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● *Original Contribution*

ACOUSTICALLY ACTIVE CATHETER FOR INTRACARDIAC NAVIGATION BY COLOR DOPPLER ULTRASONOGRAPHY

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Abstract—Navigation of intracardiac catheters by echocardiography is challenging because of the fundamental limitations of B-mode ultrasonography. We describe a catheter fitted with a piezoelectric crystal, which vibrates and produces an instantaneous marker in color flow Doppler scans. The navigation learning curve was explored first in six pigs. Accuracy and precision of targeting with the navigation marker "off" (*i.e.*, B-mode imaging) and "on" were assessed in another six pigs. Paired comparisons confirmed significantly ($p = 0.04$) shorter mean distances achieved in each pig with the color Doppler marker. Pooled (mean ± standard deviation) distance of the catheter tip from the target crystal was 5.27 ± 1.62 mm by B-mode guidance and 3.66 ± 1.45 mm by color Doppler marker navigation. Dye injection targeted into the ischemic border zone was successful in 8 of 10 pigs. Intracardiac catheter navigation with color Doppler ultrasonography is more accurate compared with conventional guidance by B-mode imaging. (E-mail: belohlavek.marek@mayo.edu) © **2017 World Federation for Ultrasound in Medicine & Biology.**

Key Words: **Acoustically active catheter, Color flow Doppler ultrasonography, Ultrasonographic navigation, Ultrasound.**

INTRODUCTION

Ultrasonography of the heart is well established for analysis of cardiovascular function and morphology. Now echocardiography is emerging as a means of navigation during cardiovascular procedures (Lee and Naqvi 2013; Zamorano et al. 2011), especially with the advent of real-time 3-D echocardiography. Practical examples include guidance for pericardiocentesis and navigation for catheter-based intracardiac devices or valves.

The fundamental properties and limitations of B-mode ultrasound signal propagation, such as attenuation, reflection, refraction, scattering and noise, can make reliable identification and navigation of minimally invasive procedures challenging. Therefore, several ultrasonographic methods for navigation of minimally invasive procedures were proposed, and we discussed them in detail elsewhere (Belohlavek et al. 2014). Briefly, one group of techniques is based on a transponder principle and was used for ultrasound-guided placement of minimally invasive instruments, including catheters (Landzberg et al. 1988; Langberg et al. 1988; Vilkomerson and Lyons 1997) or needles (Winsberg et al. 1991). Such a minimally invasive instrument is typically furnished at its tip with a piezoelectric element. However, besides acoustical communication between the instrument and transducer, there is also customization of the ultrasonographic imager circuitry and direct electrical connection required between the piezoelectric element driving unit and the ultrasonographic system. A similar transponder-based approach was adopted for ultrasonographic needle navigation using a sensor formed at the needle tip by co-polymer or piezoelectric coating (Lu et al. 2014). A second group of methods is based on generating a pattern for tracking the instrument in color Doppler scans. For example, a piezoelectric element operating in a passive impedance switching mode has been used to produce localized periodic "flashes" for detection of implanted devices by ultrasound color Doppler (Mari et al. 2013). Other investigators

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(Armstrong et al. 2001; Fronheiser et al. 2008) visualized biopsy needles in color Doppler images through mechanical vibrations induced by a piezoelectric element placed at the needle base and producing a Doppler shift. A third group of approaches benefits from ultrasound signal or image filtering and enhancement, such as in automatic needle detection and tracking in 3-D ultrasound images (Zhao et al. 2013). Ultrasonic needle tracking through coded excitation of the transmitted navigation signal has been proposed recently (Xia et al. 2016) and holds the promise of considerably increasing the signal-to-noise ratio for needle detection in B-mode images.

We previously reported on an intracardiac catheter prototype and guidance of its tip by pulsed-wave (PW) Doppler ultrasonography *in vitro* (McMahon et al. 2012) and *in vivo* (Belohlavek et al. 2014). However, PW Doppler tracking was indirect and required user interaction. In this article, we describe a color flow Doppler marker that tracks the tip of a steerable injection catheter prototype directly in real time and without user interaction. The navigation functionality of our approach is based on using an active piezoelectric crystal affixed to the catheter tip, where this crystal is driven by a continuous signal from a waveform generator. We call this type of catheter an acoustically active catheter (AAC). Interaction of the Doppler signal from the ultrasound scanner with the vibrating crystal generates a new acoustic signal. The new acoustic signal produces the real-time color marker for detection and navigation of the catheter tip. Contrary to the previous transponder-based methods (Landzberg et al. 1988; Langberg et al. 1988; Vilkomerson and Lyons 1997; Winsberg et al. 1991), any conventional clinical Doppler ultrasound imaging system can be used here because no modification of its circuitry or physical connection with the waveform generator is needed in our approach. Also, no piezoelectric adapter for vibration with the entire instrument and no special signal or image processing are needed.

The purpose of this study was to introduce the concept of catheter navigation with conventional color flow Doppler scans and test the method qualitatively by guiding the AAC tip toward an ischemic border zone and quantitatively by measuring the shortest achievable distance of the AAC tip to a pre-defined endocardial point target.

METHODS

Acoustically active catheter design

The current AAC design is based on a 9F Unison sheath (Greatbatch Medical, Minneapolis, MN, USA). The sheath features a steerable tip and a handle with a single-handed lockable slide that controls flexion of the tip. Affixed to the tip is a doughnut-shaped piezoelectric ring crystal with an outer diameter of 3.5 mm (Sonometrics, London, ON, Canada) (Fig. 1a). The crystal serves for navigation and has a central hole with a 1.0-mm diameter. Navigation crystal wiring is protected inside the sheath by a 0.9-mm-outer-diameter polyimide conduit, which is exteriorized through a 1.0-mm hole drilled into the handle wall. The wire connects the crystal to a waveform generator (Agilent 33500 B, Agilent Technologies, Loveland, CO, USA), producing a square-wave driving signal with a frequency of 95 to 100 kHz and amplitude of 0.5 to 1.0 V.

The handle has an infusion port and an integrated entry for catheters (Fig. 1b). Inserted through that entry is our custom sliding injection catheter. The distal end of the injection catheter is assembled from a 17-mm-long 20-gauge needle and a 7-cm distal segment made of a 5F flexible polyvinyl tube. A 5F angiographic catheter (Cordis Europa, Roden, Netherlands) trimmed to a 70-cm length forms the body of the injection catheter. The needle can extend up to 10 mm from the tip through the central hole in the ring crystal. The length of the needle extension can be adjusted with markers drawn on the proximal end of the needle catheter. The AAC is the sheath customized with the inner protective tubing and injection catheter and furnished with the navigation crystal at its tip.

Animal procedures

All animal procedures were approved by the Mayo Clinic Institutional Animal Care and Use Committee. We used adult male domestic pigs weighing 58 to 70 kg (mean ± SD, 67 ± 6 kg). The animal experiments were divided into two series: The first was conducted in March 2016 in six pigs, and the second was conducted in July 2016 in another six pigs. The 3-mo gap allowed time for intermediate assessment of the data and for building improved AAC prototypes.

The animal procedures were the same as previously described (Belohlavek et al. 2014). Briefly, anesthesia was induced with intramuscular tiletamine and zolazepam (Telazol), xylazine and glycopyrrolate. After intubation, each pig underwent mechanical ventilation (Narkomed 6000, Draeger, Telford, PA, USA). Anesthesia and analgesia were maintained by inhalation of isoflurane and intravenous fentanyl, respectively.

The right carotid artery was exposed, and a 14F arterial hemostasis introducer sheath (B. Braun Medical, Bethlehem, PA, USA) was inserted and filled with heparin to accommodate placement of the AAC sheath (with a 4.2-mm outer diameter). Aortic pressure was monitored with a high-fidelity catheter (Millar, Houston, TX, USA) placed in the left or right femoral artery, whereas