LETTERS TO THE EDITOR

To the Editor—A double-blind case study?

Drs Liu and Wu[1] report a successful case of mechanical deviation of the esophagus using the EsoSure device during atrial fibrillation ablation with intracardiac echocardiography and a mapping system but entirely without fluoroscopy. Acute procedural success was achieved without clinical complications. We could describe this as a double-blind technique: No fluoroscopy was used during the procedure and no endoscopic examination occurred afterward. The authors therefore could not verify the effectiveness of protection or exclude the occurrence of device-related trauma.

We do not know why the authors chose mechanical deviation to protect the esophagus. There is no randomized trial evidence to support the concept, whereas trial evidence published in the past year has addressed 2 alternative approaches: The OPERA study[2] showed that esophageal temperature monitoring probes did not reduce thermal injury; and the IMPACT trial[3] demonstrated that active thermal protection using a temperature control device (the ensoETM®; Attune Medical, Chicago, IL) reduced thermal injury by 83.4% compared to controls. No evidence of device-related esophageal trauma occurred in IMPACT, nor has any been seen in real-world registry data on the same device in 2532 ablations. The concept that underpins the method has been verified by mathematical modeling and is supported by a meta-analysis of earlier methods of cooling.[3]

Mechanical deviation of the esophagus has the potential to harm, and evidence of esophageal trauma has been demonstrated.[4] Until randomized trial evidence demonstrates protection that outweighs this risk, it makes more sense to use proven alternatives. The ensoETM could easily be used without fluoroscopy, but we image for a few seconds to verify optimal positioning. Minimal use of fluoroscopy creates minimal risk, but unproven devices pose an unquantifiable danger.

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Author's Reply—A double-blind case study?

We read with great interest the letter to the editors entitled "A double-blind case study?", authored by Drs Leung and Gallagher. It is unclear to us why the authors called the case "double-blind" when the position of the esophagus was clearly visualized by the CARTO 3-D mapping system as well as the intracardiac ultrasound. In other words, prior to esophagus deviation, we can "see" the esophagus right under the ablation catheter tip, while the esophagus is nowhere to be found in the immediate vicinity of the catheter tip on the intracardiac ultrasound post deviation. It seemed straightforward to us and to the 2 experts that peer-reviewed the paper. We did not empirically do endoscopy just to "see" the esophagus for EsoSure-related injury because we believe instrumentation using the rigid endoscopy probe right after ablation may cause further injury to the esophagus and may not be ethical.

The reason we chose to use the EsoSure device was based on the DEFLECT GUT study, which enrolled 687 patients, and the ease of use that fits our workflow.[1] The DEFLECT study did not show any serious device-related complication but demonstrated much lower esophagus temperature rise compared to the control arm. Given the extremely low incidence of atrial esophageal fistula (~0.1%), it is likely impossible for any intervention to show a significant difference in its incidence in a clinical trial, let alone comparing the superiority of one method over the other. The individual trials the authors cited looked at esophageal thermal injury, which is not the same as atrial esophageal fistula, as the vast majority of the thermal injuries identified on endoscopy do not evolve into atrial esophageal fistula and should be interpreted with this in mind. Despite anecdotal reports of EsoSure-related mechanical injury to the esophagus, we are unaware of any mortality directly attributed to the use of EsoSure, bearing in mind the complication this device was designed to prevent is frequently fatal.

We have no financial association with any companies that manufacture esophagus protection devices, unlike Drs Leung and Gallagher, and we do not advocate one method over another for reasons discussed above. The readers should choose a particular type of method for esophagus protection that is based on clinical studies and the one that suits their ablation styles.

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