**Title**: Digital Monitoring and Electronic Patient-Reported Outcomes Collection Following Atrial Fibrillation Ablation.

**Authors**: João G. Almeidaa, b (MD), Rafael Teixeiraa (MD), Paulo Fonsecaa (MD), Marco Oliveiraa (MD), Helena Gonçalvesa (MD), João Primoa (MD), Ricardo Fontes-Carvalhoa, c (MD, PhD), Sérgio Barrad (MD, PhD), Juan Pablo Martíneze, f (PhD), Rute Almeidab (PhD).

**Affiliations**

a Cardiology Department, Unidade Local de Saúde Gaia Espinho, Vila Nova de Gaia, Portugal.

b CINTESIS@RISE, Department of Community Medicine, Information and Health Decision Sciences, Faculty of Medicine, University of Porto, Porto, Portugal.

c UnIC@RISE, Department of Surgery and Physiology, Faculty of Medicine, University of Porto, Porto, Portugal.

d Luz Arrábida Hospital, Vila Nova De Gaia, Portugal.

e Aragon Institute of Engineering Research (I3A), IIS-Aragon, University of Zaragoza, Zaragoza, Spain.

f Centro de Investigación Biomédica en Red – Biomedicina, Bioingeniería y Nanomedicina (CIBER-BBN), Zaragoza, Spain.

**Institution where the study was conducted**: Unidade Local de Saúde Gaia e Espinho, Portugal

**Corresponding author**:

João Gonçalves Almeida

Rua Conceição Fernandes, 4434-502 Vila Nova de Gaia, Portugal.

Orcid ID: 0000-0001-9434-7061

E-mail: [joaotgalmeida@gmail.com](mailto:joaotgalmeida@gmail.com)

**Word count**: 3429.

**Funding**: This research received no specific grant from public, commercial, or not-for-profit funding agencies.

**Conflict of Interest**: none declared.

**Data Availability Statements**: The data underlying this article will be shared on reasonable request to the corresponding author.

**Ethics approval/patient consent statement**: This study was conducted in accordance with the ethical principles of the Declaration of Helsinki. The Unidade Local de Saúde Gaia e Espinho's ethical committee approved the study protocol, and written informed consent was waived due to the study’s retrospective design.

# abstract

**Introduction:** Atrial fibrillation (AF) remains a challenging condition to manage traditionally in clinical practice, and despite improvements in digital health, its impact on clinical outcomes remains uncertain. This study aims to assess the feasibility of a structured digital-blended follow-up for AF ablation patients, incorporating electronic patient-reported outcomes measures (PROM) while evaluating its impact on one-year clinical outcomes.

**Methods:** In this retrospective observational study, we included patients enrolled in a structured two-year digital program starting in January 2021. This featured a web platform for physicians to record clinical variables and a patient-centred mobile application to report PROM (AFEQT and PROMIS). Clinical outcomes were compared with those from a retrospective conventionally managed cohort (2017-2020) after propensity score matching (n=363 per group).

**Results:** Until May 2024, 421 patients were enrolled (mean age: 60.9 years; 33.0% female). Over a median follow-up of 546 days, 64% of patients used the app monthly, and completeness rates for AFEQT and PROMIS questionnaires were 80 and 50%, respectively. At 12 months, significant improvements were observed for AFEQT and PROMIS scores (Cognitive and Physical Function, Anxiety, and Depression). Arrhythmia recurrence significantly influenced the rates of changes for AFEQT, Depression, and Physical Function (p<0.05 for interactions). One-year clinical outcomes were similar between matched groups, although the median time to anti-arrhythmic intervention after AF recurrence was significantly lower in the digital group (-126 days, p<0.001).

**Conclusion:** Systematic electronic PROM collection after AF ablation is feasible in clinical practice. Structured digital-blended integrated care guarantees continuity of AF management, facilitating earlier interventions.

**Key Words**: Atrial fibrillation; Digital health; Patient-reported outcomes; Quality-of-life.

### **Abbreviations**

|  |  |
| --- | --- |
| AF | Atrial Fibrillation |
| AFEQT | Atrial Fibrillation Effect on Quality-of-Life |
| CI | Confidence Interval |
| IQR | Interquartile Range |
| PROM | Patient-Reported Outcome Measures |
| PROMIS | Patient-Reported Outcomes Measurement Information System |
| QoL | Quality-of-life |
| SD | Standard Deviation |
| SE | Standard Error |

# INTRODUCTION

Atrial fibrillation (AF) is an increasingly prevalent arrhythmia in adults, with high morbidity and a significant burden on healthcare services, mainly driven by heart failure and stroke.1,2 In selected patients, a rhythm control strategy reduces cardiovascular mortality and heart failure hospitalisations,3 and catheter ablation is a well-established rhythm control treatment that effectively decreases AF burden and significantly improves quality of life in patients with symptomatic paroxysmal or persistent AF.4,5 The conventional care model for these patients has traditionally been physician-centred, but a recent shift has moved towards a more patient-centred approach. Recent advancements in digital healthcare have enabled the development of tools to support the transition to multidisciplinary integrated care, as recommended by the American (Comprehensive Care)6 and the European AF guidelines (AF-CARE pathway).1 Although survival and hospitalisation outcomes are commonly documented in registries and clinical AF trials, patient-reported outcome measures (PROM) remain infrequently assessed despite growing recognition of their importance in this disease management.7,8 Additionally, there are conflicting results regarding the clinical impact of including digital tools in the follow-up of patients after AF ablation. Several models for integrated care have been proposed with mixed results (nurse-led vs. cardiologist-led), probably reflecting different methodologies.9,10

We aimed to describe a real-world implementation of a digital-blended follow-up of patients after AF ablation while assessing the feasibility of measuring electronic PROM throughout the follow-up and evaluating the impact of recurrence on different quality-of-life questionnaires. We further compared the 12-month clinical outcomes of a digital-blended follow-up with those of conventional patient management in the clinic.

# materials & methods

## Study design

This was a non-randomized single-centre retrospective observational study of patients submitted to AF ablation in a Portuguese tertiary hospital centre. Patients older than 18 with paroxysmal or persistent AF who underwent a first ablation between January 2021 and May 2024 were considered eligible. Patients were enrolled consecutively in the digital follow-up program and invited to install the monitoring mobile application one week before the procedure. Exclusion criteria included redo procedures, patients who refused the digital follow-up program, those who failed to install the application, and individuals who were lost to follow-up during the study period (Figure 1). Clinical data were collected using a web platform (Promptly - Software Solutions for Health Measures, <https://promptlyhealth.com>).

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki. The Unidade Local de Saúde Gaia e Espinho's ethical committee approved the study protocol, and written informed consent was waived due to the study’s retrospective design.

## Procedure characteristics

According to the current guidelines, all patients received at least four weeks of oral anticoagulation before the procedure and took it for at least three months. Left atrial thrombi were excluded with cardiac computed tomography on the day of the procedure. Circumferential pulmonary vein isolation was achieved with radiofrequency, second-generation cryoablation, or pulsed-field ablation. All procedures were performed under general anaesthesia. Procedural success was defined as the electrical isolation of the pulmonary veins. Additional lesions were performed at the operator's discretion.

## Follow-up program description

Our digital-blended follow-up program was based on the International Consortium for Health Outcomes Measurement standards11 . It included scheduled visits, telephonic consultations, and remote monitoring through a digital health platform (Figure 2). It featured a web platform for physicians to record baseline characteristics, medication, procedural variables, and clinical outcome measurements and access patient-reported information; a smartphone mobile application (Promptly. Version 2.5.7, Promptly Health, 2024. Apple App Store, https://apps.apple.com. Google Play Store, https://play.google.com) for patients to report symptoms, vital signs (blood pressure and heart rate), anthropometric and electrocardiographic data, and to complete health-based questionnaires. All consultations were conducted by physicians.

Additional program components included AF educational content and lifestyle recommendations, such as physical activity, which are accessible in the mobile application. Patients were advised to perform an electrocardiogram at specific time points, and these were automatically uploaded to the platform. Furthermore, an electrocardiogram was performed at each in-person visit.

## Clinical outcomes

The endpoint of 12-month AF recurrence was defined as time to any atrial tachyarrhythmia recurrence lasting ≥ 30 seconds. The first eight weeks of follow-up were defined as the blanking period, and arrhythmia recurrences occurring in this period were censored. There were two additional endpoints: i) time to anti-arrhythmic intervention, defined as the reintroduction of antiarrhythmic medication, a new ablation procedure, or electrical cardioversion, and ii) time to healthcare utilisation, including electrical cardioversion, new ablation procedure, cardiovascular hospitalisation or admission to the emergency department.

To assess the time interval between the onset of a significant arrhythmia recurrence and the subsequent anti-arrhythmic intervention, we calculated the time difference (in days) between those dates.

## Patient-reported outcomes

The Atrial Fibrillation Effect on Quality-of-Life (AFEQT) questionnaire is a validated PROM specifically designed to assess the impact of AF on a patient´s quality-of-life (QoL).12 It is beneficial after AF ablation to assess both symptom improvement and broader life impacts. The AFEQT questionnaire consists of 20 questions covering four main domains: symptoms, daily activities, treatment concerns, and treatment satisfaction. The score is calculated with the first three domains and ranges from 0 to 100, where higher scores indicate better QoL and lower scores higher disability. The Portuguese version of the AFEQT was previously validated.13 An improvement of at least 5 points in the AFEQT score was considered clinically significant.14 Patients received notification for completing the AFEQT questionnaire on the application at enrollment, one, three, six, 12, 18, and 24 months of follow-up.

Patient-Reported Outcomes Measurement Information System (PROMIS) is a set of standardised tools used to evaluate various aspects of a patient´s health condition that utilises Item Response Theory. In this study, four PROMIS short forms (four questions) questionnaires were collected: Cognitive Function (v2.0),15 Emotional Distress-Anxiety (v1.0),16 Physical Function (v2.0),17 and Emotional Distress-Depression (v1.0).16 Each domain uses a T-score system where scores above or below 50 indicate a higher or lower function relative to a relevant reference population. We used the Portuguese versions of these formularies. For scoring, we used the HealthMeasures Scoring Service web-based application. Patients received notification for completion of PROMIS questionnaires on the application at enrollment, six, 12, and 24 months.

At 12 months, patients were deemed non-responders if they failed to submit the AFEQT questionnaire on at least two occasions. This group was compared with the responder group. The completeness rate was defined by the ratio of questionnaires completed/sent at each time point.

## Retrospective propensity-matched cohort

The conventional group included all patients from our retrospective registry who underwent a first ablation procedure between January 2017 and December 2020 (n=535). Clinical, procedural, and follow-up data were collected from hospital records. Patients from this group were followed in the outpatient clinic in our centre or the referring hospital; decisions regarding the frequency of visits and clinical management were made at the referring physician’s discretion. The evaluation of outcomes for this cohort was based on the national health information platform. This centralised database tracks public healthcare interactions, including hospital stays, outpatient visits, diagnostic exams, and prescribed medication.

## Statistical analysis

﻿ Continuous variables are expressed as mean ± standard deviation (SD) or median ± interquartile range (IQR), as appropriate. Assessment of normality was performed by graphical visual analysis (histogram and QQ-plot). Accordingly, the Student’s t-test and Mann-Whitney test were used to compare numerical variables. Categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate. The AFEQT and PROMIS scores were analysed using a repeated-measures linear mixed-effects model with scores as outcome variables and time, 12-month arrhythmia recurrence, and time x 12-month arrhythmia recurrence as fixed effects. Random effects included intercepts, adjusting for individual baseline differences. Restricted maximum likelihood estimation with an unstructured covariance matrix and Kenward-Roger degrees of freedom approximation was used. No data imputation was performed. Mean differences with 95% confidence intervals (CI) between baseline and 12 months were estimated for the groups: recurrence and no recurrence.

We performed propensity-score matching to deal with the covariate imbalance between digital and conventional groups and reduce confounding bias. A propensity score-based 1:1 match was done with the nearest-neighbour method (further details in supplementary data). Survival analysis was performed using Kaplan-Meier curves and log-rank tests alongside Cox proportional hazards models with matching weights to adjust for the propensity score matching. Treatment effects were estimated with marginal hazard ratios and clustered-robust standard errors, accounting for dependencies within matched pairs.

Statistical tests used two-sided p-values, and the significance level was 0.05. Analysis was performed using R statistical software 4.4.1 (Foundation for Statistical Computing, Vienna, Austria).

## RESULTS

## Baseline characteristics and clinical outcomes

Between January 2021 and May 2024, 421 patients were enrolled (mean age 60.9±14.5 years, 33.0% female, 71.5% with paroxysmal AF) (Table 1). Pulmonary vein isolation was performed mainly with radiofrequency (74.0%), successfully achieved in 98.1%. In 21.9%, additional lesions were performed. Procedure complications occurred in 10 patients (2.4%): 4 femoral hematomas, one pericarditis, three transient phrenic nerve palsies, and two pericardial effusions (resolved with pericardiocentesis).

The median follow-up duration was 546 days (IQR 519 days). During follow-up, 59.6% of patients interrupted antiarrhythmic drugs, while 35.9% stopped oral anticoagulation. Emergency department visits occurred in 41 patients (9.8%), two requiring hospitalisation, and healthcare utilisation was reported in 68 (16.2%). A new procedure was performed in 22 patients (5.3%), and 50 (11.9%) required an anti-arrhythmic intervention.

Until May 2024, 251 patients completed at least one year of follow-up, and the 12-month recurrence was 16.4%. A total of 1620 appointments were carried out, 75.4% of which were remote consultations. The median number of remote and in-person appointments per patient was 3 and 1, respectively.

## App utilisation and Health-related questionnaires

The app was used at least monthly by 64% of patients. At least one remote electrocardiogram was uploaded for 24.1%. We found a median completeness rate of 80% for the AFEQT (proportion of completed questionnaires to those sent). A total of 1213 AFEQT questionnaires were analysed, and 82.5% of the population had ≥ two fulfilled questionaries, meeting the criteria for responders. When comparing non-responders with responders (Supplementary Table 1), we observed that non-responders were older (63.1 vs 60.0 years, p=0.007) and more often had persistent AF (36.4 vs 20.3%, p=0.022). Responders and non-responders had no significant statistical differences regarding clinical outcomes (Supplementary Table 2).

The mean AFEQT score (lower score indicates a higher disability) at baseline was 57.2 points (SD 22.7), and there was a significant increase at 12 months, with +19.5 points (95% CI, 15.3-23.7 points, p<0.001), indicating improved QoL. The mean adjusted difference was +13.2 points (95% CI, 10.5 to 16.0 points, p<0.001), and 70.8% of patients showed a clinically meaningful improvement in the AFEQT score. Regarding PROMIS, we analysed 1920 questionnaires, and the median completeness rate of each short form was 50%. We observed a significant increase in physical function (+3.9 points, 95% CI, 2.5 to 5.4 points, p<0.001) and cognitive function (+1.9 points, 95% CI, 0.5 to 3.2 points, p=0.006), and a significant decrease in depression score (-2.6 points, 95% CI, -3.9 to -1.2 points, p<0.001) and anxiety score (-4.2 points, 95% CI, -5.7 to -2.7 points, p<0.001) (Figure 3B).

For both AFEQT and PROMIS Anxiety, Depression, and Physical Function questionnaires, the magnitude of improvements in QoL was significant in patients without AF recurrence (Table 2). There was a statistically significant interaction between the variables, time and 12-month arrhythmia recurrence status, for AFEQT, PROMIS Depression and Physical function, meaning that this status influenced the rates of change in scores (p<0.05 for interactions). In the group of patients with 12-month arrhythmia recurrence, there were no significant mean adjusted differences between baseline and 12 months for the AFEQT score, PROMIS Anxiety, Depression, and Cognitive function. However, a significant decrease in physical function was observed.

## Comparison with retrospective cohort

After propensity-score matching, we observed similar baseline characteristics between groups, with 363 patients each (Supplementary Table 3). The median follow-up of the digital group was significantly lower (546 vs 1021 days, p<0.001). Nevertheless, 197 patients in the digital cohort completed one year of follow-up. The clinical outcomes at 12 months were comparable (Table 3). At one year, a documented atrial tachyarrhythmia occurred in 14.9% of the digital group and 18.5% of the conventional group, without differences in time-to-event hazard ratios and Kaplan-Meier curves (marginal HR 1.25, cluster-robust standard error of 0.20, p = 0.247), as shown in Figure 4A. There were also no differences in the composite endpoints of healthcare utilisation (Figure 4B) and antiarrhythmic intervention (Figure 5A). However, in patients who underwent an antiarrhythmic intervention (reintroduction of antiarrhythmic medication, cardioversion, or new ablation), the time from the recurrence to the intervention was significantly lower in the digital group (-126 days, p<0.001), as depicted in Figure 5B.

# discussion

This study describes a real-world implementation of a digital-blended structured follow-up for patients after AF ablation. We successfully included more than four hundred patients, revealing high inclusion rates (86.2%) and low rates of patients lost to follow-up (3.9%). The systematic collection of electronic PROM was feasible, with high completeness rates, enabling the observation of improvements across all domains. Patients were followed mainly by telemedicine, without impacting one-year clinical outcomes, and with a significantly lower time to new anti-arrhythmic interventions in patients experiencing recurrences (Central Illustration).

**Patient-Reported Outcome Measures**

The assessment of QoL after AF ablation has become a crucial aspect of comprehensive patient management, as QoL is often significantly impaired in AF patients due to symptoms like palpitations, fatigue, and anxiety. Current guidelines emphasise the importance of including QoL as a key outcome measure in clinical practice and research to evaluate the effectiveness of treatments like ablation. In this observational study, the AFEQT questionnaires, an AF-specific Health-related QoL measure, achieved 80% completeness rates, demonstrating improved adherence compared to prior real-world experiences of systematic electronic PROM collection.

The completeness rates for AFEQT were closer to those seen in clinical trials: 91% in CABANA18 and 85% in STAR AF II.19 In clinical practice, PROM collection is usually clinic-based, as described in the Utah mEVAL AF program (1586 patients; mean age 68 years old), 20 which reported a 90% completeness rate for AF symptom severity score (AF-specific QoL PROM). Previous experiences of real-world systematic electronic PROM collection relied on email notifications and online surveys, like the Cleveland Clinic experience (2175 patients; mean age 63 years old),21 which reported around 50% completeness rate for the same PROM. In our experience, mobile app-based questionnaires are feasible and probably the most convenient method to assess QoL in this group of patients. Older patients, a segment of the AF population that usually has poorer health-related QoL,22 were more frequently non-responders. Future studies should consider digital literacy in the elderly, as many older patients are less comfortable with technology. This may explain their lower completion rates when using app-based or online QoL tools. Simplified tools and help in completing the questionnaires might improve response rates in this population.

Beyond health-related QoL questionnaires, the International Consortium of Healthcare Outcome Measures for AF also considers that validated PROMIS can be used to assess other QoL domains.11 In this study, we evaluated four PROMIS questionnaires: physical function, cognitive function, depression, and anxiety, with lower completeness rates than the AFEQT questionnaire. A possible explanation might be that PROMIS is not disease-specific, and the AFEQT, on the other hand, addresses AF-specific symptoms, possibly making it more engaging for patients as it reflects their personal experiences with AF. Nevertheless, significant improvements in the four domains were observed at 12 months post-ablation. Regarding the AFEQT score, we noted a significant increase of nearly 20 points by the end of the first year, with over 70% of patients achieving a clinically meaningful improvement. This clear improvement in patients’ QoL after ablation is aligned with data from key randomised controlled trials like CABANA18 and the recent sham-control AF ablation trial, SHAM-PVI.5 Several studies have consistently shown that AF recurrences and the burden of AF negatively impact QoL.23 In our study, a recurrence during the first year significantly impacted the trajectory and rates of change in the AFEQT score, illustrating the sensitivity to arrhythmia recurrence. The impact of arrhythmia recurrence on PROMIS domains was more nuanced. While the interaction between time and recurrence was significant for the only domains of Depression and Physical function, notable between-group differences in scores at 12 months were also observed for Anxiety and Cognitive Function domains. These findings suggest that arrhythmia recurrence may influence specific aspects of QoL to varying degrees. Determining the impact of recurrences in a patient´s QoL may contribute to personalised treatment decisions regarding the continuation or cessation of rhythm control.

## Clinical impact of remote AF management

Current guidelines recommend comprehensive and integrated AF care,1,6 emphasising a patient-centred model that should involve symptom control, thromboembolic risk assessment, lifestyle modifications, and comorbidity management.

Several clinical care pathways have been proposed with mixed results in clinical outcomes but with consistent improvements in adherence to guideline-directed recommendations. 9,10,24 The integration of mobile health solutions has been widely explored, with technologies like smartphones and wearables enabling the monitorisation of patients. The TeleCheck-AF approach, developed during the COVID-19 pandemic, utilised app-based heart rate and rhythm monitoring for teleconsultations, facilitating the management of AF without in-person visits.25 Like our study, the Telecheck approach also showed no differences in emergency department visits despite an 80% reduction in face-to-face consultations.26 Furthermore, virtual clinics for patients after AF ablation offer a cost and time-effective option.27

Adherence might be a benefit driver, as in the mAFA-II trial,28 where the authors showed a reduction in the composite outcome of stroke, death, and hospitalisation risk, with adherence to the mobile health intervention reaching 92%. The tested pathway was based on the ABC approach (“A” Avoid stroke; “B” Better symptom management; “C” Cardiovascular risk and comorbidity management). On the other hand, the much smaller emPOWERD-AF trial enrolled 80 patients with AF to study the impact of implementing a physician-oriented web platform and patient-oriented smartphone application.29 At six months, the app adherence was 53.9%, and there was a significant increase in QoL, without differences in AF-related hospitalisations. However, comparisons between studies are difficult since there is considerable heterogeneity in mobile health interventions and adherence definitions.

At the end of one year of follow-up, we did not observe any significant difference in clinical outcomes when implementing a digital-blended follow-up, which was reassuring. We observed lower times from recurrence until an anti-arrhythmic intervention, which might signal that this digital-blended pathway might be associated with shorter times to intervention. This finding and its possible impact on clinical outcomes, such as AF progression, should be further studied. AF can perpetuate its progression through structural and electrophysiological remodelling,30,31 making early rhythm control essential to reduce cardiovascular events, as shown in the EAST-AFNET 4 study.3 The delay between AF diagnosis and ablation seems to worsen long-term outcomes.32,33 Several studies support early rhythm control following AF recurrence after ablation. Baman et al. observed that cardioversion within 30 days of a persistent atrial arrhythmia was an independent predictor of maintenance of sinus rhythm.34 A study from the China Atrial Fibrillation Registry found that electrical cardioversion during the blanking period after ablation was associated with significantly lower rates of one-year AF recurrence, further highlighting the benefits of early rhythm control.35

## Limitations

The main limitation of this study is the absence of randomisation to compare clinical outcomes between groups adequately. Bias was reduced using propensity-score analysis to adjust for differences between populations, but there is the potential for residual confounding, namely temporal biases. Notably, selection bias was inherently nonexistent since the digital-blended approach replaced conventional care in our centre in January/2021. The collection of PROM may be associated with selection bias, with more satisfied patients potentially more likely to complete the questionnaires than those less satisfied. Additionally, we found that older patients were more frequently non-responders, a segment of the AF population that usually has poorer health-related QoL. The single-centre design, in addition to the underrepresentation of the female sex and the predominantly Caucasian cohort, limits the generalizability of the results. The absence of QoL assessment in the conventional group also limited the comparison between groups regarding clinical outcomes. No continuous rhythm monitorisation was implemented in this study, probably contributing to the underestimation of the arrhythmia recurrences. A longer follow-up duration would also be desirable.

# Conclusions

Implementing digital tools for assessing PROM in real-world clinical practice is feasible, with high completeness rates that align with those seen in randomised clinical trials. AFEQT and PROMIS scores improve significantly after the ablation procedure and are negatively impacted by arrhythmia recurrences. A structured digital-blended follow-up, relying mainly on telemedicine, does not negatively impact one-year clinical outcomes. Conversely, it facilitates earlier interventions in case of recurrence compared to conventional care. This study supports the inclusion of digital tools in the value-based and integrated healthcare framework in the follow-up of patients after AF ablation.

**Acknowledgements**: none.

# references

1. Van Gelder IC, Rienstra M, Bunting KV, et al. 2024 ESC Guidelines for the management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J*. Aug 30 2024;doi:10.1093/eurheartj/ehae176.

2. Buja A, Rebba V, Montecchio L, et al. The Cost of Atrial Fibrillation: A Systematic Review. *Value Health*. Apr 2024;27(4):527-541. doi:10.1016/j.jval.2023.12.015.

3. Kirchhof P, Camm AJ, Goette A, et al. Early Rhythm-Control Therapy in Patients with Atrial Fibrillation. *N Engl J Med*. Oct 1 2020;383(14):1305-1316. doi:10.1056/NEJMoa2019422.

4. Andrade JG, Wells GA, Deyell MW, et al. Cryoablation or Drug Therapy for Initial Treatment of Atrial Fibrillation. *N Engl J Med*. Jan 28 2021;384(4):305-315. doi:10.1056/NEJMoa2029980.

5. Dulai R, Sulke N, Freemantle N, et al. Pulmonary Vein Isolation vs Sham Intervention in Symptomatic Atrial Fibrillation: The SHAM-PVI Randomized Clinical Trial. *JAMA*. 2024;doi:10.1001/jama.2024.17921.

6. Joglar JA, Chung MK, Armbruster AL, et al. 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. Jan 2 2024;149(1):e1-e156. doi:10.1161/CIR.0000000000001193.

7. Lan RH, Perez-Guerrero E, Saeed M, Perez MV. Rising trend in use of patient-reported outcomes in atrial fibrillation clinical trials. *Heart Rhythm*. 2024;21(9):1524-1525. doi:10.1016/j.hrthm.2024.04.015.

8. Steinberg BA. Moving Toward PRO-Guided Care of AF. *JACC: Clinical Electrophysiology*. 2023;9(9):1945-1947. doi:doi:10.1016/j.jacep.2023.07.009.

9. Hendriks JM, de Wit R, Crijns HJ, et al. Nurse-led care vs. usual care for patients with atrial fibrillation: results of a randomized trial of integrated chronic care vs. routine clinical care in ambulatory patients with atrial fibrillation. *Eur Heart J*. Nov 2012;33(21):2692-9. doi:10.1093/eurheartj/ehs071.

10. Wijtvliet EPJP, Tieleman RG, van Gelder IC, et al. Nurse-led vs. usual-care for atrial fibrillation. *European Heart Journal*. 2019;41(5):634-641. doi:10.1093/eurheartj/ehz666.

11. Seligman WH, Das-Gupta Z, Jobi-Odeneye AO, et al. Development of an international standard set of outcome measures for patients with atrial fibrillation: a report of the International Consortium for Health Outcomes Measurement (ICHOM) atrial fibrillation working group. *Eur Heart J*. Mar 7 2020;41(10):1132-1140. doi:10.1093/eurheartj/ehz871.

12. Spertus J, Dorian P, Bubien R, et al. Development and validation of the Atrial Fibrillation Effect on QualiTy-of-Life (AFEQT) Questionnaire in patients with atrial fibrillation. *Circ Arrhythm Electrophysiol*. Feb 2011;4(1):15-25. doi:10.1161/CIRCEP.110.958033.

13. Darmits B. *Efeito da Fibrilhação Auricular na Qualidade de Vida*. Master’s Thesis. University of Coimbra; 2020.

14. Holmes DN, Piccini JP, Allen LA, et al. Defining Clinically Important Difference in the Atrial Fibrillation Effect on Quality-of-Life Score. *Circ Cardiovasc Qual Outcomes*. May 2019;12(5):e005358. doi:10.1161/CIRCOUTCOMES.118.005358.

15. Lai J-S, Wagner LI, Jacobsen PB, Cella D. Self-reported cognitive concerns and abilities: two sides of one coin? *Psycho-Oncology*. 2014;23(10):1133-1141. doi:10.1002/pon.3522.

16. Pilkonis PA, Choi SW, Reise SP, Stover AM, Riley WT, Cella D. Item Banks for Measuring Emotional Distress From the Patient-Reported Outcomes Measurement Information System (PROMIS®): Depression, Anxiety, and Anger. *Assessment*. 2011;18(3):263-283. doi:10.1177/1073191111411667.

17. Rose M, Bjorner JB, Gandek B, Bruce B, Fries JF, Ware JE, Jr. The PROMIS Physical Function item bank was calibrated to a standardized metric and shown to improve measurement efficiency. *Journal of Clinical Epidemiology*. 2014;67(5):516-526. doi:10.1016/j.jclinepi.2013.10.024.

18. Mark DB, Anstrom KJ, Sheng S, et al. Effect of Catheter Ablation vs Medical Therapy on Quality of Life Among Patients With Atrial Fibrillation. *Jama*. 2019;321(13)doi:10.1001/jama.2019.0692.

19. Mantovan R, Macle L, De Martino G, et al. Relationship of Quality of Life With Procedural Success of Atrial Fibrillation (AF) Ablation and Postablation AF Burden: Substudy of the STAR AF Randomized Trial. *Canadian Journal of Cardiology*. 2013;29(10):1211-1217. doi:10.1016/j.cjca.2013.06.006.

20. Steinberg BA, Turner J, Lyons A, et al. Systematic collection of patient-reported outcomes in atrial fibrillation: feasibility and initial results of the Utah mEVAL AF programme. *Europace*. Mar 1 2020;22(3):368-374. doi:10.1093/europace/euz293.

21. Hussein AA, Lindsay B, Madden R, et al. New Model of Automated Patient-Reported Outcomes Applied in Atrial Fibrillation. *Circ Arrhythm Electrophysiol*. Mar 2019;12(3):e006986. doi:10.1161/CIRCEP.118.006986.

22. Zhang L, Gallagher R, Neubeck L. Health-related quality of life in atrial fibrillation patients over 65 years: A review. *Eur J Prev Cardiol*. Aug 2015;22(8):987-1002. doi:10.1177/2047487314538855.

23. Samuel M, Khairy P, Champagne J, et al. Association of Atrial Fibrillation Burden With Health-Related Quality of Life After Atrial Fibrillation Ablation: Substudy of the Cryoballoon vs Contact-Force Atrial Fibrillation Ablation (CIRCA-DOSE) Randomized Clinical Trial. *JAMA Cardiology*. 2021;6(11):1324-1328. doi:10.1001/jamacardio.2021.3063.

24. Stewart S, Ball J, Horowitz JD, et al. Standard versus atrial fibrillation-specific management strategy (SAFETY) to reduce recurrent admission and prolong survival: pragmatic, multicentre, randomised controlled trial. *The Lancet*. 2015;385(9970):775-784. doi:10.1016/S0140-6736(14)61992-9.

25. Pluymaekers N, Hermans ANL, van der Velden RMJ, et al. Implementation of an on-demand app-based heart rate and rhythm monitoring infrastructure for the management of atrial fibrillation through teleconsultation: TeleCheck-AF. *Europace*. Mar 8 2021;23(3):345-352. doi:10.1093/europace/euaa201.

26. Gawalko M, Betz K, Hendriks V, et al. Changes in healthcare utilisation during implementation of remote atrial fibrillation management: TeleCheck-AF project. *Neth Heart J*. Mar 2024;32(3):130-139. doi:10.1007/s12471-023-01836-6.

27. Manimaran M, Das D, Martinez P, Schwartz R, Schilling R, Finlay M. The impact of virtual arrhythmia clinics following catheter ablation for atrial fibrillation. *Eur Heart J Qual Care Clin Outcomes*. Jul 1 2019;5(3):272-273. doi:10.1093/ehjqcco/qcz011.

28. Guo Y, Guo J, Shi X, et al. Mobile health technology-supported atrial fibrillation screening and integrated care: A report from the mAFA-II trial Long-term Extension Cohort. *Eur J Intern Med*. Dec 2020;82:105-111. doi:10.1016/j.ejim.2020.09.024.

29. Lazaridis C, Bakogiannis C, Mouselimis D, et al. The usability and effect of an mHealth disease management platform on the quality of life of patients with paroxysmal atrial fibrillation - The emPOWERD-AF study. *Health Informatics J*. Oct-Dec 2022;28(4):14604582221139053. doi:10.1177/14604582221139053.

30. Wijffels MCEF, Kirchhof CJHJ, Dorland R, Allessie MA. Atrial Fibrillation Begets Atrial Fibrillation. *Circulation*. 1995;92(7):1954-1968. doi:doi:10.1161/01.CIR.92.7.1954.

31. Brundel BJJM, Henning RH, Kampinga HH, Van Gelder IC, Crijns HJGM. Molecular mechanisms of remodeling in human atrial fibrillation. *Cardiovascular Research*. 2002;54(2):315-324. doi:10.1016/s0008-6363(02)00222-5.

32. Bunch TJ, May HT, Bair TL, et al. Increasing time between first diagnosis of atrial fibrillation and catheter ablation adversely affects long-term outcomes. *Heart Rhythm*. 2013;10(9):1257-1262. doi:10.1016/j.hrthm.2013.05.013.

33. Segan L, Kistler PM, Chieng D, et al. Prognostic Impact of Diagnosis-to-Ablation Time on Outcomes Following Catheter Ablation in Persistent Atrial Fibrillation and Left Ventricular Systolic Dysfunction. *Heart Rhythm*. 2024;doi:10.1016/j.hrthm.2024.09.059.

34. Baman TS, Gupta SK, Billakanty SR, et al. Time to cardioversion of recurrent atrial arrhythmias after catheter ablation of atrial fibrillation and long-term clinical outcome. *J Cardiovasc Electrophysiol*. Dec 2009;20(12):1321-5. doi:10.1111/j.1540-8167.2009.01553.x.

35. Dong Z, Du X, Hou XX, He L, Dong JZ, Ma CS. Effect of electrical cardioversion on 1-year outcomes in patients with early recurrence after catheter ablation for atrial fibrillation. *Clin Cardiol*. Aug 2021;44(8):1128-1138. doi:10.1002/clc.23663.

# tables

Table 1. Baseline characteristics.

|  |  |
| --- | --- |
| Characteristics | Total (n = 421) |
| Age (years) | 60.9 (53.0, 67.5) |
| Female | 139 (33.0) |
| Body Mass Index (kg/m2) | 27.1 (24.7, 29.4) |
| Hypertension | 196 (47.6) |
| History of smoking |  |
| None | 257 (72.8) |
| Current | 31 (8.8) |
| Past | 65 (18.4) |
| Dyslipidemia (%) | 191 (46.6) |
| Sleep apnea | 32 (7.8) |
| Prior stroke or transient ischemic attack | 19 (4.6) |
| Type 2 diabetes mellitus | 41 (10.0) |
| Coronary artery disease | 18 (4.4) |
| Heart failure | 49 (11.9) |
| Cardiac implantable device | 19 (4.6) |
| Thyroid dysfunction | 42 (10.6) |
| History of anemia | 26 (7.1) |
| Chronic kidney disease | 27 (7.5) |
| CHA2DS2-VASc score | 1.0 (0, 2.0) |
| Systolic dysfunction | 49 (12.3) |
| Moderate or severe valvular disease | 47 (11.7) |
| Left atrial volume (ml/m2) | 37.0 (30.0, 45.0) |
| Continued use of antiarrhythmic drugs |  |
| III | 166 (41.2) |
| Ic | 78 (19.4) |
| No | 159 (39.5) |
| Oral anticoagulation |  |
| No | 12 (2.9) |
| Noac | 393 (95.2) |
| Vka | 8 (1.9) |
| Atrial fibrillation type |  |
| Paroxysmal | 298 (71.5) |
| Persistent | 119 (28.5) |
| Time since diagnosis (years) | 2.0 (1.0, 5.0) |
| Prior electrical cardioversion | 161 (44.0) |
| Ablation energy |  |
| Radiofrequency | 307 (74.0) |
| Other | 108 (26.0) |

\* Values are shown as n (%), mean (SD), or median (IQR), where applicable.

+ NOAC = Non-Vitamin K Oral Anticoagulant; VKA = Vitamin K Antagonist.

Table 2. Estimated marginal means and mean adjusted differences of AFEQT and PROMIS scores between baseline and 12 months in the groups, without or with 12-month recurrence.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Quality-of-life Questionnaires | Baseline | 12-Months | Mean Adjusted  Difference (95% CI) | p-value |
| Mean overall AFEQT score (se) |  |  |  |  |
| No Recurrence | 70.2 (1.4) | 84.6 (1.7) \* | +14.4 (10.9 to 17.9) | <0.001 |
| Recurrence | 67.1 (3.1) | 67.8 (3.5) \* | +0.6 (-6.9 to 8.1) | 0.871 |
| Anxiety PROMIS mean t-score (se) |  |  |  |  |
| No Recurrence | 54.8 (1.0) | 52.1 (0.7) \* | -2.8 (-0.7 to -4.8) | 0.008 |
| Recurrence | 55.2 (2.1) | 56.3 (1.6) \* | +1.1 (-3.4 to 5.6) | 0.631 |
| Depression PROMIS mean t-score (se) |  |  |  |  |
| No Recurrence | 51.6 (0.9) | 49.4 (0.7) \* | -2.2 (-0.4 to -3.9) | 0.018 |
| Recurrence | 50.2 (1.9) | 53.7 (1.5) \* | +3.5 (-0.4 to 7.4) | 0.082 |
| Cognitive Function PROMIS mean t-score (se) |  |  |  |  |
| No Recurrence | 49.8 (0.9) | 51.7 (0.7) \* | +1.8 (-0.1 to 3.7) | 0.058 |
| Recurrence | 49.6 (2.0) | 47.8 (1.5) \* | -1.9 (-6.0 to 2.3) | 0.377 |
| Physical Function PROMIS mean t-score (se) |  |  |  |  |
| No Recurrence | 45.3 (0.8) \* | 49.7 (0.6) | +4.4 (2.8 to 6.0) | <0.001 |
| Recurrence | 52.2 (1.8) \* | 47.5 (1.4) | -4.6 (-8.1 to -1.1) | 0.010 |

\* Statistically significant between-group differences at each time point.

+ AFEQT = Atrial Fibrillation Effect on Quality-of-Life; CI = Confidence Interval; PROMIS = Patient-Reported Outcomes Measurement Information System; SE = Standard Error.

Table 3. Clinical outcomes at 12 months for propensity-score matched groups.

|  |  |  |  |
| --- | --- | --- | --- |
| 12-Months Outcomes | Digital (N = 363) | Conventional (N = 363) | p-value |
| AT/AF recurrence | 31 (14.9) | 67 (18.5) | 0.279 |
| MACE | 2 (1.0) | 1 (0.3) | 0.301 |
| Anti-arrhythmic intervention | 11 (5.3) | 21 (5.8) | 0.804 |
| Healthcare utilisation | 19 (9.3) | 39 (10.7) | 0.540 |
| Emergency department visits | 13 (6.3) | 23 (6.3) | 0.968 |

\* Values are shown as n (%).

+ AT/AF = Atrial tachycardia/Atrial Fibrillation; MACE = Major Adverse Cardiovascular Events

# Legends

Figure 1. Study Flowchart.

Figure 2. Digital Follow-up Workflow.

Figure 3. Trends in Quality-of-life Scores Over 12 Months Following Ablation. AFEQT mean score, with 95% CI band, in the first 12 months after ablation (left panel, A). PROMIS mean T-Scores of the four studied domain questionnaires in the first 12 months after ablation (right panel, B). The round points represent specific time points of PROMs assessment.

Figure 4. Survival Analysis for the Endpoints of Arrhythmia Recurrence and Healthcare Utilisation across Follow-up Strategies. Kaplan–Meier estimates of freedom from recurrence of any atrial tachyarrhythmia (left panel, A) and freedom from healthcare utilisation (right panel, B).

Figure 5. Comparison of Anti-Arrhythmic Intervention Timings across Follow-up Strategies.

Kaplan–Meier estimates of freedom from an antiarrhythmic intervention (left panel, A), at 12 months. Violin plots of the time difference between a recurrence and an antiarrhythmic intervention for both follow-up strategies, conventional and digital (right panel, B).

Graphical Abstract Text. Real-world implementation of a digital-blended follow-up after AF ablation including electronic app-based PROM collection. Telemedicine-based care ensured efficient follow-up without impacting clinical outcomes and enabled faster interventions after arrhythmia recurrences.