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Baseline characteristics of patients from Poland enrolled in the global registry of patients with recently diagnosed atrial fibrillation (RecordAF)

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Abstract

Background: The RecordAF study is the first worldwide, prospective, observational survey on the management of patients with recently diagnosed atrial fibrillation (AF).

Aim: This paper presents the baseline characteristics of the Polish patients enrolled in this registry.

Methods: The registry enrolled patients ≥ 18 years old with recently diagnosed AF (≤ 12 months from diagnosis), eligible for rhythm or rate control strategy. The planned follow-up is 12 months. The aim of the registry is to prospectively assess the efficacy of treatment defined as (a) maintenance of sinus rhythm or (b) optimal rate control, as well as (c) the incidence of cardiovascular events.

Results: A total of 303 Polish patients were enrolled in 21 centres across Poland (mean age 63 ± 12 years, M/F ratio 174/129). Hypertension was present in 71.5% of the study subjects, ischaemic heart disease in 18.9%, and diabetes in 12.3%. In 47 (15.6%) patients, no potential cause of AF could be established. Symptoms related to AF were reported by 89.1% of patients. Mean duration of AF history was 2.9 ± 3.5 months. At the time of inclusion, 191 (63.0%) patients were in sinus rhythm, and 211 (69.6%) patients were assigned to rhythm control strategy. Rhythm control strategy was chosen more frequently in patients with a history of paroxysmal AF and those in sinus rhythm at inclusion. Rate control strategy was chosen more frequently in those with a history of persistent AF in the previous year or presenting with AF at inclusion.

Conclusions: Analysis of the baseline characteristics of the Polish population of the RecordAF study indicates a high prevalence of co-morbidities among patients with AF. The choice of treatment strategy was associated with rhythm status at inclusion and AF pattern within the previous 12 months. The RecordAF study will provide prospective data on treatment decisions and treatment success of rhythm- or rate-control strategies in patients with AF treated by office- or hospital-based cardiologists.

Key words: atrial fibrillation, rate control strategy, rhythm control strategy, registry

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INTRODUCTION

Atrial fibrillation (AF) is the commonest sustained cardiac arrhythmia, with a prevalence of 5–6% in people aged 65, rising to 10% in those aged 80 and above [1–3]. Atrial fibrillation causes a five-fold rise in stroke risk and frequently coexists with heart failure, both leading to an even further increase in mortality [4–6]. The arrhythmia is associated with significant morbidity-causing symptoms and as well as reduced quality of life [5–8]. Altogether, AF causes a significant economic burden which has grown in the past decades and is expected to grow even further with the increasing trend in AF prevalence and hospitalisations [1–3, 9–12].

Many clinical studies over the past decades have provided a framework for guidelines on the medical care of patients affected by AF [5–8]. However, the level of adherence to guidelines in everyday clinical practice, the often limited feasibility of diagnostics and therapeutic management, or constraints such as patient preference and compliance, still remain unclear. The number of prospective surveys and registries, providing information regarding the frequency and outcome of the different types of AF in the clinical setting, is limited. Furthermore, it is unknown whether the actual clinical management and therapy of AF conform to the ACC/AHA/ESC guidelines on the management of patients with AF [13]. Fresh data on AF management over a prolonged period is still needed, especially focusing on specific patient subsets, cared for by cardiologists or general practitioners in office-based practice. We present the first report of the objectives of the study as well as baseline characteristics and initial management of the patients enrolled to the RecordAF registry in Poland.

METHODS

Study process

The RecordAF (REgistry on Cardiac rhythm disORDers: an international, observational, prospective survey assessing the control of Atrial Fibrillation) study is the first worldwide, prospective, observational survey of the management of patients with recently diagnosed AF with a one-year follow-up [14, 15]. The registry was designed primarily to assess, in a prospective manner, the control of AF and to compare the clinical outcomes (see below) in rhythm vs. rate control strategies over one year in patients presenting to clinical or specialised practices. The study is conducted in 21 countries, including Poland. Baseline characteristics of all 5,604 included patients have been published [14].

Patients

The study population included patients ≥ 18 years of age with either a history of AF diagnosed ≤ one year or with AF discovered at the inclusion visit, diagnosed by standard ECG or by ECG Holter monitoring (irrespective of whether AF was treated or not treated, and of the rhythm status at inclusion). Patients also had to be eligible for a pharmacological treatment of AF (by rhythm or rate-control agents) and had to sign a written informed consent. Exclusion criteria were AF due to a transient cause (thyrotoxicosis, alcohol intoxication, acute phase of myocardial infarction, pericarditis, myocarditis, electrocution, pulmonary embolism or other pulmonary disease, hydroelectrolytic disorder, metabolic disorder, etc.); post cardiac surgery AF (< 3 months); patients with a pacemaker or implantable cardioverter defibrillator; patients scheduled for pulmonary vein ablation, AV node/His bundle ablation, or pacemaker implantation. Patients with life expectancy < one year due to a severe disease, pregnant or breastfeeding women, mentally disabled patients unable to understand or sign the written informed consent, patients unable to attend for follow-up visits, as well as patients included in a clinical trial in the field of AF in the previous three months were also not enrolled.

Selection of the study centres

To provide a representative picture of current medical practice, the study centres were randomly selected from a global list of office- or hospital-based cardiologists in each participating country. This random selection was made in accordance with each country's ratio of hospital-based or office-based cardiologists in order to reflect accurately the practices in each country. For the randomised selection of office-based cardiologists in Poland, we prepared a list containing ten times the expected number of office-based cardiologists based on data available from the internet. For the randomised selection of hospital-based cardiologists in Poland we used a publically available list of cardiology units published on the official website of the National Consultant in Cardiology [16]. The selected centres represent all levels of medical care, including academic hospitals, regional hospitals and office-based cardiologists. Each paticipating study centre was to enroll ten consecutive patients presenting with AF or treated for arrhythmia regardless of the purpose of the visit to minimise patient selection bias. Due to the slow enrollment process, this number was subsequently increased to 30 patients per site in Poland. Patient management complied with local medical practice. Globally, the registry was co-ordinated by international experts in cardiology or health economics. The local study team was responsible for managing clinical operations among participating sites in each country. In Poland, the co-ordinating centre of the registry was the 1st Chair and Department of Cardiology, Warsaw Medical University. The study protocol was approved by the Ethics Committee at the Medical Academy in Warsaw. All study participants were informed of the aims and methods of the study. Written informed consent was obtained from each patient. The list of all 21 participating centres in Poland is provided in Appendix 1.

Study visits and patient enrollment

Enrollment in the study started in April 2007. The total duration of recruitment was eight months, with two months of active recruitment for each participating centre. Follow-up was

planned for 12 months. During that time, three visits were scheduled: at baseline, after 6 ± 1 months and after 12 ± 3 months. The data collected at each study visit were previously described [14]. This paper presents data from the baseline visit of patients from Poland included in the RecordAF study.

Study end-points

The RecordAF study has two co-primary end-points. The first is to assess the rate of therapeutic success at 12 ± 3 months follow-up, defined for each patient as: being in sinus rhythm or at rate control target (≤ 80 bpm) at rest, with no incidence of major cardiovascular events and without crossover between rhythm or rate-control treatment strategies. These major cardiovascular events include cardiovascular death, stroke, transient ischaemic attack (TIA) leading to hospitalisation, myocardial infarction, hospitalisation or prolongation of hospitalisation for arrhythmic or proarrhythmic events or other cardiovascular events, or major complications of ablative procedure. The other primary end-point of the study is to compare the incidence of the above major cardiovascular events in both treatment strategies.

Statistical analysis

The statistical population assessment and methodology used in the global RecordAF registry has been described previously [14]. In the present analysis of patients from Poland enrolled in the study, baseline data is described only for eligible patients. Comparisons between treatment strategies (rhythm control vs. rate control) were made by Chi-square test or Fisher's exact test for qualitative variables, and by analysis of variance for quantitative variables.

RESULTS

Baseline demographics and vital signs

Between April and July 2007, 313 consecutive patients with recently diagnosed AF were enrolled in the study at 21 study centres across Poland. Ten of the study subjects were excluded due to procedural reasons or the patient's refusal to complete the follow-up visits. Accordingly, the final analysis was performed on a group of 303 (96.8%) eligible patients with a mean age of 63 ± 12 years (range 22–88 years). Forty-three percent of the patients were women and all were Caucasian. Mean age was significantly higher in the rate control than in the rhythm control group (67 ± 11 *vs* 62 ± 12 years of age, $p < 0.001$). Mean resting heart rate was 73.9 beats per minute (bpm) and was significantly higher in the rate control than in the rhythm control group (82.9 *vs* 69.9 bpm, $p < 0.001$). Table 1 presents the baseline clinical and demographic characteristics of the studied patients.

Co-morbidities and risk factors

Hypertension was the most prevalent concomitant disease and was present in 71.5% of the study subjects, followed by dyslipidemia (36%) and heart failure (27.8%). Among patients with heart failure, 88.1% were in the New York Heart Association (NYHA) functional class I or II, while 11.9% were in class III or IV. In 29 patients (34.5%) the suspected cause of heart failure was ischaemic. An assessment of the left ventricular (LV) function was performed in 223 of the studied patients. In those patients, lower LV ejection fraction (LVEF) was more frequently observed in the rate control as compared to the rhythm control group: 4.3% *vs* 1.9% had LVEF < 0.30, and 4.3% *vs* 1.3% had LVEF of 0.30–0.35. On the other hand, more patients in the rhythm control group (81.2%) had LVEF > 0.50 as compared to the rate control group (50.7%; $p < 0.001$ for the difference between the groups). Among the 18.9% of patients with coronary artery disease, the disease was documented by angiography in 76.6% and by perfusion scanning in 14.9%; 11.7% of patients had a history of myocardial infarction. Valvular heart disease was present in 68 patients (22.7%) with the most prevalent mitral valve disease detected in 70.6% of cases; three patients (4.4%) had previous surgical valve repair. History of stroke was present in 2.7% of patients, 12.3% had diabetes mellitus, 13 patients (4.4%) had concomitant thyroid disease, and 16 (5.3%) had renal disease. In 47 patients (15.6%) no potential cause of AF could be established. A history of smoking was observed in 45.4% of patients, and 14.6% were current smokers at the time of the baseline visit.

Risk factors for stroke and stroke prevention

Stroke risk was estimated based on the widely accepted $CHADS_2$ score [13], where one point is given for each of the following conditions: heart failure, hypertension, age over 75 years, and diabetes, and two points are given for the history of stroke or TIA. The score thus produces results from 0 (low risk) to 6 (very high risk). A $CHADS_2$ score of at least 1 was reported in 248 patients (81.8%) and a $CHADS_2$ score ≥ 2 was reported in 109 patients (36.2%). Comparing rhythm to rate control groups, more patients in the rhythm control group had a $CHADS_2$ score of 0 (20.1% *vs* 12.0%) and 1 (48.8% *vs* 40.2%), while fewer had a $CHADS_2$ score of 2 (21.1% *vs* 30.4%) and 3–6 (10.0% *vs* 17.4%) ($p < 0.035$). At the time of the baseline visit, eight patients (2.7%) had a history of stroke. Stroke etiology was documented to be ischaemic in seven of these patients. In one patient the data on stroke etiology was missing. Seven patients (2.3%) had a history of TIA, and the other three (1.0%) had a history of both TIA and stroke.

At the time of the baseline visit, vitamin K antagonists were prescribed to 40.3% of patients in the rhythm control group and 80.4% in the rate control group ($p < 0.001$), whereas 55.9% and 32.6% received antiplatelet agents, respectively ($p < 0.001$; Table 2). Among patients who received antiplatelet agents, 91.2% received acetylsalicylic acid (ASA), 2.7% received other antiplatelet agents, and 6.1% received ASA plus another antiplatelet agent. There were no patients with a history of left atrial

Table 1. Baseline characteristics of the patients from Poland included in the RecordAF study

	Rhythm control (n = 211)	Rate control (n = 92)	Total (n = 303)	P
Demographics				
Age [years]	62 ± 12	67 ± 11	63 ± 12	< 0.001[A]
Female gender	90 (42.7%)	39 (42.4%)	129 (42.6%)	0.966[C]
Ethnicity: Caucasian	204 (96.7%)	89 (96.7%)	293 (96.7%)	1.000[F]
Resting heart rate [bpm]	69.9 ± 14.6	82.9 ± 14.1	73.9 ± 15.6	< 0.001[W]
Concomitant diseases				
Hypertension	153 (72.9%)	63 (68.5%)	216 (71.5%)	0.438[C]
Coronary artery disease	41 (21.8%)	9 (11.8%)	50 (18.9%)	0.061[C]
History of MI	27 (12.9%)	8 (8.8%)	35 (11.7%)	0.306[C]
History of stroke	4 (1.9%)	4 (4.3%)	8 (2.7%)	0.254[F]
History of TIA	4 (1.9%)	3 (3.3%)	7 (2.3%)	0.441[F]
Symptomatic PAD	3 (1.4%)	2 (2.2%)	5 (1.7%)	0.643[F]
Heart failure	43 (20.5%)	41 (44.6%)	84 (27.8%)	< 0.001[C]
NYHA I + II	42 (97.7%)	32 (78.0%)	74 (88.1%)	0.007[F]
NYHA III + IV	1 (2.3%)	9 (22.0%)	10 (11.9%)	0.007[F]
Diabetes	24 (11.4%)	13 (14.1%)	37 (12.3%)	0.510[C]
Valvular heart disease	39 (18.6%)	29 (32.2%)	68 (22.7%)	0.010[C]
Thyroid disease	9 (4.3%)	4 (4.6%)	13 (4.4%)	1.000[F]
Renal disease	10 (4.8%)	6 (6.6%)	16 (5.3%)	0.578[F]
Lone AF	38 (18.2%)	9 (9.8%)	47 (15.6%)	0.064[C]
Risk factors				
Family history of premature CVD	34 (17.2%)	7 (8.4%)	41 (14.6%)	0.058[C]
Current smokers	33 (15.7%)	11 (12.0%)	44 (14.6%)	0.235[F]
Dyslipidemia	84 (40.0%)	24 (26.1%)	108 (35.8%)	0.020[C]

P value for the difference between rhythm control and rate control groups; MI — myocardial infarction; TIA — transient ischaemic attack; PAD — peripheral artery disease; NYHA — New York Heart Association; CVD — cardiovascular disease; A — analysis of variance; C — Chi-square test; F — Fisher's exact test; W — Wilcoxon test

appendage occluder implanted for thromboembolic complication prevention in the studied sample.

Within six months preceding the inclusion in the study, international normalised ratio (INR) measurements were performed in 124 patients. The INR value was reported to be within the therapeutic range (2.0–3.0) in 117 of the patients with a mean value of 2.5 ± 2.3. Mean frequency of INR measurement was 5.4 ± 4.0 times within six months preceding enrollment (range 1.0–28.0). There was no significant difference between rate and rhythm strategy in the frequency of INR monitoring (5.8 ± 4.5 *vs* 5.1 ± 3.6; p = 0.41).

Atrial fibrillation characteristics

Table 3 presents data on AF characteristics among the patients. At baseline, 191 patients (63.0%) were in sinus rhythm, while 112 (37.0%) had AF. Symptoms were present in 269 patients (89.1%) at baseline. The symptoms were more commonly found in the rhythm control group, where 92.4% of patients were symptomatic, compared to the rate control group, where 81.5% of patients were symptomatic (p = = 0.005). The average number of reported symptomatic episodes of AF within 12 months prior to inclusion was 5.3 ± 18. One hundred seventy five (57.9%) patients had paroxysmal AF and 127 (42.1%) had persistent AF. A family history of AF was present in 31 patients (10.3%).

Rate and rhythm control

Of the 303 eligible patients, rhythm control strategy was used in 211 (69.6%), and rate control in the other 92 (30.4%). Rhythm control strategy was chosen more frequently in patients with a history of paroxysmal AF and those in sinus rhythm at inclusion, as well as in patients with dyslipidemia (Table 3). In the rate control group, more patients had a history of valvular heart disease and congestive heart failure (Table 1). Rate control strategy was chosen more frequently in patients with a history of persistent AF in the previous year (92% *vs* 20%; p < 0.001) and those in AF at inclusion (94% *vs* 12%; p < 0.001). Presence of AF-related symptoms was very common among patients, as 89.1% were at least mildly symptomatic. However, rhythm control strategy was chosen slightly but significantly more frequently than rate control in symptomatic patients (Table 3). Within one

Table 2. Drug therapy at baseline visit

	Rhythm control (n = 211)	Rate control (n = 92)	Total (n = 303)	P
Atrial fibrillation treatment:				
Anti-arrhythmic drugs:				
Class IA	7 (3.3%)	0 (0.0%)	7 (2.3%)	0.109[F]
Class IC	34 (16.2%)	0 (0.0%)	34 (11.4%)	< 0.001[F]
Class III	37 (17.6%)	5 (5.7%)	42 (14.1%)	0.006[F]
Sotalol	11 (29.7%)	1 (20.0%)	12 (28.6%)	1.000[F]
Other class III drugs	26 (70.3%)	4 (80.0%)	30 (71.4%)	1.000[F]
Beta-blockers except sotalol	174 (82.9%)	82 (93.2%)	256 (85.9%)	0.018[F]
Heart-rate lowering calcium-channel blockers	3 (1.4%)	4 (4.5%)	7 (2.3%)	0.201[F]
Cardiac glycosides	6 (2.9%)	16 (18.2%)	22 (7.4%)	< 0.001[F]
Other cardiovascular treatments:				
Anti-hypertensive drugs	170 (80.6%)	83 (90.2%)	253 (83.5%)	0.037[C]
Diuretics	75 (44.1%)	52 (62.7%)	127 (50.2%)	0.007[F]
Calcium-channel blockers	30 (17.6%)	12 (14.5%)	42 (16.6%)	0.592[F]
ACE-inhibitors/angiotensin II receptor antagonists	161 (94.7%)	77 (92.8%)	238 (94.1%)	0.576[F]
Antiplatelet agents	118 (55.9%)	30 (32.6%)	148 (48.8%)	< 0.001[C]
Acetylsalicylic acid	107 (90.7%)	28 (93.3%)	135 (91.2%)	0.869[C]
Vitamin K antagonist	85 (40.3%)	74 (80.4%)	159 (52.5%)	< 0.001[C]
Lipid lowering drugs	104 (49.3%)	50 (54.3%)	154 (50.8%)	0.418[C]

P value for the difference between rhythm control and rate control groups; C — Chi-square test; F — Fisher's exact test

Table 3. Atrial fibrillation (AF) characteristics

	Rhythm control (n = 211)	Rate control (n = 92)	Total (n = 303)	P
Type of AF				
Paroxysmal AF	168 (80.0%)	7 (7.6%)	175 (57.9%)	< 0.001[C]
Persistent AF	42 (20.0%)	85 (92.4%)	127 (42.1%)	< 0.001[C]
Symptoms	194 (92.4%)	75 (81.5%)	269 (89.1%)	0.005[C]
No. of symptomatic episodes during the previous year	4.3 ± 11.7	7.9 ± 27.8	5.3 ± 17.5	0.531[W]
AF at inclusion	26 (12.3%)	86 (93.5%)	112 (37.0%)	0.001[C]
Sinus rhythm at inclusion	185 (87.7%)	6 (6.5%)	191 (63.0%)	0.001[C]
Family history of AF	24 (11.4%)	7 (7.6%)	31 (10.3%)	—
Interventions during the previous year				
Pharmacological conversion	96 (53.6%)	6 (8.8%)	102 (41.3%)	< 0.001[C]
No. of pharmacological conversions	1.2 ± 0.7	1.2 ± 0.4	1.2 ± 0.7	—
Electrical cardioversion	41 (23.0%)	11 (16.2%)	52 (21.1%)	0.239[C]
No. of electrical cardioversions	1.1 ± 0.3	1.0 ± 0.0	1.1 ± 0.3	—
Catheter ablation	0 (0%)	0 (0%)	0 (0%)	—
Surgical therapy for AF	0 (0%)	0 (0%)	0 (0%)	—

P value for the difference between rhythm control and rate control groups; C — Chi-square test; W — Wilcoxon test

year preceding inclusion to the study, electrical cardioversion was performed in 21.1% of patients (23.0% of those assigned to rhythm control and 16.2% of those assigned to rate control, p = 0.239) and pharmacological conversion in 41.3% of patients (more frequently in the rhythm control group, p < 0.001). Drugs used for pharmacological conversion included class I and class III anti-arrhythmic drugs (64.8% and 36.3%, respectively).

Pharmacological therapy of atrial fibrillation

Details of the pharmacological therapy of the patients are provided in Table 2. Beta-blockers (except sotalol) were prescribed more frequently to patients in the rate control group. Twenty-two patients (7.4%) received cardiac glycosides (more frequently those assigned to rate control), and seven (2.3%) received heart-rate lowering calcium-channel blockers (1.4% *vs* 4.5%, p = 0.201). Class III anti-arrhythmic agents were prescribed more often to patients in the rhythm control group whereas class IC anti-arrhythmic agents were prescribed exclusively to patients assigned to the rhythm control group. Class IA anti-arrhythmic drugs were used very rarely.

Antihypertensive therapy was common among the patients (n = 253, 83.5%): 94.1% received ACE inhibitors/angiotensin II receptor antagonists, 50.2% received diuretics, and 16.6% received calcium-channel blockers. Other frequently administered drugs included lipid lowering agents (50.8%) as well as antidiabetic treatments (13.2%). There were no significant differences in the frequency of usage of these drugs between both treatment strategies.

DISSCUSSION

The baseline data for patients from Poland participating in the RecordAF study provides a unique snapshot of the characteristics and real-life management of patients with recently (i.e. < 1 year) diagnosed AF in Poland. The majority of the patients studied had at least one cardiovascular risk factor or co-morbidity, and were at moderate or high risk of stroke. The most prevalent accompanying medical condition in the studied patients was arterial hypertension, followed by dyslipidemia, heart failure, coronary artery disease, and valvular heart disease. The preferred treatment strategy was rhythm control. This strategy was mostly chosen in patients with a history of paroxysmal AF, those in sinus rhythm at inclusion as well as in patients with AF-related symptoms. The rate control strategy was more often chosen in patients with a history of persistent AF, patients presenting with a current episode of AF, as well as in those with a history of heart failure or valvular heart disease. The presence of certain co-morbidities seems to have some influence on the choice of treatment strategy, as rate control strategy was more frequently chosen in patients with valvular heart disease or heart failure, and rhythm control was more likely in patients with dyslipidemia.

The present analysis represents part of a global registry of 5,604 patients with recently diagnosed AF [14]. Although it was not the subject of the present analysis, comparison of patients from Poland to the total population included in the RecordAF registry suggests that patients from Poland do not differ from the global population in terms of age, presence of co-morbidities and cardiovascular risk factors. Therapeutic behaviours of physicians managing the patients show similar trends [14]. The unique feature of the present analysis is that, to the best of the authors' knowledge, this is the first real-life report on characteristics and management of patients with AF in Poland.

The characteristics of patients with AF has been described by national and local surveys and registries in general practices and hospitals both in Europe and North America, and the prevalence of co-morbidities and risk factors in the studied populations was found to be substantial [17–24]. Prospective data on the management of AF in Europe was provided by the Euro Heart Survey on 5,333 ambulatory and hospitalised AF patients in countries that were members of the European Society of Cardiology [25]. Despite the fact that 267 patients in the Euro Heart Survey were from Poland, a separate analysis of these patients has not been published. The Euro Heart Survey found that 90% of patients with AF had at least one associated medical condition. Similar to the present data, the most commonly associated condition was hypertension, found in about two thirds of studied patients. Other frequent risk factors included diabetes and severe obesity. Recently published data from the AFNET (The Registry of the German Competence NETwork on Atrial Fibrillation) registry [26] performed in 9,582 German patients with AF found that in most cases AF is associated with at least one co-morbidity or risk factor; the most frequent was hypertension, followed by hyperlipidemia, coronary artery disease, heart failure and valvular heart disease. This is in line with data from the RecordAF Polish population, although it should be noted that EuroHeartSurvey and AFNET registries both included patients with all forms of AF, while RecordAF included only patients with recently diagnosed paroxysmal or persistent AF, with a mean duration of AF of less than three months.

Atrial fibrillation has been reported in clinical studies to be idiopathic (or 'lone') in 15% of patients with persistent AF and even in 60% of patients with paroxysmal AF [27]. In contrast, in population-based studies the prevalence of idiopathic (or 'lone') AF was much lower, somewhere between 7% and 11%, and even as low as 2.7% in a population younger than 60 years. In the Polish subset of RecordAF, the overall prevalence of lone AF was 15%.

Stroke prevention remains one of the primary treatment goals in patients with AF. This arrhythmia is associated with a five-fold increase in the risk of stroke compared to a matched population in sinus rhythm. The RecordAF study used the guideline-recommended $CHADS_2$ score to assess patients' risk of stroke [13]. Most studied subjects had at least one major stroke risk factor. Generally, higher $CHADS_2$ scores were more frequent among patients assigned to the rate control group, while patients assigned to the rhythm control group more often had lower $CHADS_2$ scores. For the prevention of thromboembolism in low-risk patients, ASA should be used, while in those with more than one moderate risk factor for stroke ($CHADS_2$ score ≥ 2), a vitamin K antagonist is preferred. For

patients with intermediate risk ($CHADS_2$ score of 1) either ASA or a vitamin K antagonist may be used. In the RecordAF study, nearly half of all patients received ASA, and 52% received a vitamin K antagonist. Salicylic acid was used more frequently in patients assigned to rhythm control, while patients assigned to rate control were more likely to receive a vitamin K antagonist. This shift probably reflects a higher risk of stroke (and thus the need for more aggressive thromboprophylaxis) in patients in whom the rate control strategy was chosen. A similar trend was also observed in the global population of patients included into the RecordAF registry, as well as in two previous registries, the AFNET German registry and the Euro Heart Survey [14, 25, 26].

Rhythm control strategy was used in most patients enrolled into the RecordAF study in Poland. For this strategy, electrical or pharmacological cardioversion in the 12 months before inclusion was chosen and/or administration of class IA or class III anti-arrhythmic drugs at the time of the baseline visit. Current guidelines recommend that the decision to apply rhythm or rate control strategy should be guided by the symptomatic status of the patient [13]. Patients enrolled in this registry were only reported as being either symptomatic or asymptomatic, so the registry does not provide information on the particular type of AF-related symptoms. However, the impact of symptoms on treatment decision appears to be limited in this study, since 93% of the patients in the rhythm control group and 87% of patients in the rate control group were symptomatic at inclusion.

Nevertheless, being symptomatic within 12 months before inclusion made it more likely for a patient to be put on rhythm control strategy. Rhythm control was also more frequent in patients who were in sinus rhythm at inclusion. In contrast, absence of symptoms during the 12 months before inclusion and AF at the time of the baseline visit both favoured the rate control strategy. The rhythm control strategy was used more often in patients with paroxysmal AF, while the rate control strategy was used more often in patients with persistent AF. In the global population of patients with recently diagnosed AF, the rhythm control strategy was also more frequent than rate control, and was chosen in 55% of patients. Similarly to the Polish patients, the presence of symptoms and being in sinus rhythm were associated with greater use of rhythm control [14].

Beta-blockers were the most frequently used class of drugs in the studied patients. They were used by nearly all patients assigned to the rate control strategy and most of the patients assigned to rhythm control. Class IC anti-arrhythmic drugs were used exclusively in patients in the rhythm control group. Class III anti-arrhythmics were used mostly in patients assigned to the rhythm control group, though they were also administered to some patients assigned to the rate control group. Nevertheless, only a minority of patients assigned to rhythm control received a class I or class III anti-arrhythmic agent for the maintenance of sinus rhythm, though most underwent electrical or pharmacological cardioversion in the year prior to inclusion. This shows that physicians very cautiously use antiarrhythmic agents in patients with recently diagnosed AF. Usage of antiarrhythmic agents was also relatively small in the AFNET German registry [26].

Limitations of the study

There are several limitations of the present study. First, statistical calculations were prepared for the total population of the RecordAF study, and thus the analysis of the data on the Polish subset of patients is only secondary. Second, the studied sample does not reflect the total population of patients with AF in Poland, due to the exclusion of some important sub-populations, such as patients with permanent AF, that accounted for nearly one third of the AFNET and Euro Heart Survey populations and are known to be associated with higher cardiovascular risk [25, 26]. Moreover, a recently published one-year follow-up of data from the Euro Heart Survey registry revealed that patients with permanent AF have a worse prognosis than patients with paroxysmal or persistent AF [28]. RecordAF also excluded patients in whom catheter ablation was planned. Third, RecordAF included only patients with recently diagnosed (< one year, mean AF duration was 2.9 ± 3.5 months). As AF is a progressive disease, the risk profile of patients with a longer history of AF may be different.

CONCLUSIONS

The present analysis of the baseline data for the Polish subset of the ongoing RecordAF study represents the most up-to-date picture of demographics, medical conditions, risk factors and therapy of the Polish population of patients with recently diagnosed AF. After completion of the study, it will be possible to assess the rate of therapeutic success of AF management in terms of AF control (maintenance of sinus rhythm or satisfactory rate control), clinical outcomes in terms of major cardiovascular events as well as change of therapeutic strategy within 12 months after inclusion.

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Charakterystyka chorych ze świeżo rozpoznanym migotaniem przedsionków objętych obserwacją w ramach rejestru RecordAF w populacji polskiej

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Streszczenie

Wstęp: Rejestr RecordAF jest pierwszym międzynarodowym, obserwacyjnym i prospektywnym badaniem oceniającym kontrolę choroby u osób ze świeżo rozpoznanym migotaniem przedsionków (AF). W niniejszej pracy przedstawiono wyjściową charakterystykę pacjentów objętych badaniem w populacji polskiej.

Cel: Celem pracy była prospektywna ocena skuteczności stosowanego leczenia określana jako: (a) odsetek pacjentów z rytmem zatokowym; (b) odsetek pacjentów z prawidłową częstością rytmu komór; oraz (c) występowanie zdarzeń sercowo-naczyniowych.

Metody: Do badania włączano chorych w wieku powyżej 18 lat, ze świeżo rozpoznanym AF (czas trwania ≤ 12 miesięcy), kwalifikujących się do farmakologicznej strategii kontroli rytmu lub kontroli częstości rytmu komór. Pacjenci byli włączani przez lekarzy kardiologów w warunkach szpitalnych lub ambulatoryjnych. Planowany czas obserwacji wynosił 12 miesięcy.

Wyniki: Do badania włączono 303 chorych z 21 ośrodków w Polsce (śr. wiek 63 ± 12, mężczyźni stanowili 57,4%). W badanej grupie nadciśnienie tętnicze występowało u 71,5%, choroba niedokrwienna u 18,9%, a cukrzyca odpowiednio u 12,3% chorych. U 47 (15,6%) badanych nie udało się ustalić potencjalnej przyczyny AF. Objawy związane z obecnością AF zgłaszało 89,1% objętych obserwacją osób. Wywiad AF wynosił średnio 2,9 ± 3,5 miesięcy. W momencie włączenia u 191 (63,0%) chorych stwierdzano rytm zatokowy, 211 (69,6%) osób zakwalifikowano do strategii kontroli rytmu. Strategię kontroli rytmu serca stosowano częściej u osób z napadowym AF oraz tych, którzy w chwili włączenia do badania charakteryzowali się rytmem zatokowym. Strategię kontroli częstości rytmu komór wybierano częściej u pacjentów z przetrwałym AF w roku poprzedzającym badanie oraz u osób z AF w momencie włączenia.

Wnioski: Analiza wyjściowej charakterystyki pacjentów wskazuje na częste występowanie chorób współistniejących w badanej populacji pacjentów z AF w Polsce. Wybór strategii terapeutycznej wiązał się z rytmem stwierdzanym w momencie włączenia oraz postacią AF w czasie ostatnich 12 miesięcy. Badanie RecordAF pozwoli na prospektywną ocenę sposobu leczenia AF oraz porównanie skuteczności terapii w zależności od wybranej strategii terapeutycznej u chorych pozostających pod opieką klinik i przychodni specjalistycznych w Polsce.

Słowa kluczowe: migotanie przedsionków, strategia kontroli rytmu, strategia kontroli częstości rytmu, rejestr

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