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First results of ultra-low cryoablation in patients with cavotricuspid isthmus dependent atrial flutter; procedural and outcome data on efficacy and safety

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Topic(s):
Supraventricular Tachycardia (non-AF) - Treatment

Citation:

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Background:
A novel ultra-low temperature Cryoablation(ULTC) system uses near critical nitrogen(NCN), with lower temperatures(-196 °C) and thermal capacity than N2O gas, leading to quicker, deeper lesions, with equal cooling distribution along the entire length of a long linear catheter. NCN can be handled under low pressure, making it possible to use a more flexible catheter with shape versatility and maneuverability for the operator.

Purpose:
Evaluate the safety and performance of a novel ULTC using NCN to achieve durable bidirectional conduction block(BDB) in patients with CTI-dependent atrial flutter.

Methods:
Cryocure-1 is a prospective, single-arm, multi-center, first in man clinical study for CTI-dependent AFL. Follow-up took place with a hospital visit including holter and ECG at 30 days post ablation, telephone call after 3 months and standard of care subsequently. Two versions of the AFL catheter were used (Gen I and II). Applications typically lasted 90 seconds, including a bonus freeze. BDB was documented by conventional pacing maneuvers.

Results:
Between January and March 2015 and between April and October 2017, a total of 17 patients were treated. Mean age was 63±9 years old, 59% male, mean LVEF 57±5. Medical history reported hypertension(53%), diabetes(18%) and coronary artery disease(18%). Total procedure time was 85±16 minutes, fluoroscopy time 12±5 minutes and 4.0±2.6 freezes per patient. Acute success, defined as persisting BDB across the CTI 30 minutes after the last freeze, was achieved in 17/17 patients (100%). During follow up, 1/17 patients presented with documented recurrence of CTI-dependent AFL, which was confirmed during EP-study. Five patients underwent a subsequent PVI procedure for AF, in which persisting BDB across the CTI was confirmed in all patients. One procedure related adverse event occurred, consisting of transient ST elevation that resolved within 1 minute and did not result in permanent ECG changes or alterations of ventricular function, and for which a transient coronary spasm was deemed probable.

Conclusion:
In this first in man clinical study, the safety and performance results demonstrate the feasibility of ultra-low temperature near critical nitrogen combined with a multifaceted catheter design, in the ablation treatment of CTI-dependent atrial flutter. One procedure related adverse event was reported. BDB was achieved in 17/17(100%) of patients and 16/17(94%) remained free of AFL during follow up.
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