

Sinus rhythm recovery in patients with atrial fibrillation treated with non-vitamin K antagonist oral anticoagulants is safe without transoesophageal echocardiography evaluation – a preliminary report

Przywracanie rytmu zatokowego u pacjentów z migotaniem przedsionków leczonych doustnymi antykoagulantami niebędącymi antagonistami witaminy K jest bezpieczne bez przezprzełykowego badania echokardiograficznego – doniesienie wstępne

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Abstract

Introduction. Atrial fibrillation (AF) is the most common type of supraventricular arrhythmia. Electrical cardioversion is a non-pharmacological method of restoring sinus rhythm in AF patients. The role of transoesophageal echocardiography (TEE) in patients subjected to electrical cardioversion has not yet been fully established.

The objective of this study was to assess the safety of electrical cardioversion procedures in AF patients who had received novel oral anticoagulants for at least 21 days prior to the procedure, and in whom electrical cardioversion was carried out without previous TEE examination.

Material and methods. The study population consisted of 132 patients receiving non-vitamin K antagonist oral anticoagulants (NOACs) and subjected to electrical cardioversion procedures at a district hospital cardiology department. Patients with valvular AF and patients receiving NOACs in an irregular fashion were excluded from the study. The incidence of thromboembolic and haemorrhagic complications was assessed over a 30-day follow-up period.

Results. In a group of 132 patients treated with NOACs, rivaroxaban was used in 65 (49.2%) patients, dabigatran was used in 62 (47.0%) patients, and apixaban was used in five (3.8%) patients. No thromboembolic or haemorrhagic complications were observed in the study group over the hospitalisation period or the 30-day follow-up period.

Conclusions. NOACs are effective and safe in the premedication of AF patients prior to electrical cardioversion procedures. Electrical cardioversion without prior TEE is a safe method of managing patients receiving regular premedication with NOACs for at least 21 days before a sinus rhythm restoration procedure.

Key words: TEE, electrical cardioversion, NOAC

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Introduction

Atrial fibrillation (AF) is the most common supraventricular arrhythmia. It is estimated to be the cause of one in three of all hospitalisations caused by arrhythmias. The incidence of AF increases with age and is above 8% in patients aged over 80. It is more frequent in men than in women [1]. The non-pharmacological method of restoring sinus rhythm is transthoracic cardioversion with direct current. This can be used alone or in combination with anti-arrhythmic drugs [2, 3]. In the retrospective analysis of Gallagher et al. [4] including more than 2,600 electrical cardioversions, it was proved that an international normalised ratio (INR) > 2.5 obtained before the procedure protects the patient from thromboembolic complications [0% of cases vs. 0.93% for INR 1.5–2.4 ($p < 0.012$)].

There is also data regarding the safety of using non-vitamin K antagonist oral anticoagulants (NOACs) in patients with AF undergoing electrical cardioversion. Post-hoc analyses of large studies have shown that dabigatran [RE-LY (Randomized Evaluation of Long Term Anticoagulant Therapy)], rivaroxaban [ROCKET-AF (Rivaroxaban Once Daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation study)], and apixaban [ARISTOTLE (Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation)] are safe in patients undergoing electrical cardioversion, with the risk of thromboembolic complications being less than 1% [5–7].

The aim of this study was to assess the safety of electrical cardioversion performed in patients with AF treated with NOACs, without a transoesophageal echocardiography (TEE) assessment prior to electrical cardioversion.

Materials and methods

The study included patients for whom an elective cardioversion was performed and who were treated in the

Cardiology Unit of The City Hospital between 1 January 2016 and 31 December 2017. Inclusion criteria were persistent AF and the use of NOACs for at least 21 days prior to elective cardioversion. Exclusion criteria were the following: urgent electrical cardioversion, valvular AF, atrial flutter, and non-compliance with NOACs. Transthoracic echocardiography was performed in all patients prior to cardioversion. Patients signed a statement confirming that they were regularly taking the drug. The incidence of thromboembolic complications was assessed: ischaemic stroke, transient ischaemic episode, peripheral embolism as well as bleeding complications during hospitalisation after electrical cardioversion and within 30 days after electrical cardioversion.

Results

In a group of 170 patients admitted to the Cardiology Unit, 38 patients (22.4%) received a vitamin K antagonist (VKA) to perform an elective cardioversion, and 132 patients (77.6%) were treated with NOACs. A further analysis was performed on these 132 patients treated with NOACs. In this group, dabigatran was used in 62 patients (46.9%), rivaroxaban in 65 patients (49.2%), and apixaban in five patients (3.9%). Figure 1 shows the dosage of NOAC in patients undergoing electrical cardioversion.

The average age among patients treated with NOACs was 69.3 years. The majority was male – 78 patients (59.1%).

The most common comorbidity in the study group was arterial hypertension, which was present in 117 subjects (88.6%). Table 1 presents the characteristics of the studied group.

In the study group, the majority of patients were at high risk of thromboembolism; the CHADS₂ ≥ score was 2 points in 80 patients (60.6%), and the CHA₂DS₂VASc score was ≥ 2 points in 59 patients (44.7%). Table 2 presents the scoring in the CHADS₂ and CHA₂DS₂VASc scales.

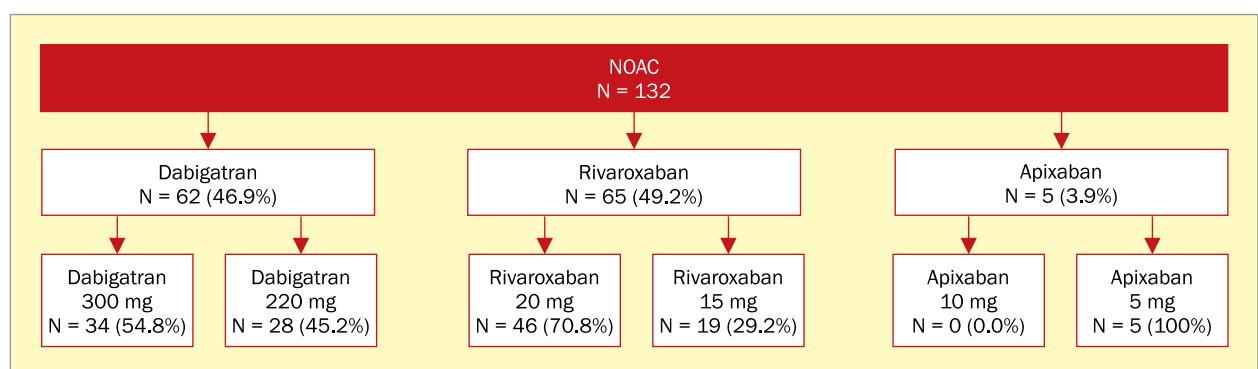


Figure 1. Dosing of anticoagulants in patients with atrial fibrillation subjected to electrical cardioversion; NOAC – non-vitamin K antagonist oral anticoagulant

Table 1. Study group characteristics

| Comorbidity | Patients treated with NOAC N = 132 |
|----------------------------|---------------------------------------|
| Arterial hypertension | 117 (88.6%) |
| Ischaemic heart disease | 68 (51.51%) |
| Diabetes | 34 (25.6%) |
| Transient ischaemic attack | 19 (14.39%) |
| Ischaemic stroke | 18 (13.6%) |
| Myocardial infarction | 16 (12.1%) |
| COPD | 17 (12.87%) |

NOAC – non-vitamin K antagonist oral anticoagulant; COPD – chronic obstructive pulmonary disease

Table 2. Scoring results in CHADS₂, CHA₂DS₂VASc scales for patients undergoing electric cardioversion

| Scale | Patients treated with NOAC N = 132 |
|---|---------------------------------------|
| CHADS ₂ score (points): | |
| • 0 | 16 (12.1%) |
| • 1 | 36 (27.3%) |
| • ≥ 2 | 80 (60.6%) |
| CHA ₂ DS ₂ VASc score (points): | |
| • 0 (or 1 only if female) | 57 (43.2%) |
| • 1 | 16 (12.1%) |
| • ≥ 2 | 59 (44.7%) |

Restored sinus rhythm persisting until discharge from the hospital was obtained in 107 patients (81.1%).

No thromboembolic complications or haemorrhagic complications were observed during hospitalisation after cardioversion in patients receiving NOACs.

During the 30-day follow-up, patients undergoing electric cardioversion treated with NOACs developed neither thromboembolic complications nor haemorrhagic complications.

Discussion

In the present study, NOACs were received by almost 80% of patients in preparation for an elective cardioversion. The percentage of patients treated with NOACs has significantly increased in recent years, including those being prepared for electrical cardioversion. This is due to the effectiveness and safety profile of NOACs, as well as to

a significantly simpler therapy regimen compared to VKA. According to the current European Society of Cardiology (ESC) guidelines for the treatment of patients with AF, NOACs should be preferred among patients starting anti-coagulant therapy [8].

Gawałko et al. [9] in a group of 859 patients showed that NOACs were used in 49% of patients undergoing elective cardioversion or ablation due to AF. Fredriksen et al. [10] in a study of 2,150 patients hospitalised for elective cardioversion between 2011 and 2016 showed that the percentage of patients treated with NOACs was lower than in the present study, and was 32%. Also, Papp et al. [11] showed that in a group of 1,101 patients, NOAC before cardioversion was used in 32% of patients. In a work by American authors, in a population of 5,320 patients hospitalised in 2011–2013, the percentage of patients treated with NOACs was 20% [12].

Most data on sinus rhythm restoration in patients treated with s comes from a subanalysis of large studies. Dabigatran was the first NOAC registered for use in patients undergoing cardioversion. Among a RE-LY population, 1,983 cardioversions were performed in 1,270 patients. Thromboembolism after 30 days cardioversion was observed in 0.8% of patients treated with dabigatran 110 mg *bis die* (BD), in 0.3% of patients treated with dabigatran 150 mg BD, and in 0.6% of patients receiving warfarin. There were no differences in the incidence of major bleeding complications in individual groups of patients [5]. Apixaban was registered for use in patients undergoing cardioversion based on a subanalysis of the ARISTOTLE study involving 540 patients. When comparing the groups treated with warfarin and apixaban, cardiovascular events and haemorrhagic complications were identical [7]. In subanalysis of the ROCET-AF study, rivaroxaban has been shown to be as effective and as safe as warfarin in AF patients undergoing electrical cardioversion [6]. The X-VerT (Explore the Efficacy and Safety of Once-daily Oral Rivaroxaban for the Prevention of Cardiovascular Events in Subjects With Nonvalvular Atrial Fibrillation Scheduled for Cardioversion) study was the first randomised trial to confirm the efficacy and safety of rivaroxaban in patients undergoing early electrical cardioversion (1–5 days after randomisation) and delayed electrical cardioversion (308 weeks after randomisation) [13].

The importance of TEE in patients treated with NOACs undergoing electric cardioversion has not been clearly established to date. Experts recommend the performance of TEE for patients with cardioversion if no effective anti-coagulation was found within 21 days in recommendations for the treatment of patients with AF [8]. However, they do not directly address patients receiving NOACs. In the RE-LY subanalysis of patients undergoing cardioversion, TEE was performed in 21% of subjects [5]. In the ARISTOTLE study

subanalysis [7] there was a similar amount, 23%, whereas in a prospective V-VeRT study [13] TEE was performed in half of the patients undergoing cardioversion.

Our present study presents the long-term characteristics and long-term observation of patients treated with NOACs who underwent cardioversion without TEE. The presented patients were mainly people at high risk of thromboembolic complications, and most were being treated with a full dose of NOACs. Patients subjected to electrical cardioversion declared systematic use of NOACs for at least 21 days. In the 30-day follow-up, no thromboembolic complications were observed. Cozma et al. [14], in a study of 82 patients with AF and atrial flutter, demonstrated the safety of patients treated with dabigatran and undergoing cardioversion without prior TEE.

Performing electrical cardioversion in patients treated with NOAC without a preceding TEE requires further research and long-term follow-up.

Conclusions

NOAC is effective and safe in the preparation of patients with AF for electrical cardioversion. In patients who regularly use NOACs for at least 21 days before the elective restoration of sinus rhythm, it is safe to perform electrical cardioversion without a preceding TEE.

Conflict(s) of interest

The authors report no conflict of interest.

Streszczenie

Wstęp. Migotanie przedsionków (AF) to najczęstszy typ arytmii nadkomorowej. Niefarmakologiczną metodą przywracania zatokowego rytmu serca u chorych z AF jest kardiowersja elektryczna. Pozycja przezprzełykowego badania echokardiograficznego (TEE) u chorych poddawanych kardiowersji elektrycznej nadal nie jest ostatecznie ustalona.

Celem pracy była ocena bezpieczeństwa kardiowersji elektrycznej u pacjentów z AF stosujących co najmniej 21 dni doustne antykoagulanty niebędące antagonistami witaminy K (NOAC), u których kardiowersję elektryczną wykonano bez poprzedzającej TEE.

Materiał i metody. Badaniem objęto 132 chorych leczonych NOAC poddawanych kardiowersji elektrycznej na oddziale kardiologii szpitala powiatowego. Z badania wyłączono chorych z zastawkowym AF oraz nieregularnie przyjmujących NOAC. Oceniono częstość występowania powikłań zakrzepowo-zatorowych oraz krwotocznych w obserwacji 30-dniowej.

Wyniki. W grupie 132 chorych leczonych NOAC 65 chorych (49,2%) otrzymywało rivaroksaban, 62 chorych (47,0%) dabigatran, a 5 chorych apiksaban (3,8%). W okresie szpitalnym i w czasie 30-dniowej obserwacji w badanej grupie nie stwierdzono powikłań zakrzepowo-zatorowych ani powikłań krwotocznych.

Wnioski. Lek z grupy NOAC są skuteczne i bezpieczne w przygotowaniu chorych z AF do kardiowersji elektrycznej. U chorych regularnie stosujących NOAC przez co najmniej 21 dni przed planowanym przywróceniem rytmu zatokowego bezpiecznym postępowaniem jest wykonywanie kardiowersji elektrycznej bez poprzedzającej TEE.

Słowa kluczowe: TEE, kardiowersja elektryczna, NOAC

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