3D-printing for Ablation Planning in Patients Undergoing Atrial Fibrillation Ablation: 3D-GALA Trial

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Abstract : Aims: Atrial fibrillation (AF) remains one of the major causes of stroke, heart failure, sudden death and cardiovascular morbidity. Ablation techniques are becoming more appealing after the latest results of randomized trials showing the overall clinical benefit. On the other hand, imaging techniques and the frontier application of 3D printing are emerging as a valuable ally for cardiac procedures. However, no randomized trial has directly assessed the impact of preprocedural imaging and especially 3D printing guidance for AF ablation. The present study is designed to investigate for the first time the effect of 3D printing of the heart on the safety and effectiveness of the ablation procedure. Methods and design: The 3D-GALA trial is a randomized, open-label, controlled, multicentre clinical trial of 2 parallel groups designed to enroll a total of 100 patients undergoing ablation using cryo-balloon for paroxysmal and persistent AF. Patients will be randomized with a patient allocation ratio of 1: 1 to preprocedural MRI scan of the heart and 3D printing of left atrium and pulmonary veins and cryoablation versus standard cryoablation without imaging. Patients will be followed up to 6 months after the index procedure. The primary outcome measure is the reduction of radiation dose and contrast amount during pulmonary veins isolation. Secondary endpoints will include the percentage of atrial fibrillation relapse at 24h-Holter electrocardiogram monitoring at 6 months after initial treatment. Discussion: To our knowledge, the 3D-GALA trial will be the first study to provide evidence about the clinical impact of preprocedural imaging and 3D printing before cryoablation.
Keywords : atrial fibrillation, cardiac MRI, cryoablation, 3-d printing
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