Other

CRT-108

Electromechanical mapping to Determine Myocardial Viability in Reperfused and Nonreperfused Myocardial Infarction Models

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Aims: Similarly to patients presenting with acute coronary syndrome two kinds of animal models were evaluated by cardiac magnetic resonance imaging (cMRI) and electromechanical mapping (EMM). The balloon occlusion model characterizes the features of patients receiving reperfusion therapy, the coil deployment method imitated the features of "late comers", who did not receive any reperfusion therapy.
Methods and Results: Balloon occlusion in the left anterior descending coronary artery (LAD balloon group) or coil deployment in the LAD (LAD coil group) or circumflex artery (Cx coil group) were applied percutaneously to induce reperfused or non-reperfused myocardial infarction (MI) in sixteen domestic pigs. Regional left ventricular viability data were captured via cMRI and EMM. The unipolar voltage (UV) value was significantly ($p<0.05$) decreased in segments containing transmural and subendocardial late enhancement as compared with viable segments in the LAD balloon (7.64±0.33, 6.5±0.26, 5.39±0.32 mV), LAD coil (8.96±0.56, 6.97±0.46, 5.97±0.5 mV) and Cx coil groups (9.57±0.53, 6.06±0.61, 5.54±1.07 mV). Receiver operator characteristic analysis revealed area under the curve 0.809 and 0.691 in the LAD infarct territory and 0.864, 0.855 ($p<0.05$) in the Cx infarct territory for the UV compared to cMRI viability results as transmural late enhancement or viable tissue and subendocardial late enhancement or viable tissue, respectively.
Conclusion: Our study provides a comparison of baseline parameters in myocardial infarcts of different pathomechanism and location via non-invasive and invasive methods and emphasizes the application of both models in preclinical studies, especially if EMM is utilized for both diagnostic and therapeutic purposes.

Physiologic Lesion Assessment

CRT-109

Gender Disparities for Intravascular Ultrasound Minimal Lumen Area Cutoff for Optimal Correlation with Fractional Flow Reserve in Intermediate Lesions

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Background: Assessment of intermediate coronary lesions is still challenging. Fractional flow reserve (FFR) measurements of 0.8 or lower are considered clinically significant for physiological ischemia. Intravascular Ultrasound minimal lumen area (IVUS MLA) was suggested to correlate with FFR for the determination of significant Stenosis. This study aimed to examine gender differences for the IVUS MLA cutoff.
Methods: The FIRST trial is a multi-center, prospective, international registry of patients with intermediate coronary lesions defined as a stenosis of 40-80% by angiography. A total of 350 patients, 367 lesions were enrolled into the study at 10 sites in the United States and Europe. Patients were followed up to hospital discharge. The primary end point was a correlation between MLA and FFR and to identity a cut-off value for MLA corresponding to FFR of 0.8. This sub-analysis examines the differences and correlations between males and females, where there were 260 males and 90 females in the study population.
Results: A receiver operating characteristic curve (ROC) identified MLA <3.1 mm2 (sensitivity 64.1%, specificity 64.9%) as the best threshold value for FFR <0.8. The same analysis between men and women showed, the minimum lumen area (MLA) cut-off for males was 3.19 mm2 (sensitivity 63.8%, specificity 64.7%, r=0.315), and 2.57 mm2 (sensitivity 65.0%, specificity 72.2%, r=0.294) for females.
Conclusion: Anatomic measurements of intermediate coronary lesions obtained by IVUS show a moderate correlation to FFR values. The MLA cutoff for female is smaller when compared to Male. These findings are correlated to smaller vessel size in female and should be taken into account when IVUS MLA is used for assessment of severity of intermediate lesions.

Lesion Characteristics

	Overall (n=344)	Male (n=242)	Female (n=92)	P Value
LAD	190 (56.9%)	133 (55.0%)	57 (62.0%)	0.249
LCX	60 (18.0%)	44 (18.2%)	16 (17.4%)	0.866
RCA	80 (24.0%)	62 (25.6%)	18 (19.6%)	0.247
Proximal	110 (32.9%)	86 (35.5%)	24 (26.1%)	0.101
Mid	198 (59.3%)	141 (58.3%)	57 (62.0%)	0.540
Distal	19 (5.7%)	12 (5.0%)	7 (7.6%)	0.350
Pre RVD	2.97 ± 0.58	3.01 ± 0.59	2.87 ± 0.54	0.063

NURSE AND TECH ABSTRACTS

CRT-110

The Execution and Management of a Complex Clinical Trial

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By providing evidence for best practice, randomized clinical trials play a critical role in shaping the care of the public. We report the operational management systems that enabled the successful execution of a landmark randomized clinical trial. We propose a model for managing high-enrolling, multidisciplinary clinical trials. From 2007-2011 238 subjects were enrolled into TAVR Trial. All patients underwent robust screening assessment(Figure 1A)which was reviewed by our Heart Team at our weekly conference. The Heart Team incorporates expertise from multiple disciplines with subinvestigators from cardiac surgery, cardiology, anesthesiology, neurology. Both research and clinical studies were required during the following phases of care: screening, baseline, preoperative, intraoperative, postoperative,discharge,1month,6month,and every year thereafter out to 5 years (Figure 1B).A minimum of 2069 data points were captured to ensure compliance. Safety reporting required review of 969 adverse events of which 80% were significant, requiring review by the PI within 24 hours. Continual education and training of all team members was required due to protocol amendments (8 total). Protocol required specifics were necessary for all diagnostic studies. We screened >1000 patients. Rate of enrollment increased from 2 patients/month to 24-32 patients/month. Weekly heart team meetings facilitated contribution from all heart team members.THV clinic days were