Second-generation cryoballoon ablation for paroxysmal atrial fibrillation: a step forward?

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This editorial refers to ‘Second-generation cryoballoon ablation for paroxysmal atrial fibrillation: 1-year follow-up’ by G.-B. Chierchia et al., on page 639.

Electrical isolation of the pulmonary veins (PVs) is the established endpoint during ablation of atrial fibrillation (AF) as implemented in the latest European guidelines. Limitations of point-by-point radiofrequency (RF) ablation commonly utilized in combination with a three-dimensional (3D) electroanatomical mapping system led to the development and evaluation of alternative ablation systems and energy sources. The second-generation cryoballoon (CB, Arctic Front Advance, Medtronic, Inc.) is currently the only available ‘single-shot’ ablation tool for pulmonary vein isolation (PVI). Its ‘over-the-wire’ system allows for easy and non-traumatic advancement into the target PV. A spiral mapping catheter (Achieve, Medtronic, Inc.) introduced through the central lumen of the balloon records PV signals and permits live verification of PVI. The cooling system of the first-generation CB consisted of four injection jets in a more proximal balloon position, providing a ring-like zone of maximal cooling along the balloon equator, sparing the distal tip. In clinical use, the first-generation CB demonstrated a high acute success rate combined with a short learning curve. In the Sustained Treatment Of Paroxysmal Atrial Fibrillation (STOP-AF) trial, the acute isolation rate was 97–100% applying a 300 s freeze cycle. The high acute success rate was accompanied by a reasonable safety profile demonstrating an incidence of phrenic nerve (PN) palsy of 6.4%, an incidence of thermal esophageal ulceration of up to 5.2%, and a rate of PV stenosis of 0.9%. However, the long-term single procedure success rate was only 62% and increased to 77% following multiple procedures.

The addition of two bonus freeze cycles when compared with a single bonus freeze application after successful PVI failed to demonstrate a significant improvement in 1-year clinical outcome. The second-generation CB was introduced to overcome the limitations seen with the first-generation system. Despite an identical outer shape, the balloon incorporates a modified refrigerant injection system with eight injection jets located in a more distal position, providing effective and homogeneous cooling of the complete northern balloon hemisphere including the distal balloon tip. The aforementioned modifications led to the recommended shorter freeze cycle duration of 240 s. Initial studies using the second-generation CB demonstrated a high acute success rate with a PVI rate of up to 89% on first attempt. Furthermore, the rate of live verification of PVI increased from 49% using the first-generation CB to 76% using the second-generation system. While the procedural efficacy has increased, Casado-Arroyo et al. reported an unacceptably high rate of PN palsy of 19% using the second-generation CB in their initial series of patients. The concern over a higher rate of PN palsy was not supported by a study from our centre reporting an incidence of 3.5%, which is comparable with the first-generation CB. However, the reported rate of esophageal thermal injury of 12–19% is higher than that for the first-generation CB. The first mid-term follow-up results using the second-generation CB were reported by Chierchia et al. demonstrating a clinical success rate of 82% after 6 months. However, 1-year clinical follow-up data had yet to be reported.

In this context, the study by Chierchia et al. published in this issue of the Journal is the first to report on the 1-year clinical outcome following PVI using the second-generation CB in patients with paroxysmal AF. All PVs were targeted and successfully isolated using only the 28 mm second-generation CB and a 240 s freeze cycle, followed by one additional bonus freeze application per vein. Live verification of PVI using the Achieve mapping catheter was recorded in 52% of all targeted PVs. The most frequent complication was PN palsy with an incidence of 8 of 42 (19%) patients while targeting the rightsided PVs. In 5 of 8 (63%) patients PN palsy resolved upon hospital discharge, while in the remaining patients PN function recovered as late as 10 months post ablation. Importantly, 7 of 8 (88%) PN injuries occurred during the initial 20 cases. After 1 year of clinical FU including a 3-month blanking period, 81% of patients were in stable sinus rhythm off antiarrhythmic drug therapy. These results are impressive but need to be verified by other centres and in larger patient cohorts. In addition, it remains to be seen whether these encouraging 1-year results sustain over time. Furthermore, the study raises the question, whether a shortened freeze cycle duration of <240 s may be equally...
effective. This in turn would decrease the overall procedure time and may reduce the rate of untoward effects such as PN injury or thermal esophageal damage. Alternately, use of a single-freeze protocol, that is forgoing the bonus freeze, may exert a similar positive effect. Finally, an individualized ablation strategy that determines the freeze cycle duration from the time to PVI as recorded by the Achieve mapping catheter may be another useful ablation strategy. In summary, the reported success rate by Chierchia et al. supports the high expectations raised by many operators. To further clarify the role of the CB as a superior ablation tool to treat patients with paroxysmal atrial fibrillation, the prospective randomized ‘Fire and Ice’ trial is presently enrolling patients to CB-based PVI or conventional RF ablation (NCT01490814).

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