

## The Atrial Fibrillation Effect on QualiTy-of-Life (AFEQT) questionnaire: cultural adaptation and validation of the Greek version

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### Abstract

**Aim:** To adapt cross-culturally the Atrial Fibrillation Effect on QualiTy-of-Life (AFEQT) for use in Greek patients with atrial fibrillation (AF) and to evaluate its psychometric properties.

**Methods:** Professional translators were involved in the inverse translation procedure. Twenty patients with AF participated in the cultural adaptation procedure. One hundred two consecutive patients participated in the validation process that included reliability (internal consistency, test-retest reliability) and validity assessment (face validity, construct validity).

**Results:** Greek AFEQT showed high internal consistency (Cronbach's alpha for overall scale: 0.97, subscales: Symptoms: 0.90, Daily Activities: 0.93, Treatment Concern: 0.91, Treatment Satisfaction: 0.83) and test-retest reliability (Spearman's rho: 0.99,  $p < 0.001$ , Wilcoxon's test,  $p = 0.959$ ). Face validity was rated with a median of 7 by the patients. Finally, Greek AFEQT showed appropriate construct validity of demonstrating adequate convergent validity with the moderate to strong correlations of AFEQT domains with the Physical and Mental Component Summaries of SF-12 (Spearman's rho: 0.53-0.78,  $p < 0.001$ ).

**Conclusions:** The Greek version of AFEQT has shown good psychometric properties and can be a useful tool in future studies on the quality of life of patients with AF. Hippokratia 2016, 20(4): 264-267

**Keywords:** Quality of life, atrial fibrillation, validation, AFEQT, questionnaire

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### Introduction

Atrial fibrillation (AF) is a very common arrhythmia and the second most important risk factor after high blood pressure, for the stroke event<sup>1</sup>. Previous studies have identified that AF patients experience a significant reduction in health-related quality of life (QoL)<sup>2</sup>. Therefore, in order to provide patient-centered care, the evaluation of QoL by health professionals is an emerging and important part of the assessment and follow up of patients with AF.

A number of instruments have been developed to address this need<sup>3-8</sup>. Among the published tools, Atrial Fibrillation Effect on QualiTy-of-Life (AFEQT) has performed strongest in psychometric properties, as recently shown by a systematic review that compared the measurement properties of AF-specific questionnaires on QoL<sup>4-9</sup>. AFEQT is an atrial fibrillation-specific health-related QoL questionnaire that has been already used in various clinical settings<sup>10-15</sup>.

Although the impact of AF on QoL is acknowledged by patients and health professionals, there is currently no validated, disease-specific questionnaire to measure the extent to which AF affects patients in Greek<sup>16</sup>. The aim of this study was to adapt culturally the AFEQT for use in Greek patients with AF and to evaluate its psychometric properties.

### Material and Method

#### *Translation Procedure*

Two professional translators performed independently the forward translation in Greek language. They reached consensus, reconciling their differences and developed a unified Greek version. A third translator performed the back-translation in English that was checked by the developer of AFEQT and was approved.

#### *Cultural Adaptation Procedure*

The Greek version of AFEQT was completed by 20

consecutive patients with AF in an outpatient primary care clinic [12 were female (57.1 %), mean age: 62 years old, standard deviation (SD): 8.5, minimum value (min): 48, maximum value (max): 83]. In order to ensure that native Greek speakers understood each item, the patients were asked to consider each question, to indicate possible problems of comprehension, language, and cultural relevance and they were encouraged to give their suggestions. According to patients' remarks, minor revisions were performed in two items, leading to the final version.

#### *Validation Procedure*

A total of 102 consecutive outpatients with AF visiting a primary care clinic were enrolled in the validation study. Inclusion criteria were the previous diagnosis of AF (paroxysmal, persistent or permanent), adequate knowledge of the Greek language, willingness and competence to participate in the study. Patients with debilitating clinical, mental or psychiatric condition were excluded from the study. The eligible patients were informed about the purposes of the study, and if they consented to participate voluntarily, they were asked to complete a paper/pencil version of the study tool, before their appointment. Approval by the Ethics Committee of the Medical School of Aristotle University of Thessaloniki was obtained for this study (protocol number 335/11.11.2016).

#### *Study Tool*

The responses on the 20-item AFEQT are scored on a 1 to 7 Likert scale (ranging from 1: "Not at all" to 7: "Extremely"). The four subscales of AFEQT are: Symptoms, Daily activities, Treatment concern and Treatment satisfaction. Overall and subscale scores range from 0 to 100. A score of 0 corresponds to complete disability, while a score of 100 describes the highest level of QoL<sup>4</sup>. Additionally, two demographic questions (age, gender), two questions concerning AF (type of AF and their medications) were included.

#### *Psychometric Tests*

Tests of reliability (internal consistency, test-retest reliability) and validity (face validity, convergent validity) were used for the validation of the Greek AFEQT. Internal consistency refers to the extent to which the 20 items within AFEQT are related to each other. A Cronbach's alpha over 0.7 shows satisfactory internal consistency. The test-retest analysis assesses stability, by examining whether the questionnaire measures the same things in the same patients over a period of time. In order to examine test-retest reliability, the AFEQT was completed by the same patients twice, with an interval of two to four weeks over a telephone survey, so that their QoL was unlikely to have changed and responders would not be able to remember their first responses. Face validity examines whether a questionnaire makes sense to those being measured. The patients were asked whether they think that

Greek AFEQT was a valid measure of their QoL and they were requested to rate the extent of its validity from 0 to 10. Convergent validity assesses the relationship between a questionnaire and underlying theories, including how closely the instrument is correlated with other measures that are thought to quantify the same concept. We examined the convergent validity of AFEQT subscales and total scores by estimating its correlation with the two domains (Physical and Mental Component Summaries) of the well-established questionnaire Sort Form Health Survey-12 (SF-12)<sup>17</sup>.

#### *Statistical analysis*

Two researchers entered the data independently, a third cross-checked them, to avoid data entry errors. For the evaluation of internal consistency, Cronbach's alpha coefficient was calculated for the total score, eliminating one item at a time, and checking whether any items significantly increased or decreased alpha. The internal consistency of each subscale and the total AFEQT was tested by calculating Cronbach's alpha. For the test-retest reliability, the AFEQT scores at baseline were correlated with those completed by telephone after two to four weeks, using Wilcoxon Signed Ranks test, since AFEQT scores were not normally distributed. Spearman correlation coefficient (rho) was used for the correlation of AFEQT scores with the Physical and Mental Component Summaries of SF-12. Data analysis was performed with the IBM SPSS Statistics software, version 21.0 (IBM SPSS, IBM, Armonk, NY, USA). All p values were two-tailed.

## **Results**

#### *Patients' characteristics*

Out of the 102 patients who participated, 47 were female (46.1 %), while the mean age was 70 years old (SD: 9.2, min: 52, max: 87). Sixty one patients (59.8 %) had permanent AF, 32 (31.4 %) persistent and 9 (8.8 %) paroxysmal AF. In 54 patients the therapy for AF was acenocoumarol (52.9 %), 44 (43.1 %) (rivaroxaban, dabigatran or apixaban), while 4 (3.9 %) received no therapy. The antiarrhythmic medications in the 102 patients were: propafenone in 69 (67.6 %), flecainide in 22 (21.6 %), amiodarone in 11 (10.8 %).

The mean AFEQT total score was 72.9 (SD: 17.2, min: 26, max: 100), while for the subscales: Symptoms 73.1 (SD: 19.4, range: 25-100), Daily Activities 73.4 (SD: 17.8, 25-100), Treatment Concern 72.2 (SD: 16.6, 30-100), Treatment Satisfaction 72.0 (SD: 19.2, 25-100).

#### *Psychometric Tests*

##### *Reliability Tests*

The Cronbach's alpha for Greek AFEQT was 0.97, while for the four subscales "Symptoms" was 0.90, "Daily Activities" was 0.93, "Treatment Concern" was 0.91 and "Treatment Satisfaction" was 0.83. The internal consistency was not changed when the items were eliminated one item at a-time.

For the test-retest reliability, the mean of the total AFEQT at baseline was 72.9 (SD: 17.2, 26-100), while at the repeated measurement 72.6 (SD: 17.4, 27-100). The two measurements were strongly correlated (Spearman's rho; 0.99,  $p < 0.001$ ). Wilcoxon Signed Ranks test shown no statistical significant difference ( $p = 0.959$ ) between the two measurements.

#### Validity Tests

Face validity was rated with a median of 7 ranging from 3 to 10 by the patients. Testing construct validity, the correlation of the AFEQT subscales with the Physical Component Summary (PCS) and Mental Component Summary (MCS) of SF-12 were medium to strong (Table 1).

#### Discussion

Patients with AF have significantly poorer QoL compared with healthy controls, the general population, and other patients with coronary heart disease<sup>18,19</sup>. Furthermore, psychological distress is often present among patients diagnosed with AF<sup>20</sup>. Symptoms of depression and/or anxiety are associated with greater symptom severity of AF<sup>21-23</sup>, and with recurrence of AF<sup>20</sup>. The Atrial Fibrillation Effect on Quality-of-Life (AFEQT) is a novel disease-specific QoL instrument for patients with atrial fibrillation/flutter<sup>15</sup>.

This paper reports on the first cross-cultural validation of the AFEQT with the development of its Greek version. The translated questionnaire went through cultural adaptation and was tested for its psychometric properties. It was found to have very high internal consistency and test-retest reliability and satisfactory face and convergent validity. This study largely replicates the findings of the original study in terms of reliability<sup>4</sup>.

Greek AFEQT showed even higher internal consistency in the total score (Cronbach's alpha 0.97) and similar alpha coefficients in the four subscales. The translated version has shown to provide reliable measurements over time as supported by the very strong correlation of test-retest measurements in stable patients, even stronger than the ones presented in the original version<sup>4</sup>. Regarding validity, the patients rated the face validity of AFEQT satisfactory. Moreover, this study also showed appropriate construct validity of AFEQT by demonstrating adequate convergent validity correlations of AFEQT domains with the commonly used and well-established generic QoL

measure SF-12. Interestingly, it showed a moderate to strong correlation with both Physical and Mental Component Summaries, although in the original validation study with SF36, the correlation was stronger with the Physical components as compared to the Mental ones<sup>4</sup>. It should be further explored if the stronger effect of QoL on mental aspects of health in Greek patients could be explained by possible cultural differences as compared to the Canadian and US population of the initial study<sup>4</sup>.

This study has several limitations. First of all, it was a single-center study, with a relatively small sample size and a rather small representation of patients with paroxysmal AF. However, since the aim of this study was the cultural adaptation and validation of the Greek version of the tool and not the investigation of predictors of QoL in AF patients, these characteristics of the study's population are not expected to influence the psychometric tests that were performed. Additionally, the second administration of AFEQT for the evaluation of test-retest reliability was performed by telephone and not in person. However, the choice of telephone for follow-up interviews was based on previously published findings supporting that it offers practical advantages over face-to-face interviewing for follow-up assessments producing comparable test-retest correlation coefficients<sup>24,25</sup>. Finally, we have not studied the responsiveness of this instrument (its ability to detect clinically meaningful changes in a patient's health status over time), as well as its ability to discriminate among different severities of AF patients' disease. Although the American AFEQT has proven to have both properties<sup>4</sup>, future studies with the Greek AFEQT are expected to confirm these comparable results.

In conclusion, this study refers to two challenging points. This was the first attempt of cultural adaptation and validation of the Greek version of an AF-specific questionnaire on health-related QoL. Secondly, challenging direction for future studies would be the administration of the AFEQT to a national representative sample of Greece. Applying the Greek AFEQT in clinical settings could further enable health professionals to capture their patients' experiences of AF and the possible effect of AF treatment in their QoL, providing them an additional tool in their effort to provide patient-centered care.

#### Conflict of Interest

Authors declare no conflict of interest.

**Table 1:** Spearman's correlation coefficient between Atrial Fibrillation Effect on Quality-of-Life (AFEQT) and its subscales and Physical Component Summary (PCS) and Mental Component Summary (MCS) of Sort Form Health Survey-12 (SF-12).

	SF-12 PCS	SF-12 MCS
AFEQT total	0.78**	0.73**
AFEQT- Symptoms	0.72**	0.72**
AFEQT- Daily Activities	0.76**	0.72**
AFEQT- Treatment Concern	0.74**	0.69**
AFEQT- Treatment satisfaction	0.71**	0.53**

AFEQT: Atrial Fibrillation Effect on Quality-of-Life, SF-12: Sort Form Health Survey-12, PCS: Physical Component Summary of SF-12, MCS: Mental Component Summary of SF-12, \*\*:  $p < 0.001$ .

## Acknowledgement

The authors would like to thank, Maria Kantziou, Department of Diabetes, Papageorgiou Hospital of Thessaloniki, for her assistance throughout the study.

## References

1. Camm A. Stroke prevention in atrial fibrillation - the unmet need and morbidity burden. *Eur Cardiol.* 2011; 7: 187-195.
2. Thrall G, Lane D, Carroll D, Lip GY. Quality of life in patients with atrial fibrillation: a systematic review. *Am J Med.* 2006; 119: 448.e1-19.
3. Braganca EO, Filho BL, Maria VH, Levy D, de Paola AA. Validating a new quality of life questionnaire for atrial fibrillation patients. *Int J Cardiol.* 2010; 143: 391-398.
4. Spertus J, Dorian P, Bubien R, Lewis S, Godejohn D, Reynolds MR, et al. Development and validation of the Atrial Fibrillation Effect on Quality-of-Life (AFEQT) Questionnaire in patients with atrial fibrillation. *Circ Arrhythm Electrophysiol.* 2011; 4: 15-25.
5. Härdén M, Nyström B, Kulich K, Carlsson J, Bengtson A, Edvardsson N. Validity and reliability of a new, short symptom rating scale in patients with persistent atrial fibrillation. *Health Qual Life Outcomes.* 2009; 7: 65.
6. Yamashita T, Kumagai K, Koretsune Y, Mitamura H, Okumura K, Ogawa S, et al. A new method for evaluating quality of life specific to patients with atrial fibrillation: Atrial Fibrillation Quality of Life Questionnaire (AFQLQ). *Jpn J Electrocardiol.* 2003; 23: 332-343.
7. Arribas F, Ormaetxe JM, Peinado R, Perulero N, Ramírez P, Badia X. Validation of the AF-QoL, a disease-specific quality of life questionnaire for patients with atrial fibrillation. *Europace.* 2010; 12: 364-370.
8. Badia X, Arribas F, Ormaetxe JM, Peinado R, de Los Terreros MS. Development of a questionnaire to measure health-related quality of life (HRQoL) in patients with atrial fibrillation (AF-QoL). *Health Qual Life Outcomes.* 2007; 5: 37.
9. Kotecha D, Ahmed A, Calvert M, Lencioni M, Terwee CB, Lane DA. Patient-Reported Outcomes for Quality of Life Assessment in Atrial Fibrillation: A Systematic Review of Measurement Properties. *PLoS One.* 2016; 11: e0165790.
10. Freeman JV, Simon DN, Go AS, Spertus J, Fonarow GC, Gersh BJ, et al; Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF) Investigators and Patients. Association Between Atrial Fibrillation Symptoms, Quality of Life, and Patient Outcomes: Results From the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF). *Circ Cardiovasc Qual Outcomes.* 2015; 8: 393-402.
11. Zhang L, Gallagher R, Lowres N, Orchard J, Freedman SB, Neubeck L. Using the "Think Aloud" Technique to Explore Quality of Life Issues During Standard Quality-of-Life Questionnaires in Patients With Atrial Fibrillation. *Heart Lung Circ.* 2017; 26: 150-156.
12. Bai Y, Bai R, Wu JH, Zhang T, Liu N, Shi XB, Liu XY, et al. Differences in Quality of Life Between Atrial Fibrillation Patients with Low Stroke Risk Treated With and Without Catheter Ablation. *J Am Heart Assoc.* 2015; 4: e002130.
13. Looi KL, Gajendragadkar P, Taha T, Elsik M, Scully E, Heck P, et al. Long-term outcomes (>2 years) of atrial fibrillation ablation using a multi-electrode ablation catheter in patients with paroxysmal atrial fibrillation. *J Interv Card Electrophysiol.* 2013; 36: 61-69; discussion 69.
14. Wynn GJ, Todd DM, Webber M, Bonnett L, McShane J, Kirchhof P, et al. The European Heart Rhythm Association symptom classification for atrial fibrillation: validation and improvement through a simple modification. *Europace.* 2014; 16: 965-972.
15. Dorian P, Burk C, Mullin CM, Bubien R, Godejohn D, Reynolds MR, et al. Interpreting changes in quality of life in atrial fibrillation: how much change is meaningful? *Am Heart J.* 2013; 166: 381-387.e.8.
16. Tsounis D, Ioannidis A, Bouras G, Raikou M, Giannopoulos G, Deftereos S, et al. Assessment of health-related quality of life in a greek symptomatic population with atrial fibrillation: correlation with functional status and echocardiographic indices. *Hellenic J Cardiol.* 2014; 55: 475-485.
17. Kontodimopoulos N, Pappa E, Niakas D, Tountas Y. Validity of SF-12 summary scores in a Greek general population. *Health Qual Life Outcomes.* 2007; 5: 55.
18. Zoni-Berisso M, Lercari F, Carazza T, Domenicucci S. Epidemiology of atrial fibrillation: European perspective. *Clin Epidemiol.* 2014; 6: 213-220.
19. Raine D, Langley P, Shepherd E, Lord S, Murray S, Murray A, et al. Effect of catheter ablation on quality of life in patients with atrial fibrillation and its correlation with arrhythmia outcome. *Open Heart.* 2015; 2: e000302.
20. McCabe PJ. Psychological distress in patients diagnosed with atrial fibrillation: the state of the science. *J Cardiovasc Nurs.* 2010; 25: 40-51.
21. Gehi AK, Sears S, Goli N, Walker TJ, Chung E, Schwartz J, et al. Psychopathology and symptoms of atrial fibrillation: implications for therapy. *J Cardiovasc Electrophysiol.* 2012; 23:473-478.
22. Thompson TS, Barksdale DJ, Sears SF, Mounsey JP, Pursell I, Gehi AK. The effect of anxiety and depression on symptoms attributed to atrial fibrillation. *Pacing Clin Electrophysiol.* 2014; 37: 439-446.
23. von Eisenhart Rothe A, Hutt F, Baumert J, Breithardt G, Goette A, Kirchhof P, et al. Depressed mood amplifies heart-related symptoms in persistent and paroxysmal atrial fibrillation patients: a longitudinal analysis--data from the German Competence Network on Atrial Fibrillation. *Europace.* 2015; 17: 1354-1362.
24. Ahmadpanah M, Sheikhabaei M, Haghghi M, Roham F, Jahangard L, Akhondi A, et al. Validity and test-retest reliability of the Persian version of the Montgomery-Asberg Depression Rating Scale. *Neuropsych Dis Treat.* 2016; 12: 603-607.
25. Cohen BB, Vinson DC. Retrospective self-report of alcohol consumption: test-retest reliability by telephone. *Alcohol Clin Exp Res.* 1995; 19: 1156-1161.