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Development and Validation of an Arrhythmia-Specific Scale in Tachycardia and Arrhythmia With Focus on Health-Related Quality of Life

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Background: Arrhythmias can cause a profoundly negative impact on a person's daily life, leading to impaired health-related quality of life (HRQOL). Assessment of HRQOL can provide valuable information before, during, and after healthcare interventions for arrhythmias. **Objective:** The aim was to develop and validate a disease-specific scale evaluating HRQOL in patients with different forms of arrhythmia. **Methods:** The Arrhythmia-Specific questionnaire in Tachycardia and Arrhythmia (ASTA HRQOL) was developed from a literature review, patient interviews, and expert panel evaluations. This version was then psychometrically evaluated in patients treated with radiofrequency catheter ablation because of different forms of arrhythmias and patients who sought emergency care because of atrial fibrillation. Construct validity was evaluated with item-total correlations, confirmatory factor analyses, and convergent and discriminant validity. Internal consistency was evaluated using Cronbach's α. **Results:** All items reached the expected level of item-total correlations of greater than 0.3 for the total scale. The content validity index was sufficient for all items, as was the total scale (0.86–1.0). The 2-factor confirmatory factor analysis model that included the physical and mental factors showed a better fit between model and data than the 1-factor model did ($P < .001$). Convergent and discriminant validities were evaluated in the correlation analyses between the ASTA HRQOL subscales and SF-36 physical and mental dimensions. A strong correlation was found between the hypothesized physical and mental scales. Internal consistency was satisfactory with a lower bound confidence interval (95%) for Cronbach's α .70 or greater for all the ASTA HRQOL scales. **Conclusions:** The ASTA HRQOL questionnaire can be a valuable contribution to HRQOL assessments in patients with different forms of arrhythmia. Until there is more evidence regarding validity and reliability, using both the total and subscale scores is recommended.

KEY WORDS: arrhythmias, disease-specific questionnaire, health-related quality of life, validation studies

Background

The unpredictable nature of arrhythmias can cause a profoundly negative impact on a person's daily life, leading to impaired health-related quality of life (HRQOL).[1–3]

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Some patients have vague and unspecific symptoms during arrhythmia episodes, whereas others experience more disabling and handicapping symptoms such as pronounced tiredness, dizziness, near syncope, and sometimes even complete syncope, irrespective of type of arrhythmias. In patients with a bothersome symptoms, there can be negative effects on social as well as physical and mental domains.[2,4–6] Never knowing when the next episode will occur can lead to feelings of insecurity and self-imposed restrictions in daily life.[6,7] Living with recurrent arrhythmia episodes often leads to insecurity with a need to find coping strategies to manage the episodes.[8]

Health-related quality of life refers to function and well-being in connection with a disease or treatment and includes evaluation of well-being with regard to physical, mental, and social domains of life.[9,10] Health-related quality of life is a multidimensional concept and is a measurement of a person's subjective perception of health and how certain diseases and treatments impact on their health status.[11–13]

Assessment of HRQOL can provide valuable information about healthcare interventions, support the choice of treatment strategies, and assess adverse treatment reactions.[14,15] Generic and disease-specific HRQOL scales can be used separately or in combination, where the questionnaires need to be properly evaluated to ensure that assessments are reliable and valid.[11,16] Generic scales make it possible to compare patients with different diagnoses. Disease-specific scales make it possible to assess to what extent a certain disease influences a patient's daily life situation.[11,17] As generic scales are limited in their ability to detect important clinical changes, they should be supplemented with disease-specific scales.[18] To avoid increasing respondent burden, short scales with sound psychometric properties are needed.

One problem concerning disease-specific scales for patients with arrhythmias is that it is not always known what type of arrhythmia the patient experiences and some have more than 1 arrhythmia diagnosis.[19] Scores from disease-specific scales that target only 1 arrhythmia diagnosis may therefore be difficult to interpret. To avoid this problem, a disease-specific scale targeting different forms of arrhythmia is needed. This type of scale should also make it possible to compare HRQOL among patients with different forms of arrhythmias. Most existing disease-specific scales in arrhythmia patients only describe symptom burden, or assess HRQOL, are developed for atrial fibrillation (AF), and do not include other forms of arrhythmias or mix the symptoms with the HRQOL concerns within the same scale.[3,20–25] In clinical practice and research, it would be valuable to have a validated arrhythmia-specific HRQOL scale suitable for different forms of arrhythmias. To the best of our knowledge, no such scale is available and validated today.

Aims

The aim of the study was to develop and validate a disease-specific scale to evaluate HRQOL, suitable for patients with different forms of arrhythmias.

Methods

The overall Arrhythmia-Specific questionnaire in Tachycardia and Arrhythmia (ASTA) was developed to assess the impact of arrhythmias on a patient's symptom burden and HRQOL. The development of the ASTA symptom burden scale is described elsewhere,[5] whereas the study reported in this article describes the development and validation of the ASTA HRQOL scale.

The Regional Ethical Review Board at the Faculty of Health Sciences, Linköping, Sweden, approved the protocol and gave permission for obtaining oral informed consent from participants (study number: M170-08 T111-08). Study participation was documented in the patients' medical records. The study complies with the Declaration of Helsinki.[26,27]

The Development Phase

The aim during the development phase was to develop a scale that included both physical and mental aspects of HRQOL. To reach content validity and identify representative and relevant items, a literature review was conducted in Medline, searching for *quality of life*, *health-related quality of life*, *arrhythmias*, *supraventricular tachycardia*, and *paroxysmal supraventricular tachycardia*. In addition, results from a previous interview study including 300 arrhythmia patients before radiofrequency catheter ablation (RFA) treatment were used to describe how the arrhythmias influenced patients' daily life situations.[6]

The research group, consisting of experienced cardiac nurses knowledgeable in psychometrics and an electrophysiologist, created the initial pool of items from the literature review and the patient interviews. The items were thereafter evaluated by an expert panel consisting of cardiologists, nurses, and arrhythmia patients referred for RFA treatment. The expert panel was asked to suggest additional items for the item pool if they found any domains or concerns that were not covered. The patients were encouraged to suggest new questions if they thought there were concerns missing at the time of data collection. During the initial and validation phases, the patients were also repeatedly asked for comments on the questionnaires' readability and understandability. The expert panel was instructed to judge the appropriateness of the items for patients with different forms of arrhythmia.

One question about intimacy and sexual life was added to the pool of items. The expert panel also gave recommendations for changes to improve clarity and the logical order of the items.

A common response scale was created for all items. The response scale included the alternatives: no (0), yes, to a certain extent (1), yes, quite a lot (2), yes, a lot (3), or I don't know. The last category was included as a result of patient recommendations, so that those who were not sure if the item was related to arrhythmia would still be able to respond. This category was not scored. Furthermore, the patients were instructed to rate how much the arrhythmia affected their daily life ("due to your arrhythmia"), but no timeframe was given. If the ASTA HRQOL scale is used separately (apart from its associated burden scale), we recommend that a timeframe be given in addition to the initial questions in part I (ASTA descriptive part). All patients start with part I, where they are asked about their most recent arrhythmia episode and current medication. For those using the whole ASTA questionnaire, including the symptom burden scale, there are questions about the number of episodes during the last 3 months and the duration of the episodes.[5]

Focusing on content validity, the ASTA HRQOL scale was then tested in a sample of 240 patients with different forms of arrhythmia. The initial test included patients with AF and atrial flutter (AFL) planned for DC-conversion and patients treated with RFA because of atrioventricular nodal reentry tachycardia, Wolff-Parkinson-White syndrome, focal atrial tachycardia (FAT), atrial macro reentry, AFL, and AF, as well as patients with ventricular arrhythmias. Patients were encouraged to comment and suggest questions that could be added if they thought that something was missing. One item concerning spending time with relatives, friends, and acquaintances was divided into 2 items, 1 for friends and relatives and 1 for acquaintances, as a result of patient recommendations. The patients distinguished between acquaintances and relatives/friends, but not between relatives and friends. Two items concerning whether patients tried to hide arrhythmia occurrence from others or if they felt neglected while having arrhythmia were tested initially but were considered not relevant for measuring HRQOL by the research group.

The development process resulted in a 13-item HRQOL scale, with 7 items in a hypothesized physical domain and 6 items in a mental domain (Table 1). As a final step, the content validity of the 13-item scale was evaluated using the content validity index (CVI). A panel consisting of 5 experienced cardiologists and 2 cardiac nurses rated the relevance of each item and the adequacy of the total scale. A 4-point scale ranging from 1 to 4 (not relevant to highly relevant) was used. The CVI was computed for each item (I-CVI) and for the 13-item scale (S-CVI). The I-CVI was computed as the percentage of experts rating 3 or higher for each of the item, and the average method of S-CVI was used to assess the CVI of the 13-item scale. According to recommendations in the literature, a level of 0.78 or greater for I-CVI and 0.80 or greater for S-CVI was used as a criterion for demonstrating content validity.[28,29]

The items can be presented separately or with sum scores. The scores for the total scale range between 0 and 39, with higher scores reflecting more negative and burdensome effects on HRQOL because of the heart rhythm disturbance. The possible score range for the physical and mental domains range between 0 and 21 and between 0 and 18, respectively. The time to complete the 13-item scale was a few minutes.

The Validation Phase

Patient Population and Inclusion Criteria

The study inclusion period lasted from May 2009 until December 2009. Patients eligible for study participation included those referred for RFA treatment because of different forms of arrhythmia, as well as atrioventricular-nodal reentry tachycardia, Wolff-Parkinson-White syndrome, FAT, atrial macro reentry, AFL, AF, and ventricular arrhythmia patients (n = 215) at a university hospital. Another 55 patients seeking acute care because of AF at 2 county hospitals in Sweden were also included. Patients were included if they were referred for RFA treatment because of arrhythmia or were seeking emergency care because of AF and were 18 years or older, with sufficient knowledge of the Swedish language and physical and mental ability to fill in the study questionnaires. During the inclusion period, another 44 patients planned for RFA were not included. The reasons were unwillingness to participate (n = 17), insufficient knowledge of Swedish (n = 5), not capable to

TABLE 1 The 13 Items in the Arrhythmia-Specific Questionnaire in Tachycardia and Arrhythmia's Health-Related Quality of Life Scale

Item No.	Item Wording	2 Subscales: Physical and Mental Subscale
1	Do you feel unable to work, study, or carry out daily activities as you would like to due to your arrhythmia?	Physical
2	Do you spend less time with your relatives and friends than you would like to due to your arrhythmia?	Physical
3	Do you spend less time with acquaintances (people you do not know that well) than you would like to due to your arrhythmia?	Physical
4	Do you avoid planning things you would like to do, for instance travelling or leisure activities, due to your arrhythmia?	Physical
5	Is your physical ability reduced due to your arrhythmia?	Physical
6	Is your ability to concentrate reduced due to your arrhythmia?	Mental
7	Do you feel low spirited or sad due to your arrhythmia?	Mental
8	Do you feel irritated or angry due to your arrhythmia?	Mental
9	Do you suffer from sleep problems due to your arrhythmia?	Mental
10	Is your sexual life affected negatively by your arrhythmia?	Physical
11	Are you afraid of dying due to your arrhythmia?	Mental
12	Has your life situation deteriorated due to your arrhythmia?	Physical
13	Do you feel worried that your symptoms will reoccur during the periods when you do not suffer from arrhythmia?	Mental

participate (n = 4), and missing/not approached (n = 18). There are no data available for missing patients in the emergency care group.

Procedures

The RFA patients were consecutively asked about participation and the outpatients were asked at the time of the acute care visit. All RFA patients received study information by mail before their RFA. They then received oral and written information at the time of admission to hospital, before the planned intervention. Most participating patients filled out the questionnaires the day before treatment. The patients seeking acute care received oral and written information at the time of their visit and filled out the questionnaires during the acute care visit.

Health-Related Quality of Life Questionnaires

A combination of a generic and a disease-specific questionnaire was used for the validation process. Together with the ASTA HRQOL scale, the 36-Item Short-Form Health Survey (SF-36 version 1.0) was used to assess general health. The SF-36 consists of 8 health scales representing physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality (energy/fatigue), social functioning, role limitations due to emotional problems, and mental health (psychological distress and psychological well-being) and 2 summary measures, physical and mental component summary (PCS/MCS). In the present study, only PCS and MCS were used for the psychometric testing. The scores for PCS and MCS can range from 0 (worst possible health) to 100 (best possible health). The scoring of the SF-36 data was done as described by Ware and colleagues.[9,30–32] The SF-36 has been used in several arrhythmia studies assessing HRQOL and has been shown to have good validity and reliability in this patient population.[1–3,6,33]

Statistical Analysis

Means, standard deviations, and frequencies were used to describe the characteristics of the sample and patient-reported general and disease-specific HRQOL. Comparisons were made using the χ^2 test for nominal variables. The Student unpaired t test was used to compare mean scores between the patients included in the psychometric evaluations and patients without complete data. The ASTA 13-item HRQOL scale was psychometrically evaluated regarding data quality, construct validity, and internal consistency reliability.

Data quality was evaluated regarding score distribution and missing data pattern. Frequencies were used to evaluate the distribution of item responses, whereas the Kolmogorov-Smirnov test was used to test if the scale scores deviated from a normal distribution. Frequencies were used to describe the missing data pattern and to describe floor and ceiling effects. Floor and ceiling effects were defined if values of the observed variables fell at the minimum or maximum possible score, that is, if most of the scores were distributed at either end of the response scale.[34]

As a first step in the evaluation of construct validity, item-total correlations adjusted for overlaps were calculated for each item and the ASTA HRQOL total scale. An acceptable level was set to 0.30 or greater.[34] In the next step, confirmatory factor analysis (CFA) was used to evaluate the hypothesized factor structure, including a physical and mental subscale. The first model (I) was specified as a 1-factor model, and the second model (II) was specified as a 2-factor model. In model II, the factors were allowed to correlate freely. In this first step, no residual variances were allowed to correlate. Both models (I and II) were thereafter respecified. Based on modification indices, residual variances were allowed to correlate. Other models, including cross-loadings between the 2 factors and the indicator variables, were also tested. As these models did not improve the fit between the model and data, they are not reported in this study. A robust weighted least square estimator using a diagonal weight matrix (WLSMV) was used in all CFAs as the assumption of multivariate normality was violated and as the indicator variables were categorical.[35,36] To evaluate the goodness of fit between the models and data, we used fit indices suitable for WLSMV, including the χ^2 goodness-of-fit, weighted root-mean-square residual (WRMR), the root-mean-square error of approximation (RMSEA), close fit for RMSEA (CFit), comparative fit index (CFI), and Tucker-Lewis index (TLI). A sufficient model fit was defined as non-significant χ^2 goodness-of-fit and CFit, WRMR of less than 1.0, RMSEA of 0.05 or less, and CFI and TLI of 0.95 or greater. As traditional $\chi^2_{\text{difference}}$ test is not appropriate for WLSMV, we used the DIFFTEST command in Mplus to make it possible to evaluate differences between the revival models.[36] All those goodness-of-fit indices were used to evaluate if the supposed measurement model fit the data.

In a final step, construct validity was evaluated regarding convergent and discriminant validity.[37] For this purpose, the physical and mental subscales in ASTA were correlated with the PCS and MCS in the SF-36. To support convergent validity, the strongest correlation should be demonstrated between the ASTA physical scale and SF-36 PCS and between the ASTA mental scale and SF-36 MCS (homotrait-heteromethod correlations). To support discriminant validity, weaker correlations should be demonstrated between the ASTA physical scale and SF-36 MCS and between the ASTA mental scale and SF-36 PCS (heterotrait-heteromethod correlations). For this purpose, Spearman correlation coefficients were used.

Internal consistency reliability in the ASTA HRQOL items was evaluated using Cronbach's α coefficients.[38] An α coefficient of 0.70 or greater was considered sufficient.[34] In addition, a lower bound confidence interval (95%) for Cronbach's α was calculated.[39] A P value of <.05 was considered significant. Statistical analyses were conducted using Stata 12.1 for Mac (Stata Corporation, College Station, Texas) and Mplus 7.0 for Mac (Muthén & Muthén, Los Angeles, California).

Results

Patient Demographics

The validation study included 270 patients, of whom 147 were available for a complete psychometric evaluation, that is, had questionnaires without missing data. Two hundred fifteen of the patients were treated with RFA and 55 patients sought emergency care because of AF. Most patients were men. There were no differences in age between men and women in the study (P = .875). Sixty-three percent had an educational level of upper secondary school certificate or more, including a university degree (Table 2). In the group of patients with complete data, that is, who participated in the psychometric evaluation, an educational level of upper secondary school certificate and/or a college/university degree was more common (χ^2_3 = 11.55, P = .009), as was treatment with class I antidysrhythmic medication (χ^2_1 = 6.69, P = .014).

There were significant differences between the RFA patients and the group of AF patients seeking emergency care. The RFA patients were significantly younger compared with the emergency care group (Δmean, 7.4 ± 2.5; t_{145} = 2.98, P = .003). However, the groups did not differ regarding gender (χ^2_1 = 0.01, P = .934), education (χ^2_1 = 0.75, P = .861), ASTA total score (t_{145} = 1.24, P < .217), ASTA physical score (t_{145} = 0.82, P < .416), or ASTA mental score (t_{145} = 1.62, P < .107).

Data Quality

Of the 270 patients included, 19 patients did not complete any of the 13 items and another 14 patients had missing values in 1 to 7 items. Because of the difficulties in interpreting and scoring the answer "I don't know," this alternative, used by 90 patients, was regarded as a missing value in this validation study. This resulted in a total of 147 patients completing the forms, who were available for a complete psychometric evaluation.

The ASTA HRQOL 13-item scale had a mean score of 13.5 ± 8.1. The mean score for the physical and mental subscales were 8.0 ± 5.2 and 5.5 ± 3.6, respectively. The total scale and the physical subscale did

TABLE 2 Sample Characteristics for the Psychometric Evaluation of the Arrhythmia-Specific Questionnaire in Tachycardia and Arrhythmia's Health-Related Quality of Life Scale

	Total Sample (n = 270)	Sample With Complete Data (n = 147)	Sample With Incomplete Data (n = 123)	P
Age, mean (SD), y	59.3 (13)	58.9 (12)	59.8 (14)	.574[a]
Gender, n (%)				.498[b]
Women	93 (34)	48 (33)	45 (37)	
Men	177 (66)	99 (67)	78 (63)	
Education, n (%)				
Elementary school certificate	26 (10)	9 (6)	17 (14)	.009[b]
Compulsory school certificate	71 (26)	36 (24)	35 (28)	
Upper secondary school certificate	96 (36)	51 (35)	45 (37)	
College/university degree	73 (27)	51 (35)	22 (18)	
Unknown	4 (2)	0 (0)	4 (3)	
Diagnose, n (%)				.644[b]
AVNRT	40 (15)	23 (16)	17 (14)	
WPW	16 (6)	9 (6)	7 (6)	
FAT	8 (3)	3 (2)	5 (4)	
Atrial macro reentry	4 (2)	1 (1)	3 (2)	
AFL	16 (6)	11 (7)	5 (4)	
AF	181 (67)	98 (67)	83 (68)	
Ventricular arrhythmia	5 (2)	2 (1)	3 (2)	
Antiarrhythmic medication, n (%)[c]				
Class I	46 (17)	33 (22)	13 (11)	.010[b]
Class II	159 (59)	87 (59)	72 (59)	.914[b]
Class III	41 (15)	20 (14)	21 (17)	.429[b]
Class IV	36 (13)	17 (12)	19 (15)	.350[b]

Ventricular arrhythmia includes ventricular tachycardia and ventricular extra beats.
Abbreviations: AF, atrial fibrillation; AFL, atrial flutter; AVNRT, AV-nodal reentry tachycardia; FAT, focal atrial tachycardia; WPW, Wolff-Parkinson-White syndrome.
[a]Student unpaired t test.
[b]χ^2 test.
[c]The antiarrhythmic medication in the validation study, where the patients can have more than 1 drug. Class I represents flecainide/propafenon; class II, β-blockers; class III, amiodarone/sotalol; class IV, calcium channel blockers.

not deviate from a normal distribution (P = .359 and .188 respectively). In contrast, the mental subscale demonstrated a positive skew distribution (P = .004). The distribution of the 13 items in the ASTA HRQOL scale showed that items 2, 3, 10, and 11 met the criteria for floor effect. None of the ASTA HRQOL items showed ceiling effects (Table 3). The SF-36 mean scores for the SF-36 PCS and MCS were 42.4 ± 10.6 and 43.5 ± 11.1, respectively.

Content Validity

The separate items and the total ASTA HRQOL scale showed good content validity. The I-CVI ranged from 0.86 to 1.0 and the S-CVI was computed to 0.99. All items except for item 3, "Do you spend less time with acquaintances (people you do not know that well) than you would like to due to your arrhythmia?" was computed to I-CVI 1.0.

Construct Validity

Item-Total Correlation

All 13 items in the ASTA HRQOL scale reached the expected level of item-total correlations ($r \geq 0.30$), ranging from r = 0.48 for item 11 to r = 0.78 for item 12 (Table 3).

Confirmatory Factor Analysis

The factor loadings for the 1-factor model ranged between 0.56 and 0.94, all significant at a level of $P < .001$ (Table 4). Despite satisfactory high factor loadings, the model fit was partly unsatisfactory for the 1-factor model. Whereas CFI and TLI exceeded the critical level of 0.95, χ^2 goodness-of-fit, WRMR, and RMSEA indicated unsatisfactory fit between model and data. A respecified model with correlated residual variances was therefore evaluated. This increased the model fit significantly according to the $\chi^2_{difference}$ test (χ^2_4 = 73.92, $P < .001$). After this refinement, only the χ^2 goodness-of-fit did not reach the criteria for acceptable fit between model and data. The RMSEA was close to 0.05, and the confidence interval showed that RMSEA did not deviate significantly from this critical level (Table 5).

In the 2-factor model, the factor loadings ranged between 0.68 and 0.94 in the physical subscale and between 0.61 and 0.86 in the mental subscale. The factor correlation between the physical and mental subscales was strong (0.84). Both the factor loadings and factor

TABLE 3 Data Quality and Item-Total Correlations for the Arrhythmia-Specific Questionnaire in Tachycardia and Arrhythmia's Health-Related Quality of Life Scale

	Item Statistics[a]		Item Score Distributions,[b] n (%)				
Item No.	Item-Total Correlation	Mean (SD)[a]	"No"	"Yes, to a Certain Extent"	"Yes, Quite a Lot"	"Yes, a Lot"	"I Don't Know"
1[c]	0.705	1.31 (1.05)	50 (19)	108 (40)	44 (16)	38 (14)	7 (3)
2[c]	0.725	0.70 (0.83)	115 (43)	93 (34)	22 (8)	12 (4)	7 (3)
3[c]	0.694	0.66 (0.79)	121 (45)	89 (33)	19 (7)	8 (3)	11 (4)
4[c]	0.722	1.31 (1.03)	63 (23)	88 (33)	46 (17)	51 (19)	2 (0.7)
5[c]	0.660	1.67 (0.97)	18 (7)	96 (36)	66 (24)	58 (22)	11 (4)
6[d]	0.698	0.88 (0.84)	73 (27)	104 (39)	37 (14)	11 (4)	24 (9)
7[d]	0.670	1.02 (0.80)	66 (24)	131 (49)	37 (14)	10 (4)	6 (2)
8[d]	0.527	0.72 (0.76)	100 (37)	107 (40)	16 (6)	8 (3)	19 (7)
9[d]	0.530	1.01 (0.92)	73 (27)	113 (42)	34 (13)	20 (7)	11 (4)
10[c]	0.575	1.12 (1.06)	80 (30)	74 (27)	27 (10)	31 (12)	36 (13)
11[d]	0.483	0.71 (0.85)	111 (41)	93 (34)	22 (8)	11 (4)	13 (5)
12[c]	0.781	1.27 (0.84)	36 (13)	114 (42)	69 (26)	23 (9)	7 (2)
13[d]	0.490	1.15 (0.92)	59 (22)	107 (40)	47 (17)	22 (8)	12 (4)
Total	Cronbach's α = .91	13.54 (8.14)					
ASTA physical subscale (7 items)[e]	Cronbach's α = .89	8.18 (5.12)					
ASTA mental subscale (6 items)[f]	Cronbach's α = .79	5.62 (3.55)					

Internal consistency reliability was evaluated using Cronbach's α coefficients. An α coefficient of .70 or greater was considered sufficient and item-total correlations adjusted for overlaps with an acceptable level set to 0.30 or greater.
Abbreviation: ASTA, Arrhythmia-Specific questionnaire in Tachycardia and Arrhythmia.
[a]Based on 147 patients, that is, those who had complete data on all 13 items and who had not answered "I don't know."
[b]Based on 270 patients.
[c]Physical subscale.
[d]Mental subscale.
[e]Based on 185 patients.
[f]Based on 183 patients.

TABLE 4 Factor Loadings and Residual Variances for the 1- and 2-Factor Model for the Arrhythmia-Specific Questionnaire in Tachycardia and Arrhythmia's Health-Related Quality of Life Scale (n = 147)

Items	1-Factor Model	2-Factor Model	
		Physical Scale	Mental Scale
Physical scale			
1. Unable to work, study or carry out daily activities	0.817 (0.333)[a]	0.826 (0.318)[a]	–
2. Spend less time with your relatives and friends	0.936 (0.124)[a]	0.941 (0.114)[a]	–
3. Spend less time with acquaintances	0.913 (0.166)[a]	0.918 (0.157)[a]	–
4. Avoid planning things you would like to do	0.799 (0.362)[a]	0.807 (0.349)[a]	–
5. Reduced physical ability	0.794 (0.370)[a]	0.805 (0.352)[a]	–
10. Negatively affected sexual life	0.674 (0.546)[a]	0.683 (0.533)[a]	–
12. Deteriorated life situation	0.854 (0.271)[a]	0.868 (0.247)[a]	–
Mental scale			
6. Reduced ability to concentrate	0.781 (0.390)[a]	–	0.860 (0.260)[a]
7. Feel low-spirited or sad	0.745 (0.445)[a]	–	0.806 (0.350)[a]
8. Feel irritated or angry	0.603 (0.636)[a]	–	0.653 (0.574)[a]
9. Suffer from sleep problems	0.566 (0.679)[a]	–	0.616 (0.620)[a]
11. Afraid of dying	0.569 (0.676)[a]	–	0.615 (0.622)[a]
13. Feel worried that symptoms will reoccur	0.556 (0.691)[a]	–	0.609 (0.629)[a]
Factor correlation		0.843[a]	

[a]$P < .001$.

correlation were significant at a level of $P < .001$ (Table 4). The initial 2-factor model also showed unsatisfactory model fit regarding χ^2 goodness-of-fit, WRMR, and RMSEA. After residual variances were allowed to correlate in the respecified 2-factor model, the model fit increased significantly according to the $\chi^2_{difference}$ test ($\chi^2_5 = 67.05$, $P < .001$), and all fit indices demonstrated satisfactory agreement, except for χ^2 goodness-of-fit. In this model as well, RMSEA was close to 0.05 and did not statistically deviate from this critical level (Table 5). A comparison between the 1- and 2-factor models, without correlated residual variances, showed that the latter had significantly better model fit according to the $\chi^2_{difference}$ test ($\chi^2_1 = 27.07$, $P < .001$).

Convergent and Discriminant Validity

Convergent validity was confirmed with the correlation analyses between the ASTA HRQOL subscales and SF-36 PCS and MCS dimensions. The strongest correlations (homotrait-heteromethod) were found between the ASTA physical subscale and the SF-36 PCS ($r_s = -0.61$) and between and the ASTA mental subscale and the SF-36 MCS ($r_s = -0.62$). Discriminant validity was supported with lower correlations (heterotrait-heteromethods) between the ASTA physical subscale and the SF-36 MCS ($r_s = -0.44$) and between the ASTA mental subscale and the SF-36 PCS ($r_s = -0.32$). In contrast, the correlation (heterotrait-homomethod) between the ASTA physical and mental scale ($r_s = 0.68$) did not support discriminant validity.

Internal Consistency Reliability

The internal consistency of the ASTA HRQOL 13-item scale was satisfactory ($\alpha = .91$), as were the physical and the mental subscales ($\alpha = .89$ and .79, respectively). Internal consistency was also sufficient according to a

TABLE 5 Goodness-of-Fit Indices for the 1- and 2-Factor Model for the Arrhythmia-Specific Questionnaire in Tachycardia and Arrhythmia's Health-Related Quality of Life Scale (n = 147)

Model	χ^2 Goodness-of-Fit			WRMR	RMSEA			CFI	TLI
	χ^2	*df*	*P*		RMSEA	90% CI	CFit		
1-factor model									
Initial[a]	214.76	65	<.001	1.149	0.125	0.117–0.144	<0.001	0.953	0.943
Respecified[b]	99.98	61	.001	0.700	0.066	0.041–0.089	0.130	0.988	0.984
2-factor model									
Initial[a]	178.70	64	<.001	1.021	0.110	0.091–0.130	<0.001	0.964	0.956
Respecified[c]	85.03	59	.015	0.626	0.055	0.025–0.079	0.361	0.992	0.989

Goodness-of-fit indices and criteria for model fit: χ^2 goodness-of-fit ($P > .05$).
Abbreviations: CFI, comparative fit index (≥0.95); CFit, close fit using RMSEA ($P > .05$); CI, confidence interval; RMSEA, root-mean-square error of approximation (≤ 0.05); TLI, Tucker Lewis index (≥0.95); WRMR, weighted root mean residual (<1.0).
[a]Model without correlations of error variances.
[b]Error variances allowed to correlate between items 2–3, 7–11, 7–13, and 11–13.
[c]Error variances allowed to correlate between items 2–3, 7–11, 7–13, 11–13, and 12–13.

95% lower bound confidence interval, total scale α = .89, physical subscale α = .87, and mental subscale α = .75. Deleting an item from the analysis would not substantially improve the overall Cronbach's α for any scale.

Discussion

The present study aimed to develop and validate a disease-specific scale evaluating HRQOL in patients with different forms of arrhythmia treated according to national and international guidelines.[40–42] In terms of data quality, construct validity, and internal consistency, this first evaluation showed that the ASTA HRQOL scale is a promising instrument for assessing HRQOL in the target population.

The disease-specific questionnaire available at the time of the development of ASTA was the arrhythmia-specific Symptom Checklist, Frequency, and Severity Scale. The Symptom Checklist, Frequency, and Severity Scale is a checklist evaluating symptoms in arrhythmia patients, mostly used in patients with AF, but it has also been used in patients with other tachycardias.[3,23,24] Questionnaires regarding HRQOL in arrhythmia patients are often developed solely for patients with AF or patients with other forms of supraventricular tachycardia. Some questionnaires mix symptoms and HRQOL in the same scale or evaluate the daily life situation very briefly.[3,20–25] We found it important to develop an HRQOL scale that focuses on the consequences that arrhythmias impose on patients' daily lives.

To cover the sufficient content of the influence of arrhythmias on HRQOL, items were chosen from patient interviews, suggestions by experienced healthcare professionals, and from a literature review. In addition, we found it most important that the ASTA HRQOL scale be inspired by patients themselves. During the development and testing phase, patients were repeatedly asked to provide feedback on the coverage of arrhythmia affected domains and the readability of the questions. Therefore, the strength of the study lies in the repeated evaluations in the research group and in the expert panel including arrhythmia patients who were encouraged to give their opinions on the chosen symptoms and HRQOL concerns.

We used a qualitative approach with interviews combined with a pretest in a large share of patients and established the content validity of the final scale by using the CVI method.[29] This is a common method used to secure content validity.[28] The index was sufficient for all the ingoing items as well as for the total scale. However, the CVI can be criticized for not adjusting for chance agreement.[43]

In some of the items, it can be difficult to define if they belong to the physical or mental dimension. In the ASTA HRQOL scale, sleep disturbances and sexual life interferences are examples of such items. When making the final decision, we were guided by items' placing in previous scales, such as the Minnesota Living With Heart Failure and SF-36. There are some similarities with the subscales in ASTA HRQOL and the disease-specific Minnesota Living With Heart Failure subscales.[44] In both, sleep disturbances, daily activities, and spending time with others belong to the physical scale, whereas feeling low spirited or sad, worry, and ability to concentrate belong to the mental scale. According to the modification index, our CFAs showed no signs of substantial improvement by allowing these items to cross-load on both the physical and mental factors. To be certain, we allowed sleep disturbance and sexual life interference to cross-load to both factors. As this CFA did not improve the goodness of fit between model and data, the findings support that these items are appropriate indicator variables for the factors to which they were assigned.

Overall, data quality was good. There was a minor problem with skewed distribution of data for both items and scales. Although 3 of 4 items demonstrating a floor effect were related to the physical subscale, neither the total scale nor the physical subscale deviated from a normal distribution. Even if the mental subscale showed a skewed distribution, the scoring range was acceptable as all response categories were used. This indicates that the ASTA HRQOL scale has the ability to discriminate between different groups.[34] The generally low frequency of missing data indicates that the ASTA HRQOL scale is relevant and not too burdensome or difficult to complete. There was no clear pattern found for missing data, which indicates that the ASTA HRQOL scale does not produce systematic missing data. One-third of the patients had chosen to answer "I don't know" in at least 1 of the 13 items, most frequently in the item concerning the arrhythmia's interference with sexual life. Possible reasons for the great number of patients who responded "I don't know" are that these patients did not have distinct or bothersome arrhythmia symptoms or that some could not judge the arrhythmia to be the reason for their daily life impairment. Difficulties in handling the "I don't know" responses resulted in a decision to exclude this alternative in the ASTA HRQOL scale.

This first evaluation of the ASTA HRQOL scale shows emerging evidence of validity and reliability. The item-total correlations for the total scale were high. This indicates that the items measure the same concept and that none of them fulfilled the criteria for removal. The findings were partly confirmed by the CFAs. The initial CFA analyses showed that the 1- and 2-factor model had similar properties, with strong factor loadings and satisfactory goodness-of-fit values according to the CFI and TLI. For both the 1- and 2-factor models, a good

fit between model and data was reached only after residual variances were allowed to correlate. According to the $\chi^2_{difference}$ test and the other fit indices, the 2-factor model seems to be preferred. However, as model fit is only 1 aspect of model evaluation, no strong conclusion regarding the factor structure can be drawn.[35,45] From this perspective, both models showed similar model fit and demonstrated strong and significant factor loadings. We also found a strong correlation between the physical and mental factor in the CFA analysis. The findings indicate a possible higher-order factor structure, that is, that both the total and subscale scores can be used in a meaningful way.

Similar findings were also shown in the evaluation of convergent and discriminant validity. There was a problem regarding discriminant validity because the strongest correlation was found between the physical and mental subscales of the ASTA HRQOL scale. This finding corresponds with the problem with a strong factor correlation. It is difficult to assess whether some domains are mostly physical or mental concerns (as mentioned earlier in the CFA discussion). This can be demonstrated in the present study by the arrhythmia's interference with the patient's sexual life or by sleeping disturbances. The high correlation between the subscales may imply that they measure the same concept. Difficulties with strong correlations between the physical and mental dimensions of HRQOL have also been demonstrated in other disease-specific scales, for instance, the Minnesota Living With Heart Failure Questionnaire.[44] Considering the findings from the CFA and the evaluation of convergent and discriminant validity, our suggestion is to report both the total and subscale scores until there is more evidence regarding the factor structure. In particular, a higher-order factor model should be considered.

All ASTA HRQOL scales demonstrated satisfactory internal consistency reliability. As the Cronbach's α is sample dependent,[37] we calculated a lower bound confidence interval for the α coefficient. As both the total scale and the subscales demonstrated lower bound confidence intervals for Cronbach's α values above the critical level of .70, the ASTA HRQOL scale can be expected to have satisfactory internal consistency reliability also in the population. It should be mentioned that Cronbach's α is an appropriate measure of internal consistency only for unidimensional scales.[34] As the factor structure needs to be evaluated further, the Cronbach's α should be interpreted with this in mind.

Study Limitations

The sample size in the present study was somewhat limited, even though all the arrhythmia diagnoses we aimed to include were represented. Reasons for the reduced number of patients were both the missing data in the ASTA HRQOL scale and the fact that a large share of the patients chose the response alternative "I don't know." A common solution for treating missing data is to impute data with estimated values, if the missing values are not too high.[46] In this development and validation phase of the ASTA HRQOL scale, we have chosen to treat both missing values and the alternative "I don't know" as missing data, with a reduced sample size as a consequence. Although this procedure reduced the sample size to 147 patients, we estimated this to be a sufficiently large sample as most of our analyses were used for description rather than inference.[34]

A related limitation is the variance in timing and location of data collection between emergency care and the RFA patients. This limitation is mostly related to the psychometric evaluation. Therefore, we compared the 2 groups with each other. As only the mean age differed between the groups, this sampling variance is probably of minor importance. Another limitation was that some patient groups were represented by only a few patients, that is, patients with FAT, atrial macro reentry, and ventricular arrhythmias. It is noteworthy that these patient groups were represented in the interviews during the development phase and included in the initial testing of the HRQOL scale. In addition, as the sample included patients of different genders, ages, and arrhythmias, the sample corresponded well to the target population of the ASTA HRQOL scale.

As the sample was somewhat limited, and as the scale was developed for different types of arrhythmias, no groups were excluded. In further studies, the factor structure needs to be evaluated regarding invariance across groups of different arrhythmia diagnoses. The ASTA HRQOL scale also needs to be further evaluated regarding known-groups validity, stability, and responsiveness.

Conclusions

Assessment of HRQOL is of importance for evaluating arrhythmia patients' subjective experiences of their daily life situation. Generic instruments are often not sensitive enough to catch the effects of a certain disease, and therefore, there is a need for a suitable validated disease-specific questionnaire. The ASTA HRQOL scale was developed together with the experts themselves, that is, patients with different forms of arrhythmias. In terms of validity and reliability, the ASTA HRQOL scale showed to be a promising tool. The scale can be a valuable contribution to the assessment of HRQOL in both clinical practice and in research. Until there is more evidence regarding validity and reliability, in particular with regard to the factor structure, using both the total and subscale scores is recommended.

What's New and Important

- A—ASTA is a newly validated arrhythmia-specific HRQOL questionnaire
- S—Suitable for patients with different forms of arrhythmias
- T—To catch the patient's perspective. Subjective assessment of HRQOL is important in the evaluation of arrhythmia patients' daily life situation.
- A—ASTA HRQOL questionnaire can be a valuable contribution to clinical practice and for research use for the assessment of HRQOL in patients with arrhythmia

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