**Suggestions for clinical studies about percutaneous left atrial appendage occlusion: authors’ reply**

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**TEXT**

The Munich consensus document is a physician-initiated effort to establish better and more consistent methodology for studies related to percutaneous left atrial appendage occlusion (LAAO). [1] The document is endorsed by EHRA, EAPCI, and other professional societies. The proposed definitions and endpoints for data collection are based on the available published data, and pertinent clinical experience. Our group aimed to provide meaningful definitions and to recommend data collection strategies that are both clinically relevant and feasible. We would like to thank the authors for their letter. [2] Herein, we try to reply to all their comments and questions.

While peri-procedural complications during LAAO are possible, they are obvious to identify. The risk of myocardial, renal or hepatic injury is not significant enough to mandate the expense of routine testing in asymptomatic patients, whereas a pre-discharge transthoracic echocardiogram (TTE) is typically performed in most centers to assess subclinical pericardial injury. As for vascular access complications, a vast majority of operators are moving towards ultrasound-guided techniques and avoidance of arterial puncture, so we don’t think routine post procedural vascular testing is necessary.

We agree that atrial natriuretic peptide (ANP) and brain natriuretic peptide (BNP) levels may be altered with the elimination of the left atrial appendage (LAA). This effect is more pronounced with epicardial exclusion using surgical ligature, Atriclip and/or the Lariat device. Most of the data on this subject come from the Lariat Homeostasis study by Dr. Lakkireddy et al., presented at HRS 2016 and AHA 2016. With an endocardial occluder like Watchman or ACP or Amulet there is no elimination of the LAA. There is no reason to suspect that mere mechanical occlusion can result in any kind of permanent alteration to the neuroendocrine function of the LAA. Preliminary evidence is not suggestive of such changes. Even with the case of epicardial exclusion, in vast majority of cases the ANP and BNP levels normalize by the end of 3 months due to possible compensatory mechanisms from the rest of the heart or other organs of the body. While the neuroendocrine modulation is an important aspect of the epicardial ligation or exclusion, the data are still evolving and routine measurement of these markers is unrealistic. As more data arrive, this will be included in our next version of the document.

The occurrence of new, late leaks beyond 12 months is very rare. Typically, a transesophageal echocardiogram (TEE) at 6 weeks, 6 months and 12 months is an acceptable standard. There are no real data to support TEE beyond these timelines, unless there is a suspicion for device related thrombus and the concern for systemic thromboembolism. So the cost benefit ratio does not support the idea of routine TEE testing beyond 12 months.

Percutaneous LAAO is a promising new therapy for the prevention of systemic thromboembolism in patients with atrial fibrillation. Having a universally accepted methodology, like the Munich consensus document, has been a necessary step for further development of this therapy. Still, a lot of work remains to be done and we would encourage independent organizations taking up some of this work in the near future.

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REFERENCES

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