

Bipolar biparietal bidirectional application of radiofrequency in experimental in vitro/in vivo environment

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Impact Paragraph

Atrial fibrillation (AF) is worldwide the most common arrhythmia in adults. In 2016, 43.6 million people were affected by AF/atrial flutter¹. The prevalence is greatly age-related, and due to the increased life expectancy, it is expected to strongly rise in future decades. Remarkably, many common pathologies typical of that age such as diabetes mellitus, hypertension, obesity, chronic kidney disease, and valvular disease are risk factors for AF, and so the prevalence could be higher². AF is strongly correlated with cardiac comorbidities, increasing 3 to 5 fold the risk of stroke, left ventricular dysfunction and heart failure in up to 30% of AF patients³⁻⁶, and 1.4 to 1.6 fold the risk of cognitive decline and vascular dementia⁷⁻¹⁰. Even depression to the extreme suicidal ideation is present in 16 to 20% of AF patients¹¹⁻¹³. The immediate consequence of this impaired quality of life is a socio-economic and public health burden¹⁴⁻¹⁶.

Pulmonary vein isolation is the conventional treatment in patients with paroxysmal AF, but in the more complicated forms, such as longstanding or permanent AF, the interventional approaches, either endocardial catheter or epicardial thoracotomy ablation, still have not been shown to fully satisfy the scientific community's requests in terms of elimination or decrease of the symptoms and restoration of an acceptable quality of life.

Treatment of the above forms is challenging because the interventional cardiologists do not have the proper tools to create reliable scars¹⁷. Transmurality achievement represents the undisputable characteristic that ablation lesions should have to ensure a durable block of aberrant electrical pathways. This evidence urges the scientific community and medical companies to find a new way to approach the problem.

Target groups

The aim of this thesis was to explore different technical possibilities to reduce at a minimum relapse in post-procedural patient lives.

The direct effects of the above said is that there is great improvement in the quality of life in a broad sense, including subsequently renovated social relationships due to an improved psychological outlook and optimistic view of the future. From a clini-

cal point of view, ending the progression of the pathology may cause the comorbidities of AF to have a lighter impact on life expectancy.

The possible technical improvements in the treatment of AF may be, if possible, more impacting on the Public Health System. Indeed, it has been estimated that the number of patients with AF in 2030 in Europe will be 14-17 million. By that time, AF will have been responsible for 3.5-4 million hospitalizations and 100-120 million outpatient visits². For example, in the Netherlands, the total cost of AF is estimated to be more than 580 million euros most of which (70%) was for hospitalizations and in-hospital procedures which accounted for 1.3% of the national healthcare budget in 2008^{18, 19}. Such a dramatic social and economic impact is significantly increased by AF recurrence, which imposes a substantial extra-cost burden on the healthcare system due to its increased morbidity, mortality, associated therapeutic interventions as well as other costs such as costs of monitoring, anticoagulation status, AF-related complications and side effects from drug therapy as well as psychological support for patients.

Output

A new technical strategy needs to involve multidisciplinary studies so that it could be admitted to clinical use. Our findings may spur new entrepreneurial activity involving external companies in the study of advanced biomaterials to fit the scientific community's request.

Moreover, the potential of the biparietal technique may define a new generation of tools specifically developed for those treatments, overcoming the dogmatic definitions of endocardial and epicardial tools. Indeed, a new design approach strategy may include multiple functions like pacing and treating in a single device, which today are truly not yet embodied in a unique device.

Likewise, the thesis results showed how the use of magnetic force might represent a possible method to ensure a firm contact force during the radiofrequency delivery. In a broader overview, the modulation of forces through the use of electromagnets could ensure perfect contact independently of the thickness of the tissue. The need for miniaturization and biological impact assessment for clinic applications could lead to the development of a new strategic sector of study, also involving electrophysiology for sensing function as well as informatics expertise to develop an algorithm to control all the processes from electrical evaluation of the tissue to be ablated and corresponding tailored output.

The use of biparietal radiofrequency may also represent a new possible application in all those intramural pathologies affecting hollow organs, like cancer of the stomach, bowel, uterus, etc.

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