radcliffe cardiology

Title: AFSymposium 24: EASY AF: Esophagus Deviation During Radiofrequency Ablation of AF
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Dr Emile Daoud

"Hello. My name is Emile Daoud. I'm chief medical officer for S4 Medical.

Problem with Thermal Ablation

A big problem for ablation of atrial fibrillation has been that when we use thermal ablation techniques, there's a risk of injury to the oesophagus. There have been various devices out there, but for S4, we felt that there's a better way of moving or protecting the oesophagus.

The E-Solution Device

Our catheter, which recently got FDA approval and is the first FDA-approved device for oesophageal protection, is designed to deviate or move the oesophagus. The key point is there are other products that have tried to move the oesophagus. However, what we do is if you move the oesophagus to the left, you have to bring along the right edge. By using suction first, we use a suction force, vacuum pulls in the oesophagus, and all edges of the oesophagus get sucked in. Then, using a mechanical deflection, you move the entire segment. This way, you don't have the issue of what's called the trailing edge not moving along with the entire deviated segment.

Purpose of the Device

The concept of the E-Solution device is to try to protect the oesophagus during ablation of atrial fibrillation. The energy, when you ablate along the posterior wall of the left atrium, extends out and can injure the oesophagus. There are fatal complications that can occur if a fistula develops. By moving the oesophagus a relatively small distance,

less than an inch or 20 millimetres, you can allow the operator to ablate on the back of the heart wall or near the pulmonary veins without risking injury to the oesophagus.

Clinical Trial Design

The unique part of the E-Solution device is that it uses suction to grab all the walls and move the entire segment away. We proposed to the FDA a randomised, placebo-controlled, multicenter, double-blinded trial. Patients indicated for an atrial fibrillation ablation, based on their electrophysiologist's opinion, were the study population. The primary exclusion criteria were people with prior preexisting oesophageal disease. The only other criterion was that they had to be undergoing ablation with general anaesthesia.

Study Procedure

Once the patient was in the room and under general anaesthesia, they were randomised to either receive our device with a temperature probe or the control group which received conventional therapy with only the temperature probe. The operator could perform any ablation lesions desired. In the deviation group, the oesophagus was deviated away from the energy, while in the control group, this was not done. All patients underwent an endoscopy procedure within 48 hours to look for oesophageal lesions related to ablation energy or any lesions attributed to the device.

Study Results and Conclusions

The conclusions of the study showed that our data safety monitoring board recommended stopping the study early after 120 patients were randomised due to the far greater efficacy of the deviating device. It reduced oesophageal lesions by 85% and there were no adverse events related to the use of the device.

Future Outlook

There is a lot of focus on pulse field ablation, which does seem to be safe for the oesophagus with the current iterations. However, it's uncertain in terms of cost, efficacy, and effectiveness whether pulse field ablation will be significantly superior to thermal ablation. We believe that there will still be plenty of thermal ablation performed. Particularly if you want to protect the oesophagus, we think this is a very inexpensive and easy way to use without any additional equipment. You don't need another piece of equipment in the lab to operate the device and provide protection for your patient.