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ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

Evaluation of the recommended prevention of thrombosis in hospitalised patients with atrial fibrillation and high thromboembolism risk

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Abstract

Background: According to the applicable guidelines for stroke prevention, patients with a high risk of thromboembolic complications should receive oral anticoagulants.

Aim: The objective of the present study is to evaluate the prevention of thrombosis in patients with diagnosed atrial fibrillation (AF) on discharge and a high risk of stroke.

Methods: The present study is a retrospective single-centre registry. The analysis was carried out on the basis of the data on 4099 patients with non-valvular AF, who were discharged from the cardiology department in the years 2004–2012. 276 (67.3%) of those patients were reported to have a high thromboembolism risk.

Results: Oral anticoagulants in monotherapy or in combination were administered to 65% of patients with AF and high risk of stroke. Oral anticoagulants were recommended for 69.7% of patients with a low risk of bleeding and 59.3% of patients with a high risk of bleeding. The number of patients treated with oral anticoagulants within nine years of analysis was increasing: 61.7% in the years 2004–2006, 63.3% in the years 2007–2010, and 71.5% in the years 2011–2012. Factors that affected a decision to not introduce oral anticoagulants in patients with AF and high risk of stroke were hospitalisation in the years 2004–2006 (hazard ratio [HR] 0.72), high risk of bleeding (HR 0.70), vascular disease (HR 0.68), age ≥ 80 years (HR 0.52), history of bleeding (HR 0.55), and paroxysmal AF (HR 0.51).

Conclusions: Oral anticoagulants were indicated on discharge for 2/3 of patients with AF and high risk of stroke, and more often in patients with low risk of bleeding events. An increase in the number of indications for oral anticoagulation has been observed in the past nine years. The factors which led to no use of oral anticoagulation among AF patients with high stroke risk were: hospitalisation in the years 2004–2006, high risk of bleeding, vascular disease, age ≥ 80 years, paroxysmal AF, and previous bleeding.

Key words: oral anticoagulation, atrial fibrillation, stroke, prophylaxis, high risk of stroke

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INTRODUCTION

Thromboembolic complications are the most serious consequences of atrial fibrillation (AF) [1]. The most common thromboembolic complication is stroke. The risk of stroke increases 17-fold among patients with rheumatic valve disease and AF, and only five-fold among patients with AF of non-valvular aetiology [2]. Patients with isolated AF associated with a low risk of thromboembolic complications constitute 2–15% of patients with arrhythmia [3–6]. Previous stroke, transient ischaemic attack, or peripheral embolism are the factors significantly increasing the recurrence of thromboembolic incident [7].

The CHA_2DS_2VASc score should be used for the stratification of the risk of thromboembolic complications. It is the extension of the previously applied $CHADS_2$ score [8, 9]. Patients whose $CHADS_2$ or CHA_2DS_2VASc score amounts

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to two points or more have a high risk of thromboembolic incident. According to the guidelines for stroke prevention, patients with a high risk of thromboembolic complications should receive oral anticoagulants (OAC) [9]. The objective of the present study is to evaluate the prevention of thrombosis in patients with diagnosed AF on discharge and a high risk of thromboembolic complications.

METHODS

The present study constitutes a retrospective single-centre registry. The analysis was carried out on the basis of the data on 4099 patients with diagnosed AF, who were discharged from the cardiology department of the regional hospital in the years 2004–2012. 2760 (67.3%) of those patients were reported to have a high thromboembolism risk. The study group consisted of the subsequently hospitalised patients with AF. The analysis was performed on medical documentation consisting of full data, which allows for the evaluation of thromboembolic and bleeding complications according to the applicable scales, as well as data on the recommended prevention of thrombosis. In case of a patient being hospitalised several times, data on the last hospitalisation were analysed. The criteria or exclusion from the study were: AF of valvular aetiology and hospitalisation ending with the patient's death.

The examined group consisted of patients hospitalised in the years 2004–2012, when the $CHADS_2$ score was primarily used, which is the reason why it was applied in the present study for the purpose of thromboembolism risk assessment. Zero points in $CHADS_2$ score indicates low thromboembolism risk, 1 point indicates moderate risk, and a score of at least 2 points is an indicator of high thromboembolism risk.

In the evaluation of the risk of bleeding complications the following factors were reported to increase the risk of bleeding according to the HAS-BLED score: anaemia defined as haemoglobin levels of less than 12 g/dL in women and less than 13 g/dL in men, and thrombocytopaenia defined as the blood cell concentrations of less than 150 g/L. Time in therapeutic range below 60% was considered an unstable anticoagulation. Renal dysfunction was defined in the HAS-BLED score as creatinine levels ≥ 220 μmol/L, long-lasting dialysis, or a state after renal transplantation, whereas liver dysfunction was defined as a transient liver disease or a severe biochemical liver injury (with bilirubin concentrations exceeding twofold the normal levels and the aminotransferase activity exceeding threefold its normal value).

The regional Bioethics Committee granted consent for the study (no. 12/2011).

Statistical analysis

The statistical analysis was based on data derived from the clinical study and was carried out with the use of the χ^2 test to approximate the significance of distribution of random variables in single classifications and to evaluate the correlation of variables in double classifications. The statistical significance of differences was designated with a p value ($p < 0.05$). The calculations were made using Med. Calc Ver. 12.4.0.0 software.

Table 1. Characteristics of the population of patients with atrial fibrillation and high risk of stroke

	Number of patients (n = 2760)	Percentage of patients
Concomitant disease		
Hypertension	2394	88.7%
Coronary artery disease:	1728	62.6%
Previous infarction	571	20.7%
Acute infarction	256	9.3%
Previous PCI	250	9.1%
Previous coronary artery bypass graft	106	3.8%
Heart failure	1988	72%
Impaired renal function (GFR < 60 mL/min)	1709	61.9%
Dyslipidaemia:	1207	43.7%
Hypercholesterolaemia	832	30.1%
Hypertriglyceridaemia	142	5.1%
Combined hyperlipidaemia	233	8.4%
Diabetes	867	31.4%
Thyroid disease:	447	16.2%
Hyperthyroidism	214	7.8%
Hypothyroidism	128	4.6%
Euthyroid nodular goitre	105	3.8%
Chronic obstructive pulmonary disease	278	10.1%
Malignancy	126	4.6%
Peripheral vascular disease	115	4.2%
Previous thromboembolism		
Stroke	434	15.7%
Transient ischaemic attack	59	2.1%
Other episodes	80	2.9%
Previous interventions		
Pacemaker implantation	1265	45.8%
ICD implantation	99	3.6%

GFR — glomerular filtration rate; ICD — implantable cardioverter-defibrillator; PCI — percutaneous coronary intervention

RESULTS

The mean age in the examined group of 2760 patients with AF and a high thromboembolism risk was 74.4 years, while the number of women amounted to 1375 (49.8%). Table 1 presents the coexisting diseases in the study group. Patients

Table 2. Anticoagulant prophylaxis recommended at discharge and the risk of bleeding complications in patients with atrial fibrillation (AF) and high risk of stroke

Anticoagulant prophylaxis	All patients with AF and high risk of stroke (n = 2760)	Risk of bleeding		
		Low HAS-BLED 0–2 (n = 1488)	High HAS-BLED ≥ 3 (n = 1272)	p
OAC in monotherapy or in combination with antiplatelet drug(s); n = 1791	1791 (64.9%)	1037 (69.7%)	754 (59.3%)	< 0.0001
Antiplatelet drug in monotherapy or two antiplatelet drugs in combined therapy; n = 761	761 (27.5%)	350 (23.6%)	411 (32.3%)	< 0.0001
Low molecular weight heparin; n = 63	63 (2.3%)	29 (1.9%)	34 (2.7%)	0.1021
Without anticoagulant and antiplatelet therapy; n = 145	145 (5.3%)	72 (4.8%)	73 (5.7%)	0.1453

Data are presented as number (percentage). OAC — oral anticoagulants

with AF were most often hospitalised for elective surgeries: implantation/reimplantation of cardiac pacing system (1077 patients; 39%), angiography or coronary angioplasty (193 patients; 7%), electrophysiological test, and/or ablation (18 patients; 0.7%). The exacerbation of a primary disease caused hospitalisation of 696 (25.2%) patients with AF. The majority of that group (471 patients; 67.7% hospitalised due to the exacerbation of a primary disease) were hospitalised due to heart failure decompensation, which occurred in a different mechanism than AF with high ventricular rate. In a group of patients where the exacerbation of a primary disease was a cause of hospitalisation 101 (14.5%) patients were admitted to the hospital due to AF with high ventricular rate, whereas 64 (9.2%) were hospitalised due to the exacerbation of coronary artery disease, and 60 (8.6%) due to hypertensive crisis. The acute coronary event led to hospitalisation of 420 (15.2%) patients with AF, while paroxysmal AF resulted in hospitalisation of 225 (8.1%) patients. Forty-seven (1.7%) patients were hospitalised for other factors than those mentioned above.

The most common type of arrhythmia was permanent AF, which occurred in 1423 (51.6%) patients, whereas paroxysmal AF was observed in 1150 (41.6%) patients, and persistent AF in 187 (6.8%) patients.

In the evaluation of the risk of thromboembolic complications the average $CHADS_2$ score in the study group was 2.9. The majority of the examined patients (n = 1184) scored 2 points.

According to the HAS-BLED score, in the study group involving 2760 subjects a high risk of bleeding was indicated in 1272 (46.1%) patients, while low risk of bleeding was reported in 1488 (53.9%) patients.

Oral anticoagulants in monotherapy or in combination therapy were administered to 65% of the examined patients. OAC was most often recommended for use in patients with AF and a high stroke risk (2760 subjects) in the prevention of thromboembolic complications, whereas OAC in monotherapy (including the new OAC) was indicated for 1599 (57.9%) patients. OAC in combination with antiplatelet drug(s) was administered to 192 (6.9%) patients, while OAC in monotherapy or with antiplatelet therapy was recommended for use in 1791 (64.9%) patients in total. Antiplatelet drugs were indicated on discharge for 761 (27.6%) patients with a high risk of stroke at the prevention of AF. Low molecular weight heparin was prescribed on discharge to 63 (2.3%) patients classified as being at high stroke risk. 145 (5.3%) patients with AF and a high risk of thromboembolic complications received no prevention of thromboembolism on discharge.

Among patients with a low risk of bleeding (53.9% of patients in the study group), OAC in monotherapy or in combination therapy was recommended for 1037 subjects (69.7% of patients with a low risk of bleeding). Conversely, if a high risk of bleeding was involved, OAC was recommended for use in a group that was smaller by 10% (Table 2).

The participants of the study were hospitalised during a period of nine years. Figure 1 shows the antithrombotic therapy administered to patients with a high stroke risk, who received treatment in particular periods of time. The time periods of a small analysis (the years 2004–2006, 2007–2010, 2011–2012) were determined on the basis of the years in which the subsequent guidelines were published, i.e. 2006, 2010, and 2012.

It has been demonstrated that the number of patients with a high-risk profile for stroke, who were treated with OAC within nine years of analysis, was increasing systematically, and amounted to: 561 (61.7%) patients in the years 2004–2006, 724 (63.3%) patients in the years 2007–2010, and 506 (71.5%) patients in the years 2011–2012. In the period 2011–2012 a statistically significant reduction of the percentage of antiplatelet drugs prescribed in the prevention

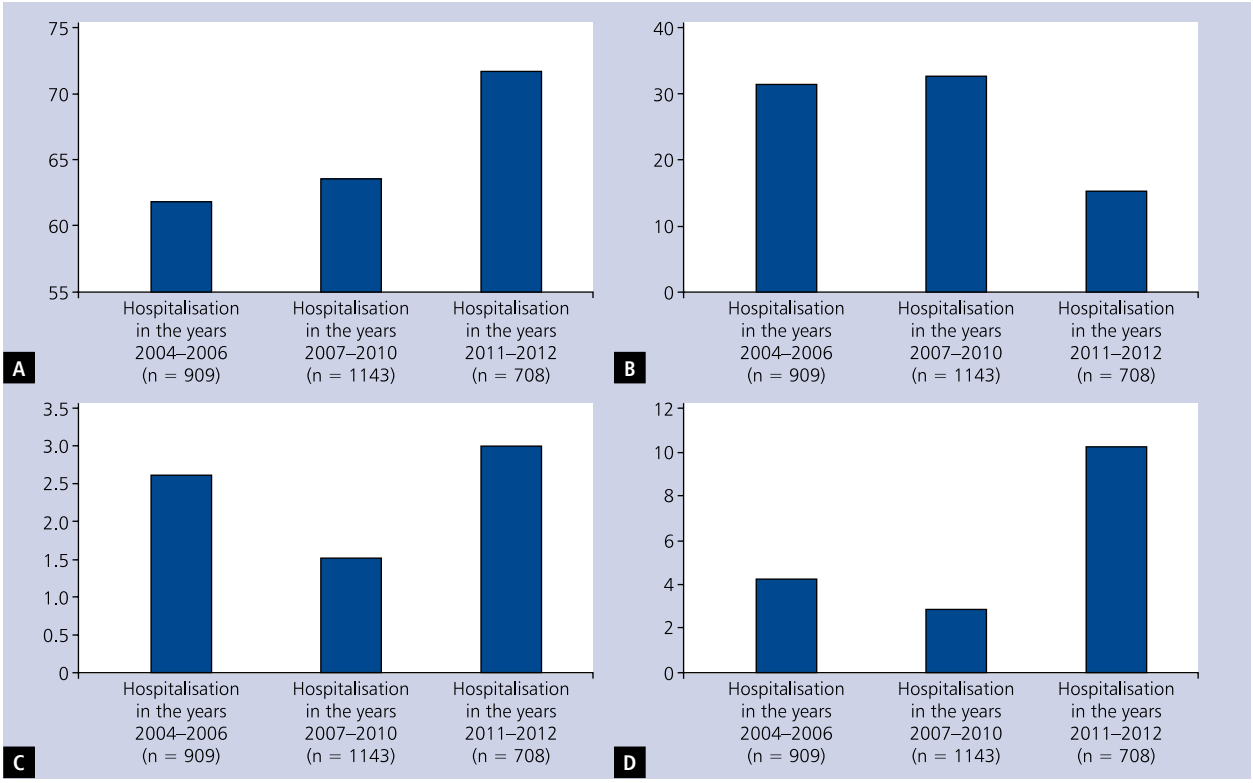

Figure 1. The frequency of prescribing oral anticoagulants (alone or in combination therapy) (**A**), antiplatelet drug(s) (**B**), low-molecular-weight heparin (**C**) and the frequency of providing no prevention of thrombosis (**D**) to patients with atrial fibrillation and high risk of stroke in different years of hospitalisation

of thromboembolic complications was observed in comparison to the years 2004–2006 (15.3% vs. 31.2%, $p < 0.0001$) and 2007–2010 (15.3% vs. 32.4%, $p < 0.0001$). An increase in the percentage of patients who received no prevention of thromboembolism in the past two years when compared to the previous years (10.2% vs. 4.5%, $p < 0.0001$ and 10.2% vs. 2.8%, $p < 0.0001$) was noted.

It has been indicated that in the study group consisting of patients rated at a high risk of stroke the percentage of prescribed OACs decreased with age. Among patients aged under 64 years OAC was recommended for use in 313 (74%) subjects, whereas in the case of patients over 80 years of age, whose number was predominant, OAC was indicated for 456 (54.7%) subjects (Fig. 2).

Among the group of patients with a high risk of thromboembolic complications, those who did not receive OAC on discharge were older than patients who received OAC (76.3 vs. 73.3 years, $p < 0.0001$), suffered more often from paroxysmal AF (51.9% vs. 31.1%, $p < 0.0001$) and vascular disease (37.7% vs. 28.3%, $p < 0.0001$), had a history of bleeding events (3.5% vs. 1.9%, $p < 0.0001$), and experienced renal dysfunction (5.3% vs. 3%, $p < 0.0001$). They were also more frequently hospitalised for acute coronary syndrome (25.2% vs. 9.8%, $p < 0.0001$) (Table 3).

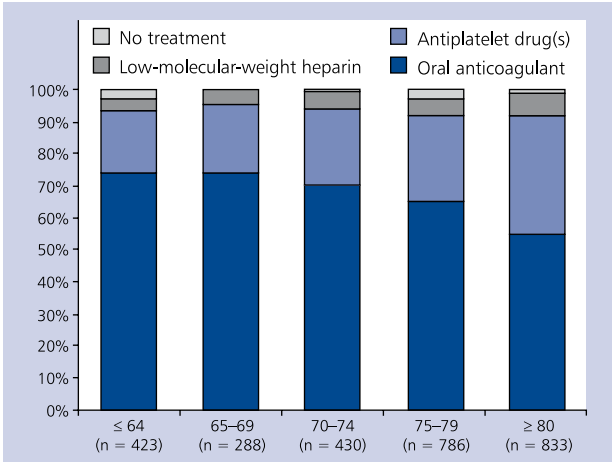

Figure 2. The recommended thromboprophylaxis in different age groups of patients with atrial fibrillation and high risk of stroke

Multivariate factor analysis showed that the following factors had an impact on the decision to not use OAC in AF patients with a high risk of stroke: hospitalisation in the years 2004–2006 (hazard ratio [HR] 0.72), HAS-BLED score ≥ 3 points (HR 0.7), vascular disease (HR 0.68), history

Table 3. Comparison of patients with high risk of stroke receiving/not receiving oral anticoagulants (OAC) in monotherapy or in combination therapy

	All patients (n = 2760)	Patients receiving OAC (n = 1791)	Patients not receiving OAC (n = 969)	p
Type of atrial fibrillation:				
Paroxysmal	1150	647 (31.1%)	503 (51.9%)	< 0.0001
Persistent	187	147 (8.2%)	40 (4.1%)	< 0.0001
Permanent	1423	995 (55.6%)	428 (44.2%)	< 0.0001
Stroke risk factors:				
Hypertension	2394	1567 (87.5%)	827 (85.3%)	0.056
Heart failure	1988	1276 (71.3%)	712 (73.5%)	0.106
Diabetes	867	559 (31.2%)	308 (31.8%)	0.378
Previous thromboembolism	556	394 (22%)	162 (16.7%)	0.0005
Age ≥ 65 years	2637	1478 (82.6%)	859 (88.6%)	< 0.0001
Vascular disease	871	506 (28.3%)	365 (37.7%)	< 0.0001
Female gender	1376	884 (49.4%)	492 (50.8%)	0.239
Bleeding risk factors:				
Impaired kidney function	104	53 (3%)	51 (5.3%)	0.012
Impaired liver function	16	12 (0.7%)	4 (0.4%)	0.199
Previous bleeding	68	34 (1.9%)	34 (3.5%)	0.0046
Malignancy	126	103 (5.8%)	52 (5.4%)	0.069
Ulcer disease	115	74 (4.1%)	47 (4.8%)	0.093
Cause of hospitalisation:				
Acute coronary syndrome	420	176 (9.8%)	244 (25.2%)	< 0.0001
Exacerbation of a primary disease	696	465 (26%)	231 (23.8%)	0.1100
Elective surgery	1282	867 (48.4%)	415 (42.8%)	0.0025
Age (mean) [years]		73.3	76.3	< 0.0001

Data are presented as number (percentage).

of bleeding event (HR 0.55), age ≥ 80 years (HR 0.52), and paroxysmal AF (HR 0.51) (Table 4).

DISCUSSION

The evaluation of adherence to the guidelines for antithrombotic treatment in patients with AF is subject to numerous studies. In the present study 65% of patients with a high risk of thromboembolic complications and AF received OAC on discharge. Table 5 shows the results of anticoagulation in the prevention of thromboembolic complications among patients with AF and high stroke risk in clinical studies [10–20]. The prospective ATRIUM study, which included participants treated in outpatient conditions in 2009 [10], demonstrated a significantly higher percentage of patients with AF and a high risk of thromboembolic complications, who received OAC (87%).

In the present study the mean age of patients was higher than that in the German register (74.4 vs. 72 years). In addition, the following conditions occurred more often among hospitalised patients who participated in the present study than among those from the ATRIUM registry: hypertension (89% vs. 84%), ischaemic heart disease (63% vs. 35%), and heart failure (72% vs. 43%). In recent years a growing tendency to recommend the prevention of thrombosis in patients with AF can be observed. Rodríguez-Manero et al. [21] examined 32,051 subjects from the CARDIOTENS 1999 study and 25,137 patients who participated in the CARDIOTENS 2009 study. It was observed that the number of patients who received warfarin increased in those 10 years from 28% to 63% [21]. The antithrombotic therapy administered to patients with AF in the period of nine years was analysed. A gradual, statistically significant increase in the administration of OAC in patients with a high risk of thromboembolic complications in the particular years of hospitalisation was also seen. In the years 2004–2006 OAC on discharge was received by 62% of patients, whereas in the years 2007–2010 it was 63% of patients, and in the last two years it was 71%. The time periods indicate years when the currently applied subsequent European Society of Cardiology guidelines for the treatment of patients with AF were published. Despite the expected, sig-

Table 4. Multivariate logistic regression analysis. Factors had an impact on the decision not to use oral anticoagulants in patients with atrial fibrillation and high risk of stroke

Factor	Odds ratio	95% confidence interval	p
Female gender	1.14	0.95–1.34	0.015
Hospitalisation in the years 2004–2006	0.72	0.61–0.85	0.0002
HAS-BLED score ≥ 3 points	0.70	0.59–0.82	< 0.0001
Vascular disease	0.68	0.57–0.81	< 0.0001
Age ≥ 80 years	0.52	0.43–0.62	< 0.0001
Paroxysmal atrial fibrillation	0.51	0.43–0.60	< 0.0001
Previous bleeding	0.55	0.33–0.91	0.02
Glomerular filtration rate < 60 mL/min	0.98	0.82–1.16	0.80

Table 5. The use of oral anticoagulants (OAC) in patients with atrial fibrillation (AF) and high risk of stroke in clinical trials

Study/author	Years in which the study was carried out	Number of patients with AF and high risk of stroke	Proportion of patients treated with OAC
ATRIUM, Meinertz et al. [10]	2009	2226	87%
Chae et al. [11]	2006–2008	1651	82%
AFNET, Nabauer et al. [12]	2004–2006	7194	71%
Present study	2004–2012	2760	65%
Scowcroft et al. [13]	2000–2009	46281	65%
Rodríguez-Manero et al. [14]	2009	1193	64%
Euro Heart Survey, Nieuwlaat et al. [15]	2003–2004	1352	61%
PINNACLE, Chan et al. [16]	2008–2009	5612	55%
Waldo et al. [17]	2002	815	55%
Cowan et al. [18]	2009–2012	132099	55%
Holt et al. [19]	2007–2010	34028	53%
Sandhu et al. [20]	2000–2005	21315	52%

nificant increase in the number of administered OAC in recent years, the growing tendency is marginal. In recent medical publications anticoagulation in patients with AF and a high risk of stroke ranges in numerous registries from 60% to 70%, and only in some analyses (e.g. in the above-mentioned ATRIUM registry) were the percentage of patients treated with OAC higher. Holt et al. [19] observed in a group of 34,028 subjects with a high risk of thromboembolic complications a lower number of OAC indications in the years 2007–2010 in comparison with the present study. In 2007 54% of patients received OAC in monotherapy or in combination with antiplatelet drugs, whereas in 2010 that percentage increased by 3% [19]. The question is: At which point are the guidelines for the prevention of thromboembolism considered to be fully met (taking into account the medical contraindications and psychosocial conditions), and could these criteria be made more feasible by introducing new OAC.

In the examined group of 2760 patients with AF and a high risk of thromboembolic complications 5.3% received no prevention of thromboembolism on discharge, whereas in the Euro Heart Survey this was the case for 6.4% of patients with a high risk of thromboembolic complications [15]. Boulanger et al. [22] showed that 18.9% of patients with AF did not receive OAC or any antiplatelet drug. The percentage of patients receiving no prevention of thromboembolic events in the period 2011–2012 (10%) was higher than that reported in the years 2004–2006 (4%) and 2007–2010 (3%). Simultaneously, in the last two years the number of patients treated with antiplatelet drugs was two times lower than that observed in the previous years of the study. Apparently, a better identification of contraindications to vitamin K antagonists and the decreasing significance of acetylsalicylic acid in the prevention of thromboembolic complications of AF led to the increase of patients who, despite a high risk of thromboembolic complications and AF, received no antithrombotic prevention. Holt et al. [19] demonstrated that the percentage of high-risk patients with no prevention of thrombosis accounted for 12.4% in 2007 and 11.3% in 2010.

In the present study OAC was more often recommended for use in patients at low bleeding risk than in a group with a high risk of bleeding. The particular factors of the risk of bleeding, also those not included in the applicable HAS-BLED score, occurred more frequently in patients who did not receive OAC despite a high stroke risk. In the examined group past bleeding reduced the probability to receive OAC by 45%. Beyth et al. [23] also showed that bleeding complications in the past significantly reduce the likelihood of anticoagulant therapy. According to the guidelines, a high risk of bleeding should not constitute a basis for discontinuation of antithrombotic therapy. However, the concern for bleeding complications is sometimes greater than that for thromboembolic events [24].

Elderly patients who are more susceptible to thromboembolic and bleeding complications require particular attention when making decisions regarding antithrombotic therapy. In the present study the majority of patients were aged over 80 years. The percentage of recommended OACs in the examined group decreased with age and accounted for 74% in patients under 65 years of age and 55% in patients over 80 years of age. Patients who did not receive OAC were older than those who did. Other results than those obtained in the presented study were achieved in the PINNACLE registry of American patients, where 9113 subjects with AF and a moderate or high risk of thromboembolic complications were analysed [16]. Age > 80 years was a predicator for OAC indication and increased the likelihood of its administration by 17%. The advanced age was a predisposing factor for the lack of OAC prescription. It can be assumed that numerous coexisting diseases, as well as cognitive impairment, which occur frequently in elderly patients with AF, and the lack of proper care provided to the elderly (which would allow for a safe treatment with vitamin K antagonists) led to the tendency to not indicate antithrombotic therapy in patients aged over 80 years.

Another factor that reduces the likelihood of anticoagulation in a group of patients with high thromboembolic complications was paroxysmal arrhythmia. Half of the patients who did not receive OAC suffered from paroxysmal AF. Although it has been scientifically demonstrated that this presentation of arrhythmia does not reduce stroke risk, the present study showed that anticoagulant therapy was more frequent among patients with persistent, and not acute, AF. Similar conclusions were drawn by the authors of the European registry [15] as well as German investigators [10]. Chae et al. [11] demonstrated in multivariate factor analysis that persistent AF rather than paroxysmal AF was a significant factor leading to the administration of OAC (odds ratio 4.95).

In the present study, participants of which were patients hospitalised in a tertiary medical centre, a high but still in a sufficient number of patients with AF at a high risk of thromboembolic complications, who were treated with OAC, is evident. Antithrombotic drugs were contraindicated for approx. 15% patients with AF [12, 13, 23]. Additionally, it appears that certain limitations associated with patients' socioeconomic status causing difficulties in using OAC still exist.

Limitations of the study

The present study is single-centre and retrospective. It was carried out on patients hospitalised within nine years, in which the standards for the treatment of AF patients changed three times. Other factors that change in time included a size of the patient population with arrhythmia, the presence of diseases coexisting with AF and the causes for hospitalisation. The retrospective design of the study did not allow for the acquisition of data on AF duration, family history of arrhythmia, and antithrombotic treatment used prior to admission to the hospital.

CONCLUSIONS

1. Oral anticoagulants were indicated on discharge for 2/3 of patients with AF and high risk of thromboembolic complications, and more often in patients classified at low risk of bleeding complications.
2. An increase in the number of indications for OAC in the prevention of thromboembolic events of AF has been observed in the past 10 years.
3. The significance of acetylsalicylic acid in the prevention of thromboembolic complications of AF is constantly decreasing.
4. Patients with a high-risk profile for thromboembolic events, who were not treated with OAC, were older and more often hospitalised for acute coronary syndrome. Additionally, the bleeding risk factors occurred more often in this group than in patients receiving OAC.
5. The factors that led to no use of OAC among patients with a high stroke risk were: hospitalisation in the earliest years of the registry, high risk of bleeding, vascular disease, age ≥ 80 years, paroxysmal AF, and prior bleeding.

Conflict of interest: *none declared*

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