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COMPARISON OF EFFECTIVENESS AND SAFETY OF ANTIARRHYTHMIC DRUGS CLASS IC AND III IN PATIENTS AFTER ELECTRICAL CARDIOVERSION

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Patients with atrial fibrillation are faced with an increased risk of thromboembolic events, myocardial infarction, chronic heart failure and death. For some patients with atrial fibrillation, direct current cardioversion (DCCV) is a strategy that can be used to reacquire sinus rhythm. Our aim was to analyse the most commonly used medications after an electrical cardioversion, the reasons for not using them, the effects of pharmacotherapy on recurrence rates, and compare results with data from studies in 2014. The prospective study includes patients with electrocardiographically confirmed atrial fibrillation who underwent direct current cardioversion, hospitalised at Pauls Stradiņš Clinical University Hospital (Rīga, Latvia). The average age was 64.6 years. 50% of the patients were female. During the six-month study period, 14.3% patients were using amiodarone, 8.3% patients were on etacizine, 7.1% received propafenone, and 57.1% used beta blockers in monotherapy or in combination. Warfarin was used in 28.0% patients, direct oral anticoagulants (DOAC's) in 29.9%, 21,4% of patients received aspirin and 16.7% did not use any antithrombotic therapy. Comparing the recurrence rate in patients using different antiarrhythmic drugs, amiodarone showed a statistically significant superiority compared to etacizine and propafenone (p = 0.02). The obtained data showed that over four years, the use of anticoagulants increased by 11.6%.

Key words: *direct current cardioversion, atrial fibrillation, oral anticoagulants.*

INTRODUCTION

Atrial fibrillation (AFib) is the most common arrhythmia affecting more than 33 million people worldwide. It is estimated that there are about 5 million new cases each year. AFib incidence and prevalence increases with age. One in four adults over age 65 years has AFib (Chugh *et al.,* 2010; Lloyd *et al*., 2004). The main problem faced by patients with AFib is an increased risk of thromboembolic events, as there is a five-fold higher risk of stroke in patients with AFib, as well as an increased risk of myocardial infarction, chronic heart failure and death (Wolf *et al*., 1991; Go *et al*., 2014). Vascular dementia is found in 10–15% of patients with AFib, which is two times more common than in the population. All of these problems can be detrimental to the quality of life (Ott *et al*., 1997).

The direct costs of AFib have reached about 1% of total health expenses in the United Kingdom. Costs in the US amounted to USD 6–26 billion in 2008 (Stewart *et al*., 2014).

The electrical cardioversion (ECV) technique relies on the application of a selected amount of energy, which is gener-

ally between 50–360 J, via two electrodes (paddles). A transthoracic direct current shock of sufficient magnitude depolarises the entire myocardium, rendering the entire heart momentarily refractory to repeat depolarisation. Thereafter, the most rapid intrinsic pacemaker, usually the sinoatrial node, reassumes control of heart rhythm (Sucu *et al*,. 2009).

Direct current cardioversion (DCCV) can be considered as an urgent and optional method for restoring sinus rhythm in patients with AFib (Kirchhof *et al*., 2007).

Anticoagulants are considered mandatory before scheduled cardioversion in atrial fibrillation, if it lasts more than 48 hours or if the duration of the episode is not known. Because of the increased risk of cardiovascular thromboembolic events, the European Society of Cardiology 2016 guidelines recommend using anticoagulants at least three weeks before and four weeks after the procedure (ECV) (Weinberg *et al*., 1989; Nuotio *et al*., 2014; Kirchhof *et al*., 2016). Patients without therapeutic anticoagulation have a post-procedural thromboembolic risk of 5–7% (Arnold *et al.*, 1992).

Depending on the source, the frequency of recurrence of AFib after an electrical cardioversion ranges from 40–60%. Adequate antiarrhythmic therapy does not always affect the frequency of recurrence. There are several risk factors that can influence the frequency of recurrences after ECV, such as age, AFib duration, left ventricular size, etc. (Cannon *et al*., 2008).

Our goal was to analyse the risk factors of developing recurrence of atrial fibrillation. We assessed the most commonly used medications after an electrical cardioversion and the reasons for not using them as well as the effects of pharmacotherapy on recurrence rate. Finally our aim was to compare the acquired results with data from studies in 2014.

METHODS

The prospective study was conducted between January and August 2017 at the Latvian Centre of Cardiology, Pauls Stradiņš Clinical University Hospital. The study included 168 patients undergoing scheduled or emergency electrical cardioversion. Patients were hospitalised due to electrocardiographically detected atrial fibrillation either by general practitioner or emergency service. Electrocardiograms were re-acquired at the department where the patient was hospitalised. An authorisation of the Ethics Committee of Rīga Stradiņš University was received. Before the questionnaire, all patients received informative material with a description of the research (in Latvian and Russian). Acquainting with it, all patients provided written consent. An anonymous patient questionnaire was used. Contact information of patients and their relatives as well as demographic data (age, gender) were acquired. Information about the type of admittance at the treatment facility, previous history and duration of AFib, history of AFib associated medication use and previous electrical cardioversion was collected. Medical records provided information about the outcome of electrical cardioversion, history of disease and biochemical parameters from blood tests. Based on the collected data, CHA2DS2-VASc was calculated.

The second questionnaire was developed as a telephone survey for patient control after three and six months. The following questions were asked during telephone interviews: if there has been repeated hospitalisation and the cause for it, recurrence of AFib paroxysms (how many times, type of treatment), drugs used for rhythm control and anticoagulation, an adverse drug reactions. In the case of death, detailed information was gathered from relatives about the cause and treatment previously used by the patient.

The study included patients, aged 31 to 84 years. The average age was 64.6 years (±10.5). Among the 168 patients interviewed, 50.0% were female. 18 (10.6%) patients were admitted to the hospital by emergency service, while 140 (83.4%) patients were referred by a general practitioner or a cardiologist. In 10 (6.0%) cases patients admitted themselves. The duration of AFib paroxysism was less than 24 hours in 2 (1.2%) cases, 24 to 48 hours in 8 (4.8%), 48 hours to seven days in 12 (7.1%) and more than seven days in 74 (44.0%) cases. Seventy-two (42.9%) patients could not report when the paroxysm had started. One hundred and twelve (66.7%) had a history of previous AFib.

Previously, medical cardioversion had been used in 126 (75.0%) patients and ECV was performed in 66 (39.3%) patients. Patient baseline characteristics are summarised in Table 1.

CHA2DS2-VASc was calculated: 12 (7.1%) patients had 0 points, 27 (16.1%) had 1 point and 129 (76.8%) had 2 or more points. The average score was 2.75. The results of patient thromboembolic risk assessment with the CHA2DS2-VASc scale are summarised in Table 2.

Table 1

PATIENT BASELINE CHARACTERISTICS

	Total, n (%)
Age (mean ± SD)	64.6 ± 10.5
Age > 65 years	98 (58.3%)
Gender, males	84 (50.0%)
Body mass index kg/m^2 (mean ± SD)	31.7 ± 5.8
Arterial hypertension	104 (61.9%)
Chronic heart failure	44 (26.6%)
Diabetes	32 (19.0%)
Myocardial infarction	14 (8.3%)
Stroke	24 (14.6%)
Implanted pacemaker	8 (4.8%)
Radiofrequency catheter ablation	12 (7.1%)
Duration of paroxysm	
< 48 h	10 (5.9%)
> 48 h	86 (51.2%)
Unknown duration	72 (42.9%)
Electrocardioversion in anamnesis	66 (39.3%)

Table 2

PATIENT THROMBOEMBOLIC RISK ASSESSMENT WITH CHA2DS2-VASC SCALE

CHA2DS2-VASc	Total, n (%)
0	12 (7.1%)
1	27 (16.1%)
2	31 (18.4%)
3	49 (29.2%)
4	26 (15.5%)
5	17 (10.1%)
6	6 (3.6%)

Data were entered and processed using Microsoft Excel and IBM SPSS Statistics 22.0. Descriptive statistical methods were used to characterise patient parameters — summary tables with columns, lane graphs or histograms, mean arithmetic and standard deviation. Statistical analysis of qualitative data using the chi-squared ($\chi 2$) test and Fisher exact test (if the number of expected cases were $n < 5$ in one of the columns in the table). A p-value less than 0.05 was considered to determine statistical significance.

RESULTS

Prior to ECV, amiodarone was used in 80 (47.6%) patients. IC group antiarrhythmic drugs were used in 24 (14.2%), and sotalol was used in 6 (3.5%), Beta blockers (BB) were used in 122 (72.6%), while 78 (46.4%) patients used angiotensin converting enzyme inhibitors (ACEI) inhibitors or angiotensin receptor blockers (ARB). The choice of oral anticoagulants before direct current cardioversion (DCCV) was: warfarin in 44 (26.2%) patients, Xarelto (rivaroxaban) in 64 (38.1%) and Pradaxa (dabigatran) in 42 (25.0%). Two (2.4%) patients were using aspirin, while 6 (3.6%) patients were on dual therapy (combination of an anticoagulant and aspirin).

After six months, three patients had died. The cause of death in all three patients was stroke. One patient did not use anticoagulants, but two of three patients used rivaroxaban and warfarin.

Sixty-two (36.9%) patients had one repeated episode of AFib and 20 (11.9%) had a repeated episode two or more times. A total of 82 (48.8%) patients had at least one episode of AFib over a period of six months. Fourty-eight (28.6%) patients were hospitalised due to arrhythmia, six (3.6%) due to pacemaker implantation, two (1.2%) due to scheduled radiofrequency ablation (RFCA), four (2.4%) due to coronary artery bypass grafting (CABG), two (1.2%) due to primary coronary intervention (PCI) and two patients was hospitalised due to acute decompensated heart failure. Reasons for hospitalisation six months after electrocardioversion are summarised in Figure 1. In 38 (22.6%) patients arrhythmia was discontinued by ECV, eight (4.8%) were treated with medications and in 36 (21.4%) the arrhythmia was not treated at all.

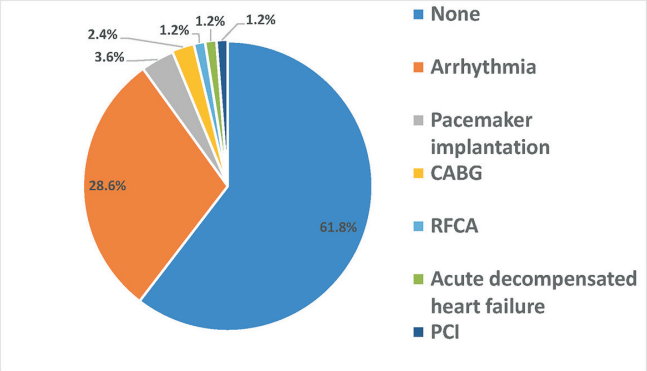

Fig. 1. Reasons for hospitalisation six months after electrocardioversion. CABG, coronary artery bypass grafting; RFCA, radiofrequency ablation; PCI, primary coronary intervention.

During the three-month control, 32 (19.3%) patients used amiodarone, 28 (16.6%) used IC group antiarrhythmic drugs, four (2.3%) patients used sotolol, while 122 (72.4%) patients reported using BB. 72 (42.7%) and 26 (15.4%) patients used ACEI and ARB, respectively. Warfarin was used in 48 (28.4%) patients, Xarelto (rivaroxaban) in 46 (27.4%), Pradaxa (dabigatran) in 14 (8.3%). Twenty-four (14.2%) patients were using aspirin, six patients were on a combination of Xarelto and aspirin, while 26 (15.7%) patients did not take any oral anticoagulants.

Later, during the six-month control, 24 (14.3%) patients were using amiodarone, 14 (8.3%) patients were on etacizine, 12 (7.1%) received Ritmonorm (propafenone), and 96 (57.1%) used BB. Sixty (35.7%) patients used ACEI, while 26 (15.4%) patients were using ARB. Warfarin was used in 47 (27.9%) patients, Xarelto (rivaroxaban) in 34 (20.4%), Pradaxa (dabigatran) in 16 (9.5%). Thirty-six (21.4%) patients were taking aspirin, two patients were using a combination of Xarelto and aspirin, while 28 (16.7%) patients did not use any oral anticoagulants.

Of those patients who did not use oral anticoagulants (OAC) after six months, 24 (85.7%) had CHADS-VASc of two or more. 77.1% of those using aspirin also had CHADS-VASc of two or more. A total of 29.6% were not using OAC despite indications.

Observed adverse reactions after six months were: six (3.6%) patients reported nausea, four (2.4%) had minor bleeding, six (3.6%) patients had cough and six (3.6%) patients reported having had oedema.

Without statistical significance, recurrence of AFib was more frequent in women vs men (60% vs 43%), in patients with diabetes vs without diabetes (56% vs 49%), congestive heart failure vs patients without congestive heart failure (60% vs 47%) and smokers vs non smokers (75% vs 49%). Patients with a history of AFib were more likely to be hospitalised (47% vs 21%) ($p = 0.002$) and have a recurrence (67% vs 22%) ($p < 0.001$). Comparing the recurrence rate in patients using different antiarrhythmic drugs, amiodarone showed a statistically significant superiority compared to etacizine and propafenone (41.7% vs 71.4% vs 83.3%) ($p =$

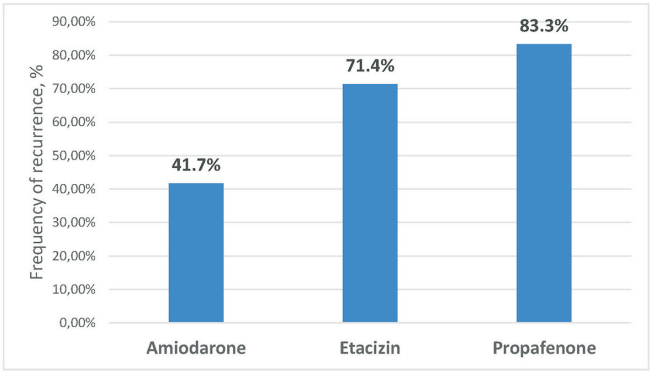

Fig. 2. Comparison of the relapse rate in patients using different antiarrhythmic drugs. Amiodarone showed a statistically significant superiority compared to etacizine and propafenone (41.7% vs 71.4% vs 83.3%) (p = 0.02).

0.02) (Fig. 2). However, in this study we did not include patients who were enrolled in another study comparing a combination of etacizine and beta-blockers to amiodarone.

DISCUSSION

The incidence of cardiovascular risk factors in the study population was consistent with world literature (Pisters *et al*., 2012; Femia *et al*., 2017).

Most of the patients (83.3%) in the study population were admitted for a scheduled ECV. 42% of patients could not report the time of onset of AFib paroxysms as they were asymptomatic. Literature data (Xiong *et al.,* 2015) show that around 40% of patients with AFib are asymptmatic, which conforms with the data obtained by our study. Patients had found out about their condition while undergoing routine check-ups. The frequency of recurrence of atrial fibrillation in patients after six months corresponds to world literature (Femia *et al*., 2017). After six months, 64 (38.0%) patients had been hospitalised, and for 48 (28.6%) patients the cause of hospitalisation was arrhythmia. The rest of patients were hospitalised mainly due to scheduled procedures.

After a six-month follow-up, three patients had died of stroke, of whom two were on oral anticoagulants (warfarin and rivaroxaban). Both patients had a high risk of thromboembolic events (CHA2DS2-VASc ≥ 2). The guidelines of the European Society of Cardiology determine that the optimal INR for patients with non-valvular AFib is 2.0–3.0. According to world literature, roughly 40% of patients reach the optimal INR succesfully. Achieving the goal can be complicated by drug interactions and diet mistakes (Kirchhof *et al*., 2016). This might have affected the INR of the patients receiving oral anticoagulation hence resulting in an INR below the therapeutic standard. The bioavailability of Xarelto (rivaroxaban) 15 mg and 20 mg is significantly reduced by 44% when taken on an empty stomach. (Stampfuss *et al*., 2013; Heidbuchel *et al*., 2017). Our study found that approximately 30% of patients were taking Xarelto on an empty stomach, which increases the risk of thromboembolic events.

Three months after ECV, 64.1% of patients received anticoagulant therapy (28.4% used warfarin and 35.7% used DOACs), while 14.2% of patients received aspirin and 15.7% did not use any antithrombotic therapy. Six months after ECV, anticoagulant therapy was continued by 57.9% of patients (28.0% used warfarin and 29.9% used DOACs), 21.4% of patients received aspirin and 16.7% did not use any antithrombotic therapy. When comparing the use of anticoagulants three and six months after ECV, use of anticoagulants had decreased by 6.2%, while the use of aspirin increased by 7.2%. The European Society of Cardiology 2016 guidelines state that aspirin is not indicated in patients with AFib (Kirchhof *et al*., 2016). There are several reasons for the increse in use of aspirin over time. One is the misinformation of general practitioners, which leads to prescribing aspirin as an alternative for patients who are not financially able to buy DOACs or have difficulties controlling INR. The second reason is lack of general knowledge among patients about their condition, which leads to being easily influenced by misleading information about use of aspirin as an alternative and adequate treatment.

Previous studies (Pupkevica *et al.*, 2014) showed that the use of anticoagulants after six months increased by 11.6%, respectively. DOACs was the biggest contributor to the rise in anticoagulant use. The use of DOACs versus warfarin increased from 1 : 3 (11.2% vs 35.1%) to 1 : 1 (29.9% vs 28.0%). Change in the use of antithrombotic therapy six months after electrocardioversion over a period of four years are summarised in Figure 3. This ratio of DOACs and warfarin complies with data from other studies (Olesen *et al.,* 2015). The use of aspirin after ECV decreased by 15.7% over six months, respectively. When comparing data over a period of time, the use of aspirin decreases, but remains high. This leads to additional concerns, because 77.1% of patients taking aspirin had a CHA2DS2-VASc > 2 and were not protected from thromboembolism.

Previous studies (Strelnieks *et al.,* 2014) showed that the use of amiodarone has decreased by 7.5%, while the use of etacizine has increased by 4.3%. The use of propafenone has remained approximately the same. The use of BB has

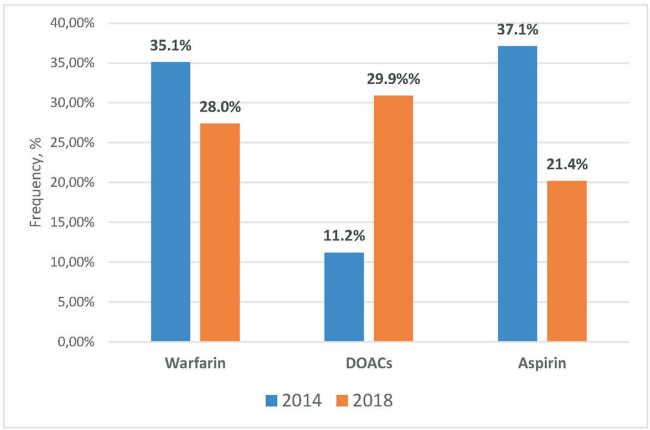

Fig. 3. Change in use of antithrombotic therapy six months after electrocardioversion over a period of four years (2014–2018). DOACs, direct oral anticoagulants.

decreased by 24.8%. The fall in use of amioadore and BB can be explained by several reasons. In the case of amiodarone, it can be explained by fear of adverse reactions that may be expressed after a prolonged use of the medicament. In the case of BB, another contributor is the vastly available negative information regarding this group of drugs coming from different sources as well as not seeking proper information instead.

Analysing the efficacy of antiarrhythmic drugs, the most effective medication still remains amiodarone, which showed a statistically significant superiority over etacizine and propafenone (41.7% vs 71.4% vs 81.3%) ($p = 0.02$). The data has limitations, because in our study we did not analyse patients enrolled in another study comparing a combination of etacizine and beta-blockers to amiodarone, in which the combination showed a superiosity to amiodarone.

Examining the risk factors contributing to recurrence, with statistical significance the recurrence presented more often in patients with previously known AFib. Without statistical significance, the recurrence was more often in patients suffering from diabetes and congestive heart disease as well as in smokers, which corresponds to previous data (Strēlnieks *et al*., 2014). This can be explained by the induced atrial remodelation in patients with these conditions, as structural changes in myocardium lead to local heterogenity of electrical conduction, which can lead to re-entry mechanism and arhythmia.

Observed adverse reactions after six months were: six (3.6%) patients reported nausea, four (2.4%) had minor bleeding, six (3.6%) had cough and six (3.6%) had oedema. The frequency of bleeding caused by antithrombotic agents in our study was found to be lower than reflected in world literature (Camm *et al*., 2014; Femia *et al*., 2017). Only 2.4% of patients complained about minor bleeding and none of the patients experienced serious, life-threatening bleeding.

CONCLUSIONS

The most commonly used and most effective medication was amiodarone. When comparing the data of patients over four years, the use of anticoagulants increased by 11.6% and the use of DOACs increased by 18.7%. Although 77.1% of patients taking aspirin had a CHADS-VASc ≥ 2, there was still a group of patients taking aspirin instead of anticoagulants, which does not lower the risk of developing thrombembolism. The main reasons for non-compliance were fear of adverse drug reactions, high drug costs as well as negative information regarding the drugs coming from unauthorised sources. With statistical significance recurrence was higher in patients with previously known AFib. 30% patients of the study population did not know that Xarelto must be taken on an empty stomach, which could lead to thrombembolic events. The number of asymptomatic AFib patients was consistent with global data.

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IC UN III KLASES ANTIARITMISKO MEDIKAMENTU EFEKTIVITĀTES UN DROŠĪBAS SALĪDZINĀJUMS PACIENTIEM PĒC ELEKTRISKĀS KARDIOVERSIJAS

Ātriju fibrilācija (ĀF) ir visbiežāk sastopamā aritmija, kas skar vairāk nekā 33 miljonus iedzīvotāju. Galvenā problēma, ar ko saskaras pacienti ar ĀF, ir paaugstināts trombemboliju risks, jo pacientiem ar ĀF ir piecas reizes lielāks insulta risks, kā arī paaugstināts miokarda infarkta, hroniskas sirds mazspējas un nāves risks. Prospektīvā pētījumā tika iekļauti pacienti, kuriem tika veikta plānveida vai akūta elektriskā kardioversija. Pētījumā kopā piedalījās 168 pacienti. Vidējais vecums bija 64.6 gadi. Sešu mēnešu kontroles laikā 14,3% lietoja amiodaronu, 8,3% etacizīnu, 7,1%, propafenonu, 57,1% beta blokatorus. Kopumā varfarīnu lietoja 28,0% pacienti, tiešos orālos antikoagulantus lietoja 29,9%, 21,4% lietoja aspirīnu, un 16,7% nelietoja antikoagulantus. Salīdzinot recidīvu biežumu, pacientiem lietojot dažādus AAL, statistiski ticamu pārākumu ieguva amiodarons, salīdzinot ar etacizīnu un propafenonu (41,7% pret 71,4% pret 81,3%) (p = 0,02).