

## High-Power Short-Duration (HPSD)–Already the Current State of the Art for Ablation of Atrial Fibrillation?

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### ABSTRACT

Pulmonary vein isolation has been widely accepted as the primary interventional therapy for Atrial Fibrillation (AF). While there are numerous modalities to achieve electric isolation of the pulmonary veins, Radiofrequency (RF) ablation is most frequently used throughout the world. While we look back on over two decades of RF therapy, there is an ongoing discussion concerning the optimal RF delivery and power, with growing interest in High-Power Short-Duration (HPSD) ablations to improve procedural outcomes and long-term efficiency.

Here, we discuss current developments in HPSD ablation for atrial fibrillation with respect to procedural efficacy, efficiency and safety, as well as their implication for our current standard of care.

**Keywords:** High-power-short-duration; CLOSE; Ablation index; PVI; EDEL

### INTRODUCTION

During the past two decades, ablation therapy has emerged as the standard of care for most patients suffering from Atrial Fibrillation (AF). While it was considered to be non-inferior to medical therapy for most of this time, newer data suggests superiority regarding both the efficiency to achieve and maintain sinus rhythm, as well as improving patient's quality of life [1]. There is even growing evidence that ablation of atrial fibrillation might have prognostic benefits concerning MACE event rates in selected patients [2].

Current models of pathogenesis of atrial fibrillation primarily concentrate on pulmonary vein triggers, i.e., premature supraventricular contractions originating from the pulmonary veins causing atrial fibrillation initiation, and therefore, Pulmonary Vein electrical Isolation (PVI) is considered the corner stone of modern AF therapy at least in early stages of disease.

### LITERATURE REVIEW

There are numerous ways and energy-forms to achieve acute PVI, most procedures performed either use circumferential Radiofrequency (RF) point-by-point ablation, or cry balloon ablation. These principles have been tested and compared in the

FIRE and ICE trial by Kuck, et al. [3] and have proven non-inferior for paroxysmal atrial fibrillation. However, AF free survival was merely achieved in 50% of patients in both groups after 2-3 years of monitoring. While the cryo-protocol was very well defined, with specific instructions regarding freeze times and cycles, the RF arm was widely open labelled-regarding mapping techniques, use of contact force measurement and the irrigation design used by the RF catheters, as well as end-points for lesion formation.

Briefly, in a standardized cryo balloon procedure, a device specific steerable sheath is advanced into the left atrium, and a lasso-shaped guiding-catheter is advanced to gain access to the pulmonary veins, over which the inflated cryo balloon is positioned in the antral region of each pulmonary vein by fluoroscopic guidance. Pulmonary vein occlusion angiographies are obtained to confirm optimal balloon positioning. Circumferential thermic lesions are generated by expansion and freezing of nitrous oxide gas passing through the distal balloon, and depend on optimal pulmonary vein occlusion to reduce balloon and lesion heating by blood-flow passing by the occlusion zone. Each freeze cycle is maintained over 180-240 seconds either once or twice per pulmonary vein, according to the protocol used, and electrical bidirectional block can be visualized live using the lasso-guidewire placed in the pulmonary

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vein. Cryo procedures are typically guided by fluoroscopy alone, or by a combination of fluoroscopy and intracardiac ultrasound.

In contrast, radiofrequency ablations are performed using guidance of 3D-mapping systems and individual electro-anatomical left atrial maps. Based on operators' preference and experience, procedures can be guided with ultralow, or even zero-fluoroscopy work flows. 3D maps are generated using either the tip-style ablation catheter, or additional lasso or high-density mapping catheters. Within the left atrial maps, the antral region can be defined based on individual atrial anatomy. Circumferential pulmonary vein isolation is achieved by point-by-point ablation with overlapping ablation lesions, typically by antral isolation of both the left and right pulmonary veins in pairs. Additional ablation targets might be defined based on operators' experience or information provided by the individual electro-anatomical map.

Creating sustainable RF ablation lesions is the key for durable chronic pulmonary vein isolation. For this purpose, parameters like the impedance drop and reduction in unipolar and bipolar voltage during ablation, the force time integral and lately, the Ablation Index (AI, Biosense Webster Inc.) were established [4,5]. The AI combines RF power, ablation-time, contact force, and catheter stability in a weighted, non-linear formula, where RF power depicts the largest contributor. While interpretation of most of the traditional parameters of lesion creation are subjective and rely on operator experience, the AI was well validated in the CLOSE protocol in a prospective outcome trial and provides a novel tool to achieve a "fire and forget"-like setting for radiofrequency ablations previously only known for cryo techniques, allowing a standardized lesion creation and description, and thereby improving the comparability of RF procedures [6,7]. The CLOSE protocol described by Taghji, et al. and Duytschaever, et al. [7,8] provides highly standardized ablation approach, aiming for an ablation index between 400 and 550 in dependence of the anatomical location. Based on these recommendations, after two decades of radiofrequency ablation for atrial fibrillation, we finally have a reliable, evidence-based protocol at our hands that can be easily established in every cath lab.

The optimal RF generator power-setting to achieve the target lesion is currently under ongoing discussion-while conventional PVI is commonly performed using 20 W-30 W on the thin posterior atrial wall in proximity to the oesophagus to avoid thermal injury, 30 W-40 W are used on the thicker anterior wall and atrial roof. However, there is growing evidence that High Power Short Duration energy application (HPSD) might be as efficient, safe, and durable, whilst shortening procedure time, and probably even increase efficacy [9,10].

## DISCUSSION

The POWER-AF study demonstrated that a circumferential 45 W RF-power CLOSE-protocol in paroxysmal AF patients significantly increases the global procedural efficiency by reducing procedure times with similar mid-term efficacy [11]. Of note, the Biosense Webster AI was only validated up to 45 W, and the most commonly used Biosense Webster Smart-Touch-

Surround-Flow (ST-SF) irrigated catheter only has a CE mark and FDA-approval up to 50 W.

Considering other mapping systems and ablation catheters Kottmaier, et al. could show that a high power short-duration ablation using 70 W for 5-7's leads to significantly less arrhythmia recurrences after 1 year, while reducing RF and procedural time-while the Abbott catheters used are certified for this energy setting, this approach does not rely on a biophysical validated lesions index (i.e., Abbott Ensite LSD), which is currently poorly investigated in the HPSD context [12].

Recently, our own group has published a highly time-efficient, ultra-low-fluoro approach for AF ablation using circumferential high power 50 W ablation guided by the CLOSE protocol, demonstrating a highly significant reduction in total procedure time without increasing complication rates, especially regarding the occurrence of Endoscopy-Detected Oesophageal Lesions (EDEL). Data published by Chen, et al. [13] in the FAFA AI trial, using the same protocol, confirm our procedural findings in all published studies, HPSD ablation reduce RF time, LA dwelling time, and total procedure time, and increase rates of first-pass PVI, without an increase in adverse events [13].

Oesophageal-safety of HPSD ablations is under extensive discussion, since the use of high-power settings in close proximity to susceptible mucosal tissue just millimetres away from the thin posterior atrial wall is widely unsettling for experienced operators-however, histological data shows that HPSD ablation lesions differ from standard RF power lesions. Standard-power RF delivery causes a conductive, indirect heating with energy transfer into more distant tissue, that continues even after RF power delivery has stopped-on the other hand, high-power RF delivery causes resistive tissue heating, resulting in formation of shallower, but wider lesions [9]. Therefore, from a biophysical point of view, it is quite conceivable that HPSD ablation may cause less damage on neighbouring structures such as the oesophagus.

Concordant to this biophysical aspect of lesion formation, in our experience, EDEL occurring after standardized HPSD ablation differ from classical oesophageal lesions, as most of them were merely superficial mucosal detachments, which are poorly characterized in the currently used Kansas-City-Classification of oesophageal lesions [14]. Only <2% of cases had small oesophageal ulcerations with swift healing tendencies in longitudinal endoscopy studies [15].

There is an ongoing discussion regarding the necessity and safety of oesophageal temperature monitoring even for standard PVI-data published by Deneke, et al. [14,16] even suggested a higher incidence of EDEL in patients that received oesophageal monitoring, caused by either mechanical alterations of the mucosa by the probe, or antenna-like heat induction within the probe. While probe design, modality of temperature measurement, as well as temperature cut-offs remain controversial, other findings published in the large, randomized OPERA trial by the group of Schoene, et al. demonstrate that the peak oesophageal temperature during AF ablation was not predictive for the development of thermal oesophageal lesions, and therefore, temperature monitoring might be omissible [17].

In a 50 W-HPSD context, these findings are supported by the randomized AI-HP ESO II trial by Chen, et al. [18] demonstrating remarkably low EDEL occurrence with our without esophageal temperature monitoring (1 out of 60 patients).

Alertness for EDEL after HPSD ablation was heightened by the power-AF study (using 45 W CLOSE-guided circumferential ablation), reporting of a single ulcerative oesophageal perforation within 19 out of 48 patients that received post-interventional endoscopy [11]. Post-hoc analysis of the concerning patient revealed use of excessive mean-contact force >30 g on the posterior wall. These findings lead to modified recommendations concerning more moderate contact-force targets and adapted stability criteria to avoid delayed VisiTag visualisation, and therefore overshooting the posterior AI-target value.

Since oesophageal perforation always have been an extremely rare, but devastating complication of AF ablation, current experience in treating AF using HPSD settings must be put into context, meaning that single-centre experiences might be misleading due to the rare nature of the complication, and high-volume centers should pool their experience in registries to address these safety issues.

Considering outcome parameters, the state-of-the-art standardized CLOSE protocol-guided atrial fibrillation ablation using 20 W/40 W is able to achieve freedom from Atrial Tachykardia (ATA) in 87% at 12 and 78% at 24 months in patients suffering from paroxysmal AF [6]. Midterm outcomes after 50 W-HPSD CLOSE protocol guided published by Chen, et al. reached promising 96% freedom of Atrial Tachycardia (ATA) at 6 Months in a comparable study cohort. A study relying on 50 W HPSD for 6-8 s posterior and 8-10 s anterior (i.e. non-AI/CLOSE-guided) resulted in 79% ATA freedom at 12 months [19].

While reported overall freedom of AF/ATA varies from different HPSD studies, all reported rates are superior compared to the efficiency data reported in the Fire-and-Ice study 3 for cryo and standard RF procedures, as well as they were superior compared to the AF recurrence rate reported in the CABANA trial 2, the largest randomized RF ablation trial to date. HPSD ablation protocols guided by biophysical indices seem superior regarding efficacy. However, all reported outcome and safety-data should be considered experimental and preliminary, as they rely on cohorts of 50-100 patients and represent mostly single-center experiences.

The current understanding of HPSD lesion formation and preliminary outcome data, both concerning efficacy, efficiency and safety, are highly promising, and warrant larger multi-center trials. Of further note, the highly standardized protocols and ablation end-points described in the pivotal AI-guided HPSD studies allow for an excellent inter-operator comparability previously only achieved with single-shot devices, making HPSD-ablations the “close-to-perfect-fire-and-forget” tool for first-time therapy of AF.

Novel ablation catheters currently under evaluation, like the Biosense Webster QDot, allow for potentially even faster “very-

HPSD” ablations using the QDot-Plus mode with 90 W/4 s lesions. While preliminary data from the QDot-fast trial was promising, yet not superior to current 50 W-HPSD ablations, the technology is still not released to open-marked, and lesion-index guidance has not been evaluated-whether new catheter designs will further improve RV delivery in the >50 W setting remains up to evaluation [20].

Most EPs believe pulsed field ablation to be the next cornerstone in ablation technology, and preliminary reports are very promising concerning procedure times and rates of acute-PVI, while midterm efficacy and safety is still under consideration, since the technology itself is less established than RF technology.

## CONCLUSION

Until pulse-filed-ablation becomes “ready for prime time”, high-power-short-duration radiofrequency ablation, especially when guided by biophysiological markers like the AI, might rise to be the standard of care. While mid-term outcome data is highly promising, large randomized multi-centre studies are required to pool current experiences and validate oesophageal safety. Meanwhile, HPSD workflows are adopted by a growing number of EP cath-labs, giving us the opportunity to treat our AF patients faster, and more sustainable than ever before.

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