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Bi-directional electrical pulmonary vein isolation as an endpoint for ablation of paroxysmal atrial fibrillation

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Abstract

Objective—Various approaches to pulmonary vein (PV) isolation have shown variable efficacy in patients with paroxysmal atrial fibrillation (AF). The purpose of this study is to report the efficacy and safety of routine isolation of all PVs using an endpoint of bi-directional electrical block.

Materials and methods—This study included 85 consecutive patients who underwent PV isolation for symptomatic paroxysmal AF. Complete isolation of all PVs was confirmed by demonstration of bi-directional block: (a) loss of all PV potentials, and (b) failure to capture the left atrium by pacing 10–14 bipolar pairs of electrodes on a circumferential catheter placed at the entrance of the PV at 10 mA with 2 ms pulse width. Induction of AF by burst pacing was attempted after PV isolation.

Results—Freedom from symptomatic or asymptomatic AF (detected by event recorder or Holter monitor) was present in 85% and 76% of patients at 6 and 12 months. Additional mitral isthmus or posterior left atrial lines were performed in seven patients with inducible atrial arrhythmias after PV isolation. Atrial tachycardia occurred in three of these patients during long-term follow-up and in two of the 78 patients without additional ablation.

Conclusion—The use of bi-directional block circumferentially across all PV ostia as an electrophysiological endpoint may improve results of PV isolation for paroxysmal AF. Avoidance of routine additional left atrial ablation lines may decrease the risk of atrial tachycardia and esophageal fistula.

Keywords

Catheter ablation; Atrium; Fibrillation; Electrophysiology

1 Introduction

Electrophysiologic and anatomic ablative approaches to isolate pulmonary veins (PV) have been used to manage paroxysmal atrial fibrillation (AF). [1] An initial approach of ablating triggers within PVs [2,3] was replaced by segmental isolation of PVs demonstrating triggers. [4,5] Since repeat procedures revealed that triggers often originated from previously untargeted PVs, [4,6] segmental isolation of at least three PVs has been proposed. [7,8] An

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alternative anatomical approach is circumferential PV ablation (CPVA), [9,10] often combined with additional empiric lines in the left atrium (LA). [11,12]

There is variability in the endpoints used with the different approaches to PV isolation. The most rigorous electrophysiological endpoint is demonstration of exit block from the PV in addition to entrance block. [13,14] Although entrance block has been considered indicative of complete electrical isolation, [7] it is not equivalent to exit block, which is the goal in preventing PV triggers from initiating AF. [13] Segmental PV isolation procedures generally use entrance block as an endpoint, but bidirectional entrance and exit block is not routinely evaluated and has not been described in published studies. With anatomic CPVA, completeness of conduction block is not routinely assessed. [9,11]

The objective of this study was to determine the efficacy and safety of an electrophysiologically directed approach using segmental ablation of all PVs with entrance and exit block (i.e., bi-directional block) as an endpoint for PV isolation in patients with paroxysmal AF.

2 Materials and methods

Study population

The study cohort included 85 consecutive patients with symptomatic paroxysmal AF who underwent PV isolation by a single operator at the Beth Israel Deaconess Medical Center, Boston, MA. AF was categorized according to the ACC/AHA clinical data standards and considered paroxysmal if it terminated spontaneously within 7 days. [15] A repeat PV isolation procedure was performed in five (6%) of the patients in the study cohort at a mean of 5.4 ± 3.0 months after the initial PV isolation procedure. Prior to ablation all patients underwent echocardiography and cardiac magnetic resonance imaging (MRI) or cardiac computed tomography (CT) to assess PV size and anatomy.

All patients provided written, informed consent prior to the PV ablation procedure. This study was approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations.

Electrophysiological procedure

The procedure was performed under local anesthesia with conscious sedation for the first ten patients and under general anesthesia for the rest of the cohort. A decapolar 5 mm spaced electrode catheter (Bard Electrophysiology, Cournand curve) was positioned in the coronary sinus (CS) via a femoral venous approach. A second electrode catheter (Bard Electrophysiology Josephson curve quadripolar catheter, or a pentapolar catheter, or a decapolar catheter) was positioned in the inferior vena cava as a reference. Recordings from the right atrium (RA) were obtained from the distal four poles of the pentapolar catheter or an additional decapolar catheter placed in the right atrium. Access to the LA was obtained by performing two atrial septal punctures, and verified by recording of LA pressures. Transesophageal echocardiography (TEE) was used in 34% of patients, and intracardiac echocardiography (ICE) using an ultrasound catheter (AcuNav[®], Acuson) placed in the RA was used in 59% of patients. TEE and ICE were utilized to guide atrial septal puncture, to identify PV anatomy and velocities before and after ablation, to identify catheter position with reference to the vein ostia, to monitor for bubble formation during ablation, and to determine the presence or absence of pericardial effusion. Intravenous heparin was administered during LA mapping and ablation in order to maintain a serum activated clotting time >250 s. The activated clotting time was monitored every 30 min and heparin dose was adjusted accordingly.

The LA and PVs were mapped at baseline using an electroanatomic mapping catheter (4 mm tip in the first 45 patients and 8 mm tip in the last 40 patients, NaviStar™, Biosense Webster). A three-dimensional LA endocardial shell was created and PVs and their ostia were defined using CARTO™ (Biosense Webster) and/or EnSite NavX™ (Endocardial Solutions) systems. A deflectable 10–14 pole circumferential catheter with distal ring configuration (Biosense Webster or Bard) was placed in the ostium of each PV guided by fluoroscopy and TEE or ICE. Bipolar and unipolar electrograms from the circumferential catheter were recorded during sinus rhythm and/or CS pacing after electrical cardioversion of patients who were in AF at the start of the procedure. Radiofrequency ablation was performed outside the PV approximating the ostium near sites with the earliest PV electrograms. Ablation was performed for 20–60 s with a target temperature of 52°C. A temperature of 45°C was considered adequate if there was a 2–3 ohm drop in impedance. Ablation site locations were tagged on the three-dimensional electroanatomic maps. The process was repeated until complete electrical PV isolation was achieved and confirmed by demonstration of bi-directional block across the ablation lines, defined by both: (a) entrance block as demonstrated by loss of PV potentials on all poles of the circumferential catheter positioned at the entrance of the PV, and (b) exit block demonstrated by failure to capture the LA by pacing (at 10 mA and 2 ms pulse width) each of the 10–14 bipolar pairs of electrodes of the circumferential catheter positioned at the entrance of the PV (Fig. 1). All PVs were routinely isolated for all patients.

After PV isolation, isoproterenol (up to 20 mcg/min) was given to assess triggers and PV reconnection requiring further ablation to complete isolation. The ability to induce AF or AT was assessed by burst pacing at 200 ms for 5 s from the CS and the RA as previously described. [16] AF that was induced and did not terminate spontaneously was electrically cardioverted. The procedural endpoint was bi-directional PV isolation, and additional ablation was not performed routinely in patients that remained inducible after PV isolation, since not all patients with inducible AF have recurrences. Electrical isolation of all PV's was reconfirmed at least 30 min after ablations were completed.

Additional left atrial ablation lines (mitral isthmus line and/or posterior LA line) were performed in six patients with inducible sustained left AT and in one patient with inducible sustained AF. These lines were created using contiguous ablation lesions with the goal of achieving local bipolar voltage reduction to <0.1 mV. However, conduction block across these lines was not validated, and in the majority of cases they were incomplete as judged by absence of split potentials or presence of voltages >0.1 mV along the lesion line. Ablation within the CS was avoided, and irrigated ablation catheters were not available. There were no left atrial lines performed in patients without inducible atrial arrhythmias after PV isolation.

Right atrial isthmus ablation with demonstration of bidirectional block was performed only in patients with a history of or inducible typical isthmus dependent atrial flutter (58% of patients).

Post procedure management

All patients were monitored overnight after the procedure. Patients were treated with warfarin to achieve an international normalized ratio of 2.0–3.0 for at least 6 months, as well as acetylsalicylic acid for at least 3 months. The majority of patients also received prednisone empirically for 1 week (tapering dose starting at 50 or 60 mg) to decrease the risk of PV stenosis. Antiarrhythmic drugs were used post procedure for patients with organic heart disease, and patients with recurrences of AF.

Follow-up

Clinical follow-up included assessment of asymptomatic or symptomatic AF by 2 week event recorder (with routine daily transmissions and additional transmissions for symptoms) and either 24 h Holter monitoring or 1 week of continuous mobile outpatient cardiac telemetry (Cardionet, Inc., San Diego, CA) at 1, 3, 6, 9 and 12 months. Additional Holter monitoring or event recording was done for patients with symptoms. Information from device interrogation in patients with implanted devices was also used to detect asymptomatic AF. Recurrent AF was deemed present if any asymptomatic or symptomatic atrial tachyarrhythmia consistent with AF was documented to last >10 s. Recurrent episodes of AF were classified as early if they occurred within 30 days post procedure and late if they occurred greater than 30 days post procedure. Freedom from symptomatic or asymptomatic AF on long-term follow-up was defined as no detected episode of AF greater than 30 days post procedure because >50% of patients with early recurrences may become free of late recurrences of AF. [17] Improvement in AF was defined as patient reported marked reduction in the frequency of symptomatic episodes of AF. Repeat MRI or CT scan was performed 1–3 months post procedure to assess for PV stenosis. TEE was also performed to assess PV velocities at the same time as the MRI or CT. The mean duration of follow-up was 15.8 ± 11.4 months.

Statistical analysis

Continuous variables are expressed as mean $\pm$ standard deviation (SD). Kaplan-Meier analysis was used to determine cumulative AF-free survival. Predictors of freedom from AF recurrence were evaluated using the log-rank test as well as multivariable Cox regression. A $p < 0.05$ was considered statistically significant. All statistical analyses were performed using SAS Release 8.2 statistical software package (SAS Institute Inc., Cary, NC, USA).

3 Results

Patient characteristics

Patients were 53 ± 12 years of age and 66% were males. Among these patients, 45% had hypertension, 11% had valvular heart disease (VHD, defined as at least moderate regurgitation or stenosis), 46% had at least mild mitral regurgitation, 12% had left ventricular hypertrophy (LVH), and 5% had cardiomyopathy (LVEF < 0.40). Overall, 24% had structural heart disease (VHD, LVH, or cardiomyopathy). The mean left ventricular ejection fraction was 0.56 ± 0.08 (range, 0.20–0.60) and the mean LA diameter measured in the parasternal long axis was 4.1 ± 0.7 cm (Table 1). A mean of 1.3 ± 1.1 antiarrhythmic drugs had been ineffective at maintaining sinus rhythm before the PV ablation procedure.

Procedural results

Successful isolation of all pulmonary veins with demonstration of bidirectional block was achieved in 99% of patients. One patient had only three of four pulmonary veins isolated due to premature termination of the procedure (see complications section). LA ablation lines were performed in 7 of the 31 patients with inducible left atrial arrhythmias after PV isolation and in none of the 54 patients without inducible AF or AT. A mitral isthmus line was performed in six patients (with an additional posterior wall line in two patients) in whom inducible left AT was sustained and attributed to macro-reentry. An empiric mitral isthmus line was performed in only one patient with inducible sustained AF.

Medication use post procedure

Antiarrhythmic drugs were used post procedure in 31 (36%) patients (amiodarone in nine, dofetilide in six, sotalol in one, flecainide in seven, dysopyramide in four, propafenone in

two, and quinidine in two patients). Anti-arrhythmic drugs were started during follow-up for recurrent AF in an additional 12% of patients. Patients with recurrent AF greater than 30 days post procedure were not considered free of AF even if they later responded to a change in antiarrhythmic therapy. Antiarrhythmic drugs were discontinued during follow-up in 26% of the entire cohort of patients. Among patients who remained free of asymptomatic or symptomatic AF, 83% were not taking any antiarrhythmic medication at last follow-up.

Other medications used post procedure included beta blockers (75%), calcium channel blockers (20%), digoxin (1%), angiotensin converting enzyme inhibitors (20%), angiotensin receptor blockers (8%), and statins (26%). There was no association between the use of these medications or antiarrhythmic drugs and freedom from AF recurrence.

Early recurrences of AF

Early recurrences of AF (30 days post PV isolation) occurred in 30 patients (35%). Among patients with early recurrences of AF, 12 (40%) remained otherwise free of AF at 12 months of follow-up. Patients without early recurrence of AF were more likely to remain free of AF (83% vs. 60% at 12 months, $p=0.002$).

Freedom from AF

Freedom from asymptomatic or symptomatic AF was present in 85% of patients at 6 months and 76% of patients at 12 months. Improvement in AF (patient-reported reduction in the frequency of symptomatic episodes) was present in 96% and 92% of patients at 6 and 12 months. There were no clinical variables that significantly predicted freedom from AF. There was no difference in freedom from AF among patients with and without additional LA ablation. During follow-up, clinical AT occurred in three of the seven patients with additional LA ablation lines and in 2 of the 78 patients who had only PV isolation.

Repeat procedures

In 5 of the 85 patients (6%), repeat PV isolation for recurrent symptomatic AF was performed 5.4 ± 3.0 months after an initial PV isolation procedure. All five patients had evidence of gaps with incomplete PV isolation, and all PVs were re-isolated. In addition, one patient had macro-reentrant LA flutter treated with a posterior LA line and another patient had a focal LA tachycardia ablated in the posterolateral LA. All patients remained free of recurrent AF 15.0 ± 9.4 months after repeat PV isolation.

Complications

Significant procedural complications occurred in 4 of the 85 patients (5%) who underwent PV isolation. A transient cerebrovascular accident with no persistent residual deficits occurred in one patient 5 h after ablation. Mitral valve entrapment of the circumferential catheter occurred in one patient with preexisting mitral valve prolapse and partially flail posterior mitral leaflet, and the catheter was successfully removed surgically without damage to the mitral valve. Bleeding complicating femoral venous access that required blood transfusion occurred in two patients. None of these procedures were complicated by cardiac tamponade, PV stenosis (defined as >70% reduction in diameter), atrio-esophageal fistula, or death.

4 Discussion

Main findings

Bi-directional electrical PV isolation for patients with symptomatic paroxysmal AF resulted in 85% and 76% freedom from symptomatic or asymptotically detected AF at 6 and 12

months, respectively. Repeat procedures for recurrent AF performed in 6% of patients revealed PV reconnection that was successfully treated with PV re-isolation.

Electrophysiological endpoints for PV isolation

While the rationale for segmental PV isolation is the prevention of PV triggers from initiating AF, most reports have considered PV entrance block indicative of complete electrical isolation. [7] Verification of exit block is uncommonly used as an endpoint despite evidence that after achieving entrance block, less than 60% of PVs demonstrate exit block. [13] The fact that tachycardias can be induced in isolated PV segments [18,19] highlights the importance of achieving PV exit block. Most recurrent AF and AT post PV isolation have been associated with recovery of PV conduction, and are treatable by repeat PV isolation without linear ablation. [20–23] Prior studies of segmental PV isolation for paroxysmal AF have reported rates of repeat procedures from 18% [11] to >50%. [4] In the current study using bidirectional electrical isolation as the endpoint, results superior to those previously reported were achieved with a lower rate of repeat procedures (6%).

Extent of lesions required for clinical success

Currently, most AF ablation procedures include segmental ostial ablation or anatomically guided CPVA. Many procedures include routine mitral isthmus and posterior LA lines to decrease risk of macro-reentrant AT more commonly associated with CPVA. [11,12,24,25] However, the routine use of these additional lines has been complicated by persistent left atrial flutter in 19% of patients. [26] Additional lesions in the posterior LA have also been associated with potentially fatal atrio-esophageal fistulas. [27,28] While one randomized study found CPVA with routine LA lines superior to segmental ablation, [11] another randomized study found CPVA with routine mitral isthmus lines inferior to PV isolation. [29] Although extensive ablation may be necessary in some patients, our study suggests that favorable results may be obtained without the empiric use of LA lines in all patients. Research efforts should focus on determining which patients are most likely to achieve long-term success with PV isolation alone, and which may benefit from additional ablation.

Study limitations

This is a prospective observational study of the efficacy and safety of bi-directional PV isolation for patients with paroxysmal AF, and may not apply to patients with persistent or permanent AF. There was no comparison of this approach with other approaches to AF ablation. The use of additional LA ablation in patients with inducible atrial arrhythmias post PV isolation was not randomized, and conduction block across these lines was not demonstrated. While an attempt was made to identify symptomatic as well as asymptomatic recurrences of AF using routine event recorders and Holter monitors, some asymptomatic recurrences may not have been detected. However, most prior studies have reported only symptomatic recurrences, and the use of event recorders has been shown to detect asymptomatic recurrences in a significant number of patients otherwise free of symptomatic AF. [30]

Conclusion

This study suggests that favorable results can be achieved in patients with paroxysmal AF treated with segmental PV isolation using bi-directional block circumferentially across all PV ostia as an electrophysiological endpoint. Avoidance of routine empiric LA lines may decrease the risk of complications such as AT and esophageal fistula. Randomized studies in patients with paroxysmal AF are necessary to compare bi-directional electrical PV isolation to CPVA with empiric LA lines in terms of success rates and complications.

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Fig. 1. Bi-directional pulmonary vein block. The figure arranged from top to bottom includes ECG leads I, II, III, and V₁; electrograms from the ten poles of a circumferential catheter (Las) placed within the ostial of a pulmonary vein (PV); electro-grams from the high right atrium (HRA); as well as proximal (p or 5) to distal (d) coronary sinus (CS) electrograms. Panel A demonstrates PV entrance block. There is loss of all PV electro-grams (in the fourth complex) while pacing from the proximal CS during ablation. Panel B illustrates PV exit block. There is loss of conduction from the PV to the atrium (in the third paced complex) despite persistent local PV capture while pacing (at 10 mA) from the circumferential catheter during ablation. Failure to conduct to the atrium while pacing sequentially from every pole of the circumferential catheter is indicative of PV exit block

Table 1

Patient characteristics

	All patients (n=85)
Age (years)	53±12
Male gender	56 (66%)
No. of failed AADs	1.3±1.1
Cardiomyopathy	4 (5%)
Valvular heart disease ^a	9 (11%)
Hypertension	38 (45%)
Left ventricular hypertrophy	10 (12%)
LVEF	0.56±0.08
LA diameter (cm) ^b	4.1±0.7
Obstructive sleep apnea	13 (15%)
Diabetes	9 (11%)
Prior typical flutter ablation	12 (14%)

AAD indicates anti-arrhythmic drug; LA, left atrium; LVEF, left ventricular ejection fraction.

^a Moderate or severe valve regurgitation or stenosis;

^b measured by echocardiogram in parasternal long axis.