Structured Care Of Patients With Atrial Fibrillation Improves Guideline Adherence

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Abstract

There are many reports of lack of guideline adherence in the treatment of patients with atrial fibrillation (AF), and AF affects health-related quality of life (HRQoL) negatively. The aim of this study was to investigate whether structured care compared to standard care of a general AF population could improve guideline adherence and HRQoL, and reduce symptoms, anxiety and depression.

In total, 376 patients were recruited to the intervention and 146 patients to the control group. The intervention consisted of a structured follow-up program, while patients serving as controls received standard care. The primary outcome was guideline adherence evaluated through: appropriate use of oral anticoagulants (OAC) and antiarrhythmics, whether echocardiogram and thyroid lab tests were performed, and patient-reported outcome measures (PROMs), assessed with the questionnaires SF-36, EQ-5D, HADS and ASTA at baseline and after one year. Guideline adherence was significantly better in the intervention group, 91% vs. 63% (p < 0.01), mainly due to appropriate OAC treatment 94% vs. 74% (p < 0.01). Symptoms assessed with ASTA were less frequent and the negative impact of AF was reduced in the intervention group after one year at follow-up. Five scales in SF-36, and the visual analogue scale for current health status in EQ-5D (EQ-VAS), improved significantly in both groups.

Structured care of patients with AF significantly improved guideline adherence and patients reported fewer symptoms and a reduced negative impact on disease-specific HRQoL compared to standard care at one year follow-up.

Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia with a prevalence of approximately 3% in the Swedish population, and increases with age.[1] Due to an aging population, the number of patients with AF will increase, which implies great demands on the healthcare services. AF is associated with heart failure, disabling symptoms, decreased health-related quality of life (HRQoL), increased mortality and risk of ischaemic stroke.[2] Approximately 15% of all strokes are due to AF and among octogenarians as many as 25%[3]. Ischaemic stroke due to AF leads to higher mortality and greater disability than a stroke caused by other reasons.[3] Although it is well-known that treatment with oral anticoagulants (OAC) in high risk patients significantly reduces the risk for stroke, there are many reports of its underuse.[4] Studies have shown that other factors than well-known risk factors for stroke are often involved in the decision on whether to prescribe OAC or not.[4] There is a lack in guideline adherence in other areas as well, especially echocardiography.[5]

Secondary to stroke prevention, the care of patients with AF should focus on symptom relief and improvement in HRQoL, since AF often leads to more or less severe symptoms and a reduced HRQoL.[6] Anxiety and depression are particularly strong predictors of HRQoL in patients with AF.[6, 7] Symptoms, anxiety, depression and HRQoL can be evaluated by patient-reported outcome measures (PROMs). PROMs provide a way to gain insight into how patients perceive their health and offer a way to measure the effects of healthcare interventions, most commonly through self-completed questionnaires.[8]

The aim of this study was to investigate whether structured care compared to standard care of a general AF-population could improve guideline adherence and HRQoL and decrease symptoms, anxiety and depression.

Methods

Study design

The study had a non-randomised prospective design. The intervention took place at the Ryhov county hospital in Jönköping, Sweden, while patients in the control group were enrolled at three county hospitals in the same area (Kalmar, Eksjö and Norrköping, Sweden). All patients were asked to fill out questionnaires at inclusion and after one year, and their medical records were examined one year after inclusion. There was no study-related contact with...
patients in the control group, while patients in the intervention
group were followed at the AF clinic as described below. Educational
level, occupation and cohabitation was registered. The first patient
was included in December 2009 and the last follow-up was made in
April 2014. Ethical approval was obtained from the Regional Ethical
Committee in Linköping (Dnr. M145-09). The study complies with
the declaration of Helsinki.

**Study population**

All patients ≥18 years who visited the emergency room (ER) due
to AF were eligible for participation. Written informed consent was
obtained prior to enrolment. Exclusion criteria were unwillingness
to participate, unstable coronary artery disease, sepsis or other
severe infection, AF early after thoracic surgery, acute pulmonary
embolism, known hyperthyroidism, malignant disease with expected
survival less than one year, dementia or insufficient knowledge of the
Swedish language making it difficult to independently fill out the
questionnaires.

**Norm population**

In 2006, a survey of the population in south-eastern Sweden was
conducted, including assessment of HRQoL measured with, among
others, SF-36. In total, 7,238 individuals responded to the survey, and
the individuals aged 65-74 years were used for comparison.

**Enrolment**

Eligible patients were informed of the study at the ER or at the
cardiac ward. Enrolled patients were then scheduled for an outpatient
visit at the AF outpatient clinic (see below) within two weeks.
Patients enrolled at the hospitals serving as control centres were only
asked to fill out the questionnaires and then received "care as usual".

**Structured care of atrial fibrillation**

**Education and preparations**

Prior to study onset, physicians at the emergency care unit at the
intervention centre were educated concerning current guidelines.
A pocket sized laminated algorithm was presented, containing
recommendations for treatment with oral anticoagulants (OAC) and
with suggestions for outpatient management.

**Atrial fibrillation outpatient clinic**

The AF outpatient clinic was active one weekly and manned by
two cardiologists and two nurses. All patients included in the study
were followed at the AF outpatient clinic for one or two weeks after
discharge and then after three and 12 months. Data was entered in
the Swedish National quality AF registry (Auricula) at the first and
last visits. The nurses’ perspective was information and education
in order to increase the patients’ knowledge about AF. They also
provided information on lifestyle with focus on overweight/obesity,
the amount of alcohol and coffee use, stress and psychological distress.
In addition to the orally given information, an information booklet
from the Swedish Heart and Lung Foundation was handed out,
containing general information about AF including basic anatomy,
physiology, symptoms and treatment. The physician’s evaluation
was made aided by a checklist to ensure that treatment was given
according to guidelines. If OAC was not prescribed when indicated,
an explanation was mandatory. Increased availability was also a part
of the structured AF outpatient clinic. Patients could reach a nurse
every weekday morning.

**Outcomes**

The primary outcomes were the effect of structured care on guideline
adherence, symptoms, anxiety, depression and HRQoL. Adherence to
guidelines was evaluated by five criteria: a) appropriate prescription
of OAC according to the CHADS, and CHA2DS2-VASc criteria
(table 1), b) echocardiogram performed, c) thyroid laboratory tests
performed, d) no antiarrhythmic drugs (AA) prescribed to patients
in permanent AF, and e) no class 1c-AA prescribed in the presence
of structural heart disease. At the onset, the recommendation in the
guidelines were based upon the CHADS, classification scheme and
suggested the use of OAC when CHADS, ≥2 in patients without
contraindications. During the study, new guidelines were published
suggesting the use of the CHA2DS2-VASc classification scheme and
treatment with OAC for scores ≥1. Symptoms, anxiety, depression
and HRQoL were assessed by the following questionnaires:

**The Medical Outcomes Study 36-Item Short-Form Health Survey**

The Medical Outcomes Study (MOS) 36-Item Short-Form Health Survey (SF-36) is a generic questionnaire designed to measure
an individual’s physical and mental health. It comprises 35 items
grouped into eight scales and one question concerning changes in
health outside the scales. The eight scales are physical functioning
(PF), role-physical (RP), bodily pain (BP), general health (GH),
vitality (VT), social functioning (SF), role-emotional (RE), and
mental health (MH). For each of the eight scales scores were coded,
summed, and transformed to a scale from 0 (worst possible health) to
100 (best possible health). The scoring of the SF-36 data was carried
out as described by Ware and colleagues[9]. SF-36 has been widely
used in research, including studies of patients with arrhythmias[6,10].

**The EuroQol Health Questionnaire, five dimensions and
EuroQol Health Questionnaire, Visual Analog Scale**

In The EuroQol Health Questionnaire, five dimensions (EQ-5D)
and EuroQol Health Questionnaire, Visual Analog Scale (EQ-VAS)
questionnaire was used to characterize health state. The EQ-5D
questionnaire assesses five dimensions; patient mobility, self-care,
activity, pain/discomfort, and mood, each with three levels of severity.
The UK EQ-5D index tariff was used to obtain a weighted index,
with a range from −0.59 to 1.0, where 1.0 represents full health[11].
The EQ-VAS records the respondents’ self-rated health status on a vertically graduated (0–100) visual analogue scale with 100
(best imaginable health state) at the top and 0 (worst imaginable
health state) at the bottom. EQ-5D/EQ-VAS has been extensively
validated and is one of the most used generic HRQoL instruments
in AF studies[10].

**The Hospital Anxiety and Depression Scale**

The domain specific questionnaire Hospital Anxiety and Depression
Scale (HADS) is used to evaluate symptoms of anxiety and depression.
It consists of two subscales, where seven questions assess anxiety
(HADS-A) and the remaining seven assess depression (HADS-D).
Responses are scored from 0 to 3 with higher scores denoting more
psychological distress. The score for each subscale can range from 0 to
21. The scores are categorized as normal (0–7), mild (8–10), moderate
(11–14) and severe (15–21) anxiety and/or depression respectively[12].
HADS has previously been used in AF studies[33].

**The Arrhythmia-Specific questionnaire in Tachycardia and
Arrhythmia**

The disease-specific Arrhythmia-Specific questionnaire in
Tachycardia and Arrhythmia (ASTA) is divided into three separate
parts where part I evaluates the patient’s latest episode of arrhythmia,
current medication and the patients’ subjective feeling of any
existence of arrhythmia. Part II evaluates symptom burden including frequency and duration of arrhythmia episodes, and contains a 10-item symptom scale with four response alternatives: "(0) No, (1) Yes, to a certain extent, (2) Yes, quite a lot and (3) Yes, a lot. Outside of the Symptom scale there are two questions concerning “near syncope” and “syncope” with the response alternatives Yes/No. Part III assesses the influence on HRQoL and consists of a 13-item scale with seven physical subscale items and six mental subscale items. The response alternatives are the same as for the symptom scale in part II[14, 15]. In order to evaluate experiences of achieved freedom from arrhythmia-specific symptoms and negatively influenced HRQoL after one year, the variables were dichotomized to the responses “Yes” or “No”.

Statistics
In order to detect a five-point difference in the scales in SF-36 between the groups using an alpha of 0.05 and a power of 0.80, 200 patients in each group were required. Normally distributed variables are presented as means ± standard deviations, whereas categorical variables are presented as percentages and numbers. Differences between the two patient groups for normally distributed variables were tested with independent t-test, and paired t-test for differences over time within the groups. For non-normally distributed variables the Mann-Whitney U test was used for testing differences between two groups, and Wilcoxon’s signed rank test within groups over time and McNemar’s test was used for dichotomous variables. For categorical variables the Chi-square test or Fischer’s exact test were used between groups, and for proportions the z-test with continuity correction was used. All calculations were made with SPSS statistical software version 20.0 (Armonk, NY: IBM Corp). P-values <0.05 were considered as statistically significant.

Results
Patient characteristics
The intervention group consisted of 199 patients and the control group of 162, and patients available for analysis were 176 (88%) and 146 (90%), respectively. (Figure 1). The two groups differed at baseline concerning educational degree, number of patients with CHADS2 0 p, and the number of patients having their first episode of AF (Table 2).

Guideline adherence
At baseline, there was no difference in treatment with OAC according to guidelines between the intervention group and the control group, 27 (65 %) vs. 17 (63 %, p = 0.88) using CHADS2, and 51 (61 %) vs. 42 (55%, p = 0.43) using CHA2DS2-VASc. The number of patients treated according to guidelines after one year, in terms of adherence to all five criteria investigated, was significantly better in the intervention group, 152 (93%) vs. 105 (74%, p < 0.01). The difference in total adherence to guidelines was greater using the CHA2DS2-VASc in favour of the intervention group after one year, 148 (91%) vs. 89 (63%, p < 0.01). This was mainly due to an improvement in OAC treatment (figure 2). However, there were also significant differences in whether thyroid function was tested or not, 175 (99%) vs. 126 (86%, p < 0.01). There were no differences in investigations with echocardiogram, 164 (93%) vs. 133 (92%, p = 0.62), in whether patients were treated with AA although in permanent AF (none in both groups), or whether a class Ic-AA drug was used despite presence of structural heart disease (two patients in each group).

During follow-up, stroke, transient ischemic attack or peripheral embolus occurred in five patients (3%) in the intervention group and three patients (2%) in the control group. Two patients in the intervention group suffered from intracerebral bleeding, while one patient in the intervention group and one patient in the control group suffered from gastrointestinal bleeding.

The number of patients with CHA2DS2-VASc 0 p after one year was 21 (12 %) and 11 (8 %) in the intervention group and control group, respectively. However, seven (33 %) and five (46 %) of those patients were treated with OAC (n.s.) and the reasons were recent or planned ablation or DC-conversion, patients’ own will to continue, close to reaching 65 years of age and in one patient a second echocardiography was planned since the left ventricular function was hard to evaluate due to arrhythmia in the first echocardiography.

Patient-reported outcome measures
The number of enrolled patients that did not return the questionnaires at follow-up was seven (4%) in the intervention group and 48 (33%) in the control group. There were also a number of missing answers within the questionnaires, hence the numbers of patients not included in the analyses of PROMs were greater for some scales.

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(79 %) patients in the control group. The degree of depression was normal in 128 (81%) and 106 (86 %) patients, in the intervention group and control group, respectively. There were no significant differences between the groups.

The degree of anxiety was reduced after one year in both groups, while depression did not change significantly (table 3). The scoring did not differ between the groups at the one year follow-up.

Health-related quality of life

At baseline, measured with the ASTA questionnaire, there were more patients in the control group who reported that they were unable to work (p=0.01), more who avoided spending time with acquaintances (p=0.03) and family/relatives (p=0.03). After one year the patients in the intervention group were to a higher degree free from a negative influence on HRQoL compared to patients in the control group, where more patients were unable to work (p = 0.01).

There were differences between the two groups at baseline also in SF-36 (table 3). Patients in the intervention group scored higher in four scales (PF, RP, SF and RE) compared to patients in the control group. After one year there was significant improvement in both groups, with no significant differences between the groups.

Comparisons with the norm population

When comparing the two patient groups at baseline with a norm population assessed by SF-36, the patients in the intervention group scored significantly worse (p<0.05) in six out of eight scales (RP, GH, VT, SF, RE, MH) while the patients in the control group scored worse in seven of the scales (PF, RP, GH, VT, SF, RE, MH) (figure 4).

After one year, the patients in the intervention group improved in two scales (SF and MH) and scored similar to the norm population, and even better than the norm population in the scale BP. The patients in the control group still scored worse in seven out of eight scales, i.e. in all except BP, equal to the situation at baseline.

Discussion

The main finding in this study on structured care given through an AF outpatient clinic was the significant improvement in guideline adherence. At the one-year follow-up the patients reached the HRQoL scores of a norm population to a higher degree compared to patients in the control group. Arrhythmia-specific symptoms were less frequently experienced in the intervention group and HRQoL improved, measured with the arrhythmia-specific questionnaire.

Several studies have shown a discrepancy between guidelines and everyday clinical practice in the management of AF[15, 16]. A Swedish study from 2002 showed that about 50 % of AF patients with indications for OAC actually received it[17]. Since the introduction of a risk factor-based approach for stroke prevention, i.e. CHADS2/CHA2DS2-VASc-scores, there has been a considerable improvement in guideline adherence concerning OAC treatment[16].

However, contemporary data still indicate significant both under- and over-treatment with OAC in patients with AF, which is associated with poorer outcome and emphasizes the importance of guideline implementation[16]. Although appropriate antithrombotic treatment was higher in the control group at follow-up than shown in the results from older studies[5] and consistent with new promising reports[16], the structured care resulted in a greater improvement in adequate use of OAC. Studies show that guideline adherence concerning AF management and especially antithrombotic treatment, is improving worldwide[16], but this study shows the importance of structured care in order to improve guideline adherence.

The structured care in this study resulted in improved guideline adherence. The results are consistent with a study conducted by Hendriks et al., which showed a significant improvement in guideline adherence leading to a significant reduction in cardiovascular mortality and hospitalisation[18]. Another similarity between these two studies is the patients’ reported measurements, where the patients in the control group had lower scores in symptom burden and HRQoL at baseline. In both studies, the scores of the generic SF-36 questionnaire improved in both groups, with no significant difference between the groups at follow-up[13]. Both studies suffer from a relatively large number of patients lost to follow-up, particularly regarding patients in the control group. However, in this study...
study, the SF-36 scores were to a greater extent improved to the level of the norm population in the intervention group.

Furthermore, in the disease-specific instrument, the intervention group improved more in HRQoL than the control group. Using the ASTA questionnaire allows both detection and reflection of disease-specific changes between patients and over time. The well-known SF-36 and EQ-5D questionnaires, which are often used in AF studies, are generic and thereby reflect general health, which is influenced by comorbidities, commonly present in patients with AF. Recommendations urge the use of disease-specific instruments, especially when measuring changes in symptom burden and HRQoL over time.[19].

The degree of anxiety was significantly reduced in both groups. The fact that anxiety is a strong predictor of HRQoL[6, 7] and that HRQoL can predict hospitalisation and mortality, emphasizes the importance of focusing on reducing anxiety in patients with AF. Treatment of patients with AF should thus focus on reducing symptoms, anxiety, depression and enhancing HRQoL in addition to being compliant with guidelines[19].

Conclusion

The study showed improvement in guideline adherence in the intervention group with structured AF care, mainly driven by improvement in OAC prescription. The degree of anxiety was reduced after one year and the scoring concerning HRQoL was improved in both patient groups. The arrhythmia-specific symptoms were less frequently experienced in the intervention group and HRQoL improved, and the SF-36 scores were more similar to the norm population compared to the control group at follow-up.

Disclosure

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