Ablation of Chronic paroxysmal atrial fibrilation: New energy sources, results, complications and future perspectives" THESIS

Submitted for partial fulfillment of MD degree in Cardiology

By

Mohamed Abd El-Fattah Mohamed Kandil, MSc

Under Supervision of

Hussien Hasan Rezk, M.D.

Professor of Cardiology,

Cairo University

Soliman Gareeb Ibrahim, M.D.

Professor of Cardiology,

Cairo University

Reda Hussien Dyab, M.D.

Lecturer of Cardiology,

Cairo University

Faculty of Medicine Cairo University 2015 Ablation of Chronic paroxysmal atrial fibrillation using cryoablation technique: Sources, results, complications and future perspectives"

Introduction AF patients require frequent clinical visits for adjustment of their medication and monitoring of anticoagulation treatment. This type of arrhythmia is also associated with increased numbers of emergency room visits, hospitalizations, and numerous procedures. Even in comparison with patients matched for age and the presence of cardiovascular disease. Due to symptoms and the risk of ischemic stroke in elderly patients, this type of arrhythmia is a source of considerable concern. AF patients have medical costs. The economic repercussions on national health systems around the world are considerable.

The aim of our study was to: 1) Compare the outcome of these two new devices in AF ablation, 2) Evaluation and analysis of both intra-procedural as well as post-procedural complications and 3) Follow up of recurrence of AF in those patients after (3, 6 and 12 months)

Patient & methods Our study included 200 patients presented with either paroxysmal or persistent AF who were divided into 2 groups according to the device used for ablation.

- a) **Gruop 1 patients: Cryoablation** was used for ablation, it included 130 patients (65%).
- b) Group 2 patients: Ablation Frontiers using novel decapolar ablation catheter (PVAC) was used for ablation it included 70 patients (35%).

Results: By Comparing the two study groups, The Overall success rate was nearly similar being 84.6% for Cryoablation technique versus 84.3% for Ablation Frontiers using novel decapolar ablation catheter (PVAC). As regards the procedural time: PVAC had less procedural time 142 ± 27 versus 172 ± 33 for cryoablation and also less fluoro time 25.6 ± 6 for PVAC versus 32.5 ± 7 for cryoablation (P value <0.001). This may be related to the more time consuming preparation of the cryoballoon catheter. The higher fluoroscopy exposure observed for the cryoablation is a clear disadvantage and may be explained by the many repositioning and the need for fluoroscopy during the ablation to ensure catheter stability. **Procedural complication:** There were few adverse events in our study 2 groups. This study demonstrated comparable outcomes with respect to immediate success (pulmonary veins isolation) and procedural complications (atrial tachycardias, phrenic nerve palsy, pericardial effusion and/ or tamponade) as compared to other studies regardless of the atrial fibrillation classification.

Key words: Cryoablation.PVAC,AF ablation, PV isolation

ACKNOWLEDGMENTS

First of all, I would like to express my deepest gratitude to Prof. Dr. *HUSEIN RIZK*, professor of cardiovascular medicine, for his kind support and valuable guidance all through the course of conducting this thesis.

I am greatly indebted to Prof. Dr. *SOLIMAN GHAREEB*, professor of cardiovascular medicine, for his inspirational instructions, contributed ideas and continued advice throughout this work.

I would like to acknowledge the support and assistance provided by Dr. *REDA DIAB*, Lecturer of cardiovascular medicine, for his continued advice, support that aided me a lot.

I would like to express my deepest gratitude for my wife and my father for their great support to accomplish this work.

Also I would like to thank electrophysiology group in **Hannover MHH University**, **Germany Dr.Gunnar Klein,Dr Hanno Oswald And Dr.Gardiwal** for their great effort in learning me and helping me in this thhesis

Finally, special thanks to my colleagues and co-workers who aided me during data collection.

MOHAMED ABD EL FATTAH

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Introduction:

Pulmonary vein (PV) isolation with radiofrequency (RF) has been widely used for the interventional treatment of atrial fibrillation (AF)¹.

Ablation of atrial fibrillation (AF) is one of the most time consuming procedures in interventional electrophysiology. Currently, the selection of catheters and ablation techniques is still a matter of debate. Due to the rapidly increasing demand of ablation procedures, technical advances would be helpful to reduce complexity and procedure time in AF ablation.

The success rates of these procedures vary between 65% and 85% in patients with paroxysmal AF depending on technique used, patient selection, and experience of the center²⁻⁴.

These results lead to a change in the guidelines on AF (2006), which recommend AF ablation as a class IIa indication for patients with paroyxsmal AF without structural heart disease and refractory to medical antiarrhythmic treatment⁵.

However, the complication rate of RF AF ablation is still high, and complications include PV stenosis, thromboembolic events, pericardial effusion, left atrial flutter, and atrioesophageal fistulae⁶.

Cryoenergy has potential advantages compared with RF with regard to safety aspects. It has been shown that cryoenergy does not lead to PV stenosis, has never been associated with atrioesophageal fistula, and has a lower thrombogenicity⁷⁻⁹.

However, cryoablation of PVs by standard steerable catheters would be very time-consuming considering that one single ablation point takes about 4 minutes¹⁰.

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A cryoballoon device now enables us to circumferentially isolate one single vein, which makes cryoablation of PVs faster and feasible. Thus, this new device raises expectations that cryoablation of PVs might be achieved with the same speed as with RF energy but that cryoablation is potentially associated with a better risk profile¹.

The feasibility of a novel decapolar ablation catheter (PVAC) combined with a duty-cycled, low-power RF generator for pulmonary vein (PV) isolation. The system does not require 3D mapping and is the first to enable mapping, pacing and circular as well as segmental ablation with a single catheter¹¹.

Aim of the work

The aim of this work was to study:

- 1. The outcome of the new devices for ablation of paroxysmal and persistent AF.
 - a) Cryoablation.
 - b) Ablation Frontiers using novel decapolar ablation catheter (PVAC).
- 2. Evaluation and analysis of both intra-procedural as well as post-procedural complications.
- 3. Follow up of patients after ablation at 3, 6 and 12 months.

Chapter 1:

Atrial fibrillation ablation

Catheter ablation strategies for the treatment of atrial fibrillation (AF) have been in a process of continuous development since 1996, and catheter ablation is now regarded as an established therapeutic approach to this frequent form of arrhythmia ^(12–14). According to a recent study in the USA, AF affects one in 25 adults aged 60 or over and nearly one in 10 adults aged 80 or over. Due to symptoms and the risk of ischemic stroke in elderly patients, this type of arrhythmia is a source of considerable concern, and its impact is likely to increase as the number of individuals affected by AF rises nearly 2.5-fold during the next 50 years⁽¹⁵⁻¹⁷⁾.

The economic repercussions on national health systems around the world will be considerable. AF patients require frequent clinical visits for adjustment of their medication and monitoring of anticoagulation treatment⁽¹⁸⁾. This type of arrhythmia is also associated with increased numbers of emergency room visits, hospitalizations, and numerous procedures. Even in comparison with patients matched for age and the presence of cardiovascular disease, AF patients have medical costs that are approximately \$2500 higher per patient year⁽¹⁹⁻²⁰⁾.

These observations show that it is imperative to promote coordinated efforts on behalf of cardiologists, electro physiologists, neurologists, and primary-care providers to meet the increasing challenge of stroke prevention and rhythm management in the growing population of patients with atrial fibrillation⁽²¹⁾.

The AFFIRM issue:

The Atrial Fibrillation Follow-Up Investigation of Rhythm Management (**AFFIRM**) study demonstrated that a rhythm control strategy conferred no survival advantage over rate control in patients with AF who had risk factors for stroke ⁽²²⁻²³⁾. However, drug inefficacy or adverse drug effects, or both, could easily account for theabsence of a survival benefit with rhythm control.

In 2003,it was reported that circumferential pulmonary vein ablation (CPVA) is associated with advantages with regard to mortality and morbidity rates in comparison with medical therapy alone ⁽²⁴⁾. They found that in both the ablation and antiarrhythmic groups, sinus rhythm (SR) maintenance was associated with significantly lower mortality and adverse event rates.

This called into question the results of three recent AF trials the Pharmacological Intervention in AF (PIAF), AFFIRM, and Rate Control versus Electrical Cardioversion (RACE) studies that demonstrated, contrary to prevailing practice, that rhythm control conferred no advantage over heart rate control by drugs (25-26).

On the one hand, these conflicting results could be explained by the fact that it is difficult to compare the study directly with others, as the patient populations were inevitably different⁽²⁴⁾. The RACE and AFFIRM studies only enrolled older patients with one or more risk factors for stroke, most of whom had persistent AF⁽²⁵⁾. Younger patients with structurally normal hearts and paroxysmal arrhythmia were disproportionately poorly represented in these trials, and the results cannot be generalized to a broader AF population⁽²⁷⁻²⁸⁾. Curing AF and maintaining SR may therefore still be the goal, at least in some groups of patients.

On the other hand, it is intrinsically unlikely that SR is *per se* harmful to the patient's life, and one could argue that the warning trend toward a higher risk of death in the rhythm