
To the Editor:

With great interest we have read the report by Hara et al about patent foramen ovale (PFO) closure using radiofrequency thermal coaptation. However, there remain several questions.

In the introduction it is stated that the number of indications for PFO closure increases. But, as recently emphasized by the US Food and Drug Administration, at present no randomized trial examining the efficacy of PFO device closure exists.

Different echocardiographic criteria exist for diagnosing a PFO. Which criteria were used in the present study?

Although 13 swine are reported to have a proven PFO, Valsalva bubble study was positive in only 8/13 swine. How was the PFO diagnosed in the remaining 5 swine? Did any of the 5 swine with a negative bubble study before the intervention have a positive bubble study after the intervention?

At autopsy, water pipette testing for patency of the interatrial septum was performed only after fixation of the hearts in 10% formalin. However, formalin is known to induce tissue shrinkage. A sealed PFO by water pipette testing could, therefore, be either a consequence of thermal coaptation or just the result of formalin-induced shrinkage of the atrial septum. Thus, the success rate of thermal PFO coaptation might be overestimated by this technique.

It is difficult to understand how a laceration of the interatrial septum can occur during euthanasia. Furthermore, it would be desirable to know if brain autopsy demonstrated cerebral infarction in any of the swine.

It would be of interest to know how often and by which technique the swine were screened for arrhythmias. It is reported that on histopathological examination, no evidence of damage of the cardiac conduction system or the atrioventricular node was found. In this respect, it would be of interest to know if the cardiac conduction system was investigated only macroscopically or by which histological technique.

In how many swine were lesions of the ascending aorta, as visualized in Figure 2E, detected? Were histological investigations of these lesions carried out, and did they affect only the outside of the posterior aorta or also the aortic endothelium, thereby creating a new lesion as a potential source of embolism?

In conclusion, as long as the clinical benefit of surgical and interventional PFO closure for stroke prevention has not yet been proven, caution is indicated even when using device-free alternatives for PFO closure, including radiofrequency thermal coaptation.

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Disclosures

None.

References


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_Circulation_. 2008;117:e176
doi: 10.1161/CIRCULATIONAHA.107.739441

_Circulation_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/117/9/e176

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