
We appreciate the questions by Stollberger and colleagues about our article on patent foramen ovale (PFO) coaptation by radiofrequency energy. Dr Stollberger comments that indications for PFO closure are not increasing and cites the US Food and Drug Administration finding no randomized data showing efficacy. We disagree. The indications for PFO closure are clearly increasing, although Food and Drug Administration approval has not yet been granted. In Europe, PFO closure is widely used for stroke and migraine. For example, the Migraine Intervention With STARFlex Technology (MIST I) trial examined PFO closure for migraine and found clear benefit for secondary end points of migraine reduction. Other syndromes associated with PFO include high-altitude pulmonary edema, obstructive sleep apnea, decompression illness, hypoxemia due to right-to-left shunts, and systemic (noncerebral) thromboembolism. All may benefit from PFO closure.

With regard to PFO diagnosis by echocardiography in our study, we used the Terumo/Spencer Bubble Study Rating System. PFO was diagnosed if the atrial septum was easily and smoothly crossed right to left using a 7 Fr catheter entering the left atrium. A “Probe-patent” PFO was diagnosed and assessed for severity using a gross examination. Fixation-based artifact would have been easily detected by a gross-histopathology discrepancy. Histopathological evaluation of patency was an important end point in this study and was used to define successful treatment.

Dr Stollberger inquires about tissue shrinkage and artifact in establishing closure efficacy. Even if artifacts from tissue shrinkage had occurred, they would not have affected the results. Each PFO was confirmed sealed or not via histopathology and not solely by gross examination. Fixation-based artifact would have been easily detected by a gross-histopathology discrepancy. Histopathological evaluation of patency was an important end point in this study and was used to define successful treatment.

Dr Stollberger asks about electrocardiograms. We evaluated the ECG at baseline, before RF treatment, immediately after RF treatment, and immediately before euthanasia. These evaluations investigated whether radiofrequency energy would induce arrhythmias either during application or afterward, either acutely or chronically. The cardiac rhythm was sinus in all cases. Tissues near the atrioventricular node showed no significant microscopic pathology. Whereas the remainder of the conduction system was not specifically investigated, sinus rhythm with a normal QRS appearance suggests that no significant conduction system damage occurred.

Dr Stollberger finally asks about detection of aortic lesions. Several swine had ascending aortic lesions. Histopathological investigation showed no effect on the outside of the posterior aorta. No emboli or sources of embolism were seen from any of these sites.

In summary, we agree that caution is indicated when any new technology is applied to the heart. We disagree that clinical benefit has not been proven and thank Dr Stollberger and colleagues for their questions.

Disclosures

Dr Eichinger is an employee of CoAptus Inc. Drs Schwartz, Van Tassel, Sommer, Jones, and Auth report equity ownership in CoAptus Inc. The remaining authors report no conflicts.

References


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