ORIGINAL ARTICLE

Results of a survey concerning atrial fibrillation ablation strategies in Poland

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KEY WORDS

atrial fibrillation, catheter ablation, cryoballoon ablation, Polish experience

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ABSTRACT

BACKGROUND Catheter ablation is an effective treatment for patients with atrial fibrillation (AF). Despite the increasing availability of the procedure, current treatment patterns of invasive AF treatment in Poland are unknown

AIMS The aim of the study was to assess data on the contemporary approaches to AF ablation in Poland, such as: target population, patients' characteristics, ablation techniques, procedural results, and complication rates.

METHODS The survey including 36 questions was conducted among 38 representatives of Polish electrophysiology centers performing AF catheter ablation to test the methods and outcomes in their laboratories.

RESULTS The survey was conducted among 38 out of 69 Polish electrophysiology centers performing AF ablation. There were 88 ablation laboratories in 2018 in Poland. They have performed 16 566 ablations, of which 6680 were AF ablations, according to the Polish National Health Fund data. Therefore, 3745 AF ablations analyzed in this study constituted 22.6% of all ablations and 56% of AF ablations performed in Poland in 2018. Paroxysmal AF was the most common type of AF in all surveyed centers. In 69% of the centers, the preferred method was cryoballoon ablation and in 31%, radiofrequency point-by-point circumferential pulmonary vein isolation. The reported complication rate was low (6.4%), with local adverse events being the most frequent. The mean reported incidence of atrial flutter or tachycardia after ablation was low (5%). Repeated procedures were performed mainly with radiofrequency ablation (89%). Procedural techniques and the type of venous access did not vary between the centers.

CONCLUSIONS Paroxysmal AF was the most common indication for percutaneous ablation of that arrhythmia in Polish electrophysiology laboratories. The preferred method was cryoballoon ablation.

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INTRODUCTION Atrial fibrillation (AF) is the most common arrhythmia in the world, and is associated with high risk of stroke, heart failure (HF), and hospitalizations. Pulmonary vein isolation (PVI) is an effective invasive method for treatment especially in patients with paroxysmal or persistent AF. This type of catheter ablation may decrease cardiovascular hospitalizations in patients with AF and coexistent HF. It is still not known whether single-shot devices or point-by-point PVI is the first-choice method in AF management. Various energy sources and

types of ablation have different learning curves and complication rates. Cryoballoon ablation (CBA) has proved to be as effective as point-by-point radiofrequency ablation.³ The relatively fast learning curve and high efficiency of CBA allowed the rapid dissemination of this method.

Numerous analyses concerning the treatment efficacy and the degree of complications have led to recommendations regarding the technique of the procedure. However, there are various strategies and preferences in the qualification for therapy, procedure optimization and treatment

WHAT'S NEW?

This is the first Polish survey presenting contemporary approaches to atrial fibrillation ablation in several Polish electrophysiology centers, including the following data derived from responses to a questionnaire: target population, patient characteristics, ablation techniques, procedural results, and declared complication rates. In almost 70% of the questioned centers, the preferred method for atrial ablation was balloon cryoablation, the complication rate was low, and high-volume centers performed more redo treatments, more often choosing radiofrequency ablation for pulmonary vein isolation. The reported procedure-related complication rate was low. Radiofrequency ablation was mostly chosen in redo procedures.

of complication across the member countries of the European Society of Cardiology.⁵ Nevertheless, catheter ablation was shown to be superior compared with antiarrhythmic drugs not only in maintaining sinus rhythm but also in improving quality of life.⁶

This analysis aimed to present current approaches to AF ablation in Polish electrophysiology laboratories including the AF subsets undergoing PVI ablation, preparation for the procedure, tools used as well as results and complications. The secondary aim was to present differences between high-volume centers performing over 100 AF ablations annually and low-volume ones with less than 100 AF ablations per year.

METHODS The survey was prepared by the authors of the analysis and sent via email to 50 Polish electrophysiology centers before a CBA meeting that took place in early 2019. The

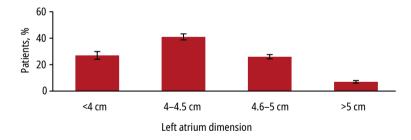


FIGURE 1 The distribution of patients undergoing atrial fibrillation ablation depending on the left atrium dimension. Whiskers indicate SD.

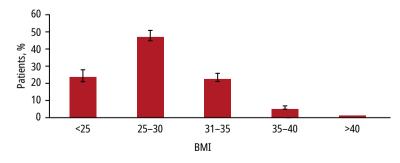


FIGURE 2 The distribution of patients undergoing atrial fibrillation ablation depending on the patient's body mass index (BMI). Whiskers indicate SD.

online survey was anonymous, voluntary, and applied to 2018. Medtronic had no access to the data and did not influence the analysis nor the text of the manuscript. Individual centers and cases could not be identified. There was 1 respondent allowed from each center (operator or electrophysiology trainee). We received completed surveys from 38 centers. The questionnaire covered the following topics: patient selection, preparation protocol of the procedure, tools used, course of the procedure, prevention of complications, and treatment after ablation. All questions were single-choice. No additional informed consent to participate in the study was required.

Large high-volume centers were defined as those performing over 100 AF ablations annually. Low-volume centers were defined as those performing less than 100 AF ablations per year.

The types of CBA were divided according to time to pulmonary vein isolation (TTI) plus additional (Bonus) freeze or arbitrarily assessed times of application (180 seconds, 240 seconds, 360 seconds, and 480 seconds).

Statistical analysis Basic descriptive statistical calculations were carried out using IBM SPSS Statistics for Windows, Version 24.0. (IBM Corp., Armonk, New York, United States) and TIBCO Satistica, version 13.1. Qualitative variables were presented as numbers and percentages. Continuous variables were presented as means with (SD) or medians with interquartile range (IQR). If the assumptions about the number expected for the χ^2 test were not met, the Fisher exact test was used to assess the *P* value. The t test or the Mann–Whitney test was used to compare 2 independent groups in terms of measured quantitative variables. The Kruskal-Wallis variance, and 1 way analysis of variance (ANO-VA) were used to compare 3 groups or more of quantitative variables. We presented the variables for which parametric tests were used, provided that their assumptions were met. For other variables, their nonparametric counterparts were used. Therefore, the skewness value was analyzed. If its absolute value did not exceed 2, it was assumed that the distribution was close to normal distribution. The Conover test was used to compare the post hoc application times. The Canover test was used in cases analyzed with the Kruskal-Wallis test. In case of the ANOVA, the post-hoc comparisons were made with the Tukey Honest Significant Difference test with correction for inequality of groups. A P value of less than 0.05 was considered significant.

RESULTS The survey was conducted among 38 out of 88 Polish electrophysiology centers; 69 of them performed AF ablations in 2018. A total of 16 566 ablation procedures were performed,

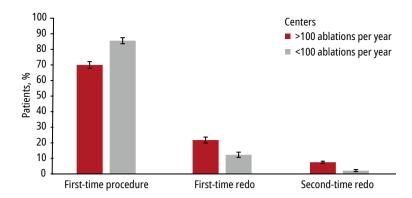


FIGURE 3 Percentage of first and redo ablation in high- (>100 ablations per year) and low-volume centers (<100 ablations per year). Whiskers indicate SD.

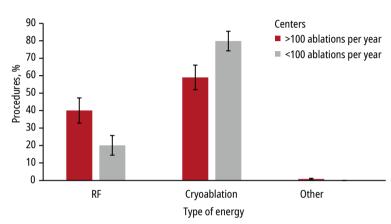


FIGURE 4 Type of energy used in atrial fibrillation ablation in high- (>100 ablations per year) and low-volume centers (<100 ablations per year). Whiskers indicate SD. Abbreviations: RF, radiofrequency

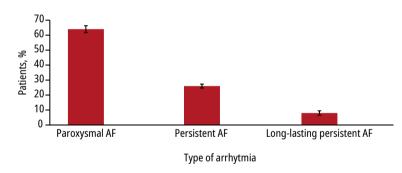


FIGURE 5 The type of arrhythmia in patients qualified for the invasive treatment of atrial fibrillation (AF) for the first time. Whiskers indicate SD.

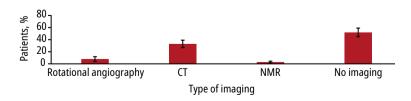


FIGURE 6 The use of left atrial imaging to assess atrium anatomy before atrial fibrillation ablation in the surveyed centers. Whiskers indicate SD.

Abbreviations: CT, computed tomography; NMR, nuclear magnetic resonance

of which 6680 were AF ablations, according to the Polish National Health Fund data. Therefore, 3745 AF ablations analyzed in this manuscript constituted 22.6% of all ablations and 56% of AF ablations performed in Poland in 2018. Twice as many ablations were performed in 2018 compared with 2016 (3512, 91 per 1 million inhabitants).⁵

The analysis of presented patient population, procedural techniques, and complication rates in the surveyed centers might have been speculative due to the nature of the source data. Data that were not a direct result of the survey were presented in the Supplementary material available online.

Symptomatic paroxysmal AF (64%) was the most frequent indication for the invasive procedure, whereas persistent and long-lasting persistent AF were less frequent (25% and 6%, respectively). In all patients, arrhythmia was refractory to at least one antiarrhythmic drug.

The qualification process included as follows: size of the left atrium (LA) (the most often reported LA size was 4-4.5 cm, FIGURE 1), body mass index (rarely greater than 35 kg/m², FIGURE 2), age (63% of the referred patients aged 60-70 years, rarely over 80 years). Over 70% of patients underwent the procedure for the first time (FIGURE 3). Crvoballoon ablation was the prevailing method of AF ablation and was performed in 69% of patients, followed by radiofrequency ablation in 31% (P = 0001; FIGURE 4). The CBA AF ablation procedure was performed in 74% of patients with paroxysmal arrhythmia. In 21% of ablated patients, arrhythmia was persistent (FIGURE 5). The vast majority of centers assessed the left atrial appendage (80%). Rotational angiography was rarely used for this purpose (8%). More often, the left atrial anatomy was assessed by computed tomography (33%). Almost half of the surveyed centers assessed the anatomy of the left atrium and pulmonary veins before the procedure (FIGURE 6). The maximal number of CBA procedures for 1 patient was 3 (P = 0.001). General characteristics of patients and procedures from the surveyed centers are presented in TABLE 1. The majority of electrophysiology laboratories, 84%, chose point-by-point radiofrequency for redo procedure after CBA (84%), 10% chose CBA after CBA, and 5% chose radiofrequency after radiofrequency.

The median hospitalization time was 3 days. In the majority of the centers (76%), the antiarrhythmic drugs were continued at least 12 weeks after ablation. If the ${\rm CHA_2DS_2}$ -VASc score was 1, the anticoagulation was prescribed for 1 to 3 months after ablation (50%). In patients with ${\rm CHA_2DS_2}$ -VASc score of 2 or higher, the decision to continue anticoagulation therapy was made individually based on the clinical presentation (53% of the centers). Anticoagulation was continued for over 12 months in 34% of the centers.

TABLE 1 Characteristics of the patients depending on the type of arrhythmia and techniques adopted in the center (continued on the next page)

| Question | | Median (IQF |
|---|--|--------------------|
| What is the percentage of the type of AF in patients qualified for the invasive treatment of AF for the first time? | Paroxysmal AF | 70 (11) |
| | Persistent AF | 25 (10) |
| | Long-lasting persistent AF | 10 (5) |
| What is the percentage of first ablation and redo procedures in your center? | First ablation procedure | 77 (12) |
| | First redo | 17 (9) |
| | Second redo | 5 (9) |
| What is the percentage of AF ablation depending on the type of energy applied? | RF | 25 (45) |
| | Cryoballoon | 72.5 (45) |
| | Other | 0 (0) |
| How often do you use left atrial imaging to assess its anatomy before AF ablation? % of the centers | Rotational angiography | 0 (0) |
| | СТ | 10 (76) |
| | NMR | 0 (1) |
| | No imaging | 72 (91) |
| | Patients with thrombus exclusion | 100 (12) |
| What is the strategy for anticoagulant therapy before | >4 weeks | 100 (6) |
| blation of AF in your center? | >2 weeks | 0 (0) |
| | >1 week | 0 (0) |
| | No anticoagulation in low CHA ₂ DS ₂ -VASc | 0 (0) |
| What is the number of diagnostic catheters used in | 1 catheter | 40 (100) |
| he standard transseptal puncture? | 2 catheters | 10 (100) |
| | No need for catheters | 0 (0) |
| What percentage of the following forms of AF were found in | Paroxysmal AF | 80 (21) |
| patients undergoing cryoablation? average value in 2018 | Persistent AF | 20 (15) |
| | Long-lasting persistent AF | 2 (10) |
| | Maximal no. of procedures for 1 patient | 3 (1) |
| What is the percentage distribution of patients undergoing | <25 | 17.5 (32) |
| F ablation depending on BMI? | 25–30 | 45 (20) |
| | 31–35 | 25 (21) |
| | 35–40 | 4 (10) |
| | >40 | 0 (0) |
| What is the percentage distribution of patients undergoing | <4 cm | 25 (22) |
| F ablation depending on the atrium dimensions? | 4–4.5 cm | 40 (20) |
| | 4.6–5 cm | 30 (13) |
| | >5 cm | 5 (7) |
| Routine transseptal puncture technique | Using contrast | 98 (27) |
| | With measurement of blood pressure | 0 (0) |
| | With transesophageal echo | 0 (0) |
| | With intracardiac echo | 0 (0) |
| | THE HELDER GIVE | |
| solation with a circular manning catheter. % of the centers | | 100 (0) |
| solation with a circular mapping catheter, % of the centers Where is the patient observed after the procedure? | Monitored bed / intensive care unit | 100 (0) 95 (90) |

TABLE 1 Characteristics of the patients depending on the type of arrhythmia and techniques adopted in the center (continued from the previous page)

| Question | | Median (IQR) |
|---|---|--------------|
| Complications associated with AF ablation, % per year | Local complications (hematoma, aneurysm, pseudo-aneurysm) | 3 (3) |
| | Temporary paralysis of the diaphragm | 1 (1) |
| | Permanent paralysis of the phrenic nerve | 0 (0) |
| | Atrial flutter or supraventricular tachycardia | 5 (5) |
| | Tamponade | 0.5 (1) |
| | Problems associated with the esophagus, lungs | 0 (0) |
| | Stroke or TIA | 0 (0.5) |

Abbreviations: AF, atrial fibrillation; BMI, body mass index; TIA, transient ischemic attack; others, see FIGURES 4, 5, and 6

 TABLE 2
 Comparison of patients and procedural characteristics in high- and low-volume centers

| Patient and procedural characteris | stics | High-volume (n = 20) | Low-volume (n = 18) | <i>P</i> valu |
|---|--|----------------------|---------------------|---------------|
| Type of AF in patients undergoing ablation for the first time, %, median (IQR) | Paroxysmal AF | 70 (10) | 70 (22.5) | 0.4 |
| | Persistent AF | 25 (10) | 27.5 (10) | 0.63 |
| | Long-lasting persistent | 10 (3.75) | 5 (12.5) | 0.13 |
| Percentage of ablations | First time, mean (SD) | 70 (10) | 86 (8) | <0.00 |
| | First redo, mean (SD) | 22 (9) | 12 (7) | <0.00 |
| | Second redo, median (IQR) | 5 (5) | 1 (5) | <0.00 |
| First time ablation energy, %, median (IQR) | RF | 35 (58.75) | 5 (41.25) | 0.02 |
| | Cryoballoon | 65 (58.75) | 95 (41.25) | 0.01 |
| | Other | 0 (0.75) | 0 (0) | 0.03 |
| Type of AF in patients undergoing cryoballoon ablation for the first time, %, median (IQR) | Paroxysmal AF | 80 (25) | 80 (19) | 0.39 |
| | Persistent AF | 19 (15) | 20 (15) | 0.44 |
| | Long-lasting persistent | 2 (10) | 2.5 (10) | 0.84 |
| BMI <25, %, median (IQR) | | 17.5 (24) | 15 (43.75) | 0.86 |
| The thrombus in the left atrial appendage not excluded before AF ablation, n (%) | Never | 16 (80) | 15 (83) | 0.7 |
| | Dependent on operator / clinical decision | 1 (5) | 2 (11) | |
| | Low CHA ₂ DS ₂ -VASc (≤1) or certainty about effective anticoagulation before ablation | 3 (15) | 1 (5.6) | |
| Routine venous access, n (%) | Both femoral veins | 2 (10) | 6 (33) | 0.12 |
| | One femoral vein | 17 (4) | 12 (67) | |
| | Femoral vein + subclavian / jugular vein | 1 (5) | 0 | |
| Method of vein puncture, n (%) | Linear ultrasonography | 4 (20) | 2 (11) | 0.66 |
| | Manual localization of the vein | 16 (80) | 16 (89) | |
| Anticoagulant therapy duration in patients with CHA ₂ DS ₂ -VASc 0–1, n (%) | 1–3 months after ablation | 12 (60) | 7 (39) | 0.2 |
| | 4–6 months after ablation | 6 (30) | 4 (22) | |
| | 6–12 months after ablation | 0 | 2 (11) | |
| | Depending on the clinical situation | 2 (10) | 5 (28) | |
| Anticoagulant therapy duration in | 1–3 months after ablation | 2 (10) | 1 (5.6) | 0.72 |
| patients with CHA_2DS_2 -VASc ≥ 2 , n (%) | 4–6 months after ablation | 2 (10) | 0 | |
| | 6–12 months after ablation | 0 | 1 (5.6) | |
| | >12 months after ablation | 6 (20) | 6 (33) | _ |
| | Depending on the clinical situation | 10 (50) | 10 (56) | _ |

Abbreviations: see TABLE 1

The most common schedule of follow-up visits was 3, 6, and 12 months after the procedure (in 37% of respondents). The primary criterion for the assessment of efficacy during follow-up visits was 24- or 48-hour Holter electrocardiogram in 74% of the centers. In the remaining ones, the evaluation was based only on the symptoms reported by the patient.

High-volume centers performed more first and second redo procedures than low-volume centers. In addition, high-volume centers more often performed point-by-point radiofrequency ablation than CBA.

Complication rate Local complications were the most frequently reported adverse events, and a difference between high- and low-volume centers was noted (3.5% vs 9.5%; P = 0.416). The prevalence of all remaining complications did not differ between the centers (Supplementary material, *Figure S1*).

To assess whether the routinely applied venous access is related to the percentage of local complications (hematoma, fistula, aneurysm, or pseudoaneurysm), the percentage of patients with complications was compared between the centers depending on the type of accessed vessels (both femoral veins, one femoral vein, femoral vein + cervical/subclavian vein; Supplementary material, *Table S1*). The type of anticoagulation monitoring during AF ablation did not influence the complication rate.

The rates of selected complications (temporal and persistent diaphragmatic nerve palsy, atrial flutter/supraventricular tachycardia, tamponade, esophageal/pulmonary/bronchial complications, stroke/transient ischemic attack) were compared between the centers depending on the strategy of CBA application (based on TTI as compared with applications of 180 seconds, 240 seconds, 360 seconds, or 480 seconds). The analysis of variance showed that more frequent and longer applications were connected with higher incidence of atrial flutter and atrial tachycardia after ablation (H = 8.01; P = 0.091). Two applications, 4 minutes each, were associated with higher incidence of atrial flutter/atrial tachycardia after the procedure in 1-year follow-up compared with other strategies (P = 0.003, for TTI, P = 0.007 for 240 seconds, P = 0.003 for 360 seconds; Supplementary material, Figure S2).

The differences were also significant for sustained diaphragmatic nerve palsy in the centers adopting the longest application times (2×240 seconds; P = 0.002). Only 1 center used the 1×3 minutes strategy (180 seconds), so it could not be compared with the others. Post hoc comparisons using the Conover test showed that the strategy of 480 seconds (PVI + Bonus) was associated with a higher rate of permanent diaphragmatic nerve palsy than the other strategies: TTI (P = 0.001), 240 seconds (P = 0.001), 360 seconds

(*P* = 0.003). The other strategies did not differ (Supplementary material, *Figure S3*).

Other complications of the ablation procedure occurred with a similar frequency regardless of the application strategy used. The results of the Kruskal–Wallis variance analysis for diaphragmatic nerve palsy, tamponade, pulmonary, esophageal, and stroke or transient ischemic attack complications were not significant.

DISCUSSION The main findings of our study are as follows: 1) Paroxysmal AF was the most common type of AF in the centers. 2) In the majority of the laboratories, the preferred PVI method was CBA. 3) The complication rate was low (6.4%). 4) The mean incidence of atrial flutter/tachycardia in the longest application times in CBA was connected with a 20% chance of macroreentrant tachycardias during follow-up. 5) Repeated procedures were performed mainly with radiofrequency ablation (89%).

Currently, the majority of patients undergoing AF ablation in Poland are patients with paroxysmal AF. In most of them, CBA is used as the first approach. The outcomes of the survey indicated that for repeat procedures, radiofrequency ablation is used more frequently than other methods. Ten percent of the laboratories perform CBA after CBA. The results of the latest research showed that second-generation cryoballoon is associated with less frequent pulmonary vein reconnection compared with radiofrequency ablation. 7-11 Cryoballoon is safe and effective for repeated AF ablation, regardless of the technique used for the initial procedure. 12

Despite its invasive nature, AF ablation is a safe procedure even in patients with HF.13 Local complications were the most frequently observed. The rates of severe complications such as tamponade (1%) and stroke (0.3%) were similar to the outcomes of a worldwide survey by Cappato et al¹⁴ among 181 centers, including 8745 patients who underwent ablation for AF between 1995 and 2002. The techniques used in that period, such as compartmentalization and triggering focus ablation, are not used any more. The second survey by Capatto et al, 15 which involved 45115 procedures from 262 centers performed between 2003 and 2006, showed 0.1% overall mortality rate with similar rate of tamponade (1.2%), being the most frequent procedure-related serious complication, and stroke (0.23%). Mortality was not related to the volume of procedure or type of catheter. 15

Our findings indicated a difference in the rate of phrenic nerve palsy and more frequent occurrence of local complications in small centers (10% vs 3%, P = 0.045). A Russian pilot study on CBA safety and efficacy profile in 62 centers showed that the major complication rate is

similar in low- and high-volume centers; however, minor events (8%) were more prevalent in large centers.¹⁶

The primary composite endpoint in the FIRE AND ICE study (arrhythmia recurrence, use of antiarrhythmic drugs, repeat ablation) occurred in 34.6% of patients in the cryoballoon cohort and 35.9% in the radiofrequency current ablation cohort confirming the equivalence of both methods. Similar results were obtained with respect to safety measure. The CBA proved to be the faster method. Simplicity and efficacy of CBA may explain its dominant role in AF ablation.

In a large multicenter retrospective analysis conducted by Aryana et al,18 AF ablation with the second-generation cryoballoon was associated with better durability of PVI compared with open-irrigated, non-force-sensing radiofrequency. Both techniques differ, however, in terms of the type of adverse events. The rate of phrenic nerve palsy in the cryoballoon group was higher than in the radiofrequency current group. On the other hand, local complications were more often observed in the radiofrequency current group.¹⁸ Unfortunately, this issue was not covered in our survey. The reported overall local complication rate in our survey was 6%. Incidence of atrial flutter and atrial tachycardia after ablation with all procedural methods in the analyzed survey was about 5%, which may be underrated. In the FIRE AND ICE study, the prevalence of atrial flutter and atrial tachycardia in the radiofrequency current group was higher than in the CBA group and reached more than 2%.19 We analyzed the influence of various CBA application times on macroreentry formation and showed that shortening of applications and TTI verification decreased the risk of atrial flutter and other atrial arrhythmias after the procedure. The CBA procedures with longer application times presented higher rate of atrial flutter and atrial arrhythmias (up to 20% vs less than 5%). Although the centers that performed CBA initially used the 2 × 4 minutes protocol, now, after technological corrections and improvement of the efficiency of balloons, single applications (1 × 240 seconds) and a TTI-based protocol are used more often. This protocol, called DOSING, was described by Aryana et al²⁰ as an effective tool. It allowed not only a reduction in the risk of diaphragmatic nerve palsy, which was also the case in our analysis, but also the rate of relapses. The protocol using TTI allowed to obtain better efficacy and safety compared with a conventional method based on an arbitrarily set number of applications as well as their length.¹⁹

It was also shown that the longer the time for vein isolation, the greater the risk of arrhythmia recurrences. In the ICE-T study, a single application protocol was applied if the time-to-isolation indicator was achieved. The mean number of cryoapplications in the group controlled by

TTI was 5.¹⁹ There were no differences between the groups in terms of effectiveness as well as safety outcomes.²⁰

In our survey, 95% of responders declared the use of a mapping diagnostic catheter. The endpoint of the procedure was proven electric isolation of the veins. ^{21,22}

The interventional methods became established tools for AF treatment, yet we still lack confirmed clinical endpoints, except in patients with HF. The main energy source is radiofrequency; however, the cryoballoon technique has been found to be safe and efficient.²³

Limitations The surveys were sent to 50 Polish electrophysiology centers; however, not all centers have filled out and sent them back. All of the received data were subjective. Due to a declarative form of reporting, the quality of achieved data might have differed between the centers and might distort real data. Moreover, the study does not cover numerical efficacy and safety data, which is a major limitation. Therefore, the analyses might have been inaccurate. On account of the fact that some of the answers were averaged, the data should be interpreted with caution. The answers of the attendees were declarations. More reliable data come from registries.

Conclusions The most common type of treated AF in all Polish centers was paroxysmal AF. In almost 70% of centers, the preferred method was CBA. The complication profile was low. High-volume centers performed more redo treatments and chose radiofrequency ablation more frequently.

SUPPLEMENTARY MATERIAL

Supplementary material is available at www.mp.pl/kardiologiapolska.

ARTICLE INFORMATION

CONFLICT OF INTEREST None declared.

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