

The results of health-related quality of life assessment depend on the prevailing rhythm at the assessment: Experience from the CAPTAF trial (Catheter Ablation Compared with Pharmacological Therapy for Atrial Fibrillation)

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Abstract

Aims: To assess whether the prevailing rhythm at the time of replying to symptom and health-related quality of life (HR-QoL) questionnaires impacts the findings.

Method: A total of 150 patients from the randomized Catheter Ablation Compared with Pharmacological Therapy for Atrial Fibrillation-trial, comparing atrial fibrillation (AF) ablation versus drugs, were included. The effect of the prevailing rhythm on the outcome results of the HR-QoL 36-Item Short-Form Health Survey, the symptom severity questionnaire (SSQ), and the European Heart Rhythm Association (EHRA) score for classification of AF-related symptoms was assessed.

Results: AF as the prevailing rhythm was independently associated with a significantly lower Vitality score; 18.4 points lower (95% confidence interval -32.7 to -4.1, $p = .01$) compared with sinus rhythm when adjusted for AF burden, median duration of episode, number of episodes, beta-blocker use, type of AF, and sex. The presence of AF did not affect the General Health score compared with sinus rhythm, nor did it influence symptoms assessed by the SSQ or EHRA score.

Conclusion: The observation that the presence of AF versus sinus rhythm when conducting HR-QoL tests had a negative impact on its outcome, leaving symptom-related questionnaires unaffected, implies that the prevailing rhythm should be taken into account when results of HR-QoL questionnaires are interpreted.

KEYWORDS

atrial fibrillation, health-related quality of life, implantable loop recorders, rhythm

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1 | INTRODUCTION

Being the most common arrhythmia, atrial fibrillation (AF) has an impact not only on morbidity and mortality but also on health-related quality of life (HR-QoL).^{1,2} Several instruments, both AF specific and general, are used to assess the HR-QoL with varying reliability and validity.^{3,4} Modifiable factors, such as treatment, and nonmodifiable factors, such as sex and age, may impact HR-QoL.⁵⁻⁷ The most recent AF guidelines recommend patient-reported outcomes (PRO) to be routinely collected.⁸ Hence, the PRO must be reliable. To our best knowledge, only a sub-study of the Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM) trial⁹ has studied the effects of the prevailing rhythm at the assessment of HR-QoL but found no impact on the outcome of the HR-QoL score. Since AFFIRM patients were mildly symptomatic, we hypothesized that more symptomatic AF patients would report more symptoms and impaired HR-QoL if AF was ongoing while filling out a questionnaire than if sinus rhythm was present. Therefore, we aimed to test if the prevailing rhythm at the time of responding to symptoms and HR-QoL questionnaires would affect the results. Patients included in the Catheter Ablation compared with Pharmacological Therapy for Atrial Fibrillation (CAPTAF) trial,¹⁰ but before randomization, constituted our cohort.

2 | MATERIAL AND METHODS

2.1 | Study population and design

CAPTAF is a multicenter trial randomizing 155 symptomatic AF patients to either AF ablation or antiarrhythmic drugs, described in detail elsewhere.¹⁰ In this substudy, 150 patients (97%) with either paroxysmal or persistent AF from the CAPTAF trial were eligible. Five patients with permanent pacemakers were excluded.¹⁰ In brief, major inclusion criteria were age between 30 and 70 years, history of symptomatic AF during the preceding 6 months, and intolerance to or treatment failure of a maximum of one antiarrhythmic drug or a beta-blocker. Major exclusion criteria were heart failure with left ventricular ejection fraction (LVEF) less than 35%, left atrial diameter more than 60 mm, and previous AF ablation. The 2-month run-in period after having received an implantable cardiac monitor (ICM) (Reveal XT® Medtronic Inc.) and before randomization constituted the study period.¹⁰ The study was approved by the Ethics Committee. Written informed consent was obtained from all patients.

2.2 | Assessment of AF

The prevailing rhythm was defined as the rhythm present at the time when the patient replied to the HR-QoL- and symptom questionnaires at baseline. The analysis was adjusted for AF characteristics, as a prior sub-study¹¹ has found statistically significant indirect relations between Vitality (VT) score and AF burden and AF median

duration, respectively. AF characteristics were therefore assessed from the ICM during the 2-month run-in period and included AF burden (percentage of monitored time in AF), median duration of episodes, and number of episodes.

2.3 | Symptoms and HR-QoL

The HR-QoL was assessed by the 36-item Short-Form Survey (SF-36) version 1. The SF-36 sub-scales General Health (GH) and VT were chosen as they are two of the four most precise subscales¹² and were mostly affected by AF in the main CAPTAF trial¹⁰ and its recent sub-study.¹¹ In the SF-36 manual,¹² a five-point change in the SF-36 score is considered as “clinically and socially relevant,” a 10-point difference as a “moderate” one, and a 20-point change as a “very large” one. Hence, a clinically significant difference in HR-QoL score was defined as more than a five-point difference in the present study.

The symptom burden was assessed by the Symptom Severity Questionnaire (SSQ), where five items (palpitations, fatigue, dizziness, lack of energy, and dyspnea) are scored on a five grade scale and where a total score (SSQ total score) of a maximum of 25 was calculated.¹³ The symptom burden was also assessed by the European Heart Rhythm Association (EHRA) classification of AF-related symptoms, where Class I is no symptoms, Class II is mild symptoms, normal daily activity is not affected, Class III is severe symptoms, daily activity is affected, and Class IV is disabling symptoms, daily activity is discontinued.¹⁴ The current modified EHRA symptom score version was not used as it was not available when the main trial started. In this study, patients in EHRA Classes III and IV were merged into one group in the statistical analyses.

2.4 | Statistical analyses

Continuous numerical data were expressed as mean \pm 1 SD or as median and interquartile range (IQR Q1-Q3). Categorical data were expressed as numbers and proportions (%). Between-group comparison was made using Mann-Whitney U test and the χ^2 test of independence as appropriate. Mann-Whitney U test was used to determine if there was any difference in HR-QoL score or SSQ total score between patients with AF or sinus rhythm when HR-QoL was assessed. Chi-square test of independence was used to analyze if the prevailing rhythm had an impact on the EHRA class. Simple linear regression analysis was used to assess linear relationship between continuous variables. Multiple linear regression analysis was used to assess the influence of the prevailing rhythm. Adjusting factors were beta-blocker medication, type of AF, and sex, as they have been shown to affect HR-QoL according to other studies⁵⁻⁷ and the AF characteristics assessed by ICM. All analyses were performed using R statistics software (Version 4.0.2; R Foundation for Statistical Computing) and package Rcmdr (Version 2.6-2). *p* values were not adjusted for multiple testing and *p* values less than .05 were considered statistically significant. The sub-study was considered exploratory even though the variables were predefined in the original CAPTAF protocol.

3 | RESULTS

3.1 | Patient demographics

Patient characteristics are presented in Table 1. Of 150 included patients, data from 145 were analyzed. Five patients could not be included in the analyses related to missing data or presences of another rhythm in three, and missing HR-QoL data in two

patients. AF was present in 35 and sinus rhythm in 110 patients when replying to HR-QoL and symptom questionnaires. The patient group with AF at HR-QoL assessment had a higher rate of persistent AF (65.7 vs. 15.6%), a higher body mass index (27.8 vs. 26.1 kg/m²), greater left atrial diameter (2.11 vs. 1.99 cm/BSA), shorter duration of AF history (2.23 vs. 4.27 years), and lower LVEF (52 vs. 57%) than patients conducting the questionnaires while in sinus rhythm (Table 1).

TABLE 1 Patient characteristics

Factor	Sinus rhythm N = 110	Atrial fibrillation N = 35	p value
Sex, men	84 (76.4)	27 (77.1)	1.000
Age, years, median (IQR)	58 (49–64)	58 (55–63)	.475
Paroxysmal AF	92 (83.6)	12 (34.3)	<.001
Heart rate at assessment, median (IQR)	59 (53–66)	86 (70.5–92)	<.001
AF history, years, median (IQR)	4.27 (1.68–7.76)	2.23 (1.05–4.46)	.008
AF burden (% of time), median (IQR)	1.7 (0.09–5.3)	99.5 (39.05–100)	<.001
AF episodes per month, median (IQR)	4.29 (1.02–16.36)	2.7 (0.73–17.05)	.605
AF median episode duration, median (IQR) ^a	6 (6–480)	4320 (35–4320)	<.001
BMI, median (IQR)	26.1 (24.15–28.85)	27.8 (26.05–29.95)	.021
LAD (cm)/BSA m ² , median (IQR)	1.99 (1.80–2.12)	2.11 (1.89–2.31)	.007
LVEF %, mean (SD)	57.39 (7.27)	52.13 (6.64)	<.001
Beta-blockers	63 (57.3)	26 (74.3)	.077
EHRA class			
2	26 (23.6)	10 (28.6)	.869
3	60 (54.5)	18 (51.4)	
4	24 (21.8)	7 (20.0)	
Hypertension	40 (36.4)	17 (48.6)	.235
Chronic lung disease	5 (4.5)	2 (5.7)	.675
Bradycardia or SSS	8 (7.3)	1 (2.9)	.450
History of heart failure	2 (1.8)	3 (8.6)	.091
Sleep apnea	5 (4.5)	0 (0.0)	.337
Coronary artery disease	3 (2.7)	2 (5.7)	.594
Diabetes mellitus	3 (2.7)	2 (5.7)	.594
Stroke/TIA/peripheral emboli	3 (2.7)	0 (0.0)	1.000
Valvular heart disease	1 (0.9)	1 (2.9)	.426

Note: Figures are numbers with % in brackets unless otherwise stated.

Abbreviations: AF, atrial fibrillation; AF burden, % of time spent in AF; AF episode, number of AF episodes/month; AF median episode duration, median AF episode duration in minutes for every patient; CI, confidence interval; General health and Vitality, dimensions in the 36-Item Short-Form Health Survey (SF-36); IQR, interquartile range; LAD, Left atrial diameter; LVEF, left ventricular ejection fraction; SD, standard deviation.

^aMissing data of 25 patients.

3.2 | Effects of AF as prevailing rhythm on HR-QoL

The VT score was significantly lower, median 40 (IQR 25–60), in patients with AF as prevailing rhythm at the time of the QoL questionnaire assessment, as compared with those who were in sinus rhythm, median 65 (IQR 41.25–75; Mann–Whitney U test, $W = 2659.5$, $p = .0007$). Numerically, the difference was greater than five points indicating a clinically significant difference. The GH score was median 62 (IQR 45–67) in the group with AF and median 65 (IQR 47–77) in patients with sinus rhythm, which was neither statistically nor clinically significantly different (Mann–Whitney U test $W = 2249$, $p = .1$).

Women reported lower HR-QoL scores compared with men for both the GH (median 62 vs. 66, Mann–Whitney U test $W = 2402.5$, p -value = .03) and the VT score (median 50 vs. 60, $W = 2431$, p -value = .02). The GH score was not different between patients with paroxysmal and persistent AF (Mann–Whitney U test $W = 2432.5$, p -value = .5). Patients with paroxysmal AF had higher VT score than those with persistent AF (median 65 vs. 45, Mann–Whitney U test $W = 2773.5$, p -value = .006).

3.3 | Multiple regression analyses

AF as prevailing rhythm at the time of HR-QoL assessment was associated with a significantly lower VT score, 18.4 points lower (95% CI –32.7 to –4.1, $p = .01$) compared with sinus rhythm when adjusted for other AF characteristics, beta-blocker use, type of AF, and sex (Table 2). AF as prevailing rhythm did not affect the GH score as compared with sinus rhythm when adjusting for the same factors (Table 2, $p = .2$).

3.4 | Symptom assessment in relation to the prevailing rhythm

There was no difference in SSQ total score between patients who had AF versus those who had sinus rhythm as prevailing rhythm

during assessment of symptom (median score 15 vs. 14, Mann–Whitney U-test, $W = 1680.5$, p -value = .3). Out of the 35 patients with AF, ten patients (29%) were in EHRA Class II and 25 patients (71%) were in EHRA Class III or IV. Out of the 110 patients with sinus rhythm, 26 patients (24%) were in EHRA Class II and 84 patients (76%) were in EHRA Class III or IV. There was no significant association between the prevailing rhythm and the EHRA score ($\chi^2 = 0.17$, $df = 1$, p -value = .7).

4 | DISCUSSION

The finding that the prevailing rhythm, that is, the presence of AF while responding to the SF-36 HR-QoL questionnaire, worsened the results has important implications. According to recent guidelines on AF management,⁸ assessment of PRO is recommended, and its extensive use is to be expected. The findings of this study are relevant in this context since PROs-related research might come to affect future treatment recommendations and must be reliable.

To our best knowledge, the present study is the first to demonstrate that the prevailing rhythm affects the HR-QoL score, which is in contrast to the sub-study of AFFIRM trial,⁹ reporting no such association. Although the HR-QoL was assessed by several instruments in the AFFIRM trial, the authors did not specify which SF-36 dimensions were included and whether summarized with other instruments in the analysis with the prevailing rhythm, making it difficult to draw any conclusion regarding differences in selected questionnaires.⁹ There are, however, two possible explanations for the conflicting results between the AFFIRM trial and the present study. First, due to the design of the AFFIRM trial,¹⁵ AF patients with more severe symptoms were less likely enrolled as inclusion criteria were age more than 65 years and with one or more risk factor for stroke or death, and it is known that younger age is associated with higher symptom burden.⁷ Moreover, 12% of the AFFIRM patients were asymptomatic at baseline¹⁶ compared with no patients in the present study and HR-QoL is less likely affected by asymptomatic

Variable	General health subscale ^a		Vitality subscale ^a	
	Estimate (95% CI)	<i>p</i> value	Estimate (95% CI)	<i>p</i> value
Prevailing rhythm [AF]	–8.2 (–20.4 to 3.9)	.2	–18.4 (–32.7 to –4.1)	.01
AF burden	0.0 (–0.2 to 0.2)	.9	0.1(–0.1 to 0.3)	.5
AF episode no	0.0 (–0.0 to 0.0)	.2	0.0 (–0.0 to 0.0)	.8
AF median duration	–0.0 (–0.0 to 0.0)	.9	–0.0 (–0.0 to 0.0)	.8
Beta-blockers	8.5 (1.4–15.6)	.02	5.3 (–3.0 to 13.6)	.2
AF type[persistent]	1.2 (–8.6 to 11.1)	.8	–7.9 (–19.5 to 3.8)	.2
Sex[woman]	–10.2 (–18.1 to –2.3)	.01	–12.7 (–22.0 to –3.4)	<.01

TABLE 2 Multiple linear regression analyses of factors predicting health-related quality of life score

Abbreviations: AF, atrial fibrillation; AF burden, % of time spent in AF; AF episode, number of AF episodes/month; AF median episode duration, median AF episode duration in minutes for every patient; CI, confidence interval; General health and Vitality, dimensions in the 36-Item Short-Form Health Survey (SF-36).

^aIncluding 119 patients.

AF episodes. Second, AFFIRM patients⁹ had more comorbidities than patients in the present study, as reflected by the more prevalent hypertension (71% vs. 39%) and history of congestive heart failure (20% vs. 3%). The presence of comorbidities could disguise symptoms related to AF per se, as they are also associated with reduced HR-QoL.⁷

In the present study, a minority (34.3%) of patients in the group with AF at the time of HR-QoL assessment had paroxysmal AF, while the distribution of sex was similar. Patients with paroxysmal AF report more severe symptoms and worse HR-QoL than patients with persistent AF, and women report higher symptom burden and lower HR-QoL than men.^{5,7} However, in the present study, AF as the prevailing rhythm was still an independent factor associated with worse HR-QoL when adjusted for the type of AF and sex. Thus the prevailing rhythm may even have a greater impact on HR-QoL than the type of AF.

In the present study, the numerical difference in VT score between patients with AF and sinus rhythm, while replying to the questionnaires, was well above 20 points. In the multiple linear regression analysis, the VT score in the cohort with AF while replying to the questionnaire was estimated to be 18.4 points lower, than in patients with sinus rhythm (Table 2). This difference in VT score was thus well above the 5-point difference defined as being a clinically significant difference and close to “very large” according to the SF-36 manual,¹² thus the difference was indeed relevant.

Our prior work suggests that AF burden, percentage of time in AF, is associated with a worse HR-QoL when compared with other AF characteristics, that is, the number of AF episodes and episode duration.¹¹ In the present study, the prevailing rhythm was independently associated with worse HR-QoL when adjusted for these AF characteristics. The multiple regression analyses, were affected by collinearity, with the highest variance inflation factor being 4.3 for the AF burden. Still, the prevailing rhythm was the variable of interest and remained significant after excluding AF burden (data not presented).

In both research and clinical settings, evaluating HR-QoL without considering the prevailing rhythm could severely impact study results and clinical management of AF, resulting in either over or underestimation of the effects on HR-QoL. Routine assessment of PRO, such as symptoms and HR-QoL, is recommended in the recent European Society of Cardiology guidelines for the management of AF.⁸ Given these strong recommendations, a more widespread clinical use of instruments to assess both symptoms and HR-QoL can be expected, followed by demands of more accurate assessments of such measurement during follow-ups. Symptoms and HR-QoL can be measured by both generic and disease-specific instruments. The HR-QoL instrument SF-36 used in the present study is a standardized generic questionnaire with high reliability and validity that has been used extensively in both original and translated versions.¹⁷ Even though the standard form of SF-36 applies a 4-week recall of the QoL and one or more items summarize every subscale, the prevailing rhythm at the time of QoL assessment did indeed affect the outcome for the VT score.

The observation that the prevailing rhythm did not affect the outcome of symptom assessment using SSQ and the EHRA score was at first surprising. We hypothesized that if AF is present, then the symptom assessment would indicate worse symptoms than in sinus rhythm. However, the EHRA score is assessed by the physician. It therefore probably reflects the clinical history, as it is instructed to be¹⁴ and unlikely accounts for the current state of the patient. In contrast, the SSQ is patient-reported and relates directly to AF-specific symptoms (palpitations, fatigue, dizziness, lack of energy, and dyspnea). Since patients are asked to rate the severity of each symptom but without indicating their presence, the prevailing rhythm is probably less likely to influence the overall memory of AF-related symptoms in the SSQ questionnaire. In contrast, the VT subscale of SF-36 includes four less AF-specific items, “full of pep,” “a lot of energy,” “worn out,” and “feel tired,” all of which more likely reflect the current health perception of the patient.

4.1 | Limitations

Intra-individual comparison of AF versus sinus rhythm may have minimized effects of interindividual difference, although such analysis would have been very challenging to conduct. A sub-study carries several concerns, and the results should be considered as exploratory and hypothesis-generating. As SF-36 has a 4-week recall, this study may illustrate recall bias in the population of patients with AF. The population of the study was relatively healthy and young which may make the generalizability limited.

5 | CONCLUSIONS

AF as the prevailing rhythm at the time of conducting HR-QoL questionnaires had a negative impact on the results while leaving outcomes of symptom questionnaires SSQ and EHRA score unaffected. This observation implies that the prevailing rhythm should be considered while interpreting the results of generic HR-QoL questionnaires. The prevailing rhythm while assessing patient-reported outcomes should thus be considered in future evaluations.

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DATA AVAILABILITY STATEMENT

The data is not available as stated in the main study.

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