The value of the ablation index in patients undergoing ablation for atrial fibrillation

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ABSTRACT

INTRODUCTION Pulmonary vein isolation (PVI) is the cornerstone of contemporary ablation procedures in patients with atrial fibrillation (AF). However, even when contact force (CF) catheters are used, the rates of late pulmonary vein reconnection and AF recurrence remain significant.

The ablation index (AI) is a formula incorporating power, CF, and catheter stability, allowing the formation of more efficient and durable ablation lesions. By combining AI with maximal interlesion distance, the CLOSE protocol was shown to be efficient in PVI. The aim of our study was to compare the efficacy of AI-guided PVI with that of conventional CF-based PVI on an unselected Polish population.

METHODS Patients This study was a single-center nonrandomized retrospective analysis. Consecutive patients undergoing their first PVI due to AF between January 2015 and April 2019 were included in the analysis. Patients with AF included those with paroxysmal and nonparoxysmal AF, but because of a small number of patients with nonparoxysmal AF, the group was analyzed jointly. All patients qualified for PVI according to current guidelines (symptomatic, drug-refractory AF). Ablations were performed with manual or VisiTag annotation of the ablation points without distance criteria. Since mid-2017, ablations with AI and the modified CLOSE protocol have been

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ABSTRACT

BACKGROUND Data on the results of ablation for atrial fibrillation (AF) in Poland are scarce.

AIMS The aim of the study was to compare the efficacy of ablation index (AI)-guided pulmonary vein isolation (PVI) with that of conventional contact force–based PVI.

METHODS Consecutive patients undergoing PVI for the first time were included in the study. A nonrandomized retrospective comparison was made between patients ablated with contact force before AI was introduced (non-AI group) and patients ablated with the use of AI (AI group). The AI threshold for the anterior wall / roof of left veins was 500 and 380 elsewhere. The maximal interlesion distance was 6 mm. The follow-up included outpatient visits and 7-day Holter monitoring 6 and 12 months after ablation.

RESULTS A total of 275 patients were included in the analysis: 133 in the AI group and 142 in the non-AI group. The duration of AF ablation was slightly longer in the AI group, but the fluoroscopy time and the radiofrequency ablation time were shorter in the same group. During the 12-month follow-up period, 25.8% and 40.6% of patients from the AI and non-AI groups, respectively, experienced recurrences ($P = 0.02$). The log-rank test with an extended follow-up period of up to 18 months confirmed the difference between the AI and non-AI groups, both in the whole group and in the paroxysmal AF and nonparoxysmal AF subgroups ($P = 0.001$, $P = 0.04$, and $P = 0.006$, respectively).

CONCLUSIONS The AI-based protocol provides a significant advantage over traditional contact force–based radiofrequency ablation in nonselected patients undergoing PVI.

KEY WORDS atrial fibrillation, ablation, ablation index, pulmonary vein isolation

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WHAT’S NEW?

Data on the results of atrial fibrillation (AF) ablation in Poland are scarce. A cohort of consecutive nonselected Polish patients undergoing pulmonary vein isolation (PVI) due to AF was analyzed. We compared the results of PVI in patients undergoing standard contact force-based radiofrequency ablation and in patients undergoing ablation index–based radiofrequency ablation. In the group of patients undergoing AI-based PVI, the procedure was slightly longer, but the fluoroscopy time and the radiofrequency ablation time were shorter. Furthermore, in the same group, a significantly lower rate of recurrence was observed in both paroxysmal and nonparoxysmal AF.

started. As the present study was a retrospective analysis of previously obtained data and the patients were treated routinely with the best current practice, the institutional ethics committee approval and patients’ written informed consent were not required.

Ablation strategy Both groups The left atrium was accessed through a double transseptal puncture. A circumferential mapping catheter and an irrigated CF catheter were used for mapping and radiofrequency ablation. Navigation of the catheters was based on fluoroscopy and on the electroanatomical CARTO 3 system (Biosense Webster, Irwindale, California, United States). The ipsilateral veins were isolated jointly. The isolation of all pulmonary veins was the endpoint of the procedure. Whenever possible, this process was verified during sinus rhythm. Ablations beyond PVI were performed only when the patient developed atrial tachycardia or atrial flutter during the procedure. After the isolation of all veins, there was a waiting period of 15 to 20 minutes and the veins were rechecked.

The non-AI group (control group) The dragging technique was used in most patients, and the power limit was 25 W at the posterior wall and 30 W elsewhere. A manual or automated lesion annotation (VistiTag, available on CARTO system) without an interlesion distance limit was used. The minimal CF was 5 g, and the minimal ablation time at one spot was 20 seconds on the posterior wall and 30 seconds elsewhere.

The AI group The point-by-point technique was used, and the AI settings were as follows: the catheter stability range of motion was 3 mm, the catheter stability time was more than 3 seconds, and the CF was more than 3 g over 25% of the time. The power limit was 35 to 40 W, and the AI threshold for the anterior wall and the roof in left pulmonary veins was 500 and 380 elsewhere. The maximal interlesion distance was 6 mm. Examples of ablation lines are shown in FIGURE 1.

Follow-up A 3-month blanking period was applied. Recurrence was defined as any atrial tachycardia lasting more than 30 seconds. All

FIGURE 1 Examples of maps from patients undergoing standard contact force–based ablation (the non–ablation index [AI] group, A and B) and patients undergoing AI-based ablation (the AI group, C and D). Force-time integral is color-coded: red, AI >500; pink, AI 380–500.
patients were recommended to discontinue antiarrhythmic drugs (AADs) immediately after catheter ablation. The patients were scheduled for 2 follow-up visits after 6 and 12 months and yearly thereafter. All asymptomatic patients underwent 7-day Holter monitoring.

### Statistical analysis

The normality of variable distribution was tested using the Shapiro–Wilk test. Descriptive characteristics were reported as median (interquartile range [IQR], first to third quartiles) or mean (SD) for continuous variables (depending on the normality of variable distribution). Categorial variables were presented as frequencies. The t test was used to compare continuous variables with normal distribution, and the Mann–Whitney test was used otherwise. For categorial variables, group comparisons were made using the $\chi^2$ test or the Fisher exact test. Kaplan–Meier curves and log-rank tests were utilized for event-free survival analysis. For all calculations, 2-tailed tests were applied, and the level of significance was set at a $P$ value of 0.05. All calculations were performed with Statistica 12 (StatSoft Inc., Tulsa, Oklahoma, United States).

### RESULTS

A total of 275 patients were included in the analysis. Of these patients, 133 underwent ablation with AI, whereas 142 underwent AF ablation before the launch of AI and served as controls. In each group, 13 patients were lost to follow-up. The groups were comparable in terms of clinical data. The baseline characteristics of the groups are shown in TABLE 1.

The duration of AF ablation in patients from the AI group was slightly longer, but their fluoroscopy time and radiofrequency ablation time were shorter. In the re-evaluation of pulmonary veins after 15 to 20 minutes, 55 patients (38.7%) required additional ablations in the non-AI group, and 28 (21.1%) in the AI group ($P = 0.002$ for comparison between the non-AI and AI groups).

During the 12-month follow-up period, only 25.8% of the patients had AF recurrences in the AI group compared with 40.6% of the patients in the non-AI group. This difference was significant ($P = 0.02$). The difference was seen in both paroxysmal and nonparoxysmal AF, although the results did not reach statistical significance (see TABLE 2). The patients were recommended to withdraw from using all AADs, but 9 patients in the non-AI group and 11 in the AI group continued to use AADs without recurrences.

The Kaplan–Meier curves with an extended follow-up period of up to 18 months are shown in FIGURE 2. There was a difference between the AI and non-AI groups both in the whole group and in the paroxysmal AF and nonparoxysmal AF subgroups ($P = 0.001$, $P = 0.036$, and $P = 0.006$, respectively).

| TABLE 1 | Baseline clinical characteristics |
|---------|----------------------------------|
| **Variable** | **Non-AI group (n = 142)** | **AI group (n = 133)** | **P value** |
| **Patient characteristics** | | | |
| Age, y, mean (SD) | 60 (10) | 60 (10) | 0.86 |
| Male sex, n (%) | 82 (58) | 81 (61) | 0.68 |
| BMI, kg/m², mean (SD) | 29.8 (4.4) | 29.9 (4) | 0.86 |
| Paroxysmal AF, n (%) | 94 (66) | 88 (66) | 0.9 |
| Time from AF diagnosis to PVI, y, median (IQR) | 2 (1–5) | 2 (1–5) | 0.44 |
| Hypertension, n (%) | 108 (76) | 94 (71) | 0.38 |
| Coronary artery disease, n (%) | 18 (13) | 30 (23) | 0.046 |
| Heart failure, n (%) | 13 (9) | 13 (10) | 0.97 |
| Diabetes, n (%) | 30 (20) | 30 (23) | 0.78 |
| Left atrial diameter, cm, median (IQR) | 4.15 (3.9–4.5) | 4.10 (3.9–4.5) | 0.54 |
| LVEF, %, median (IQR) | 60 (55–65) | 60 (55–65) | 0.36 |
| **PVI procedure parameters** | | | |
| Procedure time, min, median (IQR) | 125 (110–140) | 130 (120–150) | 0.007 |
| Fluoroscopy time, s, median (IQR) | 489 (309–625) | 347 (272–423) | <0.001 |
| Radiofrequency ablation time, s, median (IQR) | 2108 (1743–2556) | 1836 (1647–2113) | <0.001 |
| PVI only radiofrequency ablation time, s, median (IQR) | 2024 (1728–2529) | 1804 (1626–2001) | <0.001 |

Abbreviations: AF, atrial fibrillation; AI, Ablation Index; BMI, body mass index; IQR, interquartile range; LVEF, left ventricular ejection fraction; PVI, pulmonary vein isolation
There were 4 groin complications in the non-AI group (2.8%) and 6 in the AI group (4.5%). In the non-AI group, there was one cardiac tamponade observed and one death due to stroke 1 month after the procedure was performed. In the AI group, there were no tamponades, but there was one transient phrenic nerve palsy, one death due to stroke 2 months after the procedure was performed, and one sudden cardiac death (unrelated to the procedure, 5 months after PVI). In the non-AI group, there was one cardiac tamponade observed and one death due to stroke 1 month after the procedure was performed. In the AI group, there were no tamponades, but there was one transient phrenic nerve palsy, one death due to stroke 2 months after the procedure was performed, and one sudden cardiac death (unrelated to the procedure, 5 months after PVI).

In the non-AI group, 24 patients underwent a redo procedure, and 3 patients had their pulmonary veins isolated. In the AI group, 11 patients underwent a redo procedure, and 5 patients had their pulmonary veins isolated.

### DISCUSSION

We showed that in nonselected patients undergoing PVI due to AF, the AI-based protocol leads to a reduced recurrence rate in the whole group and in the paroxysmal and nonparoxysmal subgroups. We also showed that PVI is slightly longer with the use of AI, but it requires a shorter fluoroscopy time and radiofrequency ablation time.

Increasing operator experience enabled basing PVI on a 3-dimensional system, which resulted in a shorter fluoroscopy time. The shorter radiofrequency application time is primarily due to higher power settings; with good contact (10–20 g) on the posterior wall, the radiofrequency application can be as short as 10 seconds. It is unclear why the whole procedure took longer. It was probably a matter of time spent on reaching the proper position of the catheter and the acceptable CF. There are some regions where achieving catheter stability and an acceptable CF is a real challenge.

The protocol settings in our laboratory were based on the CLOSE protocol, with slightly reduced thresholds (500 for the anterior and 380 for the posterior wall). We modified the CLOSE protocol according to the observation that no reconnection of pulmonary veins was observed when the minimum AI value was 370 or higher for the posterior/inferior segments and 480 or higher for the anterior/roof segments.

The results observed in our center—although better than those before AI and the modified CLOSE protocol—are not as good as the first published results of the CLOSE protocol (94% efficacy in a 1-year follow-up in paroxysmal AF). Still, the results of Philips et al are not easily replicated in other electrophysiology laboratories. The group from London and Oxford showed that the 1-year freedom from atrial tachyarrhythmia after a single procedure was 78%. Berte et al reported 6-month efficacy of 82% to 83% in CLOSE protocol-ablated patients. Several reasons can account for these differences. Characteristics of the patient population are one of the most potent factors influencing the results. It is unlikely that our modified CLOSE protocol (500 AI threshold on anterior walls) negatively influenced the results, as almost no reconnections were observed on the anterior wall during the redo procedures. Another issue may be experience with the algorithm. Finally, all our procedures were performed in conscious sedation, which might influence the stability of the ablation catheter and the quality of the lesions.

We used power settings that are higher than average (35–40 W, regardless of the part of the atrium) based on previous observations of the safety of such an approach (pilot AF trial by T. Betts et al, unpublished data). Current analyses support this approach; it seems that ablation on the posterior wall with 40 W is safe, and ablation with this power setting is associated with a shorter procedure, fluoroscopy, and radiofrequency time.

In our opinion, the power limit is not a major factor influencing the efficacy of PVI. With higher-power radiofrequency ablation, the time to reach the AI threshold is shorter, and the lesion is slightly wider, but the depth remains comparable (available data for comparisons of 20 and 40 W). We believe that the crucial factor is an interlesion distance below 6 mm and, consequently, the obtained AI threshold.

AI and the CLOSE protocol are helpful in increasing the efficacy of AF ablation, but they are not a remedy for all issues connected with PVI. There are still numerous points to address, such as how wide the ablation lines should be placed, especially at the posterior wall, how to ablate the right veins to achieve durable isolation, and how to maintain catheter stability in the regions where stability is usually poor.
Strengths and limitations of the study  Our protocol was introduced in all patients, and the patient groups were well described. All procedures were performed by a skilled operator who performs more than 100 AF ablations per year. On the other hand, this study involved a single-center nonrandomized comparison and retrospective analysis of data, which can weaken the conclusions. The follow-up with two 7-day Holter monitoring sessions within the first year after ablation is also a limitation of the study. We understand that the results do not seem to be novel, but paradoxically, comparisons of the AI groups with historical data are not redundant.

Conclusion  In nonselected patients, an AF AI-based protocol gives a significant advantage over previous methods of lesion annotation. The number of recurrences is significantly reduced, which is particularly visible in nonparoxysmal AF.

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