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Ultra-Low-Temp Catheter Heats Up Cryoablation for AF

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BARCELONA, Spain — A novel catheter that provides ultra-low-temperature ablation showed favorable efficacy and safety results in patients with atrial fibrillation (AF) or flutter, first-in-human results suggest.

The experimental device (from Adagio Medical) operates at the near-critical point between liquid and vapor for nitrogen, or -196°C (-320.8°F). Liquid nitrogen can't circulate through a small 8-French catheter below the liquid-vapor line because evaporation of the liquefied gas results in enormous expansion up to a factor of 200, causing vapor lock, explained lead investigator, Tom De Potter, MD, Cardiovascular Center, Onze-Lieve-Vrouw Hospital, Aalst, Belgium.

"If you increase the pressure in the catheter dramatically up to the critical point of nitrogen, this phenomenon disappears. The gas no longer expands from the heating and it allows you to use these ultra-low liquid nitrogen temperatures in a percutaneous catheter. This is what this technology does," he said.

The low viscosity of near-critical nitrogen also allows for a smaller catheter size than used in traditional cryoablation systems. But it is the ability to reconfigure the catheter into any shape, ranging from a long linear line to 25- to 35-mm loops or a flutter pouch, that elicited murmurs and an audible "Wow" from attendees of the late-breaking science innovation session at the European Heart Rhythm Association (EHRA) 2018 congress.

"This catheter can be pulled back or out of the sheath as far as we want, and we can use this to our advantage to make the catheter assume different shapes," De Potter said.



After 4 years of development, researchers at two centers prospectively evaluated the system for cryoablation of isthmus-dependent atrial flutter in 17 patients (Cryocure 1) and in paroxysmal, persistent AF in 27 patients to date (Cryocure 2).

In Cryocure 1, bidirectional isthmus block (BDB) was achieved after a 30-minute waiting period in all 17 patients, with the flutter catheter pouch approach used in 14, De Potter said.

"In atrial flutter it may be very useful to use this type of configuration, which in conventional point-by-point you would call backhand ablation or something like that, but of course, this catheter freezes along the entire length of the exposed portion of the catheter," he said.

The average ablation time to BDB was 2.7 minutes, including a 14-second bonus freeze to the BDB. The best-case scenario was BDB real-time isolation in one patient in 14 seconds, he said.

On average, 2.8 applications were used to reach BDB with 12 minutes of x-ray time, resulting in a total procedure time of 85 minutes, including the 30-minute waiting period.

As for acute safety, there was one transient ST-segment elevation, presumed due to right coronary artery spasm that lasted for 2 minutes with no sequelae on further evaluation.

At 3 months, 94% of the 17 patients were free of recurrence. Additional electrophysiology studies conducted in 3 patients for other reasons at 3 and 12 months confirmed cavotricuspid isthmus (CTI) block in all.

For Cryocure 2, the 27 patients (63% male; mean age, 64 years) had a history of AF for an average of about 2.5 years, and all had mildly dilated left atrial diameters, with extreme left atrial diameter an exclusion criteria.

Pulmonary vein isolation (PVI) ablation was performed in all 27 patients and CTI block in 7 of the 10 patients with persistent AF. At the discretion of the physician, left atrial posterior wall isolation was also performed in 7 patients.

PVI was achieved in 101 of 105 veins (95%), with the procedure aborted after isolation of 1 of 4 veins in one patient after the catheter malfunctioned and a replacement was unavailable.

Posterior wall and/or cavotricuspid isthmus block isolation was achieved in 7 of 7 patients, adding an additional 5 minutes of ablation time. The total procedure time averaged 134 minutes.

"What I am showing you is our total experience from the very first case and first-in-man study and this technology is evolving continuously," De Potter said. "What we have seen so far is that we can achieve isolation extremely efficiently. Our best time so far is in one patient we isolated all four veins after 5 minutes 30 seconds."

Among 13 patients treated with PVI only using the first-generation catheter and no cryomapping, there were two cases of phrenic nerve palsy that persisted for some time but with full recovery, he said.

Among 13 patients treated with PVI with or without linear lesions using the second-generation catheter, there were no complications.

Notably, esophageal warming balloons were used for all catheters, and no tamponade, fistula, or mechanical adverse events were reported.

Commenting for theheart.org | Medscape Cardiology, session co-moderator Helmut Puererfellner, MD, Ordensklinik Linz, Austria, described the device as fascinating and said it is novel not just for the use of ultra-low temperatures but for a design not bound to a balloon.

"You can deliver a balloon quite nicely in the pulmonary vein" but "whenever you have other substrate out of the veins, you're not done with the balloon, you need something else," he said. "This design of the catheter is very flexible; you can adapt it in a way that you have linear shapes, circular shapes, whatever you want. I think this is very promising."

Additional data are needed, however, to determine safety, he noted.

"It will need some time, of course, to develop the right power settings, the right designs of the catheters, but I think this might be an alternative to radiofrequency or to cryo techniques that we have applied so far," Puererfellner said.

Session co-moderator Hildegard Tanner, MD, University of Bern, Switzerland, told [theheart.org | Medscape Cardiology](#), "I have some concerns about collateral damages this might cause because now we have quite low numbers and we know that each energy form can produce some collateral damages. So personally I'm concerned that maybe we did not see everything that can happen with this energy."

She continued, "On the other side, when it's powerful maybe there's potential for extension of indication. When I see the deepness of these lesions which can be produced with this ultra-low-energy delivery, maybe this is also a solution for some difficult areas within the ventricle, interventricular septum, for example."

Finally, Tanner said the ability to reshape and use the catheter for different indications may have economic implications in terms of healthcare resources used.

De Potter reported travel support from Abbott, Biotronik, Boston Scientific, and Johnson & Johnson and grant support to his institution from Boston Scientific and Johnson & Johnson. Puererfellner and Tanner reported having no relevant disclosures.

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