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ANTICOAGULATION BEFORE AND AFTER CARDIOVERSION OR ABLATION. CHALLENGES, PROBLEMS AND MISTAKES

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Keywords: novel oral anticoagulants, electrical cardioversion, radiofrequency ablation, atrial fibrillation, atrial flutter.

Summary

Background: Limited data exists addressing the daily use of anticoagulants for atrial fibrillation (AF) and atrial flutter (AFL) patients before and after electrical cardioversion (ECV) or catheter ablation procedures. The purpose of the study was to evaluate the appropriateness of anticoagulant therapy.

Methods: We evaluated the prescribed dosage of anticoagulant therapy for 257 non-valvular AF and AFL patients scheduled for ECV or catheter ablation and the appropriateness of periprocedural anticoagulation according to European Society of Cardiology (ESC) AF Guidelines. The statistical analysis was performed using IBM SPSS Statistics software (v.26.0).

Results: The majority of the patients (84%) used non-vitamin K antagonist oral anticoagulants (NOACs) for pre-procedural anticoagulation. An intervention was not performed for 12.2% of warfarin users because of insufficient hypocoagulation, while anamnesis of patients' missed doses with a possibility of inadequate hypocoagulation occurred only in 1.9% of patients on NOACs. The odds of having insufficient pre-procedural hypocoagulation were 7.4 times higher for warfarin users compared to the NOACs group (p=0.001, OR=7.4). An incorrect NOAC dose was assigned to 22 (8.6%) patients. Rivaroxaban was the most prescribed NOAC and this group of patients had the highest percentage of incorrect dosage according to the ESC guidelines.

Conclusions: Mistakes of prescribing the dosage of anticoagulant therapy are common. The majority of the patients in the study were prescribed with NOACs before and after ECV or catheter ablation procedures. Warfarin users had higher odds of the intervention not being performed and not reaching sufficient hypocoagulation prior to the procedure compared to NOACs users.

Introduction

It is generally known that AFL and AF patients have an increased risk of stroke, hence it is very important to administer anticoagulant therapy according to standard recommendations [1,2]. Since warfarin (vitamin K antagonist) was approved in 1954 for medical use in the United States, it has been the main and only available anticoagulant for the prevention of thromboembolism. The dominance of warfarin use as the only oral anticoagulant has changed when the first NOAC – dabigatran – was approved for the prevention of venous thromboembolism [3,4]. Even though warfarin is one of the safest and most effective medicines in the health system according to the World Health Organisation's List of Essential Medicines, a tendency can be seen that since NOACs have been introduced, the use of warfarin for the prevention of stroke and systemic embolism has been rapidly decreasing as the usage of NOACs increased [5–12]. Since the use of NOACs increases with time, it is important to understand limitations related with pharmacological properties of these drugs. As NOACs do not require regular monitoring, the problem of compliance arises [13,14]. Moreover, clinicians need to take into consideration the age, weight, renal function, and used medication of the patient when selecting the dose of NOACs as well as the $CHA_2DS_2VAS_c$ score. Prescription mistakes and failure to adhere to the guidelines are common [13,15–19]. There is evidence suggesting that the aforementioned factors may lead to an increased risk of bleeding or insufficient prevention of stroke [13,16,17,19–22]. We decided to analyse real world data about the use of anticoagulants for AF and AFL patients before and after ECV or catheter ablation procedures in our hospital.

Main objectives were to evaluate the appropriateness of the dosage of the prescribed anticoagulant therapy prior to and after the intervention as well as to analyse the reasons why the scheduled procedure was not performed.

Methods

Study population. Retrospective study included 257 patients who have been admitted to Lithuanian University

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of Health Sciences Kauno Klinikos for elective non-valvular AF or AFL treatment in 2018. The patients were divided into two groups according to the required intervention: the first group underwent an ECV, and the second one had catheter ablation (RFA for AFL or RFA for AF) performed.

Evaluation methods. All the patients before and after the intervention were on oral anticoagulation. The $CHA_2DS_2VAS_c$ score was calculated in all patients. The doses of anticoagulant therapy before and after the intervention were evaluated according to the ESC AF guidelines (2016) [23]. An insufficient hypocoagulation for warfarin users was estimated in the following cases: if at least one INR value was below 2 or there was no data about INR testing performed weekly for 4 weeks, For NOAC users - in the case of a missed dose and/or less than 3 weeks of pre-procedural anticoagulation. Patients with insufficient hypocoagulation underwent transoesophageal echocardiography (TEE), and if thrombus in left atrium appendage was not found, the intervention was performed. Creatinine clearance (CrCl) was evaluated using the Cockcroft-Gault (CG) equation: CrCl = ((140 – age (yr))*weight (kg)* sex (to be multiplied by 1.04 for women or 1.23 for men))/(serum creatinine (μmol/l))[24]. NOACs doses were assessed according to age, weight, renal function and concomitant medication [25].

Statistical analysis. Statistical analysis was performed by IBM SPSS Statistics version 26 software, *p* value less than 0,05 was considered statistically significant. One-way ANOVA test was used to describe baseline characteristics and compare the means of scale variables, crosstabs were used to calculate the odds ratio as well as to compare nominal variables, the chi-square test was used to evaluate whether differences between the variables were statistically significant. The study was performed with the permission of Kaunas Regional Biomedical Research Ethics Committee, ref. No. BE-2-48, and an informed consent was obtained from each patient.

Table 1. Baseline characteristics of the study population
ECV – electrocardioversion, RFA – radiofrequency ablation, CrCl – creatinine clearance, BMI – body mass index, AFL – atrial flutter, AF – atrial fibrillation, INR - International Normalised Ratio (for blood clotting time)
** (mean (±SD))*
***p value for ECV patients versus catheter ablation*

Variable	All patients (n=257)	ECV (n=97)	RFA (n=160)	p value**
Gender (male, %)	173 (67.3)	61 (62.9)	112 (70.7)	0.239
Age*	65.2 (±11.7)	64.8 (±10.7)	65.4 (±12.4)	0.713
CrCl (ml/min)*	80.9 (±32.7)	86.3 (±32.6)	78.0 (±32.5)	0.068
CrCl >80 ml/min (%)	100 (43.3)	40 (50.6)	60 (39.5)	0.104
INR*	1.7 (±0.8)	1.9 (±1.1)	1.6 (±0.7)	0.196
Haemoglobin (g/l)*	138.7 (±15.7)	141.3 (±15.2)	137.2 (±15.9)	0.086
BMI (kg/m^2)*	29.4 (±5.5)	30.3 (±5.7)	28.9 (±5.4)	0.061
CHA_2DS_2-VAS_C*	2.8 (±1.4)	2.7 (±1.3)	2.9 (±1.5)	0.351
• >=2 (%)	198 (78.3)	77 (80.2)	121 (77.1)	0.557

Table 2. Baseline characteristics of the study population by used anticoagulation therapy
*NOACs – novel oral anticoagulants, CrCl – creatinine clearance, BMI – body mass index, ECV – electrocardioversion, RFA for AFL – radiofrequency ablation for atrial flutter, RFA for AF- radio radiofrequency ablation for atrial fibrillation, INR - International Normalised Ratio (for blood clotting time) *(mean (±SD))*

Variable	Warfarin users (n=41)	NOACs users (n=216)	p value
Gender (male, %)	28 (68.3)	145 (67.1)	0.884
Age*	67.3 (±10.0)	64.7 (±12.0)	0.199
CrCl (ml/min)*	71.0 (±31.7)	82.7 (±32.6)	0.045
CrCl >80 ml/min (%)	11 (29.7)	89 (45.9)	0.069
Haemoglobin (g/l)*	133.2 (±16.3)	139.8 (±15.5)	0.031
BMI (kg/m^2)*	29.9 (±6.4)	29.4 (±5.3)	0.603
ECV (%)	11 (26.8)	86 (39.8)	0.114
RFA for AFL (%)	27 (65.9)	104 (48.1)	0.114
RFA for AF (%)	3 (7.3)	26 (12.0)	0.114
CHA_2DS_2-VAS_C*	3.3 (±1.4)	2.7 (±1.4)	0.025
Maximum value	6	7	
• >=2 (%)	36 (87.8)	162 (76.4)	0.106

Results

A total of 257 patients were included in the study. The patients were predominantly male (67.3%), mean age 65.2 ±11.7 years, mean CHA_2DS_2-VAS_C score 2.8 ±1.4 (78.3% of patients had CHA_2DS_2-VAS_C score ≥ 2) (Table 1). The number of the patients with AFL or AF was similar and 16% of all patients used warfarin for pre-procedural anticoagulation (Table 2). In catheter ablation group, 18.1% of the patients had AF and were admitted for RFA, these patients were significantly younger, with a better renal function and a lower thromboembolic risk (mean CHA_2DS_2-VAS_C 2.1 ±1.6).

Anticoagulation and renal function. The majority of patients (84%) used NOACs for pre-procedural anticoagulation. Patients on NOAC's had statistically significantly better renal function, higher hemoglobin values and lower mean CHA_2DS_2-VAS_C score compared to warfarin users (Table 2). The prevalence of renal dysfunction (CrCl ≤ 80 ml/min) among all patients was 56.7% with 12.6% of patients with at least moderate renal impairment (CrCl< 50 ml/min). Patients with an impaired renal function were statistically significantly older, had higher CHA_2DS_2-VAS_C mean score, lower BMI and haemoglobin levels, furthermore, they used warfarin for anticoagulation more frequently compared to patients with a normal renal function.

Anticoagulant selection, dose regimen for elective interventions. The only reason why an intervention was not performed for warfarin users was insufficient hypocoagulation, which was observed in 12.2% of patients, while anamnesis of patients' missed doses with a possibility of inadequate hypocoagulation occurred only in 1.9% of patients on NOACs. The odds of having inadequate pre-procedural hypocoagulation were 7.4 times higher for warfarin users compared to NOACs group (p=0.001, OR=7.4).

Rivaroxaban was the most frequently used NOAC (58.8%) compared to apixaban (35.1%) and dabigatran (5.1%) in our patient population. Incorrect NOAC dose on discharge according to the ESC guidelines [23] was recommended to 22 (8.6%) patients. The highest percentage of incorrect dosage was found in the rivaroxaban group (Table 3).

Discussion

Even though NOACs are preferable to warfarin, they still have limitations and require proper dose selection for every individual patient [16,17,26]. Since NOACs are eliminated through the kidneys, they can accumulate as the renal function gets worse and therefore the risk of bleeding increases. Additionally, chronic kidney disease (CKD) is an independent risk factor for bleeding events along with thromboembolism related to AF[20,27–30]. Despite the fact that CKD-EPI equation for estimated glomerular filtration rate (eGFR) is widely used in the classification and staging of CKD, when prescribing higher risk drugs such as anticoagulants, it is highly recommended to use Cockroft-Gault (CG) equation to calculate CrCl [31]. Since one of the main aims of our study was to evaluate the prescribed dosage of NOACs, we used the CG equation to assess the renal function and found that 56.7% of our patients had impaired renal function (CrCl ≤80 ml/min) with 12.6% of patients having moderate-severe renal impairment (CrCl <50 ml/min). Other studies used CG to evaluate renal function as well. Hawkins et al published the data of 559 AF patients where the prevalence of impaired renal function was 63.3% and a quarter (27.9%) of all patients had at least moderate renal impairment [32]. The study that included 2398 AF patients found a lower presence of CKD in AF patients, a total of 55.1% of patients had CKD with 18.5% of the studied population having moderate-severe renal function impairment [33]. Meanwhile, 3 out 4 patients who are newly prescribed with NOACs in the UK primary care are over 65 years old [11]. As the risk of developing chronic kidney CKD increases with age, there is a big probability that a significant number of patients prescribed with NOACs might need an adjusted dose, hence it is very important to evaluate the CrCl before selecting the dose of NOACs. However, automatic laboratory reports usually present renal function according to CKD-EPI equation, so this value could be used and as a consequence, mistakes when prescribing the dosage of NOACs are possible. Some clinicians may also evaluate renal function only by the value of serum creatinine concentration and may not take into consideration that CrCl varies depending on gender and age, included in the CG equation [26].

Various studies reflect the incidence of mistakes when prescribing the dosage of NOACs. High volume study included 30 467 patients initiating NOACs with non-valvular AF, where 23.1% of the patients were prescribed with an inappropriate dosage of NOACs accordingly: 15.8% of patients on rivaroxaban, 25.1% on apixaban and 25.6% on dabigatran [16]. Contrary to this study, we have observed the largest percentage of mistakes in the group of patients using rivaroxaban (11.3% of patients). The percentage of incorrect dosage varies between different studies from all over the world. Another large study from the USA included 7925 patients with AF and found that the dosage of NOACs was inappropriate for 4% of patients who received a standard

Table 3. Evaluation of the dosage of NOACs according to the ESC guidelines [23]
ECV – electrocardioversion, RFA - radiofrequency ablation
**p value for ECV patients versus catheter ablation patients*

Variable	All patients n=257 (%)	ECV n=97 (%)	RFA n=160 (%)	p value*
Patients discharged with rivaroxaban	151 (58.8)	61 (62.9)	90 (56.3)	0.295
• Incorrect dosage of rivaroxaban	17 (11.3)	4 (6.6)	13 (14.4)	0.132
Patients discharged with apixaban	53 (20.6)	17 (17.5)	36 (22.5)	0.339
• Incorrect dosage of apixaban	4 (7.5)	0 (0)	4 (11.1)	0.153
Patients discharged with dabigatran	13 (5.1)	7 (7.2)	6 (3.8)	0.219
• Incorrect dosage of dabigatran	1 (7.7)	0 (0)	1 (16.7)	0.261

dose and for 57% of patients who received a reduced dose [22]. Several studies regarding this topic were performed in the Netherlands: the first one included 3231 patients from Martini Hospital electronic information system, the other one collected data from the Dutch subset of the XANTUS registry (899 patients) and observed label-discordant dosage of NOACs in 10.7% and 8.3% of patients respectively [17,34]. Even though the reasons for the different incidence of incorrect dosage between various countries and hospitals are not known, it can be seen that inappropriate dosing is common, especially when it comes to underdosing. In contrast to different studies, we observed a prevalence of 8.6% of incorrect dosage of NOACs in our research with no significant differences between the patients who underwent ECV or catheter ablation.

Moreover, adherence to the recommendations of anticoagulant therapy in our studied population of patients is essential not only to prevent stroke, but also to maintain sufficient hypocoagulation which is crucial for the intervention to be performed. We evaluated the patients' persistence with NOACs therapy before the procedure and found that only 1.9% of them had missed a dose or the duration of their anticoagulant use was too short. Since the indicated duration of NOAC therapy before ECV or catheter ablation procedures is only 3 weeks, this could be the reason why we observed such a low percentage of patients not adhering to the therapy prescribed. In contrast, 12.2% of warfarin users in our studied population had insufficient pre-procedural hypocoagulation and therefore could not undergo an intervention. Thus, using warfarin in order to keep sufficient pre-procedural hypocoagulation can be challenging due to the fact that maintaining regular INR levels is difficult, whereas dose monitoring as well as dose adjustment is substantial.

This study has several limitations. First of all, this was a retrospective analysis of clinical records. Moreover, a small degree of mistakes could have been made in calculation of CrCl since practitioners sometimes file only the approximate weight of the patients. Additionally, patients' laboratory tests came from different laboratories, which somewhat could have influenced the results. Furthermore, this study was conducted in a single centre, thus there are certain limitations to adapt these findings to the general population.

Conclusions

Mistakes of prescribing the dosage of anticoagulant therapy are still common. The majority of the patients in the study were prescribed NOACs before and after ECV or catheter ablation procedures. Warfarin users had higher odds of the intervention not being performed as well as not reaching sufficient hypocoagulation prior to the procedure when compared to NOACs users. Rivaroxaban was prescribed to more than half of the patients prior to and after the procedure and at the same time this group of patients had the highest percentage of incorrect dosage according to the ESC guidelines.

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ANTIKOAGULIANTŲ VARTOJIMAS PRIEŠ IR PO ELEKTRINĖS KARDIOVERSIJOS AR RADIODAŽNINĖS ABLIACIJOS. IŠŠŪKIAI, PROBLEMOS, KLAIDOS

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Raktažodžiai: naujieji antikoaguliantai, elektrinė kardioversija, radiodažninė abliacija, prieširdžių virpėjimas, prieširdžių plazdėjimas.

Santrauka

Yra nedaug tyrimų, nagrinėjančių prieširdžių virpėjimu (PV) ar plazdėjimu (PP) sergančių pacientų kasdienį antikoaguliantų vartojimą prieš ir po elektrinės kardioversijos (EKV) ar radiodažninės abliacijos (RDA). Šio tyrimo tikslas – įvertinti antikoaguliantų vartojimo ypatumus minėtomis aplinkybėmis. Tyrimo metu įvertinta 257 nevožtuvinės kilmės PV ar PP sergančių pacientų, kuriems atlikta EKV arba RDA, vartojama antikoaguliantų dozė ir jos atitikimas Europos kardiologų draugijos PV rekomendacijas. Statistinė analizė atlikta naudojantis IBM SPSS Statistics programine įranga (v.26.0). Nustatyta, kad dauguma pacientų (84 proc.) vartojo naujuosius antikoaguliantus prieš atliekamą procedūrą. EKV arba RDA nebuvo atliktos 12,2 proc. varfarino vartotojų dėl nepakankamos hipokoaguliacijos, kai tik 1,9 proc. naujųjų antikoaguliantų vartotojų sakė praleidę vieną ar kelias dozes, traktuojant tai kaip galimą nepakankamą hipokoaguliaciją. Nepakankamos hipokoaguliacijos tikimybė buvo 7,4 kartus didesnė varfarino vartotojams, lyginant juos su naujųjų antikoaguliantų vartotojais (p=0,001; OR=7,4). Netinkama naujųjų antikoaguliantų dozė buvo paskirta 22 (8,6 proc.) pacientams. Rivaroksabanas buvo dažniausiai skiriamas naujasis antikoaguliantas. Jį vartojančių pacientų grupei dažniausiai buvo paskiriama netinkama dozė, lyginant su vartojančiais apiksabaną ar dabigatraną.

Antikoaguliantų dozavimo klaidos yra dažnos. Didžiajai daliai pacientų buvo paskirti naujieji antikoaguliantai po EKV ar RDA. Varfarino vartotojams buvo didesnė tikimybė, jog jiems nebus atlikta intervencija, ar jie nepasieks pakankamos hipokoaguliacijos prieš procedūrą, lyginant su naujųjų antikoaguliantų vartotojais.

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