A wolf in sheep's clothing

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In the current issue of the *Journal*, Bringmans and colleagues¹ laudably report a fatal case of an atrioesophageal fistula (AEF) after stand-alone epicardial ablation (EA) of persistent atrial fibrillation with a radiofrequency (RF) device. The hypothesized thermal injury mechanism was from heating of an atrial septal occluder device implanted years earlier. Although Bringmans and colleagues¹ used an RF pen on the back wall of the left atrium, they surmise that injury may have been associated with clamp use near the atrial septal occluder. After the minimally invasive EA procedure, the patient presented with a delayed diagnosis of AEF and died.

This highlights a few important elements. First, the transparency of Bringmans and colleagues¹ exemplifies their leadership in the field of surgical ablation. A report of excellent results teaches us what is achievable. A report of poor results teaches us what is to be avoided to advance the field. Second, to embrace the explanation by Bringmans and colleagues¹ of the unusual etiology of this rare or never event, we must discount the existence of alternatives. Third, the case of Bringmans and colleagues¹ illustrates a known peril of EA and should stimulate a root cause analysis for its avoidance. Root cause is defined as a nonconformance factor that should be permanently eliminated through process improvement.

Transcatheter atrial septal occluder devices have a long experience. They are known often to become so well incorporated with endothelialization and fibrosis that magnetic resonance imaging is permitted.² The occurrence of AEF after EA with thermal devices, however, is a known yet devastating complication with clear causality.^{3,4}

Thermal dispersion away from the electrode-blood-tissue interface is inherent with epicardially applied RF, with as much as 38% of delivered power reaching nontarget tissues.⁵⁻⁷ Bipolar clamps are known to deliver acceptable transmuralities but may be difficult to apply in minimally invasive lesions. Unipolar RF devices and bipolar RF pens tend to dissipate heat, with transmuralities rates under 80%.⁷ As Bringmans and colleagues¹ dutifully describe,

Left to right: Harold G. Roberts, MD, Vinay Badhwar, MD, and Lawrence M. Wei, MD

Central Message

Stand-alone surgical ablation of atrial fibrillation must be safe and longitudinally effective therapy. It is time to reevaluate whether epicardial radiofrequency ablation can hold true to this goal.

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the epicardial RF pen has been implicated in 8 known left atrial perforations since 2008. A group including one of the authors of this case report⁸ recently reported their experience in 64 patients with a 23-month success rate off antiarrhythmic drugs of 67% and a 20.3% complication rate, including 2 left atrial perforations. The recent emergence of the convergent procedure, involving RF EA without appendage obliteration, has introduced similar complications, including a report by highly experienced operators of 1 AEF, 2 strokes, and 3 deaths in just 24 patients.⁹

Not everyone is as honorable as Bringmans and colleagues.¹ Ever-increasing softly spoken accounts of unpublished perforations are now reaching the point of becoming a clearly detectable signal in the noise.

The impetus for developing off-pump EA technology has been the perceived perils of cardiopulmonary bypass. However, the intimation that EA is “safer” than open surgical ablation is challenged by several large series of minimally invasive Cox maze IV procedures with endocardial cryotherapy, demonstrating an efficacy upwards of 90% with negligible mortality, very low morbidity, and virtually no instances of collateral tissue damage.^{3,10,11} The recent abrupt suspension of the Pivotal Study of a Dual Epicardial and Endocardial Procedure (DEEP) Approach may serve as further corroborative evidence that EA may have escalating safety issues.

With evidence mounting, has the implied promise of the safety of EA performed with pens or wands become a veritable wolf in sheep's clothing? In a specialty that embraces technology to advance quality and patient safety, it is incumbent upon us to root out potential factors of nonconformance before someone else does it for us.¹²

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