One-year follow-up of the Polish subset of the RecordAF registry of patients with newly diagnosed atrial fibrillation

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ABSTRACT

INTRODUCTION Data on real-life management of atrial fibrillation (AF) in Poland is limited.

OBJECTIVES The aim of the study was to present data on 1-year follow-up of patients from Poland included in a worldwide registry of patients with AF (RecordAF).

PATIENTS AND METHODS A total of 303 patients with recent-onset AF were included in the study. Treatment strategy (rhythm control or heart rate control) was noted at baseline. Therapeutic success was assessed at 1 year (control of AF, no incidence of cardiovascular events, no switch between the strategies).

RESULTS Data from 289 patients were assessed. A rhythm control strategy was used in 70% of the patients. These patients received antithrombotic therapy less frequently than patients in whom rate control was implemented (90.4% vs. 97.6%, respectively, \( P < 0.05 \)), but they more often received class I (19.8% vs. 4.8%, respectively, \( P < 0.05 \)) and class III (20.8% vs. 4.8%, respectively, \( P < 0.05 \)) antiarrhythmic drugs. Therapeutic success was noted in 71.5% of the rhythm-control group vs. 29.1% of the rate-control group (\( P < 0.0001 \)), which was related to a better control of AF in the rhythm-control group compared with the other group (89.3% vs. 56.1%, respectively, \( P < 0.0001 \)). The rate of cardiovascular events was similar in both groups (20.6% of all patients). Progression to permanent AF occurred in 5.9% of the rhythm-control group compared with the 73.2% of the rate-control group (\( P < 0.001 \)).

CONCLUSIONS Almost all patients received antithrombotic treatment and the majority was assigned to rhythm-control therapy. Despite rare use of antiarrhythmic drugs, a rhythm-control strategy was associated with better control and slower progression of AF, but not with the lower rate of cardiovascular events in patients with recent-onset AF in Poland.
outcome of AF in the general population.‌⁷⁻⁹ AF management has also been described by national and local surveys and registries in general practices and hospitals.⁹⁻¹³ Owing to the variety of clinical presentations and treatment options for AF, there is a wide heterogeneity in real-life management of AF.

The RecordAF (Registry on Cardiac Rhythm Disorders Assessing the Control of Atrial Fibrillation) was a worldwide, 1-year observational registry of the management of AF in recently diagnosed patients. It was the first registry to investigate real-world treatment of AF based on a physician’s decision.¹⁵ This paper presents the results of 1-year follow-up of the Polish subpopulation in the RecordAF registry, which is the largest group of patients with AF so closely investigated and followed in Poland.

**PATIENTS AND METHODS** A detailed description of the methodology of the RecordAF registry,¹⁵ as well as the baseline characteristics of 303 patients enrolled into the registry in Poland¹⁵ have been published recently. Briefly, the study included 5604 patients and was conducted at 532 sites in 21 countries. The approval of an institutional review board was obtained at all sites. Recruitment started in May 2007 and was completed in April 2008. There were 21 study centers in Poland. Each center was randomly selected from a list of office- or hospital-based cardiologists in Poland. The list of all participating centers in Poland is provided in the Appendix.

The inclusion criteria were as follows: age ≥18 years, history of AF diagnosed ≤1 year prior to the study or AF discovered at the baseline visit, diagnosed by standard electrocardiography (ECG) or ECG Holter monitoring. Moreover, patients had to be eligible for a pharmacological treatment of AF and had to sign written informed consent. The 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.); a pacemaker or implantable cardioverter defibrillator; planned pulmonary vein ablation, AV node/His bundle ablation, or pacemaker implantation; and a history of cardiac surgery for AF within 3 months before enrollment. Patients with life expectancy less than 1 year due to a severe disease, pregnant or breastfeeding women, mentally disabled patients unable to understand or sign written informed consent, patients unable to present at the follow-up visit, and patients included in a clinical trial in the field of AF in the previous 3 months were also excluded. Data were collected at baseline (visit 0), 6 ±2 months (visit 1: optional), and 12 ±3 months (visit 2).

The primary outcome of the registry was the rate of therapeutic success after 1 year of follow-up defined for each patient as: being in sinus rhythm or at rate control target (±80 beats/min) at rest, with no incidence of major cardiovascular events and without crossover between rhythm- or rate-control treatment strategies. The major cardiovascular events included cardiovascular death, stroke, transient ischemic attack leading to hospitalization, myocardial infarction, hospitalization or prolongation of hospitalization for arrhythmic or proarrhythmic events or other cardiovascular events, or major complications of ablative procedure.

**Statistical analysis** Sample size calculations and description of statistical analysis for the total RecordAF population as well as for patients from Poland enrolled in the registry were described previously.¹⁵ In the present analysis, the χ² test or Fisher’s exact test for qualitative variables were used for comparisons between treatment strategies (rhythm control vs. rate control) and analysis of variance was applied for quantitative variables.

**RESULTS** Of 303 patients enrolled in the registry in Poland at baseline, 14 (4.6%) were lost to follow-up after 1 year, leaving 289 patients available for the final analysis. Patients’ baseline characteristics and therapy were described previously.¹⁶ A rhythm-control strategy was used in 70% of the patients. As compared with the rate-control group, patients from the rhythm-control group were younger (62 ±12 vs. 67 ±11 years, P < 0.001) and more often had paroxysmal AF (80% vs. 7.6%; P < 0.001). The rate-control strategy was more often selected in patients with valvular heart disease and heart failure. Lone AF was found in 15.6% of all patients.

**Follow-up data and atrial fibrillation status after 1 year** There were no patients with permanent AF at inclusion, but after 1 year of follow-up, progression to permanent AF occurred in 5.9% of the patients from the rhythm-control group as opposed to 73.2% of those from the rate-control group (P < 0.001). At the time of the follow-up visit, sinus rhythm was observed in 89.3% of the rhythm-control group and in 20.5% of the rate-control group (P < 0.001), while the corresponding percentages at baseline were 87.7% and 6.5%, respectively (P < 0.001). Ninety-one patients (32.5%) were symptomatic at the time of the follow-up visit, and 96.5% were asymptomatic at any time during the study, with no differences between the groups (Table 1).

**Rate- and rhythm-control therapy** A change of the initially selected treatment strategy was less frequent in the rhythm- compared with the rate-control group (12.1% vs. 28.9%, P < 0.001). During 1-year follow-up, pharmacological treatment was modified in 133 patients (47.2%) with no significant difference between the study groups. Electrical cardioversion was performed in 13 patients (6.6%) from the rhythm-control group and in 20 patients (23.8%) from the rate-control group (P < 0.001), while pharmacological
conversion was performed in a total of 26 patients (9.3%), without any difference between the groups (TABLE 2).

At the time of the follow-up visit, class I anti-arrhythmic drugs were used in 19.8% of the patients from the rhythm-control group and 4.8% of the patients from the rate-control group (P = 0.002): the corresponding percentages for class III drugs were 20.8% vs. 4.8%, respectively (P < 0.001). The use of these drugs was not substantially higher compared with the baseline values, when 19.4% and 17.6% of the patients from the rhythm-control group received class I and class III antiarrhythmic drugs, respectively. β-blockers were used in 76.1% of the patients in the rhythm- and in 88% of the patients in the rate-control groups (P = 0.025), and heart-rate lowering calcium-channel blockers were given to 3.6% of all patients. Cardiac glycosides were administered to 4.1% and 25.3% of the patients in the rhythm- and rate-control groups, respectively (P < 0.001) (FIGURE 1). Other cardiovascular drugs, including upstream therapy, were used with similar frequency compared with baseline and with no differences between the study groups: angiotensin-converting enzyme inhibitors or angiotensin II receptor antagonists were given to 226 patients (64.9%) and statins to 149 patients (53.2%).

Although patients with planned ablation were excluded from the registry, ablation was performed during the study in 6 patients (3%) initially assigned to the rhythm-control group. None of the patients underwent surgical therapy for AF during the study period. Pacemakers were implanted in 2 patients (1%) in the rhythm- and 5 patients (6%) in the rate-control group (P = 0.026).

**TABLE 1** Status of atrial fibrillation at 1 year

<table>
<thead>
<tr>
<th>Type of therapy</th>
<th>Rhythm control at baseline (n = 202)</th>
<th>Rate control at baseline (n = 87)</th>
<th>Total (n = 289)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sinus rhythm at the time of follow-up visit, n (%)</td>
<td>176 (89.3)</td>
<td>17 (20.5)</td>
<td>193 (68.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Types of AF, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paroxysmal</td>
<td>155 (76.9)</td>
<td>13 (30.7)</td>
<td>168 (62.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Persistent</td>
<td>19 (10.3)</td>
<td>9 (11.0)</td>
<td>28 (10.5)</td>
<td></td>
</tr>
<tr>
<td>Permanent</td>
<td>11 (5.9)</td>
<td>60 (73.2)</td>
<td>71 (26.6)</td>
<td></td>
</tr>
<tr>
<td>Symptoms at 12 months, n (%)</td>
<td>60 (30.5)</td>
<td>31 (37.3)</td>
<td>91 (32.5)</td>
<td>0.26</td>
</tr>
<tr>
<td>Symptoms at any time during the study, n (%)</td>
<td>194 (96.0)</td>
<td>81 (97.6)</td>
<td>275 (96.5)</td>
<td>0.80</td>
</tr>
</tbody>
</table>

**TABLE 2** Modification of therapy and other interventions during the study

<table>
<thead>
<tr>
<th>Type of therapy</th>
<th>Rhythm control at baseline (n = 202)</th>
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<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacological treatment, n (%)</td>
<td>86 (43.4)</td>
<td>47 (56.0)</td>
<td>133 (47.2)</td>
<td>0.054</td>
</tr>
<tr>
<td>Pharmacological conversion, n (%)</td>
<td>22 (11.2)</td>
<td>4 (4.8)</td>
<td>26 (9.3)</td>
<td>0.094</td>
</tr>
<tr>
<td>Electrical cardioversion, n (%)</td>
<td>13 (6.6)</td>
<td>20 (23.8)</td>
<td>33 (11.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Catheter ablation, n (%)</td>
<td>6 (3.0)</td>
<td>0 (0.0)</td>
<td>6 (2.1)</td>
<td>0.18</td>
</tr>
<tr>
<td>Pacemaker implantation, n (%)</td>
<td>2 (1.0)</td>
<td>5 (6.0)</td>
<td>7 (2.5)</td>
<td>0.026</td>
</tr>
</tbody>
</table>

**Abbreviations:** AF – atrial fibrillation

**Thromboembolic prevention** At the end of the follow-up period, 178 patients (90.4%) in the rhythm-control group and 81 in the rate-control group (97.6%) received some form of thromboembolic prevention (P = 0.036). Compared with patients assigned to the rate-control group, those assigned to the rhythm-control group more often received acetylsalicylic acid (46.2% vs. 24.1%), while vitamin K antagonists were more frequently used in the rate-control group (29.4% vs. 62.7%, P < 0.001) (TABLE 3). Of 140 patients who received vitamin K antagonists, data on international normalized ratio (INR) monitoring were available for 137 patients. In the last 6 months of the follow-up period, the mean number of INR measurements in each studied patient was 6.6. Nearly half of the monitored patients (46.4%) had INR values within the target range in over 80% of the measurements, and the remaining 22.7% of the patients had INR within the target range in 60% to 80% of the measurements.

There were some differences in the distribution of the CHADS2 scores in the studied patients. Higher CHADS2 scores were noted slightly more often in patients assigned to the rate-control group than in those assigned to the rhythm-control group, while a CHADS2 score of 0 was more frequent among patients from the rhythm-control group (TABLE 4).

The percentage of patients who received any form of antithrombotic therapy varied from 74.5% in patients with a CHADS2 score of 0 to 98% in those with a CHADS2 score of 2 or higher. Of 51 patients with a CHADS2 score of 0, 21 patients (41.1%) received antiplatelet agents, 10 (19.6%) received vitamin K antagonists, and 7 (13.7%) received both antiplatelet agents and vitamin K antagonists. For 126 patients with a CHADS2 score...
One-year follow-up of the Polish subset of the RecordAF registry revealed that the rhythm-control strategy was associated with a higher rate of therapeutic success compared with rate-control strategy. However, this needs to be interpreted with caution owing to the observational character of the registry and the marked differences in baseline characteristics between the studied groups, as discussed below. This therapeutic success was entirely driven by better AF control, while the rate of clinical events was similar in both study groups. This finding is consistent with the results obtained in the total population of the RecordAF registry.

In randomized studies comparing rhythm and rate control in AF, we and others did not show that rhythm control strategy is better than rate control in terms of patients’ outcomes. Nevertheles...
Classes I and III of antiarrhythmic drugs were also found to be used only in a minority of subjects in other registries and, similarly to our findings, the use of these drugs did not increase during follow-up. In our study, pharmacological and electrical conversions were also infrequent, in contrast to the results reported in the German MOVE registry. The rhythm-control strategy was associated with the higher rate of therapeutic success and better control of AF than the rate-control strategy and progression to permanent AF was significantly less frequent among patients from the rhythm-control group. In the total RecordAF population, history of heart failure, hypertension, and assignment to rate control were found to be independent predictors of AF progression. In our analysis, patients assigned to rate control were generally sicker compared with patients selected for rhythm control: they were older, had higher resting heart rate, and almost all had persistent AF. They also more often had concomitant heart failure and valvular heart disease. The results of the total RecordAF population showed that the risk of clinical events was similar in both treatment groups. The number of patients enrolled in the registry in Poland was clearly too small to draw any conclusions on the rate of clinical events, although we did document clinical events in 20% of our patients. Most of these events were cardiovascular hospitalizations.

Antithrombotic therapy was used in the majority of the study patients, but was slightly more frequent in the rate-control group and in patients with higher CHADS$_2$ scores. A substantial proportion of patients received only antiplatelet agents as antithrombotic prevention, which is not in line with the most recent European recommendations indicating that antiplatelet therapy for stroke prevention in AF should be limited to the few patients who refuse any form of oral anticoagulation. It should be noted, however, that patients were enrolled in the registry in the years 2007 and 2008, and, at that time, antiplatelet agents were considered acceptable means of thromboembolic prevention, and newer oral anticoagulants were not yet available on the market. Moreover, only about half of the patients with the CHADS$_2$ score of 2 and higher received vitamin K antagonists, indicating poor adherence to therapeutic guidelines. In the AFNET registry, oral anticoagulation was used in 55.6% of the patients with paroxysmal AF and in 74.4% of those with persistent AF, and similar findings were noted in the Euro Heart Survey. In the German MOVE registry, as many as 81.5% of the patients received drugs for thromboembolic prevention and, similarly to our results, only minor differences were reported in the use of these drugs when patients were categorized by CHADS$_2$ scores of 0, 1, and 2 or higher. Rewiuk et al. reported that in Polish outpatients with heart failure and concomitant AF, the use of anticoagulation was inversely associated with the CHADS$_2$ score, and oral anticoagulants were used in less than half of the studied patients. On the other hand, we found that the quality of anticoagulation therapy was good, both in terms of the frequency of INR monitoring and its effectiveness as indicated by the number of INR within the target range of 2 to 3.

There are a few important limitations of our analysis. First, this is a post-hoc analysis of the Polish subset of the total population of RecordAF registry. Second, the registry excluded important groups of patients, for example, those with a longer history of AF, as indicated by the CHADS$_2$ score. A substantial proportion of patients received only antiplatelet agents as antithrombotic prevention, which is not in line with the most recent European recommendations indicating that antiplatelet therapy for stroke prevention in AF should be limited to the few patients who refuse any form of oral anticoagulation. It should be noted, however, that patients were enrolled in the registry in the years 2007 and 2008, and, at that time, antiplatelet agents were considered acceptable means of thromboembolic prevention, and newer oral anticoagulants were not yet available on the market. Moreover, only about half of the patients with the CHADS$_2$ score of 2 and higher received vitamin K antagonists, indicating poor adherence to therapeutic guidelines. In the AFNET registry, oral anticoagulation was used in 55.6% of the patients with paroxysmal AF and in 74.4% of those with persistent AF, and similar findings were noted in the Euro Heart Survey. In the German MOVE registry, as many as 81.5% of the patients received drugs for thromboembolic prevention and, similarly to our results, only minor differences were reported in the use of these drugs when patients were categorized by CHADS$_2$ scores of 0, 1, and 2 or higher. Rewiuk et al. reported that in Polish outpatients with heart failure and concomitant AF, the use of anticoagulation was inversely associated with the CHADS$_2$ score, and oral anticoagulants were used in less than half of the studied patients. On the other hand, we found that the quality of anticoagulation therapy was good, both in terms of the frequency of INR monitoring and its effectiveness as indicated by the number of INR within the target range of 2 to 3.

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### Table 4: Number and percentage of patients with different CHADS$_2$ scores at 1 year

<table>
<thead>
<tr>
<th>CHADS$_2$</th>
<th>Rhythm control at baseline (n = 202)</th>
<th>Rate control at baseline (n = 87)</th>
<th>Total (n = 289)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHADS$_2$ = 0, n (%)</td>
<td>40 (20.5)</td>
<td>11 (12.9)</td>
<td>51 (18.2)</td>
<td></td>
</tr>
<tr>
<td>CHADS$_2$ = 1, n (%)</td>
<td>92 (47.2)</td>
<td>34 (40.0)</td>
<td>126 (45.0)</td>
<td>0.049</td>
</tr>
<tr>
<td>CHADS$_2$ ≥2, n (%)</td>
<td>63 (32.3)</td>
<td>40 (47.1)</td>
<td>103 (36.8)</td>
<td></td>
</tr>
</tbody>
</table>

![Figure 2](image.png)

**FIGURE 2**

Thromboembolic prevention according to CHADS$_2$

Abbreviations: VKA – vitamin K antagonist

- none
- antiplatelet
- VKA + antiplatelet
- VKA

- complex CHA$_2$DS$_2$-Vasc score to improve stroke risk assessment and facilitate the choice of antithrombotic therapy.
the CHADS₂ score of 2 and higher are already at a high risk of thromboembolic events and require proper anticoagulation. Fourth, the follow-up period of 1 year might have been too short to determine the long-term outcomes of the selected treatment strategy. In fact, a recent analysis of population-based administrative databases of patients with AF followed for a mean period of 3.1 years has indicated that rhythm-control strategy might be superior in the longer term.¹ We were also unable to calculate patients’ bleeding risk, for example, with the use of the currently recommended HAS-BLED score.⁶ This makes it hard to determine whether the relatively infrequent use of oral anticoagulants that we observed in patients with high CHADS₂ scores was related to concomitantly high bleeding risk in these patients. Nevertheless, as discussed in an excellent review published by Guo et al.²⁵ in this journal, only in rare patients with a relatively low risk of stroke and an extremely increased risk of bleeding may the withholding of oral anticoagulants be considered.²⁵ Finally, the comparison in outcomes between the strategies is affected by the differences in characteristics of the patients assigned either to rhythm- or rate-control strategy.

In conclusion, the results of 1-year follow-up of patients with newly-diagnosed AF in Poland indicate that, similarly to the worldwide RecordAF registry results, there were no differences in the rate of cardiovascular events between the rate- and rhythm-control strategies. A rhythm-control strategy was used in over two-thirds of the studied sample, yet antiarrhythmic drugs were administered only to a minority of the patients. Nevertheless, control of AF was better in patients assigned to a rhythm-control strategy, and progression to more sustained forms of AF was more frequent in patients assigned to rate control. The majority of the study patients received some form of thromboembolic prevention, but no correlation between the type of prophylaxis and patients’ stroke risk could be found. The most frequent clinical outcome was hospitalization but both the sample size and the number of cardiovascular events were too small to draw definite conclusions on the effects of therapy on cardiovascular outcomes.

Acknowledgements This study was financed by a scientific grant from Sanofi-Aventis.

REFERENCES

Abbreviations: TIA – transient ischemic attack, others – see Table 1
POLSKIE ARCHIWUM MEDYCYNY WEWNĘTRZNEJ


ARTYKUŁ ORYGINALNY

Wyniki rocznej obserwacji pacjentów z noworozpoznanym migotaniem przedsionków włączonych w Polsce do międzynarodowego rejestru RecordAF

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SŁOWA KLUCZOWE
kontrola częstotliwości rytmu serca, kontrola rytmu serca, leki antyarytmiczne, leki przeciwickrzepowe, migotanie przedsionków

STRESZCZENIE

WPRAWADZENIE Dane dotyczące leczenia migotania przedsionków (atrial fibrillation – AF) w Polsce są ograniczone.

CELE Celem badania było przedstawienie wyników rocznej obserwacji pacjentów z Polski włączonych do międzynarodowego rejestru pacjentów z AF (RecordAF).

PACJENCI I METODY Do badania włączono 303 pacjentów z noworozpoznanym AF. Wyjąćcowo notowano zastosowaną strategię leczenia (utrzymywanie rytmu zatokowego lub kontrola częstotliwości rytmu serca). Po roku obserwacji oceniono sukces terapeutyczny (kontrola AF, brak występowania zdarzeń sercowo-naczyniowych i brak zmiany strategii leczenia).

WYNIKI Ocenie poddano dane uzyskane od 289 pacjentów. U 70% pacjentów zastosowano strategię utrzymywania rytmu zatokowego. Pacjenci z tej grupy rzadziej otrzymywali leczenie przeciwickrzepowe w porównaniu z pacjentami, u których zastosowano strategię kontroli częstotliwości rytmu serca (90,4% vs 97,6%; p <0,05), ale częściej otrzymywali leki antyarytmiczne klasy I (19,8% vs 4,8%; p <0,05) oraz III (20,8% vs 4,8%; p <0,05). Sukces terapeutyczny uzyskano u 71,5% pacjentów z grupy utrzymywania rytmu zatokowego i u 29,1% pacjentów z grupy kontroli częstotliwości rytmu serca (p <0,0001), co było związane z lepszą kontrolą AF w grupie utrzymywania rytmu zatokowego w porównaniu z drugą grupą (odpowiednio: 89,3% i 56,1%; p <0,0001). Zdarzenia sercowo-naczyniowe występowały z podobną częstością w obu grupach (20,6% pacjentów). Progresja AF do postaci utrwalonej nastąpiła u 5,9% pacjentów z grupy utrzymywania rytmu zatokowego i u 73,2% pacjentów z grupy kontroli częstotliwości rytmu serca (p <0,001).

WNIOSKI Niemal wszyscy pacjenci otrzymali profilaktykę przeciwickrzepową, a u większości przyjęto strategię utrzymywania rytmu zatokowego. Mimo rzadkiego stosowania leków antyarytmicznych strategia utrzymywania rytmu zatokowego była związana z lepszą kontrolą i wolniejszą progresją AF, ale nie z niższą częstością występowania zdarzeń sercowo-naczyniowych u pacjentów z noworozpoznanym AF w Polsce.