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Intraluminal Esophageal Temperature Monitoring Using the Circa S-Cath™ Temperature Probe to Guide Left Atrial Ablation in Patients with Atrial Fibrillation

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To The Editor

Bhuta S et al[1] have recently published an interesting study investigating the usefulness of esophageal temperature probe monitoring to guide left atrial ablations. Avoidance of esophageal injury during left atrial ablations remains an important area of study to prevent severe thermal injury that may manifest as esophageal-pericardial or atrio-oesophageal fistulas, both potentially life-threatening conditions.

There are a wide range of commercially available esophageal temperature monitoring probes;the one investigated by Bhuta et al was the S-Cath (Circa Scientific LLC, Englewood, CO, USA), a multi-sensor probe with 12 insulated sensors placed uniformly along the length of the device. The probe's physical profile differs from other devices: It is flexible and self-expands into an S profile, with the purpose of delivering data from the full length and width of the portion of the esophageal lumen that is exposed to thermal threat. The advantage with this design is that it may avoid the need to adjust the probe positionduring ablation.

The study methods involved reducing the power of the ablation by 10W if temperatures rose above 39 degrees or if the rate of temperature rise exceeded 0.2degrees per second. If temperature rise continued despite dialling down on the power, ablation would be halted and the same endoscope probe that was to be used post-procedure to evaluate for thermal lesions was used to mechanically deviate the esophagus. Temperature measurements were therefore used reactivelyto trigger multiple protection strategies: ablation power limitation, force limitation and mechanical deviation of the esophagus.

The timing of the endoscopy was split into 2 groups, either immediately post-ablation with the temperature probe still in situ (n=18) or to the following day (n=18). It was not clear as to why the timing of the endoscopy had to be split or how the patients were allocated to each time window.We note that in most contemporary studies ofablation-related thermal injury, endoscopy occurs at 12-72 hours post ablation. Immediate endoscopy post ablation may be less specific at identifying clinically important thermal lesions from ablation but instead identify more trivial lesions or mechanical trauma.

The study results were interesting:Lesions were observed in patients who had supposedly had the benefit of the protection of intensive temperature monitoring by the circa device, but many of these were interpreted as evidence of mechanical trauma. The manuscript did not include enough data or photographic evidence to verify this interpretation. A sceptical viewpoint would be that the study yielded 5/36 (13.9%) positive endoscopic findings, a rate of injury thatis similar to most non-protected series.

A recent randomized trial investigating the efficacy of the S-Cath esophageal temperature monitoring probe compared to controls with no esophageal temperature monitoring during AF ablation found no evidence that its use reduced thermal injury- the S-Cath group had more endoscopically detected thermal lesions compared to controls (6/44, 13.6% versus 2/42, 4.76%; p=0.27).[2] The study had a similar protocol to that of Bhuta et al, including the use of power titration after a significant temperature rises (>39°C). Apart from this study, only 1 other randomized trial addressed the value of esophageal temperature monitoring during AF ablation:The OPERA trial[3] also which investigated the SensithermTMdevice (FIAB, Firenze, Italy) found no evidence that these probes reduced thermal injury.

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Other methodsfor avoiding thermal injury to the esophagusinclude mechanical deviation and active thermal protection. Mechanical deviation devicessuffer from the same lack of randomised trial evidence as the temperature monitoring devices. Active thermal protection, by contrast, has shown clear benefit in one substantialrandomised trial,[4] and supportive evidence from a meta-analysis of several earlier small studies.[5] All methods are worthy of further study in this important aspect of AF ablation,but the trial evidence to date indicates a clear leader: Thermal protection rather than temperature monitoring or mechanical deviation is the most promising alternative.

Yours sincerely,
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Response to a Letter to the Editor

We appreciate the concerns raised by Dr. Leung and colleagues in their letter to the editor regarding our original manuscript published in the Journal of Atrial Fibrillation1. In response to those concerns we can provide the following additional details regarding our study.

The first point raised by Leung LSW, et.al. was the "skeptical" viewpoint that the so-called mechanical traumatic lesions observed in 4 of 36 patients were actually thermal lesions, resulting in an event rate of 5 of 35 patients (13.9%). No figure is shown of these lesions as noted by Leung LSW, et.al. However, we would like to clarify that these lesions in question were described by the endoscopist as 3 mm superficial linear erosions, consistent with minor trauma likely during placement of the temperature probe itself and not likely thermal lesions. These lesions were also all reported to be ≤30 cm from the incisor teeth (in areas above the LA where no ablation was performed. The only lesion that was reported as possibly related to thermal injury (and described as a 3 mm edematous focus without erosion seen in the figure) was at 32 cm from the incisors near the LA.

The question raised by Leung LSW, et.al. as to why our study was divided into two groups (i.e. one with immediate endoscopy and one 24 hours after ablation) is due to the very fact pointed out by Leung LSW, et.al. with the statement "Immediate endoscopy post ablation may be less specific at identifying clinically important thermal lesions from ablation but instead identify more trivial lesions or mechanical trauma". We were indeed also concerned that immediate endoscopy might be insensitive to, and thus miss some thermal lesions if they took up to 24 hours do develop, thus the rationale for performing endoscopy in the second group at least 24 hours after ablation.

With regards to the comparison of our study with that of other randomized trials (including that referenced by Leung LSW, et.al. by Meininghaus DG, et.al.), due to our more aggressive protocol of power delivery reduction as LET approached 39 °C, the average maximum LET observed in all patients in our study was 37.8±1.42°C (range 36.90-39.50°C), whereas in the study by Meininghaus DG, et.al. for example the maximum LET observed was ≥40 °C in 79.5%, ≥41 °C in 63.6%, and ≥42 °C in 29.5% of patients, with their highest observed temperature 43.4°C. They also report that the likelihood of new endoscopically detected lesions was associated with these much higher temperatures. In addition up to 25% of patients in the study by Meininghaus DG, et.al. had a posterior box ablation lesion performed, which by its very nature may increase exposure of the esophagus to a greater risk of thermal injury. None of the patients in our study underwent box lesion ablation. Thus, these two studies are not really that comparable in our opinion, and maintaining lower LETs <40 °C does in fact appear to reduce risk of esophageal injury according to our data.

As noted by Leung LSW, et.al. esophageal protection by esophageal cooling may indeed be associated with fewer esophageal lesions by maintaining a lower LET, as even our data suggests.

However, we disagree with the following statements made that "All methods are worthy of further study in this important aspect

of AF ablation, but the trial evidence to date indicates a clear leader: Thermal protection rather than temperature monitoring or mechanical deviation is the most promising alternative." To our knowledge, there has in fact been no randomized study published using endoscopic documentation of esophageal thermal protection versus careful temperature monitoring associated with esophageal movement in the event of unacceptable LET rises observed during LA ablation. It is also possible that placement of a thermal protection device may cause esophageal injury, especially if not carefully done by trained users, and would also likely be more costly than existing LET monitoring and esophageal manipulation devices.

References

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