Balloon Catheters for Pulmonary Vein Isolation

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Abstract
The mainstay of catheter ablation for atrial fibrillation (AF) is pulmonary vein isolation (PVI). The shortcomings of a point-by-point ablation approach using radiofrequency current steadily kindle the interest in new energy sources and catheter designs. The most promising currently available techniques are balloon catheters using cryothermal energy (CRYO) or high-intensity focused ultrasound (HIFU).

Both technologies have proven to be efficacious. However, for both technologies treatment strategies have to be developed to overcome the relatively high incidence of collateral damage such as phrenic nerve palsy or atrial-to-esophageal fistula.

The results for patients with persistent AF in whom substrate modification is considered beneficial are poor and limit the use of balloon-based PVI to patients with paroxysmal atrial fibrillation (PAF). Moreover, based on the individual anatomy more than one balloon size may be required or may even make balloon-based PVI impossible in certain patients.

Introduction
The mainstay of catheter ablation for atrial fibrillation (AF) is pulmonary vein isolation (PVI) [16]. This procedural endpoint is achieved by destroying the muscular sleeves extending from the left atrium into the pulmonary veins (PVs) by either a segmental or a circumferential ablation approach [21, 23]. Early reports demonstrated the difficulty of achieving complete contiguous ablation lesions in the left atrium [10]. Consequently, electrical reconnection through gaps in the circumferential ablation lines has been shown to be the dominant factor for clinical recurrences of AF or atrial tachycardias following PVI procedures [22].

Moreover, radiofrequency (RF) current ablation of AF is associated with a small but definite risk of serious complications such as PV stenosis, stroke and atrial-to-esophageal fistula [5, 24].

The aforementioned shortcomings of a point-by-point ablation approach using RF current steadily kindle the interest in new energy sources and catheter designs. Ideally, the new energy should be safe and create transmural circumferential lesions with a single application. The most promising currently available techniques are balloon catheters using cryothermal energy (CRYO: CryoCath® Technologies, Inc, Canada) or high-intensity focused ultrasound (HIFU, ProRhythm®, Inc, USA). This review
article will summarize the basic principles and early clinical results of these technologies.

**Basic Principles of HIFU**

HIFU relies on the basic concepts of conventional ultrasound. By focusing highly energetic ultrasound waves to a well-defined volume, local heat rise (usually > 56 °C and up to 80 °C) occurs and causes rapid tissue necrosis by coagulative necrosis [6]. Another mechanism by which HIFU destroys tissue is called acoustic cavitation [14]. This process is based on vibration of cellular structures causing local hyperthermia and mechanical stress by bubble formation due to rapid changes in local pressure leading to cell death.

The basic principle of these balloon catheters is an ultrasound crystal housed in a fluid-filled balloon. The only currently available HIFU balloon catheter consists of a noncompliant distal balloon, which is filled with a mixture of water and contrast media (6 : 1 ratio) and an integrated 9-MHz ultrasound crystal. Proximally, a second noncompliant balloon, filled with carbon dioxide, forms a parabolic surface at the base of the distal balloon. The emitted ultrasound waves are reflected in the forward direction, focusing a ring of ultrasound energy (sonicating ring) ~ 4 mm distally to the balloon surface. The catheters are steerable through a pull wire mechanism integrated in the handle of the catheter. Three different balloon sizes are available: a 24-mm diameter balloon (20 mm sonicating ring diameter), a 27-mm diameter balloon (25 mm sonicating ring diameter), and a 32-mm diameter balloon (30 mm sonicating ring diameter). The catheter has a central lumen used for insertion of a spiral mapping catheter (ProMap®, ProRhythm®, Inc) to assess the presence or absence of PV potentials.

A major advantage of HIFU is that no direct tissue contact is needed for the generation of the ablation lesion. Lesion volume depends on sonication time and on the initial tissue temperature as well as on the amount of acoustic power [9, 12]. According to the balloon shape, it creates circular ablation lesions by a single HIFU application within 40–90 s depending on the balloon size (Figure 1).

**Clinical Results with Balloon Ablation**

In the early stage of developing balloon catheters for PVI, a balloon applying RF current was investigated with promising results [28, 32].

**Basic Principles of CRYO**

Lesions created by CRYO differ in several respects from those created by conventional RF current ablation. CRYO lesions show intact endothelial lining and hence are associated with less thrombus formation as compared to RF lesions [15, 27]. This may reduce the likelihood of thromboembolic events. While RF lesions show progressive contraction, CRYO lesions are associated with minimal collagen formation and tissue shrinkage [3]. This in agreement with experimental animal data not reporting PV stenosis even after deployment of multiple CRYO applications at a single PV [2, 11].

The CRYO balloon catheter (Arctic Front®, available in diameters of 23 and 28 mm) consists of a double-walled balloon, where the refrigerant N₂O is delivered into the inner lumen, undergoing a liquid-to-gas phase change resulting in cooling down to approximately –80 °C. The catheter is equipped with a central lumen for the insertion of a guide wire and injection of contrast medium for PV angiograms. Both, sheath (12 F) and balloon, are steerable through a pull wire mechanism. In contrast to the HIFU balloon, the CRYO balloon system requires perfect local balloon/tissue contact as a prerequisite for a transmural lesion which is assessed by PV occlusion angiogram (Figure 2).