https://doi.org/10.35336/VA-1362

SHORT- AND LONG-TERM RESULTS OF CATHETER ABLATION FOR ATRIAL FIBRILLATION UNDER THE GUIDANCE OF THE "ABLATION INDEX" MODULE

S.N.Azizov[1], R.D.Khuziakhmetov[1], V.A.Belov[1], A.T.Kozhenov[2], V.V.Lyashenko[3]

[1]FSBI "Federal Center of Cardiovascular Surgery named after S.G.Sukhanov" of the MH RF, Russia, Perm, 35 Marshall Zhukov str.; [2]Municipal Clinical Hospital No.15 named O.M.Filatov Department of Health of Moscow, Russia, Moscow, 23 Veshnyakovskaya str.; [3]High Medical Technologies Center, Russia, Kaliningrad, 4 Kaliningradskoe r.

Aim. Comparative evaluation of short-term and long-term outcomes of radiofrequency pulmonary vein isolation using the "Ablation Index" module versus without in patients with paroxysmal and persistent forms of atrial fibrillation.

Methods. The study included 286 patients with paroxysmal and persistent forms of atrial fibrillation, divided into 2 groups: the study group (110 patients) underwent radiofrequency pulmonary vein isolation using the "Ablation Index" module, while the control group (176 patients) underwent isolation without the use of the "Ablation Index" module.

Results. The average follow-up period was 38.1±9.6 months. There was no significant difference in freedom from atrial tachyarrhythmias in the long-term follow-up between the study and control groups (58.1% vs. 62.3%, p=0.667), or in the number of perioperative complications (3.6% vs. 8.5%, p=0.106). A significant reduction in the duration of the procedure was observed when using the "Ablation Index" module (92.7±20.9 min vs. 126.4±29.2 min, p<0.001), as well as in the recurrence rate of atrial fibrillation in the blanking period (1.8% vs. 8.5%, p=0.020).

Conclusion. Interventional treatment of atrial fibrillation under the control of the "Ablation Index" module shows significantly lower recurrence rates of atrial tachyarrhythmias in the blanking period and comparable safety and long-term efficacy results compared to interventional treatment using catheters with contact force sensor over a period of more than three years.

Key words: atrial fibrillation; radiofrequency ablation; pulmonary vein; ablation index; recurrence; long-term outcomes

Conflict of Interest: none.
Funding: none.
Received: 03.05.2023 **Revision received:** 19.12.2024 **Accepted:** 13.01.2025
Corresponding author: Khuziakhmetov Rustam, E-mail: rustam-huziahmetov@yandex.ru

S.N.Azizov - ORCID ID 0009-0006-1678-9175, R.D.Khuziakhmetov - ORCID ID 0009-0001-2835-9571, V.A.Belov - ORCID ID 0000-0002-0945-8208, A.T.Kozhenov - ORCID ID 0009-0005-1750-1586, V.V.Lyashenko - ORCID ID 0000-0002-8501-4801

For citation: Azizov SN, Khuziakhmetov RD, Belov VA, Kozhenov AT, Lyashenko VV. Short- and long-term results of catheter ablation for atrial fibrillation under the guidance of the "Ablation Index" module. *Journal of Arrhythmology.* 2025;32(1): 17-23. https://doi.org/10.35336/VA-1362.

Radiofrequency ablation (RFA) has become an increasingly popular treatment for atrial fibrillation (AF) over the past decade. The primary electrophysiological endpoint of ablation is achieving electrical isolation of the pulmonary veins (PVs) [1]. AF is associated with atrial dysfunction, leading to structural and electrical remodeling, which may contribute to the development of heart failure [2]. Ensuring durable PV isolation requires standardization of each radiofrequency application around the PV. Ideally, this should result in transmural myocardial damage while avoiding necrosis extending to extracardiac structures.

In recent years, hardware and software modules predicting ablation lesion depth have been integrated into three-dimensional (3D) electrophysiological navigation systems from various manufacturers. These modules help standardize radiofrequency applications in the atrium. One such module is the Ablation Index (AI; Biosense Webster, USA). AI is a dimensionless parameter calculated based on a combined analysis of three key factors: contact force (CF) of the catheter, ablation time, and power [3].

Experimental studies in canine models have demonstrated that AI reliably predicts lesion depth at catheter application sites on the endocardial surface [4, 5]. Thus, with 3D navigation system guidance, the extent of tissue injury at ablation sites can be assessed in real-time, ensuring that each application is adequate but not excessive [6], thereby potentially reducing the risk of procedure-related complications [7, 8].

METHODS

Study Protocol

This study was conducted at the Federal Center of Cardiovascular Surgery named after S.G. Sukhanov, Ministry of Health of the Russian Federation. The study included 286 patients scheduled for catheter ablation of AF who

were divided into two groups: study group (110 patients) uderwent pulmonary vein isolation (PVI) using the SmartTouch catheter (Biosense Webster, USA), which enables real-time assessment of contact force between the catheter and myocardial tissue. The procedure was performed using the VisiTag module (Biosense Webster, USA), which allows the navigation system to automatically identify application points based on pre-set contact force and catheter stability parameters, in combination with the Ablation Index (AI) module. Control group (176 patients) underwent PVI using the SmartTouch catheter with only the VisiTag module, without the Ablation Index module.

Patients were enrolled in the study between 2018 and 2021. Group allocation was determined by the availability of disposable materials required for AI module usage at the time of catheter intervention.

The primary endpoint was freedom from atrial tachyarrhythmias (AF, atrial flutter, or atrial tachycardia) in both the short-term period (first 3 months, also known as the "blanking period") and the long-term follow-up period (up to 38 months) after ablation.

The secondary endpoints included: total procedure duration, incidence of intraoperative and postoperative complications, recurrence rate during the blanking period, rate of repeat catheter interventions due to recurrent atrial tachyarrhythmias.

The primary endpoint was assessed based on the absence of symptomatic or asymptomatic atrial tachyarrhythmias lasting more than 30 seconds. Arrhythmias occurring during the blanking period were not considered when evaluating the long-term effectiveness of ablation. Recurrence detection was conducted using 24-hour ECG monitoring, implantable device data (pacemakers, ICDs), and medical record analysis.

The secondary endpoints were evaluated based on medical records (procedure duration, rate of repeat interventions), patient-reported symptoms and clinical condition, and instrumental and laboratory investigations (assessment of intraoperative and postoperative complications).

All patient data were anonymized and processed in a secure database without personal identifiers. Patients provided informed consent for study participation and for the AF ablation procedure, in accordance with current clinical guidelines.

Patient selection

The study included symptomatic patients aged from 18 to 83 years with paroxysmal or persistent AF and ineffective drug therapy (Class I or III agents). AF episodes were documented in all patients on resting electrocardiogram (ECG) or during Holter ECG monitoring.

The exclusion criteria were as follows: Previous catheter ablation for AF; unstable angina or acute myocardial infarction within the past 3 months; need for valve or coronary pathology correction; contraindications to oral anticoagulant therapy; severe chronic renal or hepatic failure.

The clinical characteristics of the patients are presented in Table 1.

Preoperative investigations

Before the procedure, all patients underwent a clinical examination, including a detailed collection of

Table 1.

Clinical characteristics of patients by groups

Characteristics	Control group (n=176)	Study group (n=110)	P
Average age, years	59.4±8.6	64.4±7.4	<0.001
Gender (male/female), %	56.3/43.8	48.2/51.8	0.183
Body mass index (BMI), kg/m^2	30.6±4.1	30.9±4.9	0.701
PAF/PeAF, %	59.7/40.3	76.4/23.6	0.004
Disease duration, months	49.9±41.9	58.3±46.1	0.105
AIS, %*	10.8	5.5	0.120
Coronary artery disease, %	32.4	35.5	0.593
Myocardial infarction, %*	6.3	7.3	0.735
Diabetes mellitus, %	11.9	8.2	0.314
Hypertensive heart disease, %	85.2	93.6	0.030
Pacemaker implantation, %*	5.7	11.8	0.063
Myocardial revascularization, %*	11.9	11.8	0.977
LVEDV, ml	97.3±23.0	96.8 ± 25.9	0.874
LVEF, %	55.5±6.7	55.2±6.1	0.674
LA volume (TTE), ml	73.2±18.6	73.9±24.5	0.643
LAVI (TTE), ml/m^2	37.2±9.2	38.0±11.2	0.984
Interventricular septum, mm	13.4±2.1	13.2±3.3	0.070
Mitral regurgitation grade 0, %	26.9	33	0.159
Mitral regurgitation grade I, %	62.3	50.5	
Mitral regurgitation grade II, %	10.3	16.5	
Mitral regurgitation grade III, %	0.6	0	
Systolic PA pressure, mmHg	35.6±5.9	37.9±7.3	0.158
Mean PA pressure, mmHg	20.1±6.5	20.8±8.2	0.684
LA volume (MSCT-CTA), ml	121.8±31.4	112.9±28.5	0.024
LAVI (MSCT-CTA), ml/m^2	60.7±14.9	57.8±15.1	0.201

Note: * - in medical history; PAF and PeAF - Paroxysmal Atrial Fibrillation and Persistent Atrial Fibrillation; AIS - Acute Ischemic Stroke; LVEDV - Left Ventricular End-Diastolic Volume; LVEF - Left Ventricular Ejection Fraction; LA - Left Atrium; TTE - Transthoracic Echocardiography; LAVI - Left Atrial Volume Index; MR - Mitral Regurgitation; PAS and MPAP - Systolic and Mean Pulmonary Artery Pressure; MSCT-CTA - Multislice Computed Tomography with Intravenous Contrast.

complaints, medical history, and assessment of objective status, as well as standard laboratory and instrumental diagnostic tests. To further detail the anatomy of the left atrium and pulmonary veins and to exclude any additional formations within the left atrium, all patients underwent multislice computed tomography (MSCT-CTA) of the left atrium and pulmonary veins with intravenous contrast enhancement.

Catheter ablation

The anesthesia method, vascular access, navigation system, and ablation catheter used were identical for both groups. The surgical procedure was performed under local anesthesia. Vascular access was achieved by catheterization of the right and/or left femoral vein. Under fluoroscopic control, the interatrial septum was punctured twice.

A three-dimensional model of the left atrium and pulmonary veins was created using the Carto3 navigation system (Biosense Webster, Johnson & Johnson, USA), through rapid anatomical modeling after respiratory compensation. The ablation catheter used was the ThermoCool SmartTouch catheter (Biosense Webster, Johnson & Johnson, USA), which includes a pressure sensor.

During PVI, the VisiTag and Ablation Index modules (Biosense Webster, Johnson & Johnson, USA) were used, with the following settings: maximum catheter deviation standard deviation: 2.5 mm, minimum stability retention time: 3 seconds, catheter contact force range: 4 to 40 g, ablation point size: 3 mm, distance between two points: 5 mm.

The first step involved right pulmonary vein isolation, followed by left pulmonary vein isolation through point-by-point ablation, strictly in one direction along the designated ablation path. To confirm PVI, the Lasso circular catheter (Biosense Webster, Johnson & Johnson, USA) was used.

In the study group, the following ablation parameters were applied: ablation power was set to 45 W for all walls of the left atrium (LA); physiological saline flow rate: 2 ml/min without ablation, 30 ml/min during ablation; target Ablation Index ranged from 400-420 for the posterior wall of the left atrium and 460-500 for the anterior wall.

In the control group, the following ablation parameters were used: ablation power was set to 45 W for the anterior wall of the left atrium and 35 W for the posterior wall; physiological saline flow rate: 2 ml/min without ablation, 30 ml/min during ablation; ablation duration was determined individually by the operator based on a combination of factors (contact force, catheter stability, and ablation area).

Postoperative management and follow-up

All patients underwent echocardiographic control (Echo) on the 2nd day after surgery to exclude hemopericardium and assess heart contractility parameters, as well as 24-hour ECG monitoring.

Oral anticoagulant and antiarrhythmic therapy was continued for at least 3 months after the procedure (blanking period). If no documented paroxysms of atrial tachyarrhythmias were observed after the blanking period, antiarrhythmic therapy was discontinued. However, the use of antiarrhythmic drugs by the patient before and after the surgery was not recorded in this study.

Patients were assigned clinical follow-up points for the study, including Holter ECG monitoring at 3, 6, and 12

Table 2.

Immediate and long-term results of catheter-based treatment of atrial fibrillation

	Control group (n=176)	Study group (n=110)	P
Procedure duration, minutes	126.4±29.2	92.7±20.9	<0.001
Recurrence of atrial fibrillation during the blanking period			
Total number of patients, n (%)	15 (8.5)	2 (1.8)	0.02
Paroxysmal form, n (%)	6 (3.4)	1 (0.9)	
Persistent form, n (%)	9 (5.1)	1 (0.9)	
Frequency of repeat pulmonary vein isolations			
Total number of patients, n (%)	55 (33.3)	24 (21.8)	0.083
Paroxysmal form, n (%)	31 (17.6)	16 (14.5)	0.098
Persistent form, n (%)	24 (13.7)	8 (7.3)	0.778

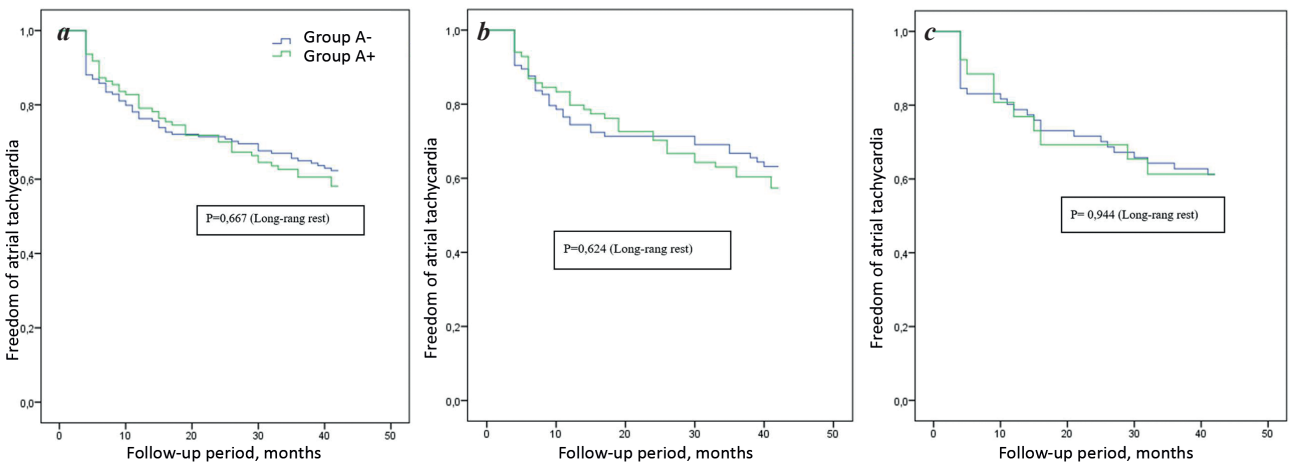

Fig. 1. Comparative graph of freedom from atrial tachyarrhythmia in the study and control groups: a - all patients, b - patients with paroxysmal AF, c - patients with persistent AF.

months, and then every 6 months after the initial treatment.

Statistical analysis

Data analysis was performed using IBM SPSS Statistics v.23. Parametric data were tested for normal distribution, and comparisons were subsequently made using either the Student's t-test or the Mann-Whitney U test. Non-parametric data were compared based on the number of events using either Fisher's exact test or Pearson's chi-square test.

RESULTS

Intraoperative data

Within the scope of the study, the duration of fluoroscopy and the left atrial stage were not assessed, as these data were not recorded in the surgical protocols of the control group. The total procedure duration was significantly shorter in the study group (Table 2).

Intraoperatively, acute PVI was successfully achieved in all patients in both groups.

Postoperative data

The mean follow-up period in the study was 38.1±9.6 months. After 40 months, 95 patients from the control group (out of 176, with 20 patients lost to follow-up and 61 cumulative events) and 35 patients from the study group (out of 110, with 32 patients lost to follow-up and 43 cumulative events) remained under observation.

During the blanking period, AF recurrence was observed in 15 patients in the control group and 2 patients in the study group. The recurrence rates during the blanking period and their distribution by AF type are shown in Table 2. As shown in the table, in the group where RFA was performed using the AI module, the recurrence rate during the blanking period was significantly lower compared to the control group.

During the mean follow-up period of 38.1±9.6 months, freedom from AF (calculated using Kaplan-Meier survival analysis) was 62.3% in the control group and 58.1% in the study group (Figure 1a). A comparative evaluation of freedom from atrial tachyarrhythmias using Kaplan-Meier was also conducted for subgroups with paroxysmal AF(Figure 1b) and persistent AF (Figure 1c). There was no statistically significant difference in freedom from atrial tachyarrhythmias during the follow-up period between the two study groups and their subgroups.

Redo ablation

The number of patients who underwent repeat ablation is shown in Table 2. No statistically significant difference was found in the frequency of repeat interventions between the study group and the control group. However, there was a trend towards a lower frequency of repeat pulmonary vein isolation in the group of patients who used the Ablation Index module (p=0.083).

Complications

No complications leading to fatal outcomes or requiring additional invasive interventions were recorded in either group. In 15 patients (8.5%) in the control group and 4 patients (3.6%) in the study group, complications such as pericardial effusion up to 1 cm or post-puncture hematoma were recorded (p=0.106).

DISCUSSION

As a result of our study, in the comparative evaluation of the two groups, we obtained the following important findings: there was no statistically significant difference in freedom from arrhythmia in the long-term follow-up period; however, the recurrence rate during the blanking period was significantly higher in the control group; the use of the AI module significantly shortened the duration of the procedure; there was a marked trend towards a lower need for repeat ablation in the study group.

Most recent studies focusing on catheter ablation with CF monitoring have shown higher efficacy and safety compared RFA without the use of contact force sensing catheters [13]. There is also evidence suggesting that CF control may positively influence the treatment efficacy in patients with persistent AF [14, 15].

In recent years, an additional marker of lesion quality (the Ablation Index, AI) has been developed, which is calculated based on the analysis of contact force, ablation time, and power. Subsequently, the evaluation of AI's effectivenessbecame relevant, and several studies were published that compared AI with CF-guided ablation. In analyzing these studies, we found that, in most of them, freedom from atrial tachyarrhythmias was significantly higher with AI use, while maintaining a comparable safety profile [9-10, 16-17]. These findings contrast with the results of our study. One of the key limitations of the above-mentioned studies is the postoperative follow-up period, which is typically limited to 12 to 14 months [10, 16-19]. However, it is known that the recurrence rate of AF after the primary procedure continues to steadily rise as the observation period extends, and by the 5th year, freedom from AF may be less than 70% [20, 21]. Our study, with 36 months or more of postoperative follow-up, demonstrates more convincing results regarding the comparative effectiveness of both techniques.

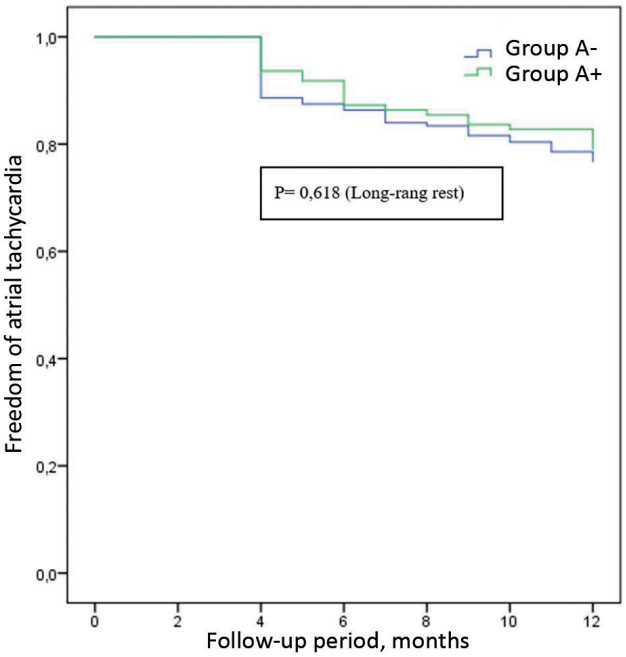

Figure 2. Comparative plot of freedom from atrial tachyarrhythmia in the study and control groups at 12 months.

If we look specifically at the 12-month follow-up results from our study (Figure 2), freedom from atrial arrhythmiaswas also higher in the AI group, although not statistically significant, which partially correlates with the findings of previous studies. Furthermore, in our study, the use of AI significantly reduced the duration of the procedure. This is likely due to the fact that pulmonary vein isolation was more frequently achieved on the first pass, without the need for additional ablations or searching for "breakthroughs". However, we did not record this data during the surgical interventions, and cannot conclusively confirm this hypothesis. Still, the operation duration data we obtained correlate with the results of most authors, whose work was analyzed and published in a large meta-analysis [17].

Our study also demonstrated that the use of the AI module significantly reduces the recurrence rate during the blanking period. This is likely related to the lower need for radiofrequency applications in the study group to achieve intraoperative pulmonary vein isolation, which in turn reduces atrial wall injury and atrial tissue edema.

Thus, according to our data, the use of the Ablation Index module does not result in a significant improvement in long-term efficacy when treating patients with AF, compared to results obtained with a similar catheter and operation protocol (using the VisiTag module and SmartTouch catheter). However, it significantly shortens the duration of the procedure and simplifies the achievement of pulmonary vein isolation, as demonstrated in most studies, including ours, by standardizing and establishing uniform criteria for the effectiveness of each ablation point.

It is likely that multicenter, randomized studies with different AI parameters will demonstrate more significant results in terms of efficacy in the future. Therefore, this topic requires further investigation.

Limitations

1. Recurrence of AF in the postoperative period was assessed using 24-hour ECG monitoring, data from implantable devices (pacemakers), and analysis of medical records. In our study, we did not implant loop recorders for diagnosing atrial tachyarrhythmias.
2. The non-randomized nature of the study means that the effect of confounding factors cannot be excluded.
3. The study was single-center, limiting the generalizability of the findings.
4. Detailed evaluation of antiarrhythmic therapy (e.g., types of medications, duration of therapy) before and after surgery was not performed for patients in either group.

CONCLUSION

Ablation of atrial fibrillation (AF) under the guidance of the Ablation Index module is associated with a lower recurrence rate of atrial tachyarrhythmias during the blanking period (the first three months) after ablation. The rate of complications and the recurrence rate over a 3-year follow-up period were not significantly different between the group using the Ablation Index module and the group without it.

REFERENCES

1. Calkins H, Hindricks G, Cappato R, et al. 2017 HRS/EHRA/ECAS/APHRS/ SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation: Executive summary. *Europace*. 2018;20(1): 157-208. https://doi.org/10.1093/europace/eux27.
2. Bisbal F, Baranchuk A, Braunwald E, et al. Atrial Failure as a Clinical Entity: JACC Review Topic of the Week. *J Am Coll Cardiol.* 2020;75(2): 222-232. https://doi.org/10.1016/j.jacc.2019.11.013.
3. Mikhaylov EN, Gasimova NZ, Ayvazyan SA, et al. Factors associated with the efficacy of atrial fibrillation radiofrequency catheter ablation: opinion of the specialists who use the "ablation index" module. *Journal of Arrhythmology.* 2020;27(3): 9-24. (In Russ.). https://doi.org/10.35336/VA-2020-3-9-24
4. Nakagawa H, Ikeda A, Govari A, et al. Prospective study to test the ability to create RF lesion at predicted depth and diameter using a new formula incorporating contact force, radiofrequency power and application time (force-power-time index) in beating heart. *Heart Rhythm.* 2014;11(Suppl): S548.
5. Das M, Loveday JJ, Wynn GJ, et al. Ablation index, a novel marker of ablation lesion quality: prediction of pulmonary vein reconnection at repeat electrophysiology study and regional differences in target values. *Europace*. 2017;19: 775-83. https://doi.org/10.1093/europace/euw105.
6. Ullah W, Hunter RJ, Finlay MC, et al. Ablation Index and Surround Flow Catheter Irrigation: Impedance-Based Appraisal in Clinical Ablation. *JACC Clin Electrophysiol.* 2017;3(10):1080-1088. https://doi.org/10.1016/j.jacep.2017.03.011.
7. Hussein A, Das M, Chaturvedi V, et al. Prospective use of Ablation Index targets improves clinical outcomes following ablation for atrial fibrillation. J Cardiovasc Electrophysiol. 2017;28(9): 1037-1047. https://doi.org/10.1111/jce.13281.
8. Phlips T, Taghji P, El Haddad M, et al. Improving procedural and oneyear outcome after contact force-guided pulmonary vein isolation: the role of interlesion distance, ablation index, and contact force variability in the 'CLOSE'-protocol. *Europace*. 2018;20(FI_3): f419-f427. https://doi.org/10.1093/europace/eux376.
9. Hussein A, Das M, Chaturvedi V, et al. Prospective use of ablation index targets improves clinical outcomes ablation for atrial fibrillation. *J Cardiovasc Electrophysiol.* 2017;28: 1037-47.
10. Casella M, Dello Russo A, Riva S, et al. An ablation index operator-independent approach to improve efficacy in atrial fibrillation ablation at 24-month follow-up: a single center experience. *J Interv Card Electrophysiol*. 2019;57: 241-9.
11. Chinitz LA, Melby DP, Marchlinski FE, et al. Safety and efficiency of poroustip contact-force catheter for drug-refractory symptomatic paroxysmal atrial fibrillation ablation: results from the SMART SF trial. *Europace.* 2018;20(FI_3): f392-f400. https://doi.org/10.1093/europace/eux264.
12. Bertaglia E, Fassini G, Anselmino M, et al. Comparison of ThermoCool® Surround Flow catheter versus ThermoCool® catheter in achieving persistent electrical

isolation of pulmonary veins: a pilot study. *J Cardiovasc Electrophysiol.* 2013;24(3): 269-273. https://doi.org/10.1111/jce.12031.
13. Nakagawa H, Jackman WM. The role of contact force in atrial fibrillation ablation. *J Atr Fibrillation.* 2014;7: 1027.
14. Hussein AA, Barakat AF, Saliba WI, et al. Persistent atrial fibrillation ablation with or without contact force sensing. *J Cardiovasc Electrophysiol.* 2017;28: 483-8.
15. Conti S, Weerasooriya R, Novak P, et al. Contact force sensing for ablation of persistent atrial fibrillation: a randomized, multicenter trial. *Heart Rhythm.* 2018;15: 201-8.
16. Solimene F, Schillaci V, Shopova G, et al. Safety and efficacy of atrial fibrillation ablation guided by ablation index module. *J Interv Card Electrophysiol.* 2019;54: 9-15.
17. Ioannou A, Papageorgiou N, Lim WY, et al. Efficacy and safety of ablation index-guided catheter ablation for atrial fibrillation: an updated meta-analysis. *Europace*. 2020;22: 1659-1671.
18. Das M, Loveday JJ, Wynn GJ, et al. Ablation index, a novel marker of ablation lesion quality: prediction of pulmonary vein reconnection at repeat electrophysiology study and regional differences in target values. *Europace*. 2017;19: 775-83.
19. Dhillon G, Ahsan S, Honarbakhsh S, et al. A multicentered evaluation of ablation at higher power guided by ablation index: establishing ablation targets for pulmonary vein isolation. *J Cardiovasc Electrophysiol.* 2019;30: 357-65.
20. Poole JE, Bahnson TD, Monahan KH, et al. Recurrence of Atrial Fibrillation After Catheter Ablation or Antiarrhythmic Drug Therapy in the CABANA Trial. *J Am Coll Cardiol.* 2020;75(25): 3105-3118. https://doi.org/10.1016/j.jacc.2020.04.065.
21. Ouyang F, Tilz R, Chun J, et al. Long-term results of catheter ablation in paroxysmal atrial fibrillation: lessons from a 5-year follow-up. *Circulation*. 2010;122(23): 2368-77. https://doi.org/10.1161/CIRCULATIONAHA.110.946806.