

Demographic and clinical characteristics of patients with atrial fibrillation and cardioversion as planned therapeutic options in the International Registry on Cardioversion of Atrial Fibrillation RHYTHM-AF Polish substudy

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Abstract

Background: Cardioversion of atrial fibrillation (AF) and maintenance of sinus rhythm are the basic strategies of treating AF patients. Precise data regarding the current practice of AF cardioversion in Europe in clinical practice is lacking.

Aim: The primary objective of this prospective observational study was to characterise patients and treatment patterns in whom cardioversion was the planned therapeutic option.

Methods: Patients with recent onset of AF were included, regardless of when the timing of the cardioversion was planned. Ten countries participated in the study, with Poland contributing 501 patients. The global enrollment period lasted from May 2010 to June 2011. Follow-up data was collected 60 days after enrollment via a medical chart abstraction or a telephone interview.

Results: The average age of the Polish patient population was 64.2 years, and 38.5% of patients were female. Mean duration of arrhythmia was 3.3 years. Paroxysmal AF was diagnosed in 38.3% and persistent AF in 43.6% of patients. The most prevalent AF risk factors were hypertension (75.0%), diabetes mellitus (20.5%), and family history of AF (12.1%). Mean body mass index of study patients was 29.5 kg/m². The most pertinent factors triggering AF were emotion (12.4%), exercise (6.5%), electrolyte disturbances (5.5%), and acute myocardial infarction (3.7%). Only 14.2% of patients were asymptomatic. Previous episodes of AF were present in 83.1% of patients and 58.5% of them had previous cardioversion: 49.8% pharmacological and 50.2% electrical. The most often used anti-arrhythmic drugs were amiodarone (53.4%) and propafenone (32.2%). The rate of antithrombotic treatment was low: 59.6%. Finally electrical cardioversion had been undergone by 165 (53%) patients and pharmacological by 146 (47%) patients.

Conclusions: The population of patients with AF and planned cardioversion represented typical patients with non-valvular AF and standard symptoms, the vast majority of whom were symptomatic. The study group in terms of comprehensive characteristics is representative of the general population of AF patients.

Key words: atrial fibrillation, cardioversion, registry, Polish patients

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INTRODUCTION

Atrial fibrillation (AF) is the most common arrhythmia in clinical practice. According to analyses conducted by the National

Heart, Lung and Blood Institute, AF was present in 2.3% of the population aged 40–60 years and in 5.9% of patients above 65 years old [1, 2]. The mean prevalence of AF is 0.5%

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in patients 50–59 years old and 8.8% in those 80–89 years old. The incidence of arrhythmia episodes ranges from 0.2% per year in men 30–39 years old to 2.3% per year in men 80–89 years old. The estimated mean number of patients with AF in the European Union is 4.5 million and 2.2 million in United States, with a median age of about 75 years [1, 3–5]. In Poland, the estimated number of AF patients is about 400,000.

Patients with AF have increased risk for stroke and death. AF accounts for about one-third of hospitalisations for arrhythmia [6]. The most common risk factors of AF are arterial hypertension, congestive heart failure, coronary artery disease (CAD), rheumatic mitral valve disease and diabetes [5]. Non-cardiac aetiologies, often reversible, include electrolyte disturbances, hyperthyroidism, hypoxic pulmonary conditions, alcohol and drug intoxication. Cardioversion of AF with subsequent maintenance of sinus rhythm, control of heart rate and prevention of thromboembolism are the basic strategies of AF management.

Precise data regarding the current practice of cardioversion of AF in Europe as well as on the adherence to the new guidelines in clinical practice is lacking. In particular, little is known about the frequency of administration of either electrical or pharmacological cardioversion, the financial and health consequences related to their use, and the burden of managing their related negative consequences in different countries and regions.

The primary objectives of the RHYTHM-AF study were to document the characteristics of patients presenting with recent onset of AF planned to undergo cardioversion treatment with special respect to underlying heart diseases and comorbidities, to describe the prevalence of different kinds of AF, and to provide a detailed review of treatment patterns for the cardioversion. This paper presents characteristics of the Polish population.

METHODS

RHYTHM-AF was a prospective observational study whose design has been previously described [7]. Data was collected at the time of AF episode in all participating countries: Australia, Brazil, France, Germany, Italy, the Netherlands, Poland, Spain, Sweden and the United Kingdom, and cumulative follow-up data was collected on day 60 ± 10 in all but Spain. The follow-up encounter occurred either directly from the patients via abstraction of medical records or a telephone interview (when such records did not exist based on standard medical practice). Polish patients comprised approximately one eighth of the study's total patients and are the focus of the current analysis.

Precise inclusion criteria have been described elsewhere and included patients in a hospital setting (emergency room, cardiac care, intensive care, etc.), age ≥ 18 years, with documented AF at the time of enrollment confirmed by electrocardiogram, for whom a cardioversion of AF was one of the

planned therapeutic options. Patients with diagnosed AF (irrespective of the duration of the arrhythmia or the presence and severity of AF-related symptoms), persistent AF (episode either lasting longer than seven days or requiring termination by cardioversion) and long-standing persistent AF (has lasted for \geq one year when it is decided to adopt a rhythm control strategy) were included, according to definitions in the European Society of Cardiology (ESC) 2010 guidelines [4]. The possibility of an action had been taken and documented in anticipation of the cardioversion to take place. A decision was taken by the doctors-researchers. Actions included the cardioversion itself, scheduled cardioversion, and anticoagulation. Patients' informed consent had been obtained.

Exclusion criteria included prior enrollment in this study or in another clinical trial, atrial flutter and treatment with vernakalant. The global enrollment period lasted for six months, starting in May 2010 followed by 60 days of follow-up, and finished in June 2011.

All data was collected via a remote, web-based data collection form using the multilingual software solution EBogen®, developed by the IHF Ludwigshafen, Germany. The eCRF was adjusted to Polish-specific requirements due to local privacy laws, which prohibit certain questions and restrict the amount of identifying data that can be collected.

Statistical analysis

The sample size calculation was based on the objective to document the success rate of different cardioversion procedures. Assuming a success rate of 50–90%, a sample size of 500 would allow the survey to estimate the success rate in the Polish population with a given precision of $\pm 4.8\%$ (range of 95% CI: 9.6%). This size guaranteed enough information for estimating the success rate of different cardioversion procedures (representing one quarter of the total population or more) with a precision of $\pm 9.6\%$ (range of 95% CI: 19.2%). Depending on pre-specified subgroups (see objectives) the treatment patterns were analysed descriptively.

The continuous variables with a normal distribution (Shapiro-Wilks test) were expressed as the mean \pm standard deviation. Discrete variables are presented as percentages. The Statistical Analysis System SAS, release 9.2 (Cary, NC, USA) was used for the statistical computations and reports.

RESULTS

A total of 501 patients from Poland were enrolled in the study, although we present results on 493 patients (eight were excluded due to incomplete data) (Table 1). The average age of this population was 64.2 years. There were fewer women (38.5%) than men. The median duration of arrhythmia was 1,207.0 days, i.e. 3.3 years. The occurrence of paroxysmal and persistent AF was almost equal, 38.3% vs. 43.6%, respectively, among patients with a history of arrhythmia. Hypertension was the most common cardiovascular risk

Table 1. Demographic characteristics of patients who met all in-/exclusion criteria in RHYTHM-AF registry

Number of Polish patients	12.7% (501)
Age [years]	64.2 ± 12.1
Female	38.5% (193/501)
Body mass index [kg/m ²]	29.5 ± 7.9
Systolic blood pressure [mm Hg]	130.2 ± 19.7
Diastolic blood pressure [mm Hg]	81.2 ± 12.2
Primary reason for admission:	
Atrial fibrillation	80.4% (403/501)
Atrial flutter	0.8% (4/501)
Acute coronary syndrome	4.6% (23/501)
Heart failure	5.4% (27/501)
Stable coronary artery disease	3.0% (15/501)
Valvular heart disease	1.2% (6/501)

factor among patients (75.0%), followed by family history of premature CAD (22.0%), and diabetes mellitus (20.5%). Family history of AF was positive in 12.1% of patients. Stable CAD was present in 3% (n = 15) of patients. The average body mass index of study patients was high at 29.5 kg/m². AF was the primary reason for hospital admission in 80.4% of patients. Other acute disease states concomitant to AF were: heart failure (5.4%), acute coronary syndromes (4.6%) and CAD (3.0%) (Table 1). The most common specific factors triggering AF were emotion (12.4%), exercise (6.5%), electrolyte disturbances (5.5%), acute myocardial infarction (3.7%) and alcohol intake (2.7%) (Table 2). Only 14.2% of patients were asymptomatic. Among symptomatic patients, the most common symptoms were palpitations (63.7%), fatigue (39.8%), shortness of breath (31.2%), chest pain (16.6%) and dizziness (9.1%) (Table 2).

Previous episodes of AF were present in 83.1% of patients; 58.5% of them had had prior cardioversion, 49.8% pharmacological and 50.2% electrical. The most often used drugs for the treatment of AF were amiodarone (53.4%) and propafenone (32.2%). Overall, previous anti-arrhythmic therapy included beta-blockers (55.0%), propafenone (17.8%), and amiodarone (9.7%) (Tables 2, 3). Finally, cardioversion was undertaken by 311 patients (63%): 165 electrical (53%) and 146 (47%) pharmacological.

Despite the high CHADS₂ score, the rate of antithrombotic treatment was low (59.6%). Therapy with vitamin K antagonists was initiated in 81% of patients and with aspirin in 31.6% of patients. Transthoracic echocardiographic examinations were performed in 71.6% of patients and, in this group, 25.2% had a transoesophageal echocardiogram (TEE). Mean size of left atrium was 44 mm and 20% of patients had impaired left ventricular ejection fraction (< 45%). Moderate mitral regurgitation was present in 25.8% of patients (Table 4).

Table 2. Characteristics of different types of atrial fibrillation (AF), triggering factors and symptoms

AF clinical type	
AF-type: first detected episode	16.8% (83/493)
AF-type: paroxysmal	38.3% (189/493)
AF-type: persistent	43.6% (215/493)
AF-type: unknown	1.2% (6/493)
Special forms of AF	
No special form of AF	96.8% (477/493)
Post-operative AF	2.8% (14/493)
Wolff-Parkinson-White syndrome	0.4% (2/493)
Triggering factors for AF	
No triggering factor found	68.0% (274/403)
Emotion	12.4% (50/403)
Acute myocardial infarction	3.7% (15/403)
Alcohol intake	2.7% (11/403)
Other triggering factor	5.5% (22/403)
Electrolyte disturbance	5.5% (22/403)
Caffeine intake	1.0% (4/403)
Postprandial (after food intake)	1.2% (5/403)
Inhaling toxic gas/electrocution	0.2% (1/403)
Exercise	6.5% (26/403)
Current symptoms	
No symptoms of AF	14.2% (70/493)
Shortness of breath	31.2% (154/493)
Fatigue	39.8% (196/493)
Palpitations	63.7% (31/493)
Syncope	3.9% (19/493)
Chest pain	16.6% (82/493)
Dizziness	9.1% (45/493)
Other symptoms of AF	3.4% (17/493)
AF symptoms in the past	64.3% (296/460)

Heart failure symptoms were present in 19.5% of patients, most falling into New York Heart Association (NYHA) class II (56.3%) and class III (27.1%). Cardiomyopathy was diagnosed in 9.5% of patients, 51.1% dilated. Ischaemic origin was suspected in 34.0% (Table 5).

DISCUSSION

Patients admitted to hospital with a planned cardioversion strategy formed a specific, middle aged population (mean age 64.2 years, women: 38.5%). For the whole population of the Multinational Rhythm-AF Study (MNR-AF), n = 3,940, mean age was 66 ± 12, women: 37.6% [8]. The occurrence of paroxysmal and persistent AF in the Polish population was: 38.3% and 43.6%, and in MNR-AF, respectively: 29.4% and 31.2% (first detected: 32.1%). The distribution of the most

Table 3. Types of formerly performed cardioversions (CV) and previous antiarrhythmic treatment in patients who met all in-/exclusion criteria

Primary CV: pharmacological	49.8% (146/293*)
First PCV with amiodarone	53.4% (78/146)
First PCV with flecainide	0.7% (1/146)
First PCV with propafenone	32.2% (47/146)
Primary CV: electrical	50.2% (147/293)
Patients with any CV	58.5% (293/493)
First CV successful	81.9% (240/293)
Previous antiarrhythmic treatment	
Amiodarone	9.7% (48/493)
Propafenone	17.8% (88/493)
Beta-blocker	55.0% (271/493)
Digoxin	5.3% (26/493)
Verapamil	2% (10/493)
Diltiazem	1% (5/493)

*Total number of CV; PCV — pharmacological cardioversion

Table 4. Results of echocardiographic examinations

Diagnostic procedures: TTE (most recent < 1 year)	
TTE	71.6% (353/493)
Performed while patient in AF	60.9% (215/353)
Size of left atrium [mm]	44.0 (40.0–47.0)
LVEDD [mm]	51.0 (47.0–56.0)
LVEF: normal (> 55%)	53.4% (187/350)
LVEF: slightly impaired (45–55%)	26.6% (93/350)
LVEF: moderately impaired (30–44%)	14.3% (50/350)
LVEF: severely impaired (< 30%)	5.7% (20/350)
LVEF < 45%	20.0% (70/350)
Abnormalities in TTE	
No abnormalities in TTE	64.3% (227/353)
Mitral regurgitation (≥ grade 2)	25.8% (91/353)
Mitral stenosis (≥ grade 2)	1.7% (6/353)
Aortic regurgitation (≥ grade 2)	4.0% (14/353)
Aortic stenosis (≥ grade 2)	1.1% (4/353)
Other abnormalities in TTE	18.7% (66/353)
Diagnostic procedure: TEE	25.2% (124/493)
Yes, to evaluate atherothrombotic risk	22.3% (110/493)
Yes, other indication	2.8% (14/493)

TTE — transthoracic echocardiogram; TEE — transoesophageal echocardiogram; LVEDD — left ventricular end-diastolic diameter; LVEF — left ventricular ejection fraction

relevant cardiovascular risk factors in this Polish population, such as hypertension (75.0%, MNR-AF: 62.4%), diabetes mellitus (20.5%, MNR-AF: 17.3%), and family history of AF (12.1%), was comparable to that of other studies [8–10].

Table 5. Congestive heart failure (CHF) occurrence in studied atrial fibrillation patients

Symptoms of CHF	19.5% (96/493)
NYHA class I	8.3% (8/96)
NYHA class II	56.3% (54/96)
NYHA class III	27.1% (26/96)
NYHA class IV	8.3% (8/96)
Prior CHF	
NYHA class in the last 6 months	24.1% (119/493)
NYHA class I, last 6 months	15.1% (18/119)
NYHA class II, last 6 months	64.7% (77/119)
NYHA class III, last 6 months	18.5% (22/119)
NYHA class IV, last 6 months	1.7% (2/119)
Cardiomyopathy	9.5% (47/493)
Ischaemic cardiomyopathy	34.0% (16/47)
Dilated cardiomyopathy	51.1% (24/47)
Hypertrophic cardiomyopathy	4.3% (2/47)
Tachycardiomyopathy	8.5% (4/47)
Other type of cardiomyopathy	4.3% (2/47)

NYHA — New York Heart Association

CAD prevalence was lower in the Polish part of the MNR-AF population: 3% vs. 22.7% (MNR-AF) [8].

The prevalence of risk factors was similar to data from the observational French EPHA Study, which included 1,331 patients, 58.8% male. Comorbidities included hypertension (80.2%), diabetes (20.0%), and coronary disease (22.5%). But cardioversion was performed only in 12.1% of those patients [11]. In the prospective, observational SITAF study of 1,256 patients with AF, of comparable age (mean age 68 ± 12 , 53.5% men), cardioversion was proposed for 43.4% of patients [12]. In the present study, cardioversion was undertaken by 311 patients (63%, MNR-AF: 75%), 165 — electrical (53%, MNR-AF: 49%) and 146 — pharmacological (47%, MNR-AF: 26%) [8].

In the Registry of the German Competence Network on Atrial Fibrillation (AFNET; $n = 9,582$, mean age 67.0 ± 12.3 years, 59.9% male), the prevalence of risk factors such as hypertension, diabetes and coronary disease was similar to the current study as well: 68.9%, 20.5% and 26.8%, respectively. Only 20.6% of patients had a history of cardioversion [13]. In the present study a history of cardioversion had 58.5% (MNR-AF: 33.2%) [8]. In the Polish group of 303 patients with recently diagnosed AF enrolled in the Record AF Study (mean age: 62 ± 12 years, 57.3% male), risk factors of arrhythmia occurrence were similar to the current study. In this group, 76.6% of patients had a history of AF conversion to sinus rhythm: 53.6% pharmacological and 23.0% electrical [14]. These registries are of particular value because they provide actual data about risk factors. The clinical presentation of AF is changing due to evolving guidelines

of treatment and new drugs in hypertension, coronary disease and heart failure which can influence the occurrence and course of arrhythmia. The Euro Heart Survey on Atrial Fibrillation results (period: 2003–2004) is consistent with the data presented above for patients with paroxysmal ($n = 1,517$) and persistent AF ($n = 1,167$). However, there were more patients with CAD, heart failure and valvular heart disease but fewer with diabetes. Cardioversion was performed in 47% (14% electrical) with paroxysmal AF and in 54% (36% electrical) of patients with persistent AF [5]. In the present study, only 20% (MNR-AF: 19.7%) of patients had impaired left ventricular ejection fraction ($< 45\%$) and 25.8% had moderate mitral regurgitation (MNR-AF: 13.7%) [8].

During the past two decades, the prevalence of arterial hypertension and diabetes as AF risk factors has grown and the frequency of CAD, valvular heart disease and heart failure in AF patients has declined. Arterial hypertension was present in 75% of the current study patients, but it was relatively well controlled: mean systolic and diastolic blood pressure values were 130 mm Hg and 80 mm Hg, respectively, similar to the whole study population (MNR-AF: 131 mm Hg and 80 mm Hg) [8]. AF itself was the primary reason for admission among the vast majority (80.4%) of patients, which is consistent with the inclusion criteria of a planned cardioversion strategy. Previous episodes of AF were present in 83.1% of patients and 58.5% of them had prior cardioversion (MNR-AF: 33.2%). Other reasons for admission, concomitant to AF, relatively rare, included heart failure (5.4%) and acute coronary syndromes (4.6%). AF in these groups of patients worsens the prognosis and often requires urgent cardioversion depending on the patient's haemodynamic condition [15].

In patients with AF requiring cardioversion, triggering factors of arrhythmia are of particular interest. Quite often there was no specific cause of AF according to patients' histories. In this study, the most common circumstances triggering AF were emotion, exercise and electrolyte disturbances. Only about 15% of included patients were asymptomatic (MNR-AF: 15%) [8]. Among symptomatic patients, the most common symptoms were rather typical: palpitations, fatigue, shortness of breath, chest pain and dizziness. In the AFNET Registry, 17.4% of patients were asymptomatic [13].

Antithrombotic treatment is especially important. The mean value of CHADS₂ score in study patients was 1.5 and CHA₂DS₂-VASc was 2.7 (MNR-AF: CHA₂DS₂-VASc > 1 had 69.7% of patients) [8]. This shows the importance of introducing a new scale of thrombotic risk evaluation, because risk of stroke in this population was relevant and it implies the need for more effective anticoagulation treatment [16]. In spite of this, the rate of antithrombotic treatment was low (59.6%, MNR-AF: 64.7%) possibly due to the high proportion of patients with paroxysmal AF (38.3%) with relatively rare episodes of arrhythmia [8]. More than half of the study population was treated with renin–angiotensin system blockers

(MNR-AF: 55.1%) [8]. This is logical, due to the high prevalence of arterial hypertension, diabetes and coronary disease. Most patients had echocardiographic examinations performed, which is quite understandable in terms of further treatment — cardioversion and estimation of sinus rhythm maintenance probability, as well as possible complications (Polish population: 71.6%, TEE: 25.2%, MNR-AF: 75.7%, TEE: 24.1%) [8].

ESC guidelines perspective [4]

The greater prevalence of AF in men, population age and risk factors (hypertension, CAD, diabetes mellitus, heart failure, obesity, genetic predisposition) were similar to data from ESC guidelines. Type of cardioversion has been generally driven by symptoms (haemodynamic instability) or by individual assessment (atrial flutter, unsuccessful pharmacological cardioversion, intolerance of anti-arrhythmic drugs, physician's evaluation and experience, hospital standards, health service reimbursement etc.). Drugs used for cardioversion procedure were limited in the Polish population. Amiodarone and propafenone with beta-blocker support (about 50%) have been used. ESC guidelines additionally recommend flecainide, ibutilide and vernakalant, not available in Poland. Proper antithrombotic treatment is crucial in the cardioversion decision. But only 59.6% of study patients were properly treated. It was an important limitation for prompt decision-making about rhythm conversion. This was why the proportion of patients who had TEE was relatively high (25%).

Limitations of the study

The study population consisted of Polish patients included in the RHYTHM-AF study. Direct comparisons to data from the whole RHYTHM-AF population were not possible for objective reasons.

CONCLUSIONS

The Polish population of patients with AF who underwent cardioversion represents the most typical patients with non-valvular AF and standard symptoms, the vast majority of whom are aware of the disease. The study group in terms of comprehensive characteristics is representative of the general population of AF patients.

Conflict of interest: Piotr Ponikowski was a member of Steering Committee of the International Registry on Cardioversion of Atrial Fibrillation RHYTHM-AF.

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APPENDIX. RHYTHM-AF Study Polish centres according to number of included patients

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Demograficzna i kliniczna charakterystyka polskiej populacji pacjentów z migotaniem przedsionków oraz planowaną kardiowersją w międzynarodowym rejestrze migotania przedsionków RHYTHM-AF

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Streszczenie

Wstęp: Kardiowersja migotania przedsionków (AF) i utrzymanie rytmu zatokowego to podstawowe strategie w leczeniu pacjentów z AF. Brakuje dokładnych danych dotyczących bieżącej praktyki klinicznej w zakresie wykonywania kardiowersji AF w Europie.

Cel: Głównymi celami prospektywnego badania obserwacyjnego była charakterystyka pacjentów z AF i planowaną kardiowersją oraz zastosowanych sposobów terapii.

Metody: Chorzy ze świeżo wykrytym AF byli włączeni do badania, niezależnie od terminu planowanej kardiowersji. W badaniu wzięli udział pacjenci z 10 krajów, w tym z Polski (501 włączonych osób). Rekrutacja do badania trwała od maja 2010 do czerwca 2011 r. Dane po okresie 60 dni od włączenia do badania uzyskiwano na podstawie dokumentacji medycznej lub poprzez kontakt telefoniczny.

Wyniki: Średni wiek polskiej populacji pacjentów wynosił 64,2 roku, 38,5% grupy badanej stanowiły kobiety. Średni czas trwania arytmii to 3,3 roku. Napadowe AF stwierdzono u 38,3%, a przetrwałe u 41,2% pacjentów. Najczęstszymi czynnikami ryzyka AF były: nadciśnienie tętnicze (75,0%), cukrzyca (20,5%) i rodzinne występowanie AF (12,1%). Średni wskaźnik masy ciała pacjentów wynosił 29,5 kg/m². Najbardziej istotnymi czynnikami wyzwalającymi epizody AF były: emocje (12,4%), wysiłek (6,5%), zaburzenia elektrolitowe (5,5%) i ostry zawał serca (3,7%). Tylko 14,2% pacjentów było bezobjawowych. Epizody AF stwierdzano w przeszłości u 83,1% chorych, a 58,5% z nich miało wcześniej kardiowersję: 49,8% farmakologiczną i 50,2% elektryczną. Najczęściej stosowanymi lekami antyarytmicznymi były: amiodaron (53,4%) i propafenon (32,2%). Odsetek chorych leczonych przeciwwkrzepliwie był niski: 59,6%. Spośród grupy badanej kardiowersję elektryczną wykonano u 165, a farmakologiczną u 146 pacjentów.

Wnioski: Populacja osób z AF i planowaną kardiowersją to typowi pacjenci z idiopatyczną, niezastawkową formą AF. Migotanie przedsionków w większości badanej populacji miało charakter objawowy. Grupa badana w zakresie ocenianych parametrów była reprezentatywna dla ogólnej populacji pacjentów z AF.

Słowa kluczowe: migotanie przedsionków, kardiowersja, rejestr, pacjenci z Polski

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