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COMPARATIVE ANALYSIS OF THREE-YEAR EFFICACY OF CATHETER ABLATION OF ATRIAL FIBRILLATION USING THE ABLATION INDEX MODULE AND THE SECOND-GENERATION CRYOBALLOON

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Aim. To compare immediate and long-term outcomes of catheter-based atrial fibrillation (AF) treatment following pulmonary vein (PV) cryoballoon ablation (CBA) using the second-generation cryoballoon and PV radiofrequency ablation (RFA) performed on the navigation system using the contact force-sensing catheter with the AI module.

Methods. The study included 199 patients referred for PV isolation between 2018 and 2021. Patients were divided into two groups: the study group (n=110) underwent PV isolation via RFA using the catheter with the AI module; the control group (n=89) underwent PV CBA using the second-generation cryoballoon. The follow-up period was limited to 36 months, with a mean follow-up of 27.9 ± 14.2 months.

Results. The three-year efficacy of CBA and RFA using the AI module was comparable (freedom from atrial tachyarrhythmias: RFA group 0.61±0.05, CBA group 0.62±0.05 (Log-Rank test, p = 0.896)), with similar complication rates and profiles (3.6% (n=4) vs. 4.5% (n=4), p=0.759). The AF recurrence rate during the blanking period was significantly lower in the RFA group using the AI module (1.8% (n=2) vs. 9.0% (n=8) in the CBA group, p=0.045). Procedure duration was significantly shorter in the cryoablation group (RFA 92.7±20.9 min, CBA 83.9±19.6 min, p=0.005). The need for repeat intervention was comparable between groups (RFA 21.8% (n=24), CBA 30.3% (n=27), p=0.171).

Conclusion. Comparative analysis of the three-year efficacy of radiofrequency antral pulmonary vein isolation using the catheter with the "Ablation Index" (AI) module demonstrated results comparable to ablation with the second-generation cryoballoon. Furthermore, during the blanking period, the RFA group showed a statistically significant reduction in AF recurrence compared to the CBA group.

Key words: atrial fibrillation; catheter ablation; radiofrequency ablation; cryoballoon ablation; pulmonary veins

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Pulmonary vein (PV) isolation is the cornerstone of invasive treatment for atrial fibrillation (AF) [1]. Currently, the most widely used catheter-based methods for PV isolation are radiofrequency (RF) ablation and cryoballoon ablation (CBA). The majority of studies have demonstrated comparable efficacy between these approaches [2-4]. However, according to published data, RF ablation has primarily been performed with irrigated contact force-sensing catheters, without the use of the ablation index (AI; Biosense Webster, USA).

AI is a technology that automatically quantifies the extent of ablation lesion formation, calculated from three main parameters: catheter contact force, application duration, and RF power [5]. The reliability of AI values in predicting lesion depth at atrial endocardial sites was first demonstrated in experimental canine studies [6, 7]. This provided the potential, when using the Carto 3 three-dimensional mapping system (Biosense Webster, Johnson & Johnson, USA), to monitor lesion depth during catheter ablation and to reduce the risk of procedure-related complications [8-10].

Subsequently, multiple studies have compared the efficacy of RF ablation with and without the use of AI. In most of these, freedom from atrial tachyarrhythmias was significantly higher when AI guidance was employed [9, 11-13]. Thus, AI has emerged as an additional tool to enhance the efficacy of RF ablation in AF treatment.

Aim: to compare the efficacy of AF treatment between cryoballoon PV isolation performed with the Arctic Front Advance balloon (Medtronic, USA) and RF ablation performed with the SmartTouch contact force-sensing

catheter (Biosense Webster, Johnson & Johnson, USA) using AI guidance.

METHODS

A total of 199 consecutive patients referred for catheter-based PV isolation between 2018 and 2021 were enrolled. Patients were divided into two groups: the study group comprised 110 patients who underwent RF ablation with the SmartTouch catheter using AI technology, while the control group included 89 patients who underwent PV isolation with the second-generation Arctic Front Advance cryoballoon. Group allocation was based on the availability of consumables at the time of the procedure.

The primary endpoint was freedom from any atrial tachyarrhythmia (AF, atrial flutter, atrial tachycardia) during long-term follow-up (up to 36 months). Secondary endpoints included: recurrence of atrial tachyarrhythmias during the blanking period (first 3 months post-procedure), complication rates and patterns, procedure duration, and frequency of repeat ablations.

Assessment of the primary endpoint was based on the absence of symptomatic or asymptomatic atrial tachyarrhythmias lasting more than 30 seconds. Arrhythmias occurring during the blanking period were not considered recurrences when evaluating long-term procedural efficacy. Arrhythmia recurrence was documented by Holter monitoring, interrogation of implanted devices (pacemakers), and review of medical records.

Secondary endpoints were evaluated using medical documentation (procedure duration, repeat ablation rate), patient complaints, clinical status, and instrumental and laboratory findings (intra- and postoperative complications).

All patient data were anonymised and entered into a dedicated database excluding personal identifiers. All patients provided written informed consent both for participation in the study and for the AF ablation procedure, in accordance with current guidelines.

Inclusion criteria were: ECG-documented, symptomatic paroxysmal or persistent AF. Exclusion criteria were: previous PV isolation, intracardiac thrombus, thyroid dysfunction, requirement for valve or vascular cardiac surgery, inability to take oral anticoagulants, and severe renal or hepatic impairment. Baseline clinical characteristics by group are shown in Table 1.

As part of the preoperative protocol, all patients underwent multislice computed tomography of the left atrium and PVs with intravenous contrast. In patients with a PV common ostium or PV ostial diameter >28 mm, RF antral PV isolation was performed. Patients older than 40 years underwent coronary angiography.

Radiofrequency and cryoballoon ablation

All procedures were performed under local anaesthesia. After femoral vein cannulation under fluoroscopic guidance, transseptal access was obtained (double puncture in the study group for RF ablation, single puncture in the control group for cryoballoon PV isolation).

RF antral PV isolation was performed using the Carto 3 navigation system (Biosense Webster, Johnson & Johnson, USA) with a ThermoCool SmartTouch contact force-sensing catheter and the Visitag and Ablation Index modules (Biosense Webster, Johnson & Johnson, USA).

Table 1.

Clinical characteristics of the patient groups

Characteristic	RFA-AI group (n=110)	CBA group (n=89)	P
Mean age, years	64.4±7.4	62.7±7.5	0.145
Sex (M/F), %	48.2/51.8	46.1/53.9	0.766
Body mass index, kg/m^2	30.9±4.9	29.7±4.8	0.136
Paroxysmal AF, %	76.4	70.8	0.373
Persistent AF, %	23.6	29.2	
ACA*, %	5.5	4.5	0.758
Coronary artery disease, %	35.5	32.6	0.671
Myocardial infarction, %	7.3	5.6	0.639
Diabetes mellitus, %	8.2	10.1	0.637
Arterial hypertension, %	93.6	92.1	0.783
Pacemaker implantation*, %	11.8	7.9	0.478
Myocardial revascularisation*, %	11.8	11.2	0.898
LVEDV, mL	96.8 ± 25.9	90.6 ± 20.1	0.085
LVEF, %	55.2±6.1	55.8±6.3	0.589
LA volume (TTE), mL	73.9±24.5	70.2±18.2	0.458
LAVI (TTE), mL/m^2	38.0±11.2	36.9±8.9	0.738
IVS thickness, mm	13.2±3.3	13.6±2.4	0.086
LVPW thickness, mm	12.5±3.5	12.5±1.9	0.556
MR grade 0, %	33	28.1	0.224
MR grade I, %	50.5	61.8	
MR grade II, %	16.5	10.1	
sPAP, mmHg	37.9±7.3	35.7±7.5	0.163
mPAP, mmHg	20.8±8.2	20.5±6.5	0.907
LA volume (MSCT), mL	112.9±28.5	116.8±27.9	0.415
LAVI (MSCT), mL/m^2	57.8±15.1	60.5±15.1	0.288

Notes: RFA-AI - radiofrequency pulmonary vein ablation with Ablation Index guidance; CBA - cryoballoon pulmonary vein isolation; AF - atrial fibrillation; ACA* - acute cerebrovascular accident; * - in medical history; PM - pacemaker; LVEDV - left ventricular end-diastolic volume; LV - left ventricle; LVEF - left ventricular ejection fraction; LA - left atrium; TTE - transthoracic echocardiography; LAVI - left atrial volume index; IVS - interventricular septal thickness; LVPW - left ventricular posterior wall thickness; MR - mitral regurgitation; sPAP and mPAP - systolic and mean pulmonary artery pressure; MSCT - multislice computed tomography with intravenous contrast.

Ablation points were automatically annotated according to the following parameters: maximum catheter SD displacement - 3 mm; minimum stability duration - 3 s; contact force range - 4-40 g. Ablation tags were 6 mm in size, with interlesion distance ≤6 mm. PV isolation was verified with a circular Lasso catheter (Biosense Webster, Johnson & Johnson, USA). RF parameters were: power 45 W at all LA sites; irrigation rate 2 mL/min during standby and 30 mL/min during ablation; target AI 400-420 for the posterior wall and 460-500 for other LA segments.

Cryoballoon PV isolation was performed with the second-generation 28 mm Arctic Front Advance cryoballoon (Medtronic, USA). Entry and exit block of the PVs was verified with the Achieve circular diagnostic catheter (Medtronic, USA). Cryoablation was initiated after complete PV occlusion was confirmed by angiography. Freeze duration did not exceed 240 s per application. Right phrenic nerve pacing was performed during right PV isolation to monitor diaphragmatic nerve function.

The intraprocedural endpoints of effective PV isolation were: elimination of PV potentials on Achieve catheter electrodes within <75 s and absence of contrast leakage from the PV during cryoablation. When these criteria were met, no additional applications were delivered.

Postoperative period and follow-up

In the early postoperative period, all patients underwent echocardiography and Holter monitoring. Scheduled follow-up visits with mandatory ECG Holter monitoring were performed at 3, 6, and 12 months, and every 6 months thereafter. Three months after the procedure, antiarrhythmic therapy was discontinued in the absence of arrhythmia recurrence. Analysis of antiarrhythmic drug use before and after ablation was not performed in this study.

Statistical analysis

statistical analysis was performed using IBM SPSS Statistics version 27. Parametric data were assessed for normal distribution, and comparisons were made using Student's *t*-test or the Mann-Whitney test, as appropriate. Non-parametric data were compared using Fisher's exact test or Pearson's χ^2 test, depending on event counts. Freedom from atrial tachyarrhythmias was assessed by survival analysis using the Kaplan-Meier method.

The statistical significance of associations with clinical factors in survival analysis was evaluated using the Mantel-Cox log-rank test. A p-value <0.05 was considered statistically significant.

RESULTS

Intraoperative data

fluoroscopy time and duration of the left atrial stage were not evaluated, as these data were not documented in the operative protocols of the control group. Overall procedure duration was significantly shorter in the study group (Table 2). Intraoperatively, acute isolation of all PVs was achieved in all patients in both groups.

Postoperative date

The mean follow-up period was 27.9±14.2 months. By month 36, 54 of 89 patients remained under observation in the control group (34 patients with documented atrial tachyarrhythmias, one lost to follow-up) and 61 of 110 in the study group (41 patients with documented atrial tachyarrhythmias, eight lost to follow-up).

During the blanking period, AF recurrence was recorded in 8 patients in the control group and 2 patients in the study group. The incidence of recurrences during the blanking period and their distribution by AF type are presented in Table 2. In the RF ablation group with AI guidance, recurrence rates in the blanking period were significantly lower compared with the control group.

Kaplan-Meier survival analysis demonstrated freedom from atrial tachyarrhythmias of 0.62±0.05 in the control group and 0.61±0.05 in the study group (log-rank test, p=0.896) (Fig. 1). Subgroup analysis of freedom from atrial tachyarrhythmias by AF type using the Kaplan-Meier method showed values of 0.69±0.06 in the CBA group versus 0.60±0.06 in the RF AI group for paroxysmal AF (log-rank test, p=0.400) (Fig. 2), and 0.42±0.09 in the CBA group versus 0.61±0.09 in the RF AI group for persistent AF (log-rank test, p=0.173) (Fig. 3). No statistically significant differences in freedom from atrial tachyarrhythmias were found between the two treatment groups or their subgroups over the follow-up period.

Table 2.

Immediate and long-term outcomes of catheter ablation for atrial fibrillation

	RFA-AI group (n=110)	CBA group (n=89)	P
Procedure duration, min	92.7±20.9	83.9±19.6	0.005
Complications, n (%)	4 (3.6)	4 (4.5)	0.759
Recurrence of atrial tachyarrhythmias			
During the blanking period, n (%)	2 (1.8)	8 (9.0)	0.045
Overall, n (%)	43 (39.1)	34 (38.2)	0.898
In paroxysmal AF, n (%)	33 (39.3)	19 (30.2)	0.252
In persistent AF, n (%)	10 (38.5)	15 (57.7)	0.165
Repeat procedures for atrial tachyarrhythmias			
Total patients, n (%)	24 (21.8)	27 (30.3)	0.171
Procedures per patient	0.26±0.55	0.37±0.65	0.179

Repeat ablation

No statistically significant difference in the rate of repeat interventions was observed between the study and control groups. No complications resulting in death or requiring additional invasive intervention were recorded in either group. In 4 patients (4.5%) in the control group and 4 patients (3.6%) in the study group, complications such as pericardial effusion up to 10 mm (one case in each group) or post-puncture hematoma (three cases in each group) were documented, with no significant difference in the frequency or distribution of complications (p=0.759).

DISCUSSION

The present study yielded the following findings: (1) the three-year

efficacy of cryoballoon PV isolation and RF antral PV isolation with Ablation Index (AI) guidance was comparable; (2) recurrence rates during the blanking period were significantly lower in the RF ablation group; (3) procedure duration was significantly shorter in the cryoballoon group; and (4) the need for repeat interventions was similar in both groups.

Multiple studies have compared the efficacy of CBA and RF antral ablation. These investigations have used different devices, including first- or second-generation cryoballoons and RF catheters with or without contact force sensing. As technology evolved, each subsequent trial compared the latest available iterations of these catheters.

The most widely recognised study directly comparing CBA and RF ablation is the multicentre randomised FIRE and ICE trial. This study found no statistically significant difference in the primary endpoint (first documented AF recurrence >30 seconds, occurrence of atrial flutter or atrial tachycardia, initiation of antiarrhythmic therapy, or repeat AF ablation after a 90-day blanking period) between RF ablation and CBA at long-term follow-up [4]. However, secondary analyses of this trial demonstrated that patients treated with CBA had lower rates of repeat ablation, electrical cardioversion (ECV), repeat hospitalisations for any cause, and repeat hospitalisations for cardiovascular disease compared with RF ablation [14]. Importantly, this study did not stratify results by the type of RF catheter used (contact force-sensing vs non-sensing) or the generation of cryoballoon applied.

Similar findings were reported by domestic investigators who compared RF ablation with the SmartTouch contact force-sensing catheter (Biosense Webster, Johnson & Johnson, USA) and first- and second-generation Arctic Front cryoballoons (Medtronic, USA) [15]. They found no significant difference in long-term efficacy between the two methods, although, unlike the FIRE and ICE trial, the frequency of repeat procedures was comparable between groups [14, 15].

Later studies incorporated technological advances by comparing only second-generation cryoballoons with contact force-sensing RF catheters [2, 16]. For example, T.J. Buist et al. (2018) compared the second-generation cryoballoon with contact force-sensing RF catheters in terms of arrhythmia-free survival, PV reconnection after the index procedure, and repeat ablation rates. Their findings demonstrated a significant advantage of CBA: freedom from atrial arrhythmias after a single procedure was higher, repeat ablations were less frequent, and PV reconnection rates during redo procedures were lower compared with RF ablation [16].

Similarly, W. Maskoun et al. (2021) reported that CBA achieved significantly greater long-term arrhythmia-free survival than RF ablation, both with and without contact force sensing, in patients with paroxysmal AF. The repeat ablation rate was also lower in the CBA group [17]. Other studies, however, have shown comparable long-term efficacy between CBA and RF ablation but did not specifically assess secondary endpoints such as repeat interventions, hospitalisations, or ECV during the blanking period [18].

Taken together, most studies suggest that freedom from atrial tachyarrhythmias after second-generation CBA is comparable to RF ablation with contact force sensing, and in some cases superior [2, 16-18]. Repeat ablation and ECV rates, however, have generally been higher in the RF group [16, 17].

To date, no published studies have directly compared CBA with RF ablation incorporating AI guidance. Most

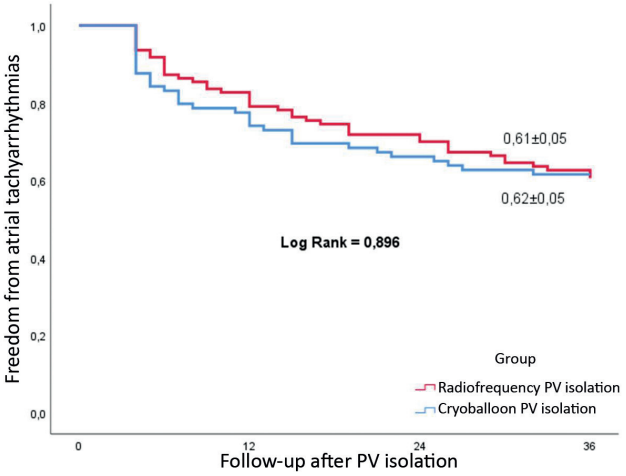

Fig. 1. Overall freedom from atrial tachyarrhythmias at 36 months of follow-up. Abbreviations: RF - radiofrequency ablation; PV - pulmonary vein.

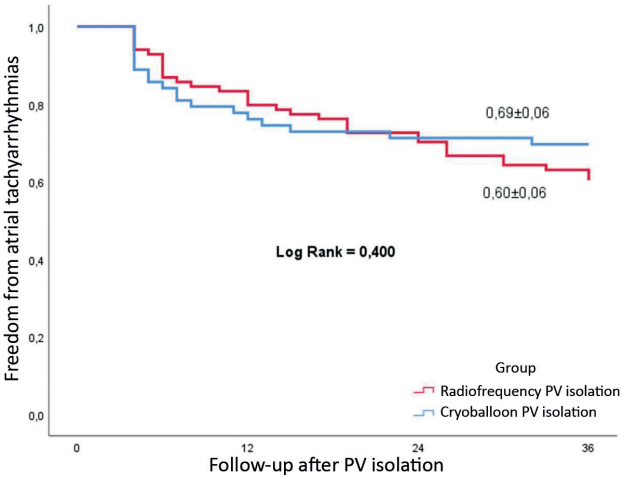

Fig. 2. Overall freedom from atrial tachyarrhythmias in patients with paroxysmal AF at 36 months of follow-up.

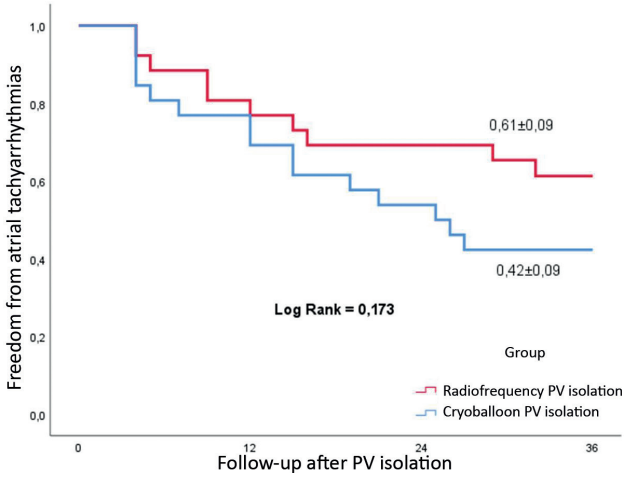

Fig. 3. Overall freedom from atrial tachyarrhythmias in patients with persistent AF at 36 months of follow-up.

have instead evaluated RF ablation with and without AI. These studies consistently showed higher arrhythmia-free survival with AI-guided ablation, with a similar safety profile [9, 11-13]. This supports the utility of AI as an effective adjunct. Theoretically, AI-guided RF ablation may yield outcomes equal to or better than CBA. In our study, where RF ablation was performed with both contact force-sensing catheters and AI, no significant difference was observed in long-term efficacy compared with CBA. However, analysis of secondary endpoints revealed discrepancies with prior studies: the need for repeat procedures was similar in both groups (21.8% [24/110] in the RF group vs 30.3% [27/89] in the CBA group, p=0.171), while recurrence rates during the blanking period were significantly lower in the RF group (1.8% [2/110] vs 9.0% [8/89], p=0.045).

Thus, the advantages of CBA (fewer repeat procedures and ECV during the blanking period), reported in prior large-scale studies [14, 16, 17], were only partially confirmed here. Although the number of ECVs performed during the blanking period could not be reliably quantified in our study, we hypothesise that the higher recurrence rate during this period in the CBA group indirectly reflects a higher need for ECV. Previous studies attributing superior or comparable long-term efficacy of CBA to more durable PV isolation and lower rates of PV reconnection compared with RF ablation [16, 17, 19-21] support this interpretation.

The introduction of AI has led to the standardisation of RF ablation by enabling operators to deliver lesions along a predefined line, with defined target AI values required for transmural atrial lesions, durable PV isolation, and minimal risk of reconnection. The predictive accuracy of AI for lesion depth has been confirmed in experimental canine models [6, 7].

Our findings regarding procedural duration are consistent with prior studies, with cryoablation being faster. Current contact force-sensing catheters have limitations in maximal power delivery, meaning that achieving target AI requires longer application times, dependent on contact force. By contrast, CBA often achieves PV isolation with a single application per vein.

Overall, the present results suggest that AI provides a valuable adjunct that improves RF ablation outcomes without requiring major engineering modifications of the catheter itself, making RF ablation comparable to CBA in terms of long-term arrhythmia-free survival, repeat ablation rates, and blanking period recurrences (a surrogate for ECV frequency). However, our study did not assess arrhythmia recurrence rates at repeat ablation, the number of ECVs during the blanking period, or perform a detailed comparative analysis of these endpoints. Further studies with larger sample sizes and robust designs are warranted to clarify these aspects.

Study limitations

Our study has several important limitations. Implantable loop recorders were not used for the detection of atrial tachyarrhythmias. Recurrence of AF in the postoperative period was assessed by Holter monitoring, interrogation of implanted devices (pacemakers), and review of medical records. The study design was non-randomised and single-centre, and postoperative pharmacological therapy was not systematically evaluated.

CONCLUSION

A comparative analysis of three-year outcomes demonstrated that radiofrequency antral pulmonary vein isolation with Ablation Index guidance yielded results comparable to those of second-generation cryoballoon ablation. Notably, during the blanking period, the RF group showed a statistically significant reduction in atrial tachyarrhythmia recurrences compared with the CBA group.

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