Patient-reported outcomes following ablation for atrial fibrillation in the era of digital health

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Over the last two decades, significant progress has been made in our understanding of the pathophysiology of atrial fibrillation (AF) and its pharmacological and non-pharmacological treatment [1].In patients with paroxysmal and persistent AF, where conventional anti-arrhythmic pharmacotherapy has significant limitations as a rhythm control strategy, pulmonary vein isolation (PVI) catheter ablation procedure with its high success rate has emerged as the standard of care. A major outcome measure of the ablation procedure that has been commonly used in randomized trials and meta-analyses to gauge success is the post-procedure recurrence of arrhythmia detected clinically or by digital technologies. However, patient-reported outcomes (PROs) which are comprehensive quality metrics comprising health-related quality of life (QoL) scores; physical, emotional, and cognitive functions; symptom severity; exercise tolerance; and ability to work, have not received much emphasis. Arguably, these PROs are as important as the "hard" clinical endpoints namely death, stroke, and major bleeding that are used in the clinical trials [2, 3].

The question, whether emerging digital technologies could be exploited to their full capacity to provide real-time patient metrics for early recognition of recurrence or complications of the procedures and seamless assessment of the efficacy of therapy and to improve engagement between patients and the health care providers toward the final goal of overall improvement of patient care, remains unanswered.

As seen in the other fields of medicine, a parallel growth of cutting-edge advanced digital technologies especially machine learning and artificial intelligence and the availability and usage of numerous health applications (apps) on tablets and smartwatches is evident in the current contemporary specialty of AF arrhythmology. Early detection of AF by smartwatches demonstrates the feasibility of wider usage of digital technologies in AF management [1]. A mobile smart device web–based app could prove particularly useful in the management of AF in a post-ablation setting. To that end, in the publication by Molon et al. [4], in the current issue of the journal, the authors analyze the utility of a mobile smart device web–based app for patient-reported outcomes and its correlation with AF recurrence after pulmonary vein isolation (PVI) by cryoablation (PVI-C) for AF.

The study (1STOP—participating to the One Shot TO Pulmonary vein isolation) cohort consisted of patients undergoing PVI-C in the midst of the COVID-19 pandemic period. Healthcare delivery was particularly challenging during this time due to severe lockdown restrictions and pandemic-related concerns. To obviate some of the complexities of AF management, certain innovative measures and remote monitoring were utilized during the COVID-19 lockdown [5]. In the 1STOP study, patients were enrolled from 7 Italian centers that were participating in a new smartphone app, the MYCRYOAPP utility project. The study cohort of 865 patients was divided into (a) the app group: 41% of patients and (b) the no-app group: 59% of patients. The two groups were not comparable for age, sex, type of AF, and body mass index. At a mean follow-up of 7.9 ± 13.8 months, detection of AF recurrence was higher in the app group versus the no-app group (10.99% vs. 7.36%). Among patients in the app group, reporting of "feeling bad" was independently associated with AF recurrence on follow-up.

The authors are to be commended for executing this large study with low dropout rates, in the midst of a pandemic.

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The study emphasizes the utility of novel technological applications in electrophysiology to collect PROs in post-ablation patients and demonstrates the association between PRO and AF recurrence. The questionnaire, though, has not been well validated, appears to be much faster, and is simpler and user-friendly compared to traditional patient questionnaires, which likely explains the strong compliance seen. In essence, since AF-related symptoms are one of the main indications for AF ablation, PROs as in this study's findings in our view are equally impactful and relevant than rhythm-related endpoints used in AF ablation trials. There are several limitations of this study that are noteworthy. The non-randomized design opens up room for selection bias, resulting in unbalanced patient characteristics such as compliance, engagement, educational level, family support, and socioeconomic status thus impacting the outcome of the study. This is particularly important given the importance of behavioral characteristics in dictating patient behavior and reporting practices. Given the added emphasis on self-care and health during the pandemic, one would wonder whether the study's results would be replicated in the current age with a resumption of normal clinical care. Furthermore, the generalizability of these findings to more resource-limited settings with poor access to mobile internet remains in question.

While the study by Molon et al. [4] highlights the feasibility and utility of collecting patients' self-reported outcomes, especially in a post-procedural setting, it also serves as an important complement to existing digital health tools available for AF patients. In the current landscape of AF-related digital health, while several challenges have been identified, many unique opportunities have emerged. For example, the most updated roadmap initiative by the World Heart Federation emphasizes the widespread use of smartphones and apps to facilitate improved healthcare delivery and community AF awareness, with the goal of reducing death and disability related to AF [6]. The CATCH ME (Characterizing Atrial fibrillation by Translating its Causes into Health Modifiers in the Elderly) consortium, in collaboration with the European Society of Cardiology (ESC), has funded the creation of two AF apps, one for patients and the other for health care professionals [7]. The patient app aims to enhance patient education, improve communication with healthcare professionals, and encourage active patient involvement in the management of their condition. The healthcare professional app is an interactive tool incorporating the new ESC Practice Guidelines on AF and is supported by the European Heart Rhythm Association [7]. There is a distinct need to shift the focus of emerging apps from appearance to core functionality. As shown by Turchioe et al. [8] app quality appears to be highest in terms of their ease of use, navigation, layout, and visual appeal (for example, functionality and aesthetics) and

lowest for the more important aspects of behavioral change support and subjective impressions of quality.

The future is rife with opportunity, and the alliance of emerging technology with clinical cardiology will undoubtedly reshape how we perform clinical trials, while also impacting the delivery of care. Going forward, the utility of PROs and how to use them in clinical decision-making will need to be better defined. The granular data provided by these apps and wearables will increasingly dictate patient selection, follow-up, and prognostication of these patients. The work by Molon et al. [4] demonstrates the positive impact of novel and innovative technology use in clinical practice.

Declarations

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