ATRIAL FIBRILLATION

RESEARCH ARTICLE

Creating Transmural, Linear Epicardial Ablation Lesions via a Non-surgical, Percutaneous, Subxyphoid, Electrogram-guided Approach

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ABSTRACT. Surgical arrhythmia ablation techniques can achieve epicardial transmural lesions but require a combination of surgical access and endoscopic approaches. We sought to adapt a surgical ablation catheter to a percutaneous subxyphoid approach. The EpiSense nContact (Epi) is a surgical ablation catheter that contains a 3-cm ablation coil, an open irrigation system, and a suction mechanism to maintain tissue contact. Four sensing electrodes were added to the ablation coil to allow monitoring of electrograms. Six pigs were used for the study. A subxyphoid pericardial puncture was performed to advance a wire into the pericardial space. The subcutaneous tissue was dilated with a 1 × 5 cm angioplasty balloon to advance the Epi catheter into the pericardium without endoscopy or surgical tools. Manipulation was achieved by snaring and looping the wire over which the Epi catheter was advanced, or by positioning the wire across the transverse sinus to deliver atrial lesions. The catheter position in three dimensions was tracked with the NavX system. Adequacy of tissue contact was verified by monitoring electrograms recorded by the four Epi diagnostic electrodes. Epicardial ablations were performed in both atria (left atrial appendage, vein of Marshall, left atrial roof, right atrial roof and lateral right atrium) and both ventricles. Explanted hearts confirmed the accuracy of lesion locations as tracked by NavX and transmurality of the lesions. The Epi catheter delivers linear transmural lesions without surgical access or endoscopic approaches. Diagnostic electrodes in the Epi catheter allow for accurate tracking of catheter position in three dimensions and estimation of tissue contact.

KEYWORDS. catheter ablation, epicardial.

Introduction

Surgical approaches to ablation of arrhythmias, particularly atrial fibrillation, offers important potential advantages over conventional endovascular catheter ablation, including but not limited to the use of larger ablation tools that enable the creation of large linear lesions, or the application of ablative energy onto epicardial targets, such as the atrial neural plexus or the ligament of Marshall.

However, surgical approaches entail a necessary invasion of the chest that causes significant morbidity. Efforts to decrease invasiveness of surgical ablation approaches have been intense and relatively successful: from the initial maze procedure that required open median sternotomy and cardiopulmonary bypass, to...
minimally invasive approaches using bilateral or unilateral thoracotomies using several ports to introduce ablation catheters and endoscopes.4,5

In its least invasive iteration, a surgical non-thoracotomy approach has been designed. Via an abdominal incision, entry into the subdiaphragmatic peritoneum enables access to the pericardial space via an endoscopically guided incision in the diaphragm. Then, a large tube (2 cm diameter) is inserted into the pericardial space through which an endoscope and a surgical ablation catheter (Numeris, nContact, Morrisville, NC) are introduced. At the cost of not dissecting the pericardial reflections, which makes the procedure necessarily hybrid, requiring a combined endovascular catheter ablation, this approach enables delivery of large, transmural linear lesions in the posterior left atrium and pulmonary vein antra without requiring any form of thoracotomy.7 Nevertheless, this approach requires a ~3 cm abdominal incision, plus additional abdominal punctures for 5 mm trocars, CO2 inflation of the peritoneal cavity, and the insertion of an endoscope and coagulation tools to incise the diaphragm. A surgical team is needed to facilitate this part of the procedure, which has to be integrated within the workflow of a conventional cardiac electrophysiology procedure, and requires modification to the staff and laboratory equipment.

Here we sought to modify an existing surgical ablation catheter to a percutaneous, non-endoscopic, non-surgical subxyphoid approach that could enable electrophysiologists to have access to a large surgical ablative catheter without requiring surgical approaches. We show that the catheter can be manipulated in the pericardial space and tracked with three-dimensional (3D) mapping techniques, and that effective ablation lesions can be delivered into targeted sites in atria and ventricles.

**Methods**

Farm pigs of either sex (n=6) were used for the study. After sedation with general anesthesia and endotracheal intubation, vascular access was obtained in the right internal jugular vein and femoral veins. A decapolar catheter was advanced in the coronary sinus. As needed, an intracardiac echocardiogram catheter was also advanced in the right atrium (AcuNav catheter, Siemens, Malvern, PA). A subxyphoid pericardial puncture was then performed following the technique described by Sosa et al,6 and a wire was advanced into the pericardial space. Contrast was injected in the pericardium to outline the heart’s anatomy, and confirm absence of ventricular perforation. As needed, additional pericardial punctures (up to three) were performed to introduce additional wires.

In order to allow introduction of the ablation catheter, the subcutaneous space and pericardial puncture were sequentially dilated with a peripheral angioplasty balloon (1 cm by 5–10 cm, see Figure 2 below).

The nContact EpiSense epicardial ablation catheter (Epi) has a lumen for wire introduction, and an ablation coil (1 or 3 cm long) exposed only on one side (opposite to the wire lumen). Embedded in the ablation coil are four electrodes that allow collection of the extracellular voltage signals (two electrodes in the 1-cm version). The coil is surrounded by insulation silicone in all but one side. Thus, tissue contact of the ablation coil is necessarily associated with electrode contact and signal recording. Suction can be applied that results in tight apposition of the coil to myocardial tissue, while a closed irrigation circuit circulates saline solution through the catheter to cool the ablation coil. (Figure 1).

Tracking the position of the epicardial ablation catheter in three dimensions was performed with the NavX system (St Jude Medical, St Paul, MN) using patches attached to the pig’s chest and the coronary sinus catheter as a reference. A quadripolar catheter was introduced via the right femoral vein into the right atrium and ventricle. A transseptal puncture was then performed to introduce the catheter in the left atrium and ventricle. 3D geometry of atria and ventricles was performed by roving the quadripolar catheter using NavX, which also was used to confirm apposition of the endocardial catheter to the epicardial location of the Epi catheter, and to record electrogram amplitudes.

Navigation of the Epi catheter in the pericardial space was initially attempted by manipulation of the catheter itself. Positioning of the wire over which the catheter was advanced in different locations was achieved initially by manipulation of the catheter itself, or by selectively directing the wire with an Agilis sheath (St Jude Medical). A second

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**Figure 1:** EpiSense ablation catheter and its modification for the current study. (a) Ablation catheter used in this study. An ablation coil is surrounded by insulating silicone and exposed only on one side, preventing collateral damage and ensuring that electrodes only record signals from the exposed side. Two pairs of electrodes are embedded in the ablation coil. (b) Ablation mechanisms. Once the target is selected, the coil is apposed to targeted tissue. Suction is applied to maximize tissue contact. A closed circuit of saline irrigation provides cooling.
strategy, designed to mimic the catheter tip bending of its surgical counterpart, entailed snaring of the wire (over which the Epi would be advanced) with a wire snare (Amplatz Gooseneck, EV3, Plymouth, MN) introduced via a second pericardial puncture. The wire tip was then exteriorized and used to introduce an Agilis sheath to bend the Epi catheter tip in different directions.

Clinically relevant ablation targets were chosen in the right and left ventricles (as potential targets of ventricular tachycardia ablation), as well as in the atria (left atrial appendage, vein of Marshall, lateral left atrium, roof of left atrium, Bachmann’s bundle, right atrial roof and lateral right atrium, right atrial appendage). In all experiments, a minimum set of ablation lesions was delivered in the right and left atria (two or more in each) and at least one in each ventricle. Radiofrequency ablation lesions were delivered using both a 1 and 3-cm Epi catheters. Application duration was set at 90 s and power was set to an upper limit of 30 watts for the 3-cm device and 10 watts for the 1-cm device. Saline perfusion was set to 6 ml/min, with a vacuum pressure of $-400$ mmHg. Power titration was based on the impedance response. Upon an increase in impedance, indicative to loss of contact or tissue desiccation, power was stepped down and allowed to gradually increase, reducing the likelihood of tissue vaporization and providing input about the ablation performance. At the end of the experiments, the hearts were explanted and inspected to assess lesion length and transmurality, as well as location correlation with the mapped targeted sites.

Results

**Pericardial access and signal recording**

Access to the pericardial space and dilation of the pericardial puncture and subcutaneous tissues was achieved in all six pigs without complications, allowing free passage of the Epi catheter. Epicardial signals were recorded from atrial and ventricular tissues in all pigs by rotating the Epi catheter so that its electrodes faced myocardial tissues rather than the parietal pericardium. Fluoroscopically, this could be identified by the position of the coil relative to the wall (the wire being on the edge opposite to the electrodes). **Figure 2** shows representative examples of pericardial access and puncture dilation, as well as the fluoroscopic identification of the side of the ablation coil in contact with the myocardium. When the electrodes (embedded in the ablation coil, exposed in only one side) were not in contact with myocardium, no signal was detected.

**Navigation to ablation target sites**

Simple torquing of the Epi catheter allowed us to reach ventricular targets in the right and left ventricles. A sheath (Agilis, St Jude) was usually necessary to redirect the wire from left to right or vice versa, in order to navigate to targets on different sites. With this strategy, target sites in the left atrial appendage, superior right atrium (junction with superior vena cava), lateral and posterior right atrium, and posterior left atrium were reached. Owing to catheter size limitations, reaching the pulmonary veins or the coronary sinus was not attempted. **Figure 3** shows examples of ablation coil positions: all anatomical positions were matched by an endocardial catheter.

Fine-tuning the ablation coil position was achieved by bending the wire close to the ablation catheter tip. This required snaring and exteriorizing the wire tip and advancement of a sheath over the wire tip. In this configuration, a wire loop was in the pericardial space. This could be done by advancing a snare over a separate pericardial puncture, which was then manipulated to snare the first wire (**Figure 4a–c**), or more simply by advancing both a wire and a snare over a large sheath inserted in a single pericardial puncture (**Figure 4d–f**). Once the wire tip was snared out and exteriorized, the Epi catheter was advanced over one end of the wire loop, and the Agilis sheath was advanced over the other end, which was advanced and bent in order to achieve the desired deflection of the Epi catheter tip (**Figure 4**).

Reaching the roof of the left atrium is attractive, since this location is not reachable in the current subxyphoid surgical approach. To achieve this, the Agilis sheath was advanced along the left lateral pericardial space and probed with a wire towards the right and posterior to the great vessels, so that the wire would advance into the transverse sinus of the pericardium. The transverse sinus provided anchoring to the wire, which remained stable and over which the ablation coil was sequentially advanced from left- to right, allowing a sequence of ablations from the posterior left atrial appendage, vein of Marshall, lateral left atrium, left atrial roof, Bachmann’s bundle, right atrial roof–SVC (superior vena cava) junction, and lateral right atrium (**Figure 5**).
3D tracking of catheter position

Using the NavX system, geometries of the right atrium and left atrium were created, including the superior vena cava and the right pulmonary veins. This was performed endocardially by maneuvering a quadripolar catheter in these chambers. In three pigs, limited geometries of the right and left ventricles were also generated. NavX could accurately track the position of the Epi catheter in the pericardial space. By moving the Epi catheter in the pericardial space, NavX also generated a geometry of the pericardial space. This was hidden in order to visualize the endocardial structures. Ablation sites in the pericardium were marked as floating points so that their relation to the corresponding endocardial chambers could be visualized (Figures 6 and 7).

Radiofrequency ablation

Radiofrequency applications were performed at different atrial and ventricular sites. Using the algorithm described, there were no steam pops. Ventricular lesions were applied two consecutive times (Figures 6 and 7). Lesion

Figure 3: Simultaneous epicardial-endocardial mapping. Simple torquing and manipulation of the catheter and wire could move the ablation catheter tip into several atrial and ventricular targets. An endovascular catheter was moved to match the epicardial coil positions endocardially. (a, b) Ablation coil in the posterior aspect of the left atrial appendage in anterior-posterior view (a) and right anterior oblique view (b), with matching endocardial catheter. (c–e) Ablation catheter in the right atrium: adjacent to the superior vena cava (c), in the lateral right atrial wall (d), and posterior right atrial wall (e, right anterior oblique view). (f, g) Ablation catheter in the right ventricle outflow tract (f) and base (g). (h) Ablation catheter in the left ventricle.

Figure 4: Wire snaring technique for ablation catheter tip deflection. (a–c) Two pericardial punctures were performed: over one, a wire was advanced (wire 1). Over the second puncture (wire 2), a snare was used to securely grab the first wire tip. (b) Snaring and pulling the wire 1, eventually externalizing it so that a sheath could be advanced over the wire tip, left a wire loop in the pericardial space. (c) The Epi catheter was advanced over the looped wire. A deflectable sheath was then advanced over the other end of the wire. (d–f) Over a single pericardial puncture, both a wire and a snare were advanced over a large sheath, facilitating snaring and exteriorizing the wire tip (b) over which a deflectable sheath was advanced (f). By pulling and deflecting the wire with the deflectable sheath, the Epi catheter tip can be directed to desired positions. The circular catheter shown was used to create a left ventricular endocardial geometry.
Completeness was demonstrated in vivo by showing simultaneous attenuation of endocardial and epicardial bipolar voltage signals. (Figure 7a,b). At the end of the experiments, incisions over the radiofrequency lesions demonstrated that transmural lesions were consistently achieved in atrial tissues with single radiofrequency applications, whereas complete transmurality in the ventricles required repeated radiofrequency applications for a total of 180 s. Of note,

Figure 5: Sequential atrial lesion set along the transverse sinus of the pericardium. Top panels are anterior-posterior views, bottom panels are right anterior oblique views. (a) The ablation coil is in the lateral right atrium, posterior to the crista terminalis (lesion 1). Simultaneously, a deflectable sheath is on the left side, directing a wire through the transverse sinus of the pericardium. There is contrast in the pericardium outlining the aorta (Ao) and pulmonary artery (PA) and catheters in the coronary sinus and left atrium. The wire is posterior to the aorta, confirming its position in the transverse sinus. (b) The sheath is removed and the Epi catheter is advanced over the wire in the transverse sinus (held in place by the great vessels). A lesion in the posterior left atrial appendage–vein of Marshall area is delivered (lesion 2). The catheter is then sequentially advanced to deliver lesions in the left atrial roof (c, lesion 3), Bachmann’s bundle (d, lesion 4), and right atrial roof–superior vena cava (e, lesion 5).

Figure 6: Three-dimensional maps and ex vivo images of lesions delivered along the transverse sinus. See Figure 5 for corresponding fluoroscopic images. (a–c) Three-dimensional maps (NavX) of the right (blue) and left (red) atrium. Lesions numbered as in Figure 5 are shown (yellow dots). Anatomical references are the left atrial appendage (LAA), right superior pulmonary vein (RSPV) and superior vena cava (SVC). Lesions in the LV are also marked. (d–f) Ex vivo images in a lateral view (d), superior view (e) and posterior-superior view (f). Lesions are numbered corresponding to the catheter positions in Figure 5. Additional anatomical markers are shown: pulmonary artery (PA), aorta (Ao), right atrial appendage (RAA), Bachmann’s bundle (BB).
epicardial fat did not affect efficacy of the ablation, and deep lesions were possible even when applied directly over epicardial fat by using multiple applications (Figure 7).

Discussion

Our studies show that the EpiSense™ epicardial ablation catheter can be successfully adapted to a non-surgical percutaneous approach. The addition of sensing electrodes to the ablation catheter coil, and the modification of the subxyphoid pericardial puncture with dilation of the puncture allow for this successful adaptation.

Epicardial mapping: potential clinical utility

The addition of two pairs of electrodes to the ablation catheter enables its use as a diagnostic electrophysiology catheter rather than a surgical ablation tool. This, combined with 3D mapping systems (NavX) allows for non-fluoroscopic tracking of the catheter position, the creation of maps of epicardial voltage, and characterization of electrogram characteristics. These features are attractive for ablation of atrial and ventricular arrhythmias.

The current surgical approach to ablation of atrial fibrillation relies exclusively on an anatomically determined set of lesions. While that has been shown to be reasonably effective, success in rhythm control remains comparable to that of conventional catheter-based procedures, and there is no possible customization of the lesion set for the individual patient. Without signal recordings from ablation sites, patients may receive ablation at sites previously scarred, which harbor little relevance in the maintenance of atrial fibrillation. Additionally, ablations are assumed to be effective based on arbitrary power settings and ablation durations, but no real verification of electrical signal abolition is present in the current technology. These limitations are effectively corrected with the epicardial ablation catheter presented here. However, there remain limitations inherent to a purely epicardial approach, such as the lack of endocardial signal recording, and the potential need for pacing on the sides of the ablation lines for testing of block. Even though pulmonary vein isolation was not tested here, this catheter (without the sensing electrodes) has been used clinically in atrial fibrillation with successful creation of pulmonary vein antral isolations. We can only expect similar results with the addition of electrodes in the version tested here.

Besides atrial fibrillation, other arrhythmias appear suitable for treatment with the electrode-enabled Epi catheter. Sinus node modification for inappropriate sinus tachycardia often requires radiofrequency application at sites in close proximity to the phrenic nerve. Such sites are typically determined by mapping the earliest signals, endocardially or epicardially. The Epi catheter could be used to epicardially map and ablate such signals, but further testing is necessary to support its safety.

Ventricular tachycardias may have epicardial circuits not amenable to endocardial radiofrequency ablation. Although the subxyphoid puncture allows treatment with ablation catheters designed for endocardial ablation, there is a need for ablation tools designed specifically for the epicardium that can deliver large transmural lesions, without the limitations of endovascular technologies (steam pops, volume overload from open irrigation, etc.) and with optimized tissue contact. Additionally, such epicardial ablations require mapping and characterization of epicardial electrical signals to delineate tachycardia.
substrates and circuits. Thus, the Epi catheter presented here promises clinical utility in ventricular tachycardia.

**Modified subxyphoid approach**

Since its description by Sosa et al, the subxyphoid pericardial access technique has enabled electrophysiologists to diagnose and treat cardiac arrhythmias originating in the epicardial aspect of the heart. Its use is most extended in the treatment of ventricular tachycardia, as originally described, but it has also been a useful tool for other arrhythmias when a conventional approach fails. Limitations on its use include adhesions from prior cardiac surgery. Surgical instrumentation with the creation of small pericardial windows have been used to expand the access site and allow access to the pericardial space in difficult cases. The approach presented here—balloon dilation of the subcutaneous track and pericardial puncture site—is technically simple and allowed the introduction and manipulation of a larger diameter catheter. To reach different cardiac targets, torquing and additional manipulation were required. Such manipulation was fairly limited using the catheter alone. We were able to replicate the tip bending used by surgeons by snaring the wire that runs in the lumen of the catheter and advancing a deflectable sheath over it. Deflecting such a sheath close to the catheter tip could replicate the tip deflection surgeons achieve (Figure 4). This necessarily leads to the need of having two catheters entering the pericardium percutaneously, one being the Epi catheter itself, and the other being the sheath to bend the Epi catheter tip. We found no difficulties in manipulating both. To reach the roof of the right and left atrium required passage of a wire into the transverse sinus. This was readily achieved using a deflectable sheath. Once the wire was in the transverse sinus, the ablation catheter could be advanced sequentially from left to right achieving transmural ablations with radiofrequency.

**Limitations**

The current study was performed in swine. Therefore, it remains an unproven assumption that maneuverability of the catheter in humans will be similar. However, it is expected that manipulation in humans would be easier given the larger size. Owing to constraints of the swine pulmonary vein anatomy, the pulmonary vein ostia were not targeted. Clinical utility will be limited by the extent of pericardial access. Additionally, given the large lesion size, there are potential complications, such as damage to the coronary arteries, that we did not evaluate. Pacing was not performed to test for conduction block or loss of capture after ablation; however, we believe that the signal attenuation and the morphological appearance of ablated tissue are solid evidence of effective ablation.

**Conclusions**

The Epi catheter delivers linear transmural lesions without surgical access or endoscopic approaches. Diagnostic electrodes in the Epi catheter allow for accurate tracking of catheter position in three dimensions and estimation of tissue contact. This catheter along with the modification of the subxyphoid pericardial puncture allow a successful transformation of a surgical ablation tool into an electrophysiological ablation catheter that can be used percutaneously without surgical intervention. Further refinements are needed to allow autonomous tip deflection, and further studies are needed to define the role of such catheters in clinical electrophysiology.

**References**