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IRBM
IRBM 36 (2015) 351–354

RITS 2015

Validation of an intracardiac ultrasonic therapy–imaging dual mode transducer

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Received 16 January 2015; received in revised form 8 March 2015; accepted 13 April 2015

Available online 29 May 2015

Abstract

Atrial fibrillation is associated with increased risk of stroke and heart failure. Currently it can be treated with minimally invasive radio-frequency catheter ablation. However, the lack of monitoring and assessment of the transmural extent of the lesion currently limits the success rate of this technique. In this study we have developed a novel dual-mode intracardiac echocardiography catheter capable of performing ultrasound imaging and high-intensity focused ultrasound ablation. Using the same device we demonstrate in vivo the feasibility of intracardiac shear-wave elastography to evaluate thermal ablation as well as the feasibility of creating transmural and linear lesions (up to 10-mm wide) in the atrial wall.

1. Introduction

Radio-Frequency Catheter Ablation (RFCA) is a well-established clinical procedure for the treatment of Atrial Fibrillation (AF) but suffers from a low, single-procedure success rate. Recurrence of AF is most likely attributable to discontinuous or non-transmural ablation lesions [1]. Despite this urgent clinical need, there is no clinically-available imaging modality that can reliably map the lesion transmural extent in real time. Moreover it is difficult to control power and heat deposition on the tissue and thus predict a lesion's extent. Finally the major limitation of RFCA is the difficulty of creating transmural or mid-wall lesions in the ventricular wall and the associated necessity of an invasive transthoracic approach for epicardial ablation [2].

In order to visualize the thermal lesion with ultrasound, evaluation of tissue stiffness has recently been introduced as an effective means to map ablated regions [3–7], providing stiffness contrasts between normal and ablated tissues of more than a factor of 2. It was shown in vivo that the stiffening of a thermally ablated tissue is linked to the applied thermal dose [8], and thus, to its viability.

In this study, we have developed a customized dual-mode [9] intracardiac echocardiography catheter. Using the same transducer, first, we demonstrated the feasibility of Shear-Wave Elastography (SWE) to map quantitatively the stiffness of RFCA-induced thermal lesions in cardiac tissues in vitro and in vivo. Second, we validated the feasibility of an intracardiac therapy approach with high-intensity focused ultrasound to finally perform both with the same device.

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http://dx.doi.org/10.1016/j.irbm.2015.04.002

2. Material

2.1. Dual-mode transducer

A 64-element intracardiac transducer (6 MHz, 64 elements, 0.2 mm pitch, Vermon, France) mounted on a 9F catheter (3-mm diameter) was designed and built for dual mode (i.e. same elements used for) imaging and therapy. An ultrafast ultrasound scanner (Aixplorer®, SuperSonic Imagine, France) was used to perform SWE sequences on RFCA induced lesions and an ultrafast scanner prototype (256 emission, 128 reception channels, 10 W/channel, SuperSonic Imagine, France) for ultrasound therapy was used to perform both imaging and HIFU sequences.

3. Methods

3.1. Shear-wave elastography

The principle of SWE relies on the synergetic combination of the acoustic radiation force [10] and ultrafast ultrasound imaging [11] leading to real time and quantitative imaging of stiffness. A shear-wave is generated remotely by focusing ultrasound using the probe and then imaged in real time with plane wave ultrafast imaging. When assuming the medium to be semi-infinite, the group velocity c_t of the shear-wave is proportional to the shear modulus μ of the examined tissue according to:

$$\mu = \rho c_t^2 \quad (1)$$

where ρ is the local density. In this study radiation "pushes" were generated by focusing ultrasound for 300 μs at 6 MHz and imaged using one or three compounded ($-1°$, $0°$, $+1°$) plane wave emissions at 7 MHz. The resulting frame rate was approximately 19 kHz (100 images) and 6 kHz (30 compounded images), respectively. Up to 5 push and imaging sequences were used in order to increase the field of view and the signal-to-noise ratio of the shear modulus maps for a total acquisition time of 25–30 ms. A time-of flight algorithm was used to track and estimate the shear-wave group velocity c_t locally and a final 'stiffness map' was obtained with an average of all the five acquisitions.

3.2. High-intensity focused ultrasound

HIFU sequences consisted on focusing an ultrasonic beam at 5.5 MHz using the whole probe for two minutes with a duty cycle of 50%. The transducer was capable of delivering a total acoustic power of 3.8 ± 0.1 W (measured with an acoustic radiation force balance) which corresponds to an acoustic intensity of 14.4 ± 0.2 W/cm [2] at the surface of the probe. As the probe is a linear array the focus could be moved electronically without moving the transducer.

3.3. Ex-vivo and in vivo experiments

3.3.1. RFCA evaluation with shear-wave elastography

SWE sensitivity to modifications of cardiac tissue exposed to RFCA was first validated in ex vivo porcine ventricular samples ($N = 5$). The 6 to 24 hours old samples were degassed before the experiments and studied in a temperature controlled (37 °C) saline water tank. Both B-mode imaging and SWE were performed on normal cardiac tissue before and after RFCA. Boundaries of the lesions were determined first by applying a 60 kPa threshold on the SWE shear modulus maps and second with gross pathology by using a k-means clustering algorithm [12] on tissue color change by discriminating viable tissue (red) from ablated (white). Depths of such obtained areas were finally compared. SWE was then performed *in vivo* in three sheep ($N = 3$), in five ($n = 5$) right-atrial tissues. The ultrasonic intracardiac transducer was inserted into the right atrium via the femoral vein under fluoroscopy. First the stiffness of normal atrial tissues was assessed quantitatively as well as its variation during the cardiac cycle. SWE was then performed in atrial tissue after RFCA. Fig. 1 shows an example of alignment of the RFCA and ultrasound imaging catheter in the right atrium.

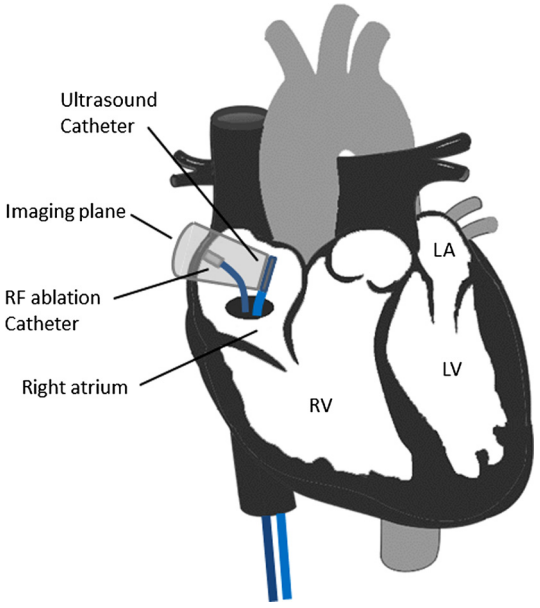

Fig. 1. Example of US and RFA catheters placement in the right atrium. The catheters are inserted through the femoral vein.

3.3.2. High-intensity focused ultrasound

The same procedure as the SWE sensitivity validation was performed but RFCA was replaced by HIFU ablation. Tissues were imaged with B-mode and SWE before ablation then HIFU was performed using the same probe as for imaging, without moving it. Depending on the tissues' morphology up to 5 focus' positions (from 5 mm up to 15 mm in depth and ±3 mm laterally from the probe's center) were chosen to perform the ablation by using the electronic steering. No cardiac wall movement was addressed during ablation. The ultrasonic transducer targeted locations in the right atrium ($n = 2$) and the right ventricle ($n = 3$) in two ($n = 2$) sheep. After ablation B-mode and SWE imaging were performed to investigate the presence of a lesion which was finally confirmed with a gross pathology study.