ORIGINAL ARTICLE

Factors determining elective cardioversion preceded by transesophageal echocardiography: experiences of 2 cardiology centers

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KEY WORDS

atrial fibrillation, cardioversion, non–vitamin K antagonist oral anticoagulants, transesophageal echocardiography

EDITORIAL

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ABSTRACT

INTRODUCTION Although guidelines endorse cardioversion after adequate non–vitamin K antagonist oral anticoagulant (NOAC) treatment without prior transesophageal echocardiography (TEE), the majority of patients still undergo this examination.

OBJECTIVES The aim of this study was to assess factors determining the decision to perform TEE in patients with atrial fibrillation (AF) who are eligible for elective cardioversion.

PATIENTS AND METHODS In this study, we evaluated the medical records of consecutive patients with AF who were admitted for elective cardioversion after prior NOAC treatment.

RESULTS Of a total of 668 patients included in the study, 362 individuals (54%) underwent TEE before cardioversion. In the univariable analysis, paroxysmal AF, hypertension, coronary artery disease (CAD), thromboembolic events, a history of percutaneous coronary intervention, a history of bleeding, left ventricular ejection fraction, left ventricular end-diastolic diameter, a reduced dose of NOACs, hemoglobin levels, impaired renal filtration, and a high CHA_2DS_2-VASc score were significant predictors of the decision to perform TEE. In the multivariable logistic regression analysis, a history of CAD, bleeding, and stroke/transient ischemic attack/thromboembolism remained independent predictors of referring a patient for TEE (odds ratio [OR], 3.92, P <0.001; OR, 7.92, P <0.001; and OR, 2.36, P = 0.02, respectively). In contrast, paroxysmal AF (OR, 0.31; P = 0.02) and hypertension (OR, 0.28; P <0.001) were indicators of refraining from TEE.

CONCLUSIONS Transesophageal echocardiography before cardioversion was more frequently performed in patients with a history of CAD, bleeding, or thromboembolic events. Patients with paroxysmal AF and hypertension more often received cardioversion without prior TEE.

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INTRODUCTION Atrial fibrillation (AF) increases the risk of thromboembolic complications, contributing to thrombus formation especially in the left atrial appendage (LAA). Cardiogenic stroke accounts for approximately 15% to 20% of all cases of cerebral ischemia.[1] One of the main purposes of using oral anticoagulation is to reduce the risk of embolic complications when restoring the sinus rhythm by electrical/pharmacological cardioversion.

Data from clinical trials and the 2016 ESC guidelines for AF treatment indicate that cardioversion without transesophageal echocardiography (TEE) is safe, provided that patients take non–vitamin K antagonist oral anticoagulants (NOACs) for at least 3 weeks before cardioversion.[2-6] However, the practice of numerous cardiology centers shows that TEE examination before elective cardioversion is performed much more often than it is recommended. The aim of our study

WHAT'S NEW?

We aimed to identify clinical characteristics that prompt physicians to refer patients for transesophageal echocardiography (TEE) before elective cardioversion despite the fact that they earlier received adequate anticoagulant treatment. Transesophageal echocardiography was performed more frequently in patients diagnosed with coronary artery disease or with a history of bleeding or a thromboembolic event. Those with paroxysmal atrial fibrillation and hypertension more often received cardioversion without prior TEE. Factors that have been identified to predispose patients to left atrial appendage thrombus formation (such as heart failure with left ventricular ejection fraction below 50% and kidney disease) still influence clinical decisions regarding TEE before cardioversion, even in hypothetically effectively treated individuals.

was to identify factors determining the decision to perform TEE in patients with AF who are eligible for elective cardioversion.

PATIENTS AND METHODS **Study design and patients** It was an observational study based on the medical records of consecutive patients with AF who were admitted to 2 Polish cardiology departments (in the Military Institute of Medicine in Warsaw and in the Świętokrzyskie Cardiology Centre in Kielce) between January 2018 and April 2019 for elective cardioversion after having been previously treated with NOACs with confirmed good treatment compliance. Adequate anitcoagulation was defined as taking NOACs regularly as recommended. Every patient had to sign the document confirming adequate NOAC intake and, before signing it, they were informed about the side effects of omitting even a single dose of NOACs. Decisions regarding the performance of TEE examination before cardioversion were made on a case-by-case basis according to the rules adopted in each cardiology center. We chose 2 tertiary cardiology centers having the possibility to perform TEE in each patient with AF in order to analyze what factors influence withdrawal from this examination. In that way, we aimed to avoid a situation in which lack of access to TEE was the decisive factor for performing cardioversion without prior TEE.

The collected data included baseline demographic characteristics, results of clinical evaluation, laboratory tests, echocardiography, and the treatment strategy at the time of TEE performance. Data were obtained both directly from patients and from the medical databases of the 2 hospitals. Clinical evaluation was focused on age, sex, comorbidities, the type of AF, and the type of NOACs used. The CHA_2DS_2-VASc score was calculated for each patient in line with the current recommendations.[2] Paroxysmal AF was defined as AF lasting 2 to 7 days.[2] The study patients were divided into 2 groups based on the AF type: paroxysmal or nonparoxysmal, based on a careful and thorough analysis of all the available medical data, including current and previous medical records, electrocardiograms, and, in some patients, Holter monitoring (if available). Laboratory tests included the evaluation of renal function (estimated glomerular filtration rate [eGFR]) and red blood cell count (hemoglobin levels). The estimated glomerular filtration rate was calculated from the Modification of Diet in Renal Disease formula.[7] Impaired renal filtration was defined as an eGFR below 60 ml/min/1.73 m^2.[8] Exclusion criteria were as follows: valvular AF (significant mitral stenosis or a prosthetic valve), patients undergoing renal replacement therapy, an eGFR below 15 ml/min/1.73 m^2, and inadequate anticoagulation therapy.

Transthoracic echocardiography The analyzed echocardiographic examinations were performed in one of the 2 cardiology centers within 12 months of the patient's admission for cardioversion. The analysis included the left atrial anteroposterior diameter, the left ventricular end--diastolic diameter, and left ventricular ejection fraction (LVEF).

Transesophageal echocardiography Transesophageal echocardiography was usually performed a few hours before cardioversion (not more than 24 hours) in a grade C accredited (according to the Section of Echocardiography of the Polish Cardiac Society) echocardiography laboratory. General Electric Vivid E95 (Milwaukee, Wisconsin, United States) and Philips EPIQ 7 (Andover, Massachusetts, United States) ultrasound systems were used. During TEE, both atria and the LAA were scanned in detail with a continuous sweep of the probe from 0 to 180 degrees. Only patients without left atrial appendage thrombus (LAAT) received cardioversion.

Statistical analysis Statistical calculations were performed using the Statistica software, version 12 (Statsoft, Inc., Tulsa, Oklahoma, United States). The normality of continuous variable distribution was tested with the Shapiro–Wilk test. Since none of the parameters were normally distributed, continuous variables were presented as medians (interquartile ranges). Categorical variables were presented as percentages. The study groups were compared using the Mann–Whitney test for continuous variables and the χ^2 test with the Yates correction for categorical variables. Univariable logistic regression was performed using numerous variables, and, in the multivariable logistic regression analysis, only the parameters found to be significant in the univariable analysis at the level of $P = 0.05$ were included. If the factors were linked (eg, presence of coronary artery disease [CAD], previous myocardial infarction, previous percutaneous coronary intervention, and previous coronary artery bypass grafting), only the major parameter was included in the multivariable logistic regression analysis. Colinearity was checked for all quantitative parameters included in the multivariable logistic regression analysis. For all calculations, 2-tailed tests were used, and the level of significance was set at 0.05.

Ethics The study was conducted according to the Good Clinical Practice guidelines and the Declaration of Helsinki. The study protocol was approved by the local ethics committee. The ethics committee waived the requirement of obtaining informed consent from patients to participate in the study.

RESULTS A total of 668 patients (men, 64%) were included in the study, and 362 of them (54%) underwent TEE before cardioversion (the TEE[+] group). The remaining patients had cardioversion performed without prior TEE (the TEE[–] group).

Patients from the TEE (+) group, compared with the TEE (–) group, had a higher CHA_2DS_2-VASc score (P <0.001) and a higher prevalence of nonparoxysmal AF (P <0.001), impaired renal filtration (P <0.001), CAD (P <0.001), and a history of bleeding (P <0.001). The treatment of patients taking various types of NOACs in both TEE (+) and TEE (–) groups was similar except for those on apixaban. However, the TEE (+) group more often received reduced doses of NOACs (P = 0.045). Patients with a history of bleeding demonstrated similar rates of reduced NOAC doses compared with the rest of the study patients (7.8% vs 9.2%; P = 0.93), but they more often had impaired renal filtration (49% vs 28%; P = 0.003). Patients in the TEE (+) group, compared with the TEE (–) group, presented with a longer anteroposterior left atrial diameter (P = 0.03) and end-diastolic left ventricular diameter (P = 0.001). Left ventricular ejection fraction below 50% was also more frequent in the TEE (+) group (P = 0.03). Detailed characteristics are shown in **TABLE 1**.

In the univariable logistic regression analysis, numerous predictors of TEE performance before cardioversion were found (**TABLE 2**). However, in the multivariable logistic regression analysis, only a history of CAD, bleeding, and stroke / transient ischemic attack / thromboembolism remained independent predictors of referring a patient for TEE (odds ratio [OR], 3.92; 95% CI, 2.36–6.51; P <0.001; OR, 7.92; 95% CI, 2.76–22.69; P <0.001; and OR, 2.36; 95% CI, 1.12–4.97; P = 0.02, respectively) (**TABLE 3**). In contrast, paroxysmal AF and hypertension (OR, 0.31; 95% CI, 0.12–0.84; P = 0.02 and OR, 0.28; 95% CI, 0.15–0.54; P <0.001, respectively) were associated with TEE avoidance before cardioversion.

In the TEE (+) group, LAAT was observed in 26 patients (7.18%). None of the patients had a thromboembolic event within the first month of follow-up.

DISCUSSION In this observational study, we investigated premises for the clinical decision to perform TEE in AF patients treated with NOACs who were eligible for elective cardioversion in 2 cardiology centers. The current guidelines recommend physicians to perform TEE in patients in whom prior adequate anticoagulation treatment cannot be confirmed. Both the European and the American Society of Cardiology state that TEE is not necessary in most patients treated regularly with NOACs for least 3 weeks before cardioversion.[2,9] However, it seems that, in numerous cardiology centers, TEE is still performed more often than would appear necessary based on the recommendations. In our study group, 362 patients of those with AF (54%) underwent TEE before cardioversion despite receiving adequate anticoagulation.

One could intuitively assume that, if the CHA_2DS_2-VASc scale is the gold standard in assessing thromboembolic events, we should perform TEE in AF patients with a high CHA_2DS_2-VASc score regardless of prior anticoagulant treatment. However, some studies[10] found no significant correlations between the CHA_2DS_2-VASc score and the occurrence of LAAT and / or sludge. In a recent Polish study, Kosmalska et al[11] showed no correlation between CHA_2DS_2-VASc score and LAAT or sludge in patients with AF when those with a CHA_2DS_2-VASc score ≤1 were excluded from the analysis. In that study, the authors did not find any thrombus or sludge in AF patients with a CHA_2DS_2-VASc score ≤1. The authors recommended physicians to perform TEE before cardioversion in most patients with AF regardless of the fact whether they received adequate anticoagulation treatment or not. These findings were confirmed in another study that suggested that there is a clinically relevant risk of stroke even in patients with a low CHA_2DS_2-VASc score.[12] In that study, Chao et al[12] reported ischemic stroke in 1858 individuals out of 12 935 male patients with AF (14.4%) with a CHA_2DS_2-VASc score of 1 at follow-up (mean [SD] time, 5.2 [4.3] years).

In our study, we found a higher incidence of nonparoxysmal AF and impaired renal filtration in patients who underwent TEE before cardioversion. A greater frequency of LAAT in those with kidney disease and nonparoxysmal AF has been reported in several previous studies.[13,14] Kapłon-Cieślicka et al[13] proved that the new CHA_2DS_2-VASc-RAF score (where R stands for renal dysfunction and AF for nonparoxysmal AF) was more reliable than CHADS and CHA_2DS_2-VASc scales in predicting LAAT in patients with AF. Following the new scale provided by these authors, we also calculated the CHA_2DS_2-VASc-RAF score for our patients and it appeared that its value in those with prior TEE was higher compared with the TEE (–) group (7.66 vs 6.63). Moreover, the mean CHA_2DS_2-VASc-RAF score for patients with LAAT was clearly higher than the CHA_2DS_2-VASc score: 10.4 and 3.5, respectively. These findings justify considering patients' parameters in everyday practice to decide whether to perform TEE before cardioversion or not.

Another interesting issue is the use of reduced NOAC doses. Among patients in our study, those who underwent TEE more often received reduced doses of NOACs. Unfortunately, we did not have exact data available to show whether these lower doses were appropriate in light of guidelines or justified by other reasons. Our study group could

TABLE 1 Baseline characteristics of the study population

Variable	All patients (n = 668)	TEE (–) group (n = 306)	TEE (+) group (n = 362)	*P* value
Demographic data				
Age, y, median (IQR)	66 (60–72.5)	66 (59–73)	66 (60–72)	0.92
Female sex, n (%)	239 (36)	106 (35)	133 (37)	0.63
Type of AF, n (%)				
Paroxysmal AF	37 (5.5)	29 (9.5)	8 (2.2)	<0.001
Clinical characteristics				
Heart failure, n (%)	209 (31.4)	94 (30.7)	115 (31.9)	0.83
Hypertension, n (%)	558 (83.5)	269 (87.9)	289 (79.8)	0.08
Diabetes, n (%)	139 (20.8)	55 (18)	84 (23.2)	0.12
Stroke, n (%)	53 (7.9)	22 (7.2)	31 (8.6)	0.61
Stroke/TIA/thromboembolism, n (%)	86 (12.9)	39 (12.7)	47 (12.9)	0.93
CHA_2DS_2-VASc score, median (IQR)	2 (1–4)	2 (1–3)	3 (2–4)	<0.001
CHA_2DS_2-VASc-RAF score, median (IQR)	7 (6–9)	7 (5–8)	7 (6–9)	<0.001
Impaired renal filtration[a], n (%)	185 (29.8)	65 (24.3)	120 (34)	<0.001
Coronary artery disease, n (%)	255 (38.2)	72 (23.5)	183 (50.5)	<0.001
History of PCI, n (%)	66 (9.9)	39 (12.7)	27 (7.5)	0.03
CABG, n (%)	30 (4.5)	9 (2.9)	21 (5.8)	0.11
MI, n (%)	53 (7.9)	30 (9.8)	23 (6.4)	0.13
History of bleeding, n (%)	51 (7.6)	7 (2.3)	44 (12.2)	<0.001
Laboratory data, median (IQR)				
Hemoglobin, g/dl	14.4 (13.4–15.4)	14.6 (13.4–15.5)	14.3 (13.4–15.2)	0.03
Echocardiographic data[b]				
LVEF, %, median (IQR)	55 (50–60)	55 (50–60)	55 (50–60)	0.69
LVEF <50%, n (%)	262 (52.5)	197 (49.9)	65 (62.5)	0.03
Left atrial diameter, mm, median (IQR)	45 (42–49)	45 (42–48)	46 (43–49)	0.03
Left ventricular diameter, mm, median (IQR)	51 (47–55)	50 (47–54)	52 (48–55)	0.001
Oral anticoagulation, n (%)				
Dabigatran	316 (47.3)	135 (44.2)	181 (50)	<0.001
Rivaroxaban	313 (46.8)	138 (45.1)	175 (48.3)	
Apixaban	39 (5.8)	33 (10.8)	6 (1.7)	
Reduced dose of NOACs	61 (9.1)	20 (6.5)	41 (11.3)	0.045

a Estimated glomerular filtration rate <60 ml/min/1.73 m^2

b Data available in 499 patients: 395 in the TEE (–) group and 104 in the TEE (+) group

Abbreviations: AF, atrial fibrillation; CABG, coronary artery bypass grafting; IQR, interquartile range; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NOACs, non–vitamin K antagonist oral anticoagulants; PCI, percutaneous coronary intervention; TIA, transient ischemic attack

have included patients taking an inappropriately low dose of NOACs. Surprisingly, a history of bleeding did not influence the decision to prescribe a reduced dose of NOACs. Overall, approximately 9.1% of our study patients received a reduced dose of NOACs. In those with no history of bleeding, 9.2% took a reduced dose of NOACs compared with 7.8% in the group with a history of bleeding. The difference was nonsignificant ($P = 0.93$). A history of bleeding turned out to be the main determinant of TEE performance. In an additional analysis, we showed that patients with a history of bleeding more often had impaired renal filtration. Perhaps, in light of the aforementioned study,[13] this may explain the role of previous bleeding as an independent determinant of TEE performance before cardioversion. Despite this bias, taking low-dose NOACs increased the likelihood that TEE would be conducted prior to cardioversion. Is doctors' anxiety regarding the limited effectiveness of NOACs justified? Jelonek et al[15] showed that, although the standard doses of NOACs are prescribed to most patients, the frequency of administration of inadequately reduced NOAC doses is also high. Recent studies have shown that inappropriately reduced NOAC doses may increase the thromboembolic risk.[16-18] Cho et al[18] reported that, in particular, the use of a lower dose of apixaban showed a marked reduction in efficacy compared with warfarin. On the other hand, Wang et al[19] reported that the effect of reduced-dose NOACs (in patients eligible for reduced NOACs), compared with that of warfarin, on stroke or systemic embolism and on major bleeding was similar to the effect of full-dose NOACs compared with warfarin. Similarly, a large meta-analysis (including

TABLE 2 Factors determining elective cardioversion preceded by transesophageal echocardiography: results of the univariable logistic regression analysis

Parameter	Univariable logistic regression analysis	
	OR (95% CI)	*P* value
Paroxysmal AF	0.22 (0.09–0.48)	<0.001
Heart failure	1.06 (0.76–1.47)	0.73
Hypertension	0.54 (0.35–0.84)	0.005
Diabetes	1.38 (0.95–2.02)	0.09
Stroke	1.21 (0.68–2.14)	0.51
Stroke/TIA/thromboembolism	2.26 (1.34–3.81)	0.002
Coronary artery disease	3.32 (2.37–4.64)	<0.001
PCI	0.55 (0.33–0.92)	0.02
CABG	2.04 (0.92–4.53)	0.07
MI	0.62 (0.35–1.09)	0.1
History of bleeding	5.91 (2.62–13.32)	<0.001
LVEF, %	0.98 (0.97–1.01)	0.15
LVEF <50%	1.67 (1.07–2.61)	0.02
Left atrial diameter, mm	1.035 (0.99–1.07)	0.08
Left ventricular diameter, mm	1.04 (1.01–1.07)	0.02
Reduced dose of NOACs	1.83 (1.05–3.19)	0.04
Hemoglobin (per 0.1 g/l)	0.87 (0.78–0.97)	0.02
Female sex	1.09 (0.79–1.51)	0.58
Impaired renal filtration[a]	1.60 (1.12–2.28)	0.009
CHA_2DS_2-VASc	1.18 (1.07–1.3)	<0.001
Age (per 1 year)	1 (0.99–1.02)	0.81

a Estimated glomerular filtration rate <60 ml/min/1.73 m²

Abbreviations: OR, odds ratio; others, see **TABLE 1**

TABLE 3 Factors determining elective cardioversion preceded by transesophageal echocardiography: results of the multivariable logistic regression analysis

Parameter	Multivariable logistic regression analysis	
	OR (95% CI)	*P* value
Paroxysmal AF	0.31 (0.12–0.84)	0.02
Hypertension	0.28 (0.15–0.54)	<0.001
Stroke/TIA/thromboembolism	2.36 (1.12–4.97)	0.02
Coronary artery disease	3.92 (2.36–6.51)	<0.001
History of bleeding	7.92 (2.76–22.69)	<0.001
LVEF <50%	1 (0.53–1.9)	0.99
Reduced dose of NOACs	2.52 (0.91–6.92)	0.07
Impaired renal filtration[a]	1.19 (0.69–2.05)	0.51
Left ventricular diameter, mm	1.03 (0.99–1.08)	0.15
Hemoglobin, g/l	0.90 (0.76–1.07)	0.23

a Estimated glomerular filtration rate <60 ml/min/1.73 m²

Abbreviations: see **TABLES 1** and **2**

14 observational cohorts) comparing the efficacy and safety of reduced-dose NOACs versus warfarin in patients with AF revealed that the use of reduced NOACs was associated with a decreased risk of stroke or systemic embolism, ischemic stroke, and bleeding complications.[20]

As expected, the independent predictors of TEE performance before cardioversion included comorbidities such as stroke, transient ischemic attack, thromboembolism, CAD, and a history of bleeding. Most of these are components of the CHA_2DS_2-VASc scale; therefore, it is not surprising that they influenced doctors' decisions to perform an additional test to increase patient safety. In our study, LVEF below 50% also affected the decision to perform TEE before cardioversion, but it did not prove to be an independent factor in the multivariable regression analysis. Numerous authors have demonstrated a significantly higher incidence of LAAT or stroke in patients with reduced LVEF.[21-23] As shown in a large study (n = 1010), moderate-to-severe left ventricular systolic dysfunction is a strong predictor of stroke.[22]

The relationship between the diagnosis of CAD and the patient's eligibility for TEE remains unclear. Of note, the definition of CAD adopted in our study was uniform. Looking for an explanation of this finding, we arrived at a large study of over 20 000 patients.[24] The authors showed that severe diastolic left ventricular dysfunction was a high-risk feature for left atrial thrombus formation. In our study, we did not have echocardiographic data available that would allow us to accurately assess the degree of left ventricular diastolic dysfunction. However, more markedly impaired left ventricular diastolic dysfunction is usually suspected in patients with AF. If they are also diagnosed with CAD, it is an additional factor impairing left ventricular function. Perhaps, this observation may therefore explain our findings.

Quite an interesting observation derived from our study is that hypertension was one of 2 factors negatively related to TEE performance before cardioversion. Very likely, hypertensive patients, especially those with a low CHA_2DS_2-VASc score, were perceived as being at lower risk for thrombus formation and, thus, were not referred for TEE before cardioversion. This result is relevant given the fact that while, in the general population of patients with AF, rate and rhythm control strategies improve the functional status of patients in a similar manner, rhythm control may be more appropriate for those with AF and comorbid hypertension.[25]

The results of our study prove that the decision to perform TEE before cardioversion is still challenging. Patients with AF constitute a large and, at the same time, highly diverse group, which, due to many therapeutic dilemmas, requires the cooperation of doctors of various specialties.[26] In numerous cases, physicians present a more conservative approach than that endorsed by the current recommendations, which was also confirmed in a large survey conducted by the European Heart Rhythm Association.[27] Many clinical factors, including the components of the CHA_2DS_2-VASc scale, prompt doctors to perform echocardiographic verification, even when the patient declares good treatment compliance. These discrepancies prove that the individual assessment of patients and physicians' clinical experience are still the leading determinants of therapeutic decisions as far as patient safety is concerned.

Strengths and limitations Our study showed diagnostic and therapeutic decisions made in patients with AF in the real-life setting. It was a 2-center study including a well-characterized and quite homogenous group. The study was primarily limited by its partly retrospective design. This obviously limits the completeness of the available data. In this case, we had no information about the reason for administering a reduced NOAC dose nor did we have any data regarding the predefined criteria used by doctors to decide whether to conduct TEE or not. However, it is known that the decision was not determined by technical conditions, such as the inability to perform TEE. Admittedly, the choice of 2 tertiary cardiology centers can limit the generalizability of the study findings. However, a study performed in a center with no access to TEE would be of limited value.

Another limitation of our study was the fact that we had to analyze anteroposterior left atrial dimensions as the determinant of left atrial enlargement. We are aware that left atrial volume or the left atrial volume index would be a better parameter for assessing left atrial abnormalities.

Finally, the study sample size was small (especially the group of patients treated with apixaban), and our findings reflect diagnostic decisions made in only 2 Polish cardiology centers. Doctors in other centers may use their own clinical strategies.

Conclusions The results of our 2-center study showed that TEE before elective cardioversion was more frequent in patients with a history of CAD, bleeding, and thromboembolic events. Patients with paroxysmal AF and hypertension more often received cardioversion without prior TEE performance.

ARTICLE INFORMATION

CONTRIBUTION STATEMENT BU-Ż and IG conceived the concept of the study. BU-Ż, IG, and MK contributed to the study design. MK and BU-Ż analyzed the data statistically. BU-Ż, MK, and PK analyzed and interpreted the data. BU-Ż and MK wrote the manuscript. All authors made substantial contributions to the acquisition of data, the critical revision of the manuscript for important intellectual content, and the final approval of the submitted version.

CONFLICT OF INTEREST IG received honoraria for lectures from Bayer and Boehringer Ingelheim. BW-K received honoraria for lectures from Bayer, Boehringer Ingelheim, and Pfizer. Other authors declare no conflict of interest.

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