

Why just detect? We can protect: A letter to the authors of “Prevention of left atrium esophagus fistula”

Dear Sir,

We read the article by Jiang et al,¹ with great interest. The authors have provided an overview of technologies and strategies to minimise esophageal injury during ablation for atrial fibrillation that is comprehensive. We would like to share recently available data on thermal protection that would not have been available when they wrote their manuscript but may add to the discussion on the topic reviewed by Jiang et al. Atrio-esophageal fistula remains a major cause of mortality from these procedures, so consideration of all information is important.

In their review, Jiang et al explore the current methods routinely used to minimise esophageal injury: restraint in applying force and power, deflection of the esophagus away from the site of energy application, monitoring of temperature and inhibition of gastric acid production. A large part of the review is devoted to methods of temperature measurement, although these have an obvious flaw: they may predict the occurrence of injury, but do not directly protect the threatened tissue. Esophageal temperature monitoring probes aim to detect temperature rise but even this ability may vary between different types of commercially available esophageal temperature monitoring probes.²

Esophageal cooling was explored briefly in this article, noting that various forms of cooling based on local infusion of cold water have shown some benefit in reducing esophageal injury, but that results were inconsistent. A recent systematic review and meta-analysis of these methods give a more favourable impression: despite the limited heat-extraction capability of water-infusion, a small but significant reduction in esophageal injury is evident on meta-analysis when compared to controls.³

These early studies on esophageal cooling showed promise; this led us to design and conduct the recently completed IMPACT study (NCT03819946),^{4,5} which may be of interest to the authors and journal readers. This double-blind randomised trial evaluated a controlled method of esophageal cooling during Atrial Fibrillation (AF) ablation compared to standard care; at the study site this consisted of a single sensor esophageal temperature monitoring probe was the standard of care.

The EnsoETM device was utilised in the IMPACT study to deliver controlled esophageal cooling. This device is already in routine clinical use as a method of controlling body temperature via the esophagus,

providing therapeutic hypo/normothermia in patients who are recovering from traumatic brain injury or are susceptible to hyperpyrexia.⁶ The physical profile of the device and its insertion are similar to that of an orogastric tube; it is a silicone, multi-lumen probe, and when the non-patient end is connected to a mobile console, it allows distilled water to flow in a closed loop system. The temperature of the water can be set and controlled at 4–42°C, depending on the clinical indication. In IMPACT, it was set at 4°C for the whole duration of posterior ablation.

The EnsoETM is irrigated at 2.4 L/min, giving a capacity to control local temperature that is more powerful and more precise that can be accomplished by direct infusion of water. The concern raised by Jiang et al about instrumentation of the esophagus is certainly relevant to devices designed to deviate the esophagus, which can be a delicate structure, but may be less concerning for the EnsoETM device as it exerts minimal force and is commonly used for many days at a time in its established role.

The design of the IMPACT study included 1:1 randomisation to the protected group with the esophageal cooling device or to standard of care during their AF ablation. All participants were required to attend a follow-up endoscopic examination after the ablation. Patients and endoscopists were blinded to the results of the randomization. As esophageal injury was a risk to all those receiving left atrial ablations, regardless of ablation methodology or type of AF, all those previously screened at our centre as being appropriate for ablation treatment under general anaesthesia were subsequently approached for potential recruitment to the study. The results therefore reflect real-world management of risk for all those attending for AF ablation. The ablation operators were not blinded, as the EnsoETM device is clearly visible on fluoroscopy. All ablations were in line with normal practice using the ablation parameters customary at our centre and were guided by Ablation Index, a recognised marker of lesion quality. The ablations were performed using Thermocool Smart Touch Surround Flow (Biosense Webster Inc., Irvine, CA) irrigated contact force sensing catheters at 30 W and 350 AI posteriorly and 40 W at ≥ 450 AI anteriorly.

The IMPACT study was completed in January 2020 with long-term follow-up results awaited. A total of 188 participants were enrolled, with 120 completing endoscopy after the ablation procedure. In this study, there were significantly fewer esophageal thermal injuries in

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patients protected by the EnsoETM device compared to controls, with a risk reduction of 83.4%⁴ and without any evidence that the device makes it any more difficult to achieve procedural end points.⁵ Blinded endoscopy reports showed that no instrument-related abrasive trauma occurred in the protected group. No case of hypothermia and no adverse effect of the device were detected during or after any ablation procedure. Complexity was not an issue during conduction of the study: insertion of the device proved easier than the placement of a transesophageal echo probe, and workflow of the procedure was made slightly more efficient compared to using a temperature probe.⁴

The process of cooling the esophagus while therapeutically heating the adjacent left atrium is inherently paradoxical. The possibility of undermining the intended therapeutic effect is obvious: if the cooling effect extends into the atrial myocardium, it could increase the difficulty of achieving transmural lesions. Recently presented analysis of the ablation data⁴ shows that this does not occur; procedural end points and workflow were similar to the control group with no effect on impedance drop, a surrogate for lesion depth (8.6 Ω [interquartile range, IQR: 6-11.8] vs 8.76 Ω [IQR: 6-12.2] $P = .25$). Median ablation catheter tip temperature was the same as the control group at 25.5 degrees. Short-term ablation end points were unaffected, but long-term follow-up data are required to confirm how ablations performed with esophageal cooling compared to standard care.

AF ablations are already expensive procedures, and cost is a factor that must be considered when choosing equipment. The EnsoETM is less expensive than some temperature monitoring probes but substantially more than the cheapest models. With the benefit demonstrated in the IMPACT trial and the great importance of avoiding esophageal thermal injury, we now use the device routinely adjunct to previously established equipment whenever possible.

Controlled esophageal temperature is a logical strategy for any method of ablation that creates thermal injury. Accurate measurement of temperature may help the operator to detect a temperature change at an early stage; we believe that it makes more sense to actively protect the esophagus by taking control of the local temperature.

CONFLICT OF INTEREST

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Lisa W.M. Leung MRCP
Mark M. Gallagher MD

Cardiology Clinical Academic Group, St George's University Hospitals NHS Foundation Trust, London, UK

Correspondence

Mark M. Gallagher, Department of Cardiology, St George's Hospital, London SW17 0QT, UK.

Email: mark.gallagher@stgeorges.nhs.uk

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