the one-year risk of DLI in coronary lesions where revascularization was not performed following FFR assessment.
Methods: A prediction model for DLI was developed from a cohort of 721 patients with 882 coronary lesions where revascularization was deferred based on FFR between 10/2002 and 7/2010. DLI was defined as any revascularization of a lesion previously deferred following FFR. The final model for DLI was developed using stepwise Cox regression, and internally validated and calibrated using bootstrapping techniques. An algorithm was constructed to predict the one-year risk of DLI.
Results: During a mean (±SD) follow-up period of 4.0 ± 2.3 years, 18% of lesions deferred after FFR underwent DLI; the one-year incidence of DLI was 5%. Besides FFR values, the final Cox model included several predictors of DLI (current or former smoking, history of coronary artery disease [CAD] or prior PCI, and multivessel CAD), and two variables negatively associated with DLI (age and creatinine). The c statistic for the DLI prediction model was 0.66 (95% CI 0.61-0.70).
Conclusions: Patients deferred revascularization based on FFR have variation in their risk for DLI. A clinical prediction model consisting of 5 clinical variables and the FFR value can help predict the risk of DLI in the first year following FFR assessment.

TCT-84

Fractional Flow Reserve versus Angiography in Guiding Management to Optimize Outcomes in Non-ST Elevation Myocardial Infarction (FAMOUS – NSTEMI) Clinical Trial: Study Design and Baseline Characteristics of Randomized Participants.

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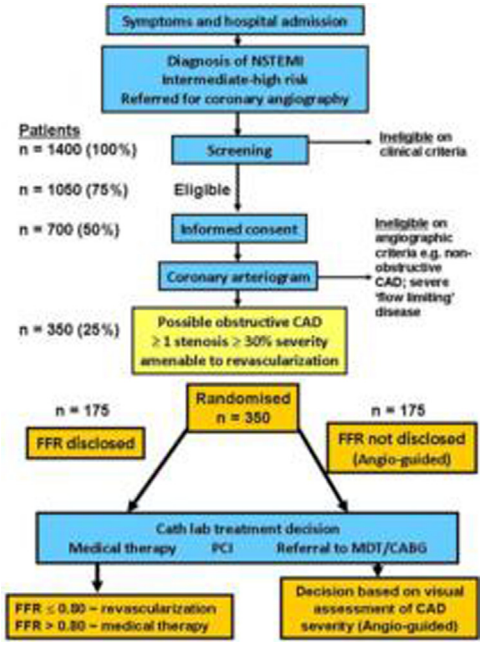
Background: Invasive management guided by coronary angiography is the standard of care in NSTEMI. We hypothesized that functional assessment of coronary stenosis severity with fractional flow reserve (FFR) would have additive diagnostic, clinical and health economic utility, as compared to angiography-guided standard care.
Methods: A prospective multicenter randomized double-blind controlled trial in acute NSTEMI patients with ≥1 coronary stenosis ≥30% severity (threshold for FFR measurement) in culprit and non-culprit lesions. Patients were randomized immediately after coronary angiography to the FFR-guided group or angiography-guided group. The study design is shown in Figure 1. The primary outcome is the between-group difference in the proportion of patients allocated to medical management compared to revascularization. Secondary outcomes include health outcomes, quality of life, and healthcare costs. The minimum/average follow-up periods are 6 & 18 months, respectively.



Results: 350 patients were randomized between Oct 2011-May 2013 in 6 UK hospitals. The participant characteristics are: mean ± SD age 60±15 years, 74% men, 14% treated diabetes, 8% prior PCI and 10% prior MI. The median (IQR) time from the index event to the initial angiogram was 3.0(2.0,6.0) days. The median (range) GRACE Score was 180 (8,269). On average each patient had 1.9±0.8 angiographically diseased coronary arteries (left main 10%, RCA 58%, LAD/Diagonal 54%, Cx/OM 64%).
Conclusions: The FAMOUS NSTEMI population has high risk characteristics and differs in several ways from the FAME trial participants.

ORALS

Percutaneous Treatment of Mitral Valve Disease

Moscone West, 2nd Floor, Room 2004

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TCT-85

Ventricular and Atrial Remodeling after the Percutaneous MitraClip: 4 year Follow-up Data from the EVEREST II Randomized Controlled Trial

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Background: Reverse remodeling of the left ventricle (LV) and left atrium (LA) is a desirable outcome after mitral valve repair (MVR) for significant mitral regurgitation (MR). Using data from the EVEREST II randomized trial, we compared the extent of left-sided chamber reverse remodeling between the percutaneous and surgical mitral repair cohorts.
Methods: The EVEREST II trial is a prospective, multicenter, randomized, non-blinded evaluation of the percutaneous MitraClip system compared in 2:1 fashion to surgical MVR in the setting of moderate to severe MR. Four year follow up echocardiographic data was available for 85 individuals with percutaneous repair (PR) and 42 with surgical repair (SR). Successful repair was defined as ≤2+ residual MR.
Results: Baseline characteristics and LV and LA dimensions were similar in PR and SR groups except for a greater proportion of history of heart failure in the PR group. At 4 years, 73% (62/85) of the PR group and 93% (39/42) of the SR group had ≤ 2+ MR. LV systolic and diastolic dimensions were significantly reduced in both groups at 4 years, although the SR group had significantly more reverse remodeling (Table 1,