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Compliance of patients with atrial fibrillation using new oral anticoagulants – results survey

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SOUHRN

Úvod: U pacientů s fibrilací síní užívajících nová perorální antikoagulancia (NOAC) je nezbytné kontinuální užívání léků. Vyšší věk a polymorbidita mohou ovlivnit compliance související s antikoagulační léčbou.
Metody: Observační kohortová studie (STROBE) hodnotila compliance pacientů s vybranými kardiovaskulárními diagnózami a dalšími komorbiditami, kteří dostávali NOAC a ambulantní péči na specializovaných klinikách v České republice, v dotazníkovém průzkumu v období od dubna do května 2023.
Výsledky: Pacienti splňující kritéria studie byli osloveni ošetřujícím lékařem k zařazení do studie (4 kardiologické a 1 neurologická ambulance). Studie se zúčastnilo celkem 274 pacientů (146 žen, 128 mužů) s hlavní diagnózou fibrilace síní a alespoň jednou potvrzenou vedlejší diagnózou srdečního infarktu, mozkového infarktu, tranzitorní ischemické ataky (TIA), obezity, arteriální hypertenze nebo diabetes mellitus. Statistická analýza potvrdila, že pacienti s anamnézou cévní mozkové mozkové příhody nebo TIA měli vyšší počet pravidelných kontrolních návštěv (jednou za tři měsíce) (p = 0,002492). Analýza dat dále prokázala, že pacienti, kteří byli léčeni kratší dobu, měli tendenci k častějším pravidelným kontrolním návštěvám (délka léčby do 3 měsíců/průměrná kontrola 1,7krát; 3–5 měsíců/0,9krát; 6–12 měsíců/0,7krát). U jednoho pacienta (55 let) s paroxysmální fibrilací síní a diagnózou TIA, který deklaroval nepravidelnost užívání NOAC po dobu 3–5 měsíců léčby, byla zjištěna recidiva TIA.
Závěr: Ve sledovaném souboru byla zjištěna vysoká zátěž dalšími komorbiditami spolu s nedostatečnou deklarací pravidelnosti užívání medikace NOAC a z toho plynoucích rizik. Vzhledem k narůstajícímu počtu předepsaných NOAC je nezbytná vhodná edukace pacientů, zejména u starších pacientů s vysokým rizikem cévní mozkové příhody.

Keywords:
Atrial fibrillation
Compliance
New oral anticoagulants
Risk
Stroke

ABSTRACT

Introduction: Continuous medication use is essential for patients with atrial fibrillation using new oral anticoagulants. Older age and polymorbidity may affect compliance related to the anticoagulation therapy.
Methods: An observational cohort study (STROBE) assessed patients' compliance with selected cardiovascular diagnoses and other comorbidities who received NOAC and outpatient care in specialized clinics in the Czech Republic in the questionnaire survey between April and May 2023.
Results: Patients meeting the study criteria were approached by the treating physician for inclusion (4 cardiology and 1 neurology clinic). A total of 274 patients (146 women, 128 men) with a primary diagnosis of atrial fibrillation and at least one confirmed secondary diagnosis of heart attack, cerebral infarction, transient cerebral ischemic attack (TIA), obesity, arterial hypertension, or diabetes mellitus participated. Statistical analysis confirmed that patients with a history of stroke or TIA had a higher number of regular follow-up visits (once every three months) (p = 0.002492). Furthermore, data analysis demonstrated that patients who had been on treatment for a shorter time tended to have more frequent regular follow-up visits (treatment duration up to 3 months/average check-ups 1.7 times; 3–5 months/0.9 times; 6–12 months/0.7 times). In one patient (55 years) with paroxysmal atrial fibrillation and a diagnosis of TIA, who declared irregularity of NOAC use for 3–5 months of treatment, a relapse of TIA was identified.
Conclusion: A high burden of additional comorbidities was identified in the observed sample, along with the inadequate declaration of the regularity of NOAC medication use and the resulting risks. Appropriate patient education is essential, especially among older patients at a high risk of stroke, considering the increasing prescription rates.

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Introduction

Arrhythmias can be one of the underlying causes of cardiovascular diseases, which can lead to cardiomyopathies and systemic embolism.[1] The incidence and prevalence of most cardiovascular diseases increase with age, and it has been confirmed that cardiovascular diseases are a leading cause of death worldwide.[2] Sudden cardiac death accounts for 15–20% of adult deaths.[2] Approximately 20–30% of patients with ischemic stroke and transient ischemic attack (TIA) were confirmed to have atrial fibrillation before the onset of the disease. The other 70–80% of patients are diagnosed with atrial fibrillation after cardiac monitoring.[3–5] Atrial fibrillation is the most common arrhythmia with a 1–2% prevalence, and its incidence increases with age.[6]

In the clinical guidelines for the treatment of atrial fibrillation (AF), new oral anticoagulants (NOACs) are globally recommended. Studies have demonstrated their high efficacy in long-term use for the prevention of recurrent ischemic events in individuals with stroke (associated with AF) and a lower risk of major bleeding.[7–11] While the term "direct oral anticoagulants" (DOACs) is commonly used to refer to this class of medications, the abbreviation NOAC is still utilized nationally in the Czech Republic.[12] One advantage of using NOACs is eliminating the need for laboratory monitoring compared to vitamin K antagonists (VKA), along with removing drug-food interactions. Following the recommendations of the Czech Society of Cardiology in the Czech Republic, the prescription of NOACs has been expanded in clinical practice.[13]

Comprehensive care is crucial for patients diagnosed with atrial fibrillation, with the first step being the treatment and prevention of thromboembolic complications. This involves assessing the risk of thromboembolism and bleeding complications using scoring systems, followed by the selection of anticoagulation therapy.[14] During the course of treatment, the patient's symptoms are monitored, and a long-term outpatient follow-up is conducted to minimize additional cardiovascular risks. The treatment choice must be individualized for each patient, and the patient's tolerance should be regularly monitored. A vital component of treatment is providing sufficient education and promoting patient's compliance.

Methods

An observational cohort study was conducted to assess the compliance of patients with selected atrial fibrillation and other comorbidities (Table 1) receiving NOACs and outpatient care in specialized clinics. The patients meeting the inclusion criteria were approached directly by the treating physician from the selected specialized clinics (4 cardiology clinics and 1 neurology clinic) to participate in the study. The STROBE checklist guidelines for reporting observational (cohort) studies were used.

The research tool

Information from the respondents was obtained using a non-standardized questionnaire, which included items of demographic nature and items defining the settings of NOACs therapy and patient compliance (see Table 2). Completing the questionnaire required a time commitment of up to 10 minutes. The treating physician handed the questionnaire to the patient during a regular visit to the selected specialized clinic and labelled it with an assigned identification number. If needed, the questionnaire could be deanonymised by the treating physician of the respective clinic, and any missing information could be supplemented directly from the documentation.

Data collection

The questionnaire data collection was conducted from 17th April to 31th May 2023 by providing the questionnaire form to the patients by their treating physicians after meeting the inclusion and exclusion criteria in selected cardiology and neurology clinics. No follow-up assessments were conducted as part of the study.

Table 1 – Research criteria

Inclusion criteria	Exclusion criteria
Age >18 years	Age <18 years
Primary (main) diagnosis (according to ICD-10): I48.0 – Paroxysmal atrial fibrillation I48.1 – Persistent atrial fibrillation I48.2 – Chronic atrial fibrillation	Patients without diagnosed cardiovascular and endocrinological diseases
At least one secondary diagnosis (according to ICD-10): I10 – Essential (primary) hypertension E10, E11 – Diabetes mellitus (type 1 or type 2) E66[a] – Obesity I21.0[a] – Heart attack I64 – Cerebral infarction G45.9 – Transient cerebral ischemic attack	Therapy with NOACs in the period after 10/2022
NOACs therapy: – first group – factor Xa inhibitors (rivarobaxan, apixaban, edoxaban), – second group – thrombin inhibitors (dabigatran)	Disagreement to participate in research
Therapy NOACs from at least 10/2022	
Consent to participate in research	

Table 2 – Areas/batteries of items in the questionnaire
Sociodemographic data about the patient
Age (years)
Sex (M/W/not applicable)
Educational attainment (primary school, high school, university)
Occupation (student, working, retired, disabled)
Duration of atrial fibrillation (years since diagnosis)
Specification of primary (main) diagnosis – I48.0, I48.1, I48.2
Specification of secondary diagnosis – I10, E10, E11, E66*, I21.0*, I64, G45.9
Specific items for the use of NOACs
Frequency of check-ups in specialist outpatient clinic (cardiology, neurology)
Type of NOAC (rivarobaxan, apixaban, edoxaban, dabigatran)
Duration of treatment with NOAC (interval)
Consistency of use of NOAC (interval)

Data analysis

Data analysis involved conducting a descriptive analysis followed by statistical verification. Linear regression models and correlations, including Pearson's product-moment correlation, were used to test the hypotheses at a significance level of 0.05.

Data availability statement

The data supporting this study's findings are available from the corresponding author upon reasonable request.

Ethical approach and data protection

All steps followed the relevant guidelines and regulations of the Declaration of Helsinki (DoH-Oct. 2008). The collected data were used solely for research purposes in the field of public health. They were neither disclosed nor utilized by any other institutions or for alternative objectives. The obtained data were processed and analyzed anonymously, adhering to the applicable law, specifically Act No. 110/2019 Coll. on the Protection of Personal Data in Information Systems, as amended. Ethical approval for the study was granted by the Ethics Committee blinded for review.

Ethical aspects – informed consent

Participation in the questionnaire study was entirely voluntary, and by completing the questionnaire, the patient provided an informed consent to participate in the research.

Results

A total of 5 outpatient clinics participated in the study, including 4 cardiology clinics and 1 neurology clinic, which provided care for both cardiology and neurology patients. The study approached 305 patients who met the inclusion and exclusion criteria, out of which 274 patients (146 women; 53%, 128 men; 47%) agreed to participate. The average age of the respondents in the study sample was 69.2 years, ranging from 39 to 91 years. The largest representation of respondents was in the age category of 66–75 years (N = 141, 51.5%). Among other characteristics, the highest level of education attained was assessed. The majority of respondents reported having completed secondary education with higher education (N = 139; 50.7%), and in terms of occupation, the largest group consisted of retirees (N = 188; 68.6%). A summary evaluation of the sociodemographic characteristics is presented in Table 3.

Characteristics

The majority of respondents had been diagnosed with a cardiac rhythm disorder less than five years ago (N = 132, 48.2%). In comparison, 110 respondents (40.1%) had been identified within 5 to 10 years, and only 32 (11.7%) reported more than 10 years of follow-up for their cardiac rhythm disorder. The diagnosis I48.0 was reported in 199 cases (72.6%), I48.1 in 60 cases (21.9%), and I48.2 in 15 cases (5.5%). Other comorbidities were assessed to determine the burden of additional health conditions. Among the respondents, 66.1% had two or more additional comorbidities. In the study sample, the highest number of patients had a history of stroke (N = 135), with 18 of them having experienced recurrent events and simultaneously being diagnosed with obesity, arterial hypertension, and diabetes mellitus.

Management of NOAC therapy

The study monitored the frequency of follow-up visits based on the type of NOAC therapy. Out of the total participants, 84 patients (30.6%) visited the clinic every three months, while 163 patients (59.5%) had biannual visits. A smaller proportion of patients (27, 9.9%) had less than one visit annually. Among the different anticoagulant therapies, dabigatran was the most commonly prescribed medication (61.6%), followed by rivaroxaban (24.5%) and apixaban (13.9%). None of the patients in the study sample were prescribed edoxaban. Regarding the duration of NOAC use, 3.6% of patients reported using it for less than three months, 32.9% for 3–5 months, 49.3% for 6 months to 1 year, 9.5% for 2–4 years, and 4.7% for more than five years.

The frequency of regular follow-up visits was statistically analyzed concerning age, education, comorbidities, type of NOAC, and treatment duration. All the determinants were analyzed in the comprehensive model which was statistically significant, with a p-value of <2.2e-16 and a coefficient of determination of $p = 0.6672$. Testing confirmed that the patients with a history of stroke or TIA had a higher number of regular follow-up visits (once every three months) (p 0.002492). Furthermore, data analysis demonstrated that patients who had been on treatment for a shorter time tended to have more frequent regular follow-up visits (p for the duration of NOAC use less than three months $p = 1.6969$, for 3–5 months $p = 0.8602$ and for 6 months to 1 year $p = 0.7187$). Patients with a NOAC treatment duration of up to 3 months generally attend check-ups 1.7 times, patients with a treatment duration of 3–5 attend check-ups on average 0.9 times, and patients with a treatment duration of 6–12 attend check-ups on average 0.7 times.

Table 3 – Sociodemographic characteristics

Characteristics	Total N/%	Mean	Min	Max
Gender				
Female	146/53.3%	70	39	91
Male	128/46.7%	68.4	49	89
Age				
40 years and younger	1/0.4%	39	39	39
41–55 years	17/6.2%	53.2	49	55
56–65 years	59/21.5%	62.6	56	65
66–75 years	141/51.5%	69.8	66	75
76 and older	56/20.4%	80.2	76	91
Level of education				
Primary education	12/4.8%	73.6	63	90
Secondary education	30/11.0%	70.3	49	91
Higher education (college)	139/50.7%	68	49	87
Bachelor's degree (EQF 6)	34/12.4%	72.1	61	82
Master's degree (EQF 7)	59/21.1%	69.1	39	89
Employment				
Student	0/0%	0	0	0
Employed	70/25.5%	64	39	82
Retirement pension	188/68.6%	71.7	62	91
Invalidity pension	15/5.5%	64.1	49	82
Unemployed	1/0.4%	60	60	60
Total	**274/100%**	**69.2**	**39**	**91**

Adherence to NOAC therapy

The adherence to NOAC therapy was investigated in the observed cohort, with only 75.9% of the participants reporting regular use of NOAC as prescribed by their attending physician. Approximately 21.7% responded "rather yes", while 2.9% responded "rather no" or "no". The correlations presented in Table 4 demonstrate a negative association when patients use NOACs for a period of 3–5 months. This suggests that if patients take the medication within the time frame of 3–5 months from the initiation of NOAC therapy, their adherence is less frequent. Similarly, if NOACs are used less frequently, and the treatment duration is 3–5 months, the direction of causality in the correlation is unknown. Among patients treated with NOACs for 6–12 months, the highest proportion indicated regular use of NOACs.

Among patients using NOACs, no statistically significant correlation was observed between the use of any specific medication within the NOAC group (dabigatran, rivaroxaban, apixaban) and regular adherence to NOAC therapy. However, a statistically weak but significant correlation was identified between the regular use of NOACs and respondents who had experienced a myocardial infarction (p = –0.1475506) or a stroke (p = 0.1665899).

Discussion

Based on the conducted study, it was possible to identify the basic treatment characteristics among patients using NOACs and verify their compliance. A total of 274 respondents from five participating institutions (outpatient healthcare providers) were included in the study, where demographic characteristics were collected along with specifications of NOAC medication. Comparing the duration of atrial fibrillation with the duration of NOAC therapy, it was found that 100% of respondents using NOACs within the 0–6 months range had no prior history of anticoagulant therapy. Statistically, it was confirmed that the frequency of follow-up visits was higher at neurology clinics for patients with a history of stroke and TIA. A retrospective review of the care provided by the participating clinics revealed that among 24 patients who visited the clinic three times a year, changes in clinical condition were the reason for their visits. However, no adverse effects related to NOAC medication or changes in medication settings were identified in any patient in the observed cohort.

Regarding regular use of NOACs, the highest compliance was statistically confirmed in patients treated for 6–12 months (p = 0.1795627) following myocardial infarction or stroke. One patient (55 years old, master's degree,

employed) with paroxysmal atrial fibrillation (ICD-10 code I48.0) and concurrent TIA (ICD-10 code G45.9) without other comorbidities, who was treated for a period of 3–5 months, declared irregularity in NOAC (rivaroxaban) usage. During the follow-up, a TIA recurrence was confirmed in this patient, necessitating hospitalization. Studies focusing on NOACs demonstrate an effective reduction in the risk of stroke. However, continuous medication adherence is crucial due to the rapid decline in anticoagulant activity when doses are missed.[15–17]

In the observed sample, predominantly older patients with atrial fibrillation were identified (average age 69.2 years), with additional comorbidities increasing cardiovascular risk (such as arterial hypertension, obesity, and diabetes mellitus). Advanced age and polymorbidity can affect compliance and adherence to anticoagulant therapy. Studies have demonstrated improved quality of life among patients who switched to NOAC therapy compared to previous anticoagulant regimens.[18] However, for chronic prophylactic treatment, adherence is essential, and inconsistent NOAC use can lead to complications.[19] Although NOACs do not require laboratory monitoring, patient education and adherence monitoring are necessary. Due to the increasing incidence of atrial fibrillation associated with age, stroke prevention is of great importance. After the introduction of NOACs into routine practice, the number of prescriptions issued to older individuals has increased. However, oral anticoagulation is still underutilized, with up to 30% of high-risk stroke patients not receiving adequate treatment.[20]

In line with the implementation of the presented questionnaire survey, the attending physician approached approximately 20 respondents involved in the study to obtain additional information related to the use of NOAC medication. Studies analyzing the cost-effectiveness of NOACs compared to VKA treatment at the national level in the Czech Republic have found greater benefits in terms of overall survival, improved quality of life, prevention of cardiovascular events, and increased prescription rates of NOACs.[12]

Implications for practice

The results of our study provide information on the compliance of the observed cohort of patients with atrial fibrillation using NOACs in a pilot study in the Czech Republic, which has not been available so far. A high burden of additional comorbidities was identified in the observed sample, along with the inadequate declaration of regularity in NOAC usage and the resulting risks. Sufficient patient education is essential, especially among older patients at a high risk of stroke, considering the increasing prescription rates.

Conclusion

Currently, the Czech Society of Cardiology is preparing recommendations for general practitioners to optimize the management of NOAC therapy, as well as lay recommendations for knowledge transfer to support evidence-based decision-making in healthcare at the national level in the Czech Republic.

Authors' contributions

PB, JB, AP, KD, MŠ, MH, DD, MT – study conception and design; PB, JB, KD – data collection; PB, JB, MD, MŠ, AP – data analysis and interpretation: PB, JB – drafting of the article; PB, JB, AP, KD, MŠ, MH, DD, MT – critical revision of the article; PB, JB, AP, KD, MŠ, MH, DD, MT – final approval of the version to be published.

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Conflict of interest

The authors declare that there are no conflicts of interest.

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Ethical statement

Ethical approval for the study was granted by the Ethics Committee of the Faculty of Medicine, Masaryk University, under ID number 11/2023.

Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on a reasonable request.

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