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Validation of the Danish translation of the atrial fibrillation severity scale: a study on linguistic and cultural adaptation



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Abstract

Background Atrial fibrillation (AF) stands as the most common cardiac arrhythmia on a global scale with a substantial symptom burden impacting the quality of life (QoL) of patients with AF. Consequently, assessing and monitoring symptoms in patients with AF has gained increased interest, leading to a rise in patient-reported outcome measures (PROMs). PROMs provide valuable insights into the patient's perspective, allowing for a more patient-centric approach to care. One of these PROMs is the Atrial Fibrillation Severity Scale (AFSS), a convenient and straightforward instrument for assessing symptom severity in patients with AF, potentially enabling healthcare professionals to tailor interventions accordingly. However, no Danish version of AFSS exists. This study aims to translate and linguistically validate the AFSS in accordance with MAPI Research Trust Guidelines.

Methods The translation of AFSS from English to Danish was conducted using forward and backward translation, yielding versions 1 and 2, respectively. Afterwards, the translated AFSS was linguistically validated in patients with AF by cognitive interviews producing a third version. The third version was then proofread, finalizing the Danish version of AFSS.

Results Derived from the cognitive interviews, the Danish version of AFSS demonstrated comprehensibility and readability among all included patients with AF. No revisions were deemed necessary based on the patient testing, culminating in the submission of the final version of AFSS for approval.

Conclusion A certified and linguistically validated Danish version of the AFSS has been established and is accessible through MAPI Trust Research.

Keywords Patient-reported outcome measure (PROM), Atrial fibrillation, Validation, Linguistics & symptom burden

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Background

Atrial fibrillation (AF) is the most prevalent cardiac arrhythmia worldwide. Current estimates suggest that AF is present in approximately 2-4% of adults in the western world [1]. Due to increased longevity, improved overall survival from cardiac diseases, and increase in risk factors causing AF, AF is expected to increase 2.3fold in the near future [2]. In Denmark, 20,000 patients are diagnosed with AF yearly and over 130,000 patients are living with AF [3]. AF is related to considerable morbidity, especially a higher risk of stroke and heart failure thus having a significant impact on the patient's life. As demonstrated by several studies, AF and its substantial morbidity significantly impact the daily lives of patients thereby reducing their quality of life (QoL) [4, 5]. The large studies conducted by Schnabel et al. [5] (n = 6196)and the ORBIT-AF [4] (n = 10,087) demonstrated an inverse correlation between the European Heart Rhythm Association (EHRA) symptom classification and selfreported QoL as assessed using the EQ-5D-5 L and the Atrial Fibrillation Effect on Quality-of-Life Questionnaire (AFEQT), respectively. The EHRA symptom classification assesses AF-related symptoms like palpitations, chest pain, dizziness, and fatigue based on their impact on daily activities. Consequently, AF management aims to prevent stroke, improve rate and rhythm control as well as maintain or even improve the patient's QoL by minimizing symptoms [6].

A large number of patient-reported outcome measures (PROMs) are currently available to assess AF symptoms and QoL [7]. However, the Atrial Fibrillation Severity Scale (AFSS) stands out as a frequently used symptom scale for the monitoring of AF symptoms [8]. The AFSS has been found to be superior in reliability compared to other AF specific PROMs and has a short completion time of less than 5 min [9].

AFSS has the potential to evaluate patient-rated symptoms, disease severity and the burden of these symptoms conveniently and easily for the patients. AFSS includes the same symptoms as those found in the EHRA symptom classification. Nevertheless, language poses a barrier to AFSS utilization due to non-English native speakers in other countries including Denmark. AFSS's initial development at the University of Toronto, Canada, also necessitates consideration of cultural differences. The reliability and validity of AFSS has been tested and the instrument has also been translated into several languages [10, 11]. The AFSS has currently not been translated into Danish.

We aimed to translate and linguistically validate the AFSS, ensuring conceptual equivalence, cross-language comparability, cultural relevance, and ease of understanding for the target population. All the above in accordance with MAPI Research Trust Guidelines [12].

Methods

Questionnaire

The self-administered AFSS questionnaire is a diseasespecific PROM in patients with AF focusing on AF symptoms and captures subjective ratings of AF related symptoms, health care utilization, and AF disease severity. The questionnaire is divided into 3 sections, A, B, and C, consisting of a total of 19 questions. Part A contains 8 questions regarding general characteristics, overall wellbeing and the frequency, duration, and overall severity of AF episodes. Part B includes 4 questions regarding history of cardioversions, specialist appointments, emergency room visits and hospitalizations within the past year as a result of AF episodes. Finally, part C consists of 7 questions concerning the presence and severity of AF related symptoms within the previous 4 weeks such as palpitations, dyspnea, dizziness, chest pain, fatigue, and weakness. The symptoms are scored on a scale from 0 to 5 with higher scores suggesting more severe and present symptoms. AF severity is calculated by combining the equally contributing parts where each part ranges from 1 to 10 to yield a total AF severity score ranging between 3 and 30. A higher score indicates a more substantial AF burden. Symptom burden is obtained by calculating a score based solely on the 7 questions from part C. The total symptom severity score ranges from 0 to 35 where a higher score indicates more severe symptoms [8, 13].

Translation

The translation and linguistic validation consisted of four phases; (1) Forward translation, (2) Backward translation, (3) Cognitive interviews, and (4) Proofreading.

The process was conducted according to the structure and algorithm of MAPI Research Trust Guidelines (9). As such, every phase was finalized with generating a questionnaire version along with an associated report. Figure 1 depicts the comprehensive multistage process of the translation and linguistic validation. The first author engaged in the process as a local coordinator, having the responsibility for managing the different phases and compiling corresponding reports.

Step 1: forward translation

Four translators were included in the forward translation phase, all of whom were native target language speakers (Danish) as well as being bilingual and thus proficient in the source language (English). Each translator independently created a forward translation of the original AFSS questionnaire. Following the completion of the four forward translations, the local coordinator and translators met to discuss conceptual definitions and address linguistic and cultural considerations. Several items in the individual translations were discussed including the most accurate translation of "specialist" equivalent to



Fig. 1 Flow chart summarizing the translation and linguistic validation process. Legend: AFSS; Atrial Fibrillation Severity Scale, FT1; Forward translator 1, FT2; Forward translator 2, FT3; Forward translator 3, FT4; Forward translator 4, BT1; Backward translator 1, BT2; Backward translator 2, BT3; Backward translator 3

the original questionnaire. The translation of the term "fatigue" into the target language also posed inquiries, as there is no exact equivalent word for "fatigue" in the Danish language. Additional considerations during the reconciliation process were included in the version 1 report.

Step 2: backward translation

Three local translators, being native speakers of the source language and bilingual in the target language, were included in the backward translation process and translated the target language version back into the source language. None of them had any access to the

Table 1 Patients characte	eristics
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Characteristics	N=6
Age, years, median (IQR)	75.5 (72.8–78.3)
Women	3 (50.0)
Atrial Fibrillation	
Paroxysmal	4 (66.7)
Persistent	1 (16.7)
Permanent	0 (0.0)
Unclassified	1 (16.7)
Cardioversion	4 (66.7)
RFA	2 (33.3)
Medical History	
Hypertension	4 (66.7)
Heart Failure	1 (16.7)
Hypercholestorelaemia	3 (50.0)
Pacemaker	2 (33.3)
ICD	2 (33.3)

Legend: Values are counts (column percentages) unless stated otherwise

 $\label{eq:IQR} IQR = interquartile \ range; \ RFA = radiofrequency \ ablation; \ ICD = implantable \ cardioverter \ defibrillator$

original version of the questionnaire; they only had access to the reconciled version of the forward translation. After completion of the three backward translations the local coordinator and colleague (co-author) compared the backward translations to the original questionnaire. Few minor differences in the backward translation were discussed. All backward translations translated the Danish wording of "put to sleep" from part B question 9 of the original questionnaire into "general anesthesia". The minor difference was accepted as the phrase "put to sleep" cannot be readily translated to the target language. Another issue was the backward translation of "I have had" resulted in "I have experienced". The sentence is used several times in the source instrument thus being important for the comprehension of the source instrument. As such, the sentence in the target language was adjusted to avoid the word "experienced" in the backward translation.

Step 3: patient testing

The Danish translation of the AFSS was linguistically validated through cognitive interviews and questionnaire testing on six patients with atrial fibrillation admitted to the Department of Cardiology at Herlev and Gentofte University Hospital, Denmark. Patients were included to represent a diversity of age, gender, atrial fibrillation type, and diagnoses (see Table 1), and all patients were native speakers of the target language (Danish). The number and diversity of patients conform to the standards set by linguistic validation literature [14, 15]. The local coordinator conducted the interviews and testing, and the interviews took place in a quiet room with no disturbances. First five minutes of the interview consisted of a short description of the purpose of the interview as well

as an introduction to the questionnaire. Afterwards the patients systematically went through the questionnaire by reading all text and answers to all questions. The interviewer assessed the patients' questionnaire comprehension and verified their interpretation of every question and item in the questionnaire by asking the patients clarifying questions. Patients were encouraged to think aloud while answering, and the interviewer probed for any difficulties or misunderstanding. Furthermore, the interviews were recorded for quality monitoring.

Step 4: proofreading and final report

The local coordinator and co-authors discussed and compared the patient comprehension of the Danish translation with the original AFSS source instrument to identify any discrepancies. After agreeing upon a final version, which ensured that the information content of the source instrument remained unchanged, a final proofreading was conducted by a person experienced in editing for grammar, typing, and spelling Danish translations from English. The proofreader was a native speaker of the target language and highly proficient in English. The proofreading resulted in only a few suggestions, with the main recommendation being a slight reordering of the questions 11 and 12 to improve the coherence of the questions. The suggestions were accepted and the final linguistically validated and equivalent Danish of the AFSS was produced.

Results of patient testing

Utilizing cognitive interviews, the AFSS proved to be comprehensible, readable, and straightforward to complete for all the participants included in the study. However, the participants experienced minor difficulties with two elements of the questionnaire. Four out of six participants had issues with interpreting question number 4: "How do you feel about your life at the present time?". Yet, the difficulties with the question were not primarily related to its translation, but rather centered around its overall meaning in the original version as the question is inherently imprecise and challenging to interpret due to its broad scope. The participants struggled to determine which factors to include in their comprehension of the question. Patients made statements like:

... that is a difficult question to answer. It can include many aspects of one's life, so you do not really know what to answer.

... I don't really know what to answer, I am about to get my pacemaker changed. Other than that, I don't have any symptoms from the heart.

Additionally, one patient also asked if he should include mental well-being when considering the question. To change the translation to make it more precise would include major modifications to the original question which would not ensure that the information content remained unchanged. As such, no changes were made to the translation of question 4.

One patient had difficulties with the comprehension of question number 8: "How severe was your *first* episode of irregular heart rhythm?". The patient stated:

... it's difficult to answer how severe... a disease you do not know anything about, you do not know the severity of... I could not relate it to any other experience of illness.

Other than the two elements mentioned above causing minor difficulties, the patients found the questionnaire easy to interpret and comprehend. As such, the linguistic validation process generated no suggestions for alterations to the translation.

Discussion

The AFSS was developed specifically to measure patientreported disease severity and symptom severity in patients with AF. The questionnaire has been extensively tested in several studies with both good internal and external validity as well as good reliability to evaluate AF severity [7, 9–11]. Our study has provided a Danish version of the AFSS linguistically validated by patients with documented AF. The Danish version of the questionnaire has received approval from the MAPI Research Trust.

In the past decades, PROMs have been established as important measurements for research and practice in the fields of health and medicine [16]. Consequently, the use of PROMs have increased, emphasizing the need for quality measurement tools being available in native languages for best assessment of patient-reported outcomes such as QoL and symptoms. Using PROMs in routine clinical practice can not only help monitor treatment responses but also provide patients with a structured approach during consultations with healthcare professionals [17].

International practice guidelines also acknowledge the importance of PROMs and recommend routinely collecting data on patients' self-rated symptom burden and disease severity to measure treatment success and optimize patient care [6]. Besides anticoagulation therapy for stroke prevention, other treatments for AF are based on evaluation of symptoms, making reliable and valid symptom questionnaires important in the clinical shared decision-making between patients and healthcare professionals. Additionally, digital capture of patient-reported outcomes has been gaining substantial interest in the routine practice due to the potential real-time monitoring, virtual consultations, and prompt interventions to prevent AF-related adverse outcomes [18, 19]. AFSS holds promise as a valuable digital tool for PROMs in the AF symptom management.

Conclusion

A certified and linguistically validated Danish translation of the AFSS has been established and is accessible through MAPI Trust Research.

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Not applicable.

Author contributions

MH: Conducted the primary work, including the conception and design of the study, acquisition, analysis, and interpretation of data, and drafting the manuscript.SSR: Made substantial contributions to the conception and design of the study, analysis, and substantive revisions of the manuscript. Approved the submitted version and is accountable for all aspects of the work.ML: Substantively revised the manuscript and approved the submitted version, ensuring accuracy and integrity.TBR: Substantively revised the manuscript and approved the submitted version, ensuring accuracy and integrity.TBR: Substantively revised the manuscript and approved the submitted version, ensuring accuracy and integrity.

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Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request, subject to compliance with institutional and ethical guidelines. Access to the Danish translation of the Atrial Fibrillation Severity Scale (AFSS) is governed by the MAPI Research Trust.

Declarations

Human ethics and consent to participate

Informed consent was obtained from all individual participants included in the study.

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Conflict of interest

None declared.

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