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Safety and Efficacy of Remote Magnetic Ablation for Atrial Fibrillation

Carlo Pappone, and Vincenzo Santinelli
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Table 1 Device Interactions in Patients With Advanced Cardiomyopathy

Manufacturer	Operating Frequency	Wireless Telemetry
Medtronic*	A: 175 kHz (pulsed code modulated) B: 175 kHz (frequency modulated)	MICS band 402–405 MHz
Boston Scientific/Guidant*	100 kHz	ISM band 914 MHz
St. Jude*	8 kHz†/64 kHz‡	N/A
Thoratec HMII/XVE*	7.2 kHz	N/A

Summary of operating and wireless telemetry ranges for major implantable device companies.

*All operating frequencies obtained from email communication with technical support for the above companies. †Old generation device. ‡New generation device.

pending approval LVADs (Heartmate XVE and Heartmate II, respectively).

Implantable cardioverter defibrillator therapy is a primary option for prevention of sudden cardiac death in advanced cardiomyopathies and CHF (3,4). In the post-LVAD patient, ventricular arrhythmias are associated with a more malignant course both by the frequency and timing of their appearance (5). This adverse association has theoretically justified the use of ICDs in the setting of LVAD-supported cardiomyopathy, with more studies necessary to assess their role in outcomes. As device therapy becomes commonplace with more complex disease, device interactions will need to be factored into the complex nature of patient management (6). Careful planning by the FCC and device manufacturers will play a major role in their avoidance.

*Rohit Mehta, MD

*Division of Cardiovascular Medicine
The Ohio State University College of Medicine
473 West 12th
HLRI Room 200
Columbus, Ohio 43210
E-mail: rohitmehta@alumni.duke.edu

Amit A. Doshi, MD
Ayesha K. Hasan, MD
Charles J. Love, MD
Marg Pizzuto, RN

Chittoor Sai-Sudhakar, MD David P. Chan, MD

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Letters to the Editor

Safety and Efficacy of Remote Magnetic Ablation for Atrial Fibrillation

We read the recent study by Di Biase et al. (1) published in the *Journal*. Our pivotal experience demonstrated that remote ablation is effective and safe without tip charring (2). These results were subsequently confirmed in hundreds of patients undergoing atrial fibrillation ablation. What is surprising in this study (1) is that after their initial "presumably ineffective" 48

procedures, the investigators continued to use it, further exposing their patients to the risk of charring and embolic events and that the ethics committee further approved the study despite potentially dangerous complications.

Considering Natale's extensive experience, he certainly understands that unlike the perpendicular orientation of manual catheters, the stable parallel wall contact obtained with soft magnetic catheters results in rapid and effective lesions, within a few seconds from the onset of radio frequency (RF) application, thus preventing charring. However, if abatement of the atrial potentials is not rapidly achieved because the magnetic tip is not completely aligned with the endocardial wall, continuous and prolonged application of

high RF energy, as performed by the investigators (1), could result in charring and ineffective lesions. No data were reported on important parameters including tip orientation, temperature, RF energy, and impedance values before and at the time of charring formation. We presume that parameters and potential changes were collected throughout, but surprisingly were not reported precluding any possible interpretation and discussion to explain why charring formation and ineffective lesions were so frequent in their experience. We know that even a single RF application of long duration by a soft magnetic catheter requires an accurate and continuous monitoring of all parameters to evaluate potential changes to prevent catheter tip charring. Remote ablation is a novel and simple system, but at the beginning, it may be complex because it is totally different from the conventional system. Optimization of RF application by this system is crucial and may be challenging at the beginning, requiring a learning curve. However, once familiarized with this system, "effective" remote ablation can be easily performed. Currently, in our laboratory, "joystick" ablation is performed by many electrophysiologists after widely different learning curves. In our pilot study, we specified that remote ablation was performed by a single expert operator after his learning curve. How many of the 20 reported investigators (1) actually performed the initial 48 procedures and how many the final ones? It is surprising that remote ablation was demonstrated to be safe and effective in eliminating even left-sided accessory pathways and not atrial potentials. On the other hand, it is well known that prolonged RF applications can result in charring even with manual catheters. It seems that the purpose of that study was to limit the enthusiasm of preliminary encouraging results of joystick ablation. However, this will not delay robotic development because irrigated-tip magnetic catheters are already available, making remote procedures less challenging.

***Carlo Pappone, MD**
Vincenzo Santinelli, MD

*Department of Cardiology, Electrophysiology, and Cardiac Pacing Unit
San Raffaele University Hospital
Via Olgettina 60
20132 Milan
Italy
E-mail: carlo.pappone@hsr.it

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Reply

We thank Drs. Pappone and Santinelli for their interest in our paper (1).

Overall, our study (1) demonstrated that remote magnetic navigation is feasible and safe for mapping in the left atrium. Our major concern was limited to the use of the 4-mm catheter tip (the only one available at the time of the study) which, in our experience, was unable to create effective lesions to achieve complete electrical isolation of the

pulmonary vein antrum; in addition, ablation with this catheter was associated with charring in a large number of patients (1).

Regarding the specific questions contained in their letter, our reply follows.

In the first 48 cases (considered the learning curve), we did not perform ablation. These cases were used to practice mapping and navigation in the left atrium and no radiofrequency energy was delivered.

Two of the 20 authors performed all the procedures in the learning curve group and subsequently performed the ablation procedures in the 45 patients who were the object of the study.

As far as the alignment of the catheter tip and the abatement of the atrial potentials are concerned, it is well established (2) that reduction of local electrograms does not necessarily reflect the transmuralty of the lesions. In addition, in our experience, the soft tip did not appear to increase the ability to position the catheter parallel to the tissue plane. However, regardless of the catheter orientation, lesion formation should follow the same biophysical principles. Indeed, previous experimental data show that the time to steady-state tissue temperature during radiofrequency catheter ablation is approximately 60 to 90 s (3,4).

In the patients undergoing ablation, the duration and maximum power were reduced from 60 to 45 s and from 50 to 40 W once charring was observed. This did not abolish charring, which was observed even after a few seconds of energy delivery.

The setting parameters during catheter ablation were clearly reported in the Methods section. Similarly, we mentioned that to prevent charring, we tried to reduce lesions duration and maximum power, and realized, by monitoring with intracardiac echo, which was not used in the Pappone et al. (5) study, that charring can form within a few seconds and most of the time it is not associated with any change in impedance. On average, there was no difference in delivery settings between lesions with and without charring. Besides direct visualization of the charring with intracardiac echo, the only indirect clue observed at times was a sudden drop of the delivered power.

Our results were shared and endorsed in the editorial of Lindsay (6), who appeared to have experienced similar problems. In this respect, even ablation of left side pathways has been associated with a wide range of success (from 67% to 92%) based on the catheter design (7).

We do not share the conclusions of Drs. Pappone and Santinelli that our study "limits the enthusiasm of preliminary encouraging results of joystick ablation" with magnetic navigation. We are enthusiastic about remote catheter ablation. We are currently using the new 8-mm catheter tip and are waiting for the development of the irrigated cool tip catheter, because we are sure that it will improve the results.

On the other hand, we do not understand why Drs. Pappone and Santinelli are so eager to use the new cool tip catheter considering that they had no problems with the standard 4-mm catheter tip. It is ironic that they consider the irrigated tip catheter important in moving this technology forward.

Luigi Di Biase, MD
J. David Burkhardt, MD
Robert A. Schweikert, MD
Walid I. Saliba, MD
***Andrea Natale, MD**

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