

Atrial fibrillation ablation: pitfalls and potential solutions

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Valorisation



Valorisation

Summary

This thesis may help to reduce the complications of current treatment modalities for the most common heart arrhythmia, i.e., atrial fibrillation (AF) during a hybrid procedure and a cryoablation, increase the success rate and standardize the procedure for a possible general adoption in the future.

New parameters for ablation: Recurrence of arrhythmias is due to incomplete, non-uniform and non-transmural lesions causing the conduction of unwanted electrical impulses. Addition of a new parameter like "temperature time integral" (TTI) to existing cryoablation, can help to further describe its efficacy in a better way. Even for epicardial lesions using radiofrequency, addition of contact force parameters may help in achieving uniform lesions.

Automation: To standardize a procedure and make it free of operator-dependent errors, and their respective learning curve, "Automation" must be introduced in the hybrid procedure setting to make it more efficient. Further, new combinations of energy sources can be tested to make a better ablation line and increase its success rate.

Least invasive lesions: To make minimally invasive cardiac surgery (MICS) less invasive by possibly using holes (making this a single-sided approach) to access the heart to put ablative lesions and if possible limit them to one side only.

Contiguous and transmural lesions: Cox Maze IV has the highest success rate among all procedures. The single important limitation to replicate this procedure is the non-uniform and/or non-transmural lesion (either endocardial alone or in a minimally invasive setting).

Relevance

The most common arrhythmia worldwide is AF with an incidence of 6 million patients in the United States. AF is a major cause of stroke and an independent risk factor for mortality. Despite advances in medical therapy, it has only been effective in restoring sinus rhythm (SR) in half of all the patients with AF. This disease entity also independently predicts the risk of death, hospitalization, stroke, and all-cause mortality. The global prevalence and costs of AF are expected to surge owing to factors such as economic growth, an ageing population, and increased prevalence of risk factors for AF in both Western countries and rapidly developing countries such as Brazil, China, India, and Indonesia.

Epidemiological and clinical studies have also proven that AF is a strong independent risk factor for stroke, exposing patients to a 3- to 5-fold increased risk. Uncontrolled AF may contribute to the development of chronic heart failure. Due to the increasing age of the general population, the AF burden will grow further. By the year 2050, there will be a 2.5-fold increase in the number of affected US adults, resulting in almost 6 million patients and half of them will be 80 years or older.

Target groups

My work can be of special interest to the arrhythmologists and health care providers who use these techniques for treating patients with AF. It may give them insight into how to achieve better success rates, and avoid the complications.

Inherently to my theme of research, this work might also interest the patient who undergoes such procedures, their well wishers including family members, and relatives too. Opting for ablation therapy not only affects the procedural outcomes, e.g., complications and success rates, but also can help to restore faith in the medical community due to the AF burden.

These research results should interest medical companies because of the favourable outcomes this novel device may bring about. It could help them technically modify and improve their product that we have discussed in various chapters of the thesis.

Activities/Products

With the findings regarding complications, a cryoballoon (Medtronic, Inc) can be made safer for clinical use. Furthermore, a new parameter, i.e., temperature-time curve can be used during cryoablation. The new parameter may give a more realistic approach for an effective cryotherapy.

Moreover, one of the chapters describes the unique combination of epicardial and endocardial ablation; the real contrasts of radiofrequency and freezing in the same patient for the first time. This opens a whole new window of opportunities for device makers to explore this domain and to attempt different energy combinations.

The possibility of using hot water/steam in a balloon based catheter as an ablative medium rather than using nitrous oxide or laser can be attempted.

One of the suggestive combinations is a cryoballoon with thin electromagnetic wafers which will be placed inside PVs and epicardially another energy source, e.g., a cryo probe or radiofrequency probe would be attached and then ablation will be done. By

using this hybrid approach and acting on both sides of the heart, transmural of the ablation lesion created might ultimately become better, thus transforming to better success rates. Simultaneous use of an epicardial and an endocardial energy source may be better employed to complement each other for different purposes, e.g., not only for pacing but also signal detection. “Automation of an electrophysiological procedure” is the key to increasing the efficiency of the staff members and an institution. I really believe in the concept of a fusion device that combines a pacemaker (as it can detect signals as PV potential) after pacing from an endocardial coronary sinus (CS) catheter, and an epicardial ablation system placed around the target PV (with inner surface divided into 5-6 segments). A small current will be sent from the CS catheter and the sensors in the epicardial device would detect the PV potential using the same algorithm of the pacemaker. And whichever segment of the device detects them, it would start to automatically and selectively ablate in only that segment.

Innovation

TTI is a new parameter that has never been used for cryoablation.

To standardize a procedure and make it free of operator-dependent errors and their respective learning curve, “automation” must be tried in a hybrid procedure setting to make it more efficient. This can be achieved easily based on existing technologies which are used in a modern pacemaker- everything that is needed is to modify them suitably and test them further. For physicians, both electrophysiologists and surgeons, the procedures will become less complex. More importantly, the possibilities to get information on the mechanisms of AF from a completely new perspective may potentially bring about a patient-tailored ablation approach, making it more affordable.

Schedule & Implementation

Development of the new parameter of TTI may take up to 16-18 months including 5-6 months for development of a new program and later finally testing it to see its effect and annual success rate.

However for the rest it may take 2-3 years minimum with the aims of developing and evaluating this platform of new instruments. To obtain the functionality needed, existing technologies can be used and combined. Previously developed animal models in our institution will facilitate this tract. In addition, the presence of a hybrid intervention room offers the right conditions to evaluate results in humans. In parallel to the tool development part of the program, patient-related mechanisms of AF would be studied from a new perspective as mapping studies could be performed simultaneously from the inside and outside of the atrial wall. This approach is necessary

to enhance our knowledge of AF as the mechanism of AF is considered three dimensional in nature.

Patents

There is neither a European nor US patent existing on these concepts.