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Safety and efficacy of atrial fibrillation ablation guided by Ablation Index module

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Abstract

Purpose Reconnection of pulmonary veins (PVs) remains common following radiofrequency catheter ablation for atrial fibrillation (AF). Ablation Index (AI) is a novel ablation quality marker that incorporates stability, contact force (CF), time, and power in a weighted formula. Its use seems to improve lesion durability. This is a prospective, single-arm registry to investigate on the safety and mid-term efficacy of AF ablation guided by the AI.

Methods One hundred fifty-six consecutive patients (mean age 58 ± 10 years, 49% males, 44% with structural heart disease) referred for paroxysmal (124) or persistent (32) AF underwent antral PV isolation using a surround flow CF-sensing catheter guided by the AI. Radiofrequency was delivered targeting interlesion distance ≤ 6 mm and Ablation Index of 330–350 at posterior wall and 400–450 at anterior wall.

Results Mean overall procedure time was 95 ± 30 min with a mean fluoroscopy time of 5 ± 6 min. Mean ablation time was 26 ± 10 min, 627/628 targeted PV were isolated. One pericardial effusion and two groin hematomas were reported; none required intervention. During a mean follow-up of 14 ± 6 months, 17 (10.8%) (9% paroxysmal AF vs 22% persistent AF, $p = 0.09$) patients had an atrial arrhythmia recurrence.

Conclusions PV ablation guided by AI resulted feasible, achieving a high rate of isolated PVs, with a low complication rate, and allowed a high single-procedure arrhythmia-free survival at 14 months.

Keywords Atrial fibrillation · Catheter ablation · Contact force · Ablation Index · Safety · Mid-term outcome

1 Introduction

Permanent electrical isolation of the pulmonary veins (PVs) is well established as the cornerstone of AF ablation [1]. Despite the importance of this ablation endpoint, permanent PV isolation is frequently not achieved. Most studies report that recurrence of PV conduction is observed in one or more PVs in more than 60% of patients, also among patients who are AF free after an initial PV isolation procedure [2–5]. The likelihood of obtaining permanent PV isolation is related to the quality of ablation energy delivery and lesion formation. With radiofrequency energy, it is well recognized that important variables that impact lesion size and transmurality include catheter stability, contact force (CF), power output, temperature, and duration of RF output [1]. CARTO VISITAG™ Module with Ablation Index (AI) (CARTO®3 V4, Biosense Webster, Inc., Diamond Bar, CA) is a novel marker of RF application quality that incorporates stability, contact force, time, and power in a weighted formula, and has been shown to accurately estimate lesion depth in canine studies [6, 7] and humans [8, 9]. Preliminary data on AF ablation guided by the AI have demonstrated acute durable PV isolation followed by a high single-procedure arrhythmia-free survival at 1 year [10, 11]. The aim of our study was to report on the safety and mid-term efficacy of ablation guided by the AI in a consecutive series of patients with AF.

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2 Methods

2.1 Patients selection

Patients aged between 18 and 90 years with documented symptomatic paroxysmal or persistent AF episodes refractory to drug therapy (class I or III drugs) were enrolled. Exclusion criteria were (1) long-standing persistent AF, defined as AF being the sole rhythm for > 12 months before the enrolment; (2) previous catheter ablation of AF; (3) New York Heart Association functional class > II; (4) unstable angina or acute myocardial infarction within 3 months; (5) need for or prior cardiac surgery within 6 months; (6) contraindication to treatment with oral anticoagulants or bleeding diathesis; and (7) severe chronic renal or hepatic impairment.

This study was approved by the institutional review committees, and all patients signed informed consents. The principle outlined in the latest update of the Declaration of Helsinki was followed.

2.2 Study protocol

This is a prospective, single-arm registry to investigate on the safety and mid-term efficacy of AF ablation guided by the AI. Results were compared to 120 cases performed by the same two operators, with conventional CF-guided PV isolation and enrolled in a previous series [12].

2.3 Ablation procedure

Through femoral vein access, a decapolar electrode catheter was inserted in the coronary sinus. The left atrium was accessed by a patent foramen ovale, when present, or by a single transseptal puncture. A fixed curve sheaths (Preface, Biosense Webster, or SL0, St Jude Medical) was used in each patient. After transseptal catheterization, 3D electroanatomic maps of the left atrium and PVs were reconstructed using a nonfluoroscopic navigation system (CARTO®3, version 4, Biosense Webster Inc., Diamond Bar, CA, USA) as previously described [13, 14]. Maps were acquired during AF or sinus rhythm using respiratory gating. Fast anatomic mapping was performed in all patients. Radiofrequency pulses were delivered using the 3.5-mm Thermocool SMARTTOUCH® SF Catheter (Biosense Webster, Inc., Diamond Bar, CA, USA) in power control mode. Radiofrequency power was set between 25 and 35 W depending on different left atrial sites (up to 25 W at the posterior wall, and up to 35 W at the roof and anterior wall) and the catheter tip was irrigated by saline at a flow rate of 2 mL/min during mapping and of 8 mL/min and 15 mL/min used for outputs of less than and greater than 30 W, respectively [12]. Radiofrequency energy was delivered to produce a wide area circumferential ablation (WACA) around the proximal part of each PV's ostium or around ipsilateral PVs according to the anatomy or operator preference. The lesion around the PV ostium was created by sequential point-by-point application of radiofrequency energy (Fig. 1). Real-time automated display of RF applications (CARTO VISITAG™ Module, Biosense Webster) was used with predefined settings of catheter stability (3 mm for 3 s) and minimum CF [minimum time 8 s, maximum range 3 mm, minimum CF 30% of time > 5 g in Hussein et al. [10], > 4 g in Taghji et al. [11]]. RF was delivered until an AI of 330–350 at the posterior wall/roof and 400–450 at the anterior wall. In case of dislocation, a new RF application reaching the AI target was applied. Maximal interlesion distance between two neighboring lesions was ≤ 6 mm [< 5 mm in Hussein et al. [10], ≤ 6 mm in Taghji et al. [11]]. Upon completion of circumferential ablation, a circular decapolar mapping catheter (LASSO®, Biosense Webster Inc., Diamond Bar, CA, USA) was used to confirm PV isolation. In the absence of isolation after completing the circle, touch-up ablation was delivered until PV isolation. Resumption of left atrium to PV conduction was evaluated for 30 min after ablation. In case of reconnection, PVs were newly isolated targeting the residual electrical breakthroughs.

2.4 Ablation Index

The formula used to calculate AI is a complex weighted exponential formula assigning different weights to power, contact force, and time:

$$\text{Index} = \left(k * \int_0^t \text{CF}^a(\tau) P^b(\tau) \mathrm{d}\tau\right)^c$$

where CF is contact force, P is radiofrequency power, t is application time, and a, b, c, and k are constants.

This nonlinear formula is weighted unequally with power receiving a higher weighting than CF and generates a value termed the AI.

The target AI values we chose were rounded up from the values of 400 and 330 that had been found to have 100% positive predictive value for acute PV isolation, in the anterior/roof and posterior/inferior segments respectively, in a retrospective analysis of our first 10 patients in which the AI was used. In the first 17 patients enrolled in the study, the AI values were 330 at the posterior wall/roof and 400 at the anterior wall, then we slightly increased them to 350–450 since other authors [8] reported higher values.

2.5 Post-ablation management and follow-up

Oral anticoagulation was continued the same day for all patients and administered for at least 3 months and with no time limit in patients with a CHA_2DS_2-VASC score ≥ 2. Antiarrhythmic drugs were usually discontinued ≥ 5 half-

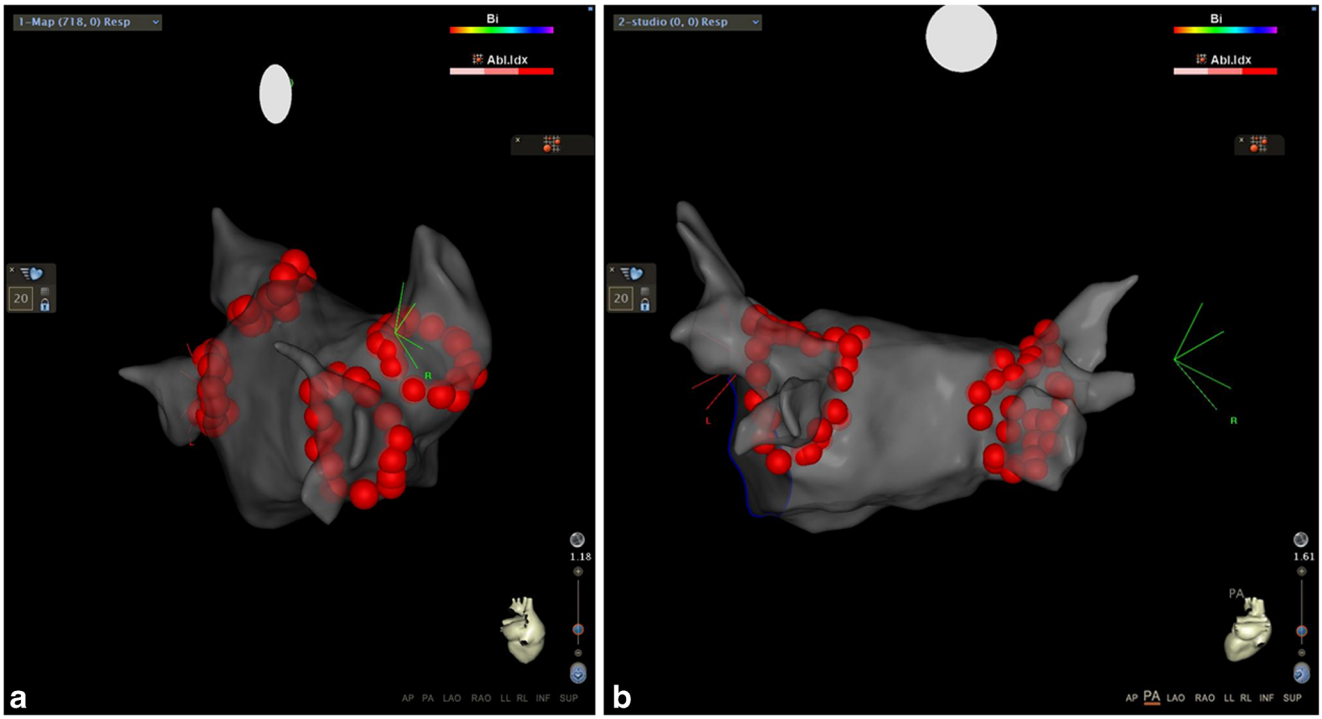

Fig. 1 Views of left atrium CARTO®3 reconstruction. Radiofrequency energy was delivered to produce a wide area circumferential ablation around the proximal part of each PV's ostium (a) or around ipsilateral PVs (b) according to the anatomy. The lesion around the PV ostium was created by sequential point-by-point application of radiofrequency energy. Red tags are the radiofrequency ablation points

lives prior to ablation, except for amiodarone. Patients with paroxysmal AF were discharged without antiarrhythmic drugs. Patients with persistent AF were discharged with or without antiarrhythmic drugs according to clinician preference. Patients were scheduled for clinical and ECG follow-up examinations 3,6, and 12 months, and then every 6 months, after the initial treatment. A Holter monitoring was performed 3, 12, and then every 12 months, after the initial treatment.

Ablation was deemed successful in the absence of symptomatic or asymptomatic atrial tachyarrhythmias lasting more than 30 s identified on surface ECG or on Holter monitoring, off antiarrhythmic drug therapy. In patients with persistent AF, we considered the ablation successful in absence of symptomatic or asymptomatic atrial tachyarrhythmias regardless of antiarrhythmic drug therapy used. As early relapse of atrial tachyarrhythmias within the first 3 months after RF ablation may be a transient phenomenon, this transition period was excluded from the final analysis [15].

2.6 Statistical analysis

Normally distributed continuous variables were expressed as mean (±SD) and compared by unpaired Student's t test. Skewed variables were expressed as median (25–75 quartiles) and compared by the rank-sum test. Normality was assessed by the Shapiro–Wilk test. Categorical variables were presented as counts and percentages, and compared by chi-square test (Pearson's, Yates, or Fisher's exact test as appropriate). A Kaplan–Meier (KM) curve was plotted for the time to first atrial arrhythmia recurrence following initial ablation procedure. The probabilities of freedom from atrial arrhythmia recurrence at each 3-month follow-up time point post-blanking were presented. Differences between the curves were tested for significance by means of the log-rank statistics. A p value < 0.05 was considered statistically significant. Analysis was performed by means of SPSS (version 11.0, SPSS Inc., Chicago, IL, USA).

3 Results

3.1 Study population

One hundred fifty-six consecutive patients (mean age 50 ± 10 years, 49% males, 44% with structural heart disease) were included in the study, 132 (80%) patients had paroxysmal AF, 24 (20%) had persistent AF. Their clinical characteristics are showed in Table 1. Of the 24 patients with persistent AF, 17 (71%) were on amiodarone and 7 (29%) were on flecainide. There were no differences in baseline clinical characteristics between study and control group (Table 1), with the exception of a higher male prevalence in the control group (69 vs 49%, $p < 0.001$).

Table 1 Clinical characteristics of study and control population

	Study group ($n = 156$)	Control group ($n = 120$)	p
Mean age (years)	58 ± 10 (range 29–74)	56 ± 11 (range 24–75)	0.11
Male sex	49%	69%	< 0.001
Left atrium diameter (mm)	45 ± 9 (range 33–61)	46 ± 11 (range 34–66)	0.36
Left atrium volume (ml)	84 ± 31 (range 40–138)	82 ± 33 (range 37–141)	0.67
Left ventricle ejection fraction (%)	57 ± 6 (range 40–70)	57 ± 7 (range 42–65)	0.88
Previous stroke/TIA	1%	2%	0.42
Heart disease	44%	45%	0.77
Hypertensive	43%	40%	0.56
Ischemic	2%	3%	0.45
Valvular	1%	1%	0.82
Restrictive	1%	3%	0.20
Diabetes	4%	8%	0.1

3.2 Procedural data

In the study group, mean overall procedure time was 95 ± 30 min with a mean fluoroscopy time of 5 ± 6 min, and a mean of 65 ± 11 RF pulses/patient. An impedance drop ≥ 10 Ω was observed in 57.1% (5790/10141) of RF pulses. First-pass isolation was documented in 598/628 (95%) PVs. Overall mean ablation time (radiofrequency time needed for PV isolation) was 26 ± 10 min, and 627/628 targeted PV were isolated. The median interlesion distance was 4.6 mm (IQR 4.1 to 5.0 mm).

Intraprocedural early PV reconnection occurred in 47/627 (7.5%) PVs and all PVs were effectively re-isolated. At the end of the procedure, 11/156 (7%) patients were in AF and required electrical cardioversion to restore the sinus rhythm. In Table 2 are summarized the main procedural data in the study and control group.

3.3 Follow-up data

In the study group, during the blanking period 8/132 (6%) patients with paroxysmal AF had an atrial arrhythmia recurrence. Among them, one was an atrial tachycardia and the remaining had AF episodes. During the blanking period, 2/24 (8.3%) patients with persistent AF had an atrial arrhythmia recurrence; in all cases, an AF episode was documented. During a mean follow-up of 14 ± 6 months, 17 (10.8%) (9% paroxysmal AF vs 22% persistent AF, $p = 0.09$) patients had an atrial arrhythmia recurrence (Fig. 2). In the control group, during a mean follow-up of 12 ± 5 months, 16 (13.3%) patients had an atrial arrhythmia recurrence. In the study group, at the time of atrial arrhythmia recurrence, 14/24 (58%) patients with persistent AF were on antiarrhythmic drugs. Off drug recurrence rate was 33% (3/10 patients).Overall, 2/17 (11.7%) patients with atrial arrhythmia relapses underwent a second ablation procedure. In these patients, we observed three reconnected segments: one left anterior (AI 450), one right anterior (AI 400), and one right posterior (AI 350).

3.4 Complications

In the study group, only one pericardial effusion and two groin hematomas were reported; none required intervention.

4 Discussion

In patients with paroxysmal and persistent AF, radiofrequency catheter ablation, aiming at PV isolation, guided by the use of the AI resulted feasible, achieving a high rate of isolated PVs, with a low incidence of complications, and a high mid-term freedom from arrhythmias recurrences. These results were achieved with lower AI values than previously reported [8, 10, 11].

4.1 Ablation Index

Catheter-based radiofrequency ablation utilizes alternating electrical current to create a tissue lesion through resistive heating, and conductive heating spreading away from this

Table 2 Procedural data of study and control population

	Study group ($n = 156$)	Control group ($n = 120$)	p
Mean procedure time (min)	95 ± 30	96 ± 36	0.81
Mean fluoroscopy time (min)	5 ± 6	7 ± 6	0.16
Mean ablation time (min)	26 ± 10	29 ± 13	0.1

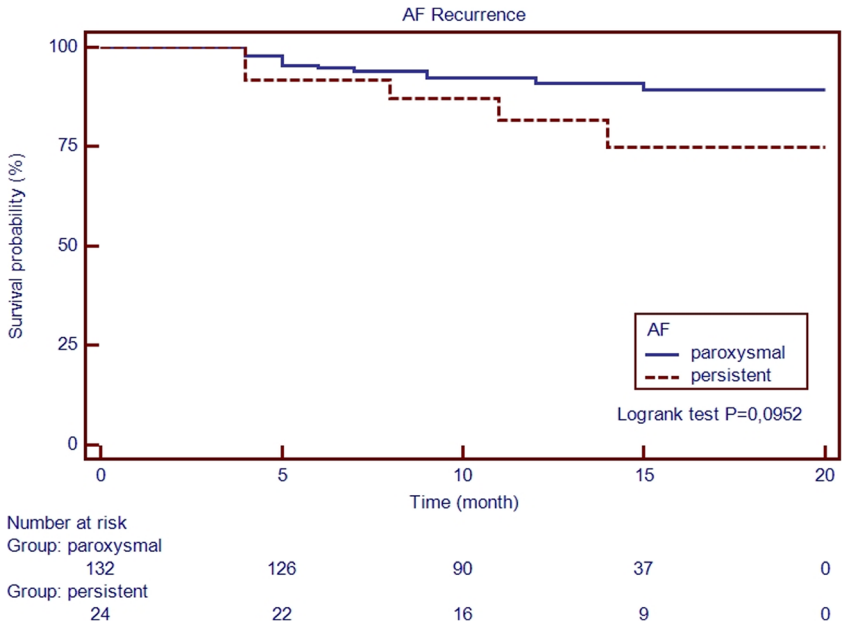

Fig. 2 Kaplan–Meier estimation of the time to atrial arrhythmia recurrence after the blanking period in patients with paroxysmal (PAROX) and persistent (PERS) patients

latter zone. One method of increasing efficacy is to produce larger volume lesions during ablation. This ensures continuity and transmurality of lesions. Several parameters affect the lesion size, as catheter-tip temperature, power output, diameter and catheter orientation, duration of ablation, and degree of contact between the catheter and the tissue. Recently, the introduction of catheters that allow the monitoring of the catheter-tissue CF has been found to be associated with a reduction in fluoroscopy, procedure, and ablation times, as well as the prevalence of PVs early reconnection and AF recurrence rates at 12 months in some studies, without increasing complications [16–21].

The CARTO VISITAG™ Module with Ablation Index is a commercially available software (Biosense Webster Diamond Bar, CA) that incorporates contact force, time, and power in a weighted formula. This nonlinear formula is weighted unequally with power receiving a higher weighting than CF and generates a value termed called the AI. In a canine model, Nakagawa et al. [6, 7] demonstrated that the AI was effective in creating RF lesions at a predicted depth and diameter.

4.2 Clinical studies

Only few studies have evaluated the AI in the clinical setting. Das et al. [8] to studied AI's and force time integral (FTI)'s relationships with PV reconnection at repeat electrophysiology study (at 2 months), and regional threshold values that predicted no reconnection in 45 patients with paroxysmal AF. They found that AI correlates with impedance drop, and the minimum AI value within a WACA segment is predictive of reconnection of that segment at repeat electrophysiology study. In a multivariable model incorporating minimum AI and minimum FTI, both remained independently predictive of WACA segment reconnection, but minimum AI had the smaller *P* value. Furthermore, higher AI and FTI values are required to prevent reconnection in anterior and roof segments of the WACA circle compared with posterior and inferior segments. From the same group, Hussein et al. [10] studied 89 consecutive drug-refractory AF patients (49% paroxysmal) who underwent AI-guided ablation (AI-group), compared to 89 propensity-matched controls who underwent CF-guided ablation (CF-group). All 178 procedures were otherwise similar, and both groups were followed-up for 12 months. In their series, AI-guided ablation was associated with significant improvements in the incidence of acute PV reconnection and atrial tachyarrhythmia recurrence rate compared to CF-guided ablation. Finally, Taghij et al. [11] evaluated the safety and the acute and 1-year outcomes of an ablation protocol aiming to enclose the PV with a contiguous and optimized RF circle by targeting region-specific criteria for lesion depth assessed by Ablation Index and interlesion distance, in 130 patients with paroxysmal AF. At 12 months, single-procedure freedom from AF/AT/AFL was 91.3% in those 104 patients off antiarrhythmic drug therapy and 96.2% in those 26 patients on antiarrhythmic drug therapy. Our study, on 156 patients, at a mean follow-up of 14 ± 6 months, confirms these data with a freedom from arrhythmia recurrences in 91% of patients with paroxysmal AF and in 78% of patients with persistent AF. However, larger, multicenter, and randomized studies are needed to assess whether the use of the AI can determine a reduction in the incidence of acute PV reconnection and long-term AF recurrences.

The AI module was an improvement of the an automated ablation lesion tagging module (VISITAG™) that already incorporates indirect parameters of lesion formation that can be indexed by the user, according to the ablation strategy. Anter

et al. [22] demonstrated that this radiofrequency ablation annotation algorithm reduced the incidence of linear gaps and reconnection after PV isolation. Zucchelli et al. [23] evaluated the clinical outcome of paroxysmal AF ablation (200 patients) with contact force technology, using the VISITAG™ module with strict criteria of catheter stability. They found that recurrence rates at the 12-month follow-up were significantly lower than in a comparison group of 80 patients without VISITAG™ module (22.5 vs 41.2%; $p = 0.02$). The 1-year success rate reported in our series and others [10, 11], using the AI, was slightly superior to this reported with the VISITAG™ module.

4.3 Safety concerns

In our study a complication was observed in less than 2% of patients, and all of them were conservatively treated without any permanent injury for the patient. A major concern is the AI value that should guide the ablation. Significantly, we used a lower AI values than those previously reported, in order to avoid long radiofrequency application above all in the posterior wall that will be required to reach higher AI values in case of poor CF. Das et al. [8] reported that no reconnection was seen where the minimum AI value was ≥ 370 for posterior/inferior segments and ≥ 480 for anterior/roof segments. In Hussein et al.'s [10] series, AI targets were increased to 550 for the anterior/roof and 400 for the posterior/inferior left atrial segments. Taghij et al. [11] used an AI ≥ 400 at the posterior wall and ≥ 550 at the anterior wall. In our population, we used an AI value of 330–350 at the posterior wall/roof and 400–450 at the anterior wall; nevertheless, we observed a clinical success in almost 90% of patients. Our clinical data support Ullah et al.'s [9] findings that ablation beyond 430 AI provides minimal additional biophysical efficacy, suggesting an upper limit to use for clinical ablation.

4.4 Limitations

Several limitations of our study have to be addressed. An obvious limitation is the lack of a control group. We consecutively used the new AI in a series of patients undergoing PV isolation. Second, the length of mean follow-up was a little more than 1 year. A conclusion on long-term success rates is therefore not yet available. Third, the AI values we used were empirically chosen. Although it was significantly lower than those reported in other studies, it allowed us a comparable clinical success. Further studies are need to assess the minimum AI value to ensure high clinical success and low complication rate. Fourth, we did not do an invasive analysis of all patients to look for reconnection. Therefore we cannot give data on the AI value and interlesion distance related to long-term PV reconnections. Finally, we did not provide data on asymptomatic cerebral ischemia and esophageal lesions were not searched for by endoscopy. Neither a standardized methodology for screening for PV stenosis was used, but a routine surveillance took place in each center according to local practice.

5 Conclusions

PV ablation guided by AI resulted feasible, achieving a high rate of isolated PVs, with a low complication rate, and allowed a high single-procedure arrhythmia-free survival at 14 months. These results were achieved with lower AI values than previously reported. Longer follow-up and larger, multicenter, and randomized studies are needed to confirm these results.

Compliance with ethical standards

Conflicts of interest The authors declare that they have no conflict of interest.

Ethical approval The study was approved by the institutional review committees, and all patients signed informed consents.

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