Unleaded: The Fluoroless 3D Lead Implant

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OBJECTIVE: Intracutaneous fluoroscopy during cardiac pacing lead implantation presents an occupational hazard to implanting physicians and their staff, both through cumulative radiation exposure and the orthopedic burden of wearing protective lead (Pb) garments. Pacemaker and defibrillator implantation is typically performed using fluoroscopy in a highly rationed manner due to the radiation hazard. We assessed preliminary feasibility of anatomic mapping and device lead implantation using an unrationed non-fluoroscopic 3D imaging system based on impedance.

METHODS: A 44 kg swine was premedicated with xylazine and atropine and anesthetized with isoflurane. The animal was placed in dorsal recumbency. A jugular venotomy was made in the jugular vein for introduction of transvenous catheters and leads. The subject was instrumented with body surface electrodes as used with the Medtronic LocaLass™ cardiac navigation system. A research system, Implant sans Fluoro (IsF), was constructed using the LocaLass position sensing unit, a notebook PC running Windows XP and customized software application.

Eight device implanting physicians (7 EP, 1 surgeon) from four countries presented to the operating suite in groups of 1, 2, 2, 1 prior experience with swine cardiac anatomy. This was consistent with their questions during the instruction/proctoring demonstration prior to their hands-on experience. The swine right ventricle is oriented such that its largest profile is parallel to the long axis of the heart. The swine right ventricle in this study was considerably smaller than hearts to which the physicians were accustomed to in their clinical practice. The smaller size necessitated smaller radius bends, especially to negotiate the turn from the incised valve to the right ventricular outflow tract. The propensity of the balloon to follow blood flow when extended beyond the sheath was useful in directing it to the pulmonary artery.

The physicians were asked to implant the lead in the right ventricle (RV). Locations varied but all were within the RV. Stimulation thresholds varied considerably and some would likely be unacceptable for chronic use. Variation in thresholds might be attributed to unfamiliarity with the swine, with the deflectable sheath or the lumenless pacing lead.

LIMITATIONS: The number of physicians varied between groups, some had the benefit of observing colleagues map and implant before it was their turn, some were more adventurous and entered the heart more thoroughly than others who completed their task more quickly. There was an inequitable level of familiarity with swine anatomy and defibrillator and pacing lead implantation experience between implanters.

CONCLUSIONS: This was the first exposure for all physicians to the IsF system and all were able to implant following a brief introduction. Experience or lack thereof with the deflectable sheath, the catheter delivered lead or swine anatomy did not appear to affect the results. The Swan-Ganz pacing catheter with the deflectable sheath allowed safe exploration and creation of a right heart image. No complications were observed during the procedure although one lead implantation may have perforated the heart.

Time reduction from the first to second mapping suggests IsF may be practical for introduction to clinical practice which might lead to a reduction of radiation and orthopedic occupational hazards for the implantation of pacemakers and defibrillators.

Clinical trials are needed to assess the feasibility in humans.

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Prior Experience

Results