Vein Sensing Technique for Hospital System Application

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Abstract – In order to exploit operationally vein sensing data for hospital applications efficient and automated methods are required towards the accurate detection of pulmonary vein isolation for atrial fibrillation. We hypothesized that pulmonary vein (PV) orientation effects tissue contact of the contact force (CF) sensing radiofrequency ablation catheter (CFC) and thus atrial fibrillation (AF) free survival after pulmonary vein isolation (PVI). The goal of this study was to regulate the association between PV orientations, sixty consecutive patients undergoing CFC PVI was included. ECG-triggered cardiac CT scans were found in all patients before PVI, and the PV orientation was measured at the insertion in the LA for all PVs in both the crosswise and forward plane. CF and AF free survival in patients undergoing CFC PVI. PVs were given to 1 of 4 location groups: ventral–caudal, dorsal–caudal, ventral–cranial and dorsal cranial.

Index Terms – Atrial fibrillation, Pulmonary vein isolation Radiofrequency catheter ablation, Contact force sensing catheter system, Pulmonary vein orientation (key words)

1. INTRODUCTION

Pulmonary vein isolation (PVI) is measured the cornerstone in the ablative treatment of atrial fibrillation (AF) [1,2]. Many methods have been developed to perform PVI [3–5]. Currently, the most widely used technique is point-by-point radiofrequency (RF) ablation directed by a 3D electro-anatomical mapping system. Earlier reports attempting to identify geometrical features of pulmonary veins (PVs) that effect AF free survival in patients undergoing point-by-point PVI yielded disagreeing results [6,7]. A new study showed that PV alignment is associated with AF free survival later laser balloon PVI [8]. We hypothesized that PV alignment influences optimal contact between the ablation catheter and atrial tissue, causing in less durable lesion sets. The purpose of this study was to regulate whether PV orientation effects interaction force and AF free survival after PVI with an interaction force sensing catheter ablation system (CFC).

2. METHODS

Sixty serial patients with very symptomatic, drug-refractory AF who underwent a primo PVI using CFC were included. Exclusion conditions were: former PVI attempt, severe valvular heart disease and contraindications to post-procedural anti-coagulation. A transesopha-geal echocardiogram to law out LA thrombus was performed in all patients directly prior to the PVI.

2.1. CT characteristics

All patients experienced CT scanning of the left atrium to guide the procedure. Cardiac multislice CT (MSCT) angiography was completed by a team of very experienced CT technologists using a 64-slice scanner (Lightspeed VCT XT, GE Healthcare). A bolus of 70 ml of nonionic divergence average of agent (Optiray 350, Mallinckrodt, The Netherlands) was infused through a great antecubital vein at a rate of 5 ml/s, followed by 50-ml saline solution flush. Automatic detection of the difference bolus in the left atrium was used to time the start of the scan. Delay times varied significantly because of flow rate variances in patients, but were normally in the range of 5–15 s. Craniocaudal scanning was performed through breath-hold and using reflective ECG gating (to be able to determine volume changes of the LA, but not used in this study). The collimation was 64×0.5 mm, turning time 400 ms, and the tube voltage was 120 kV with mA dose modulation adjustable between 80 and 200 mA. All images were checked for adequacy before the end of the procedure to assurance adequate image quality in all patients. After acquisition, the raw MSCT data were exported, post-processed, and considered on a dedicated workstation (GE Healthcare). The images were reviewed by an independent investigator who was not complicated in the CFC guided PVI ablation procedures and was not informed about the PVI outcome in these patients.

2.2. Pulmonary vein orientation measurement

The PV trunk location measurement has been designated before ([9,10], Association between pulmonary vein orientation and atrial fibrillation free existence in patients undergoing endoscopic laser balloon ablation [8]).

The orientation of the PV trunk at the site of supplement into the LA was assessed for all PVs in both the transverse and frontal plane. A streak was drawn in the direction of each PV trunk in both the transverse and frontal plane. Thereafter, the position among the PV trunk direction and the intersection line of the sagittal plane was measured in the trans-verse and frontal plane (Fig. 1). Median PV trunk directions were calculated in the transverse and frontal plane for all four PV trunks. PVs were allocated to a ventral/dorsal or caudal/cranial orientation depending on the PV trunk angle as compared to the median angle. So, each PV trunk was allocated to one of four orientation groups: ventral–caudal, dorsal–caudal, ventral–cranial and dorsal–cranial.

2.3. Electrophysiological procedure

All patients experienced CFC guided PVI under general anesthesia supervised by a cardiovascular anesthesiologist. First, a 6F quadripolar feed was placed in the coronary sinus to obtain a procedural intra-cardiac electrogram. Two transseptal punctures were done using a Brockenbrough needle under fluoroscopy and pressure guidance. 10,000 IU of unfractionated heparin was managed after the first transseptal puncture. A circular mapping catheter (LASSO®, Biosense Webster Inc., Diamond Bar, CA, USA) was introduced into the LA over an 8.5F sheath (SL-1, St. Jude Medical, Minnetonka, MN, USA) and an 8.5F sheath (SL-1, St. Jude Medical, Minnetonka, MN, USA) stayed used for PV angiography. Both sheaths were flushed always with a saline answer containing 2500 UI heparin per 500 ml saline. The targeted activated clotting time was between 300 and 350 s and addi-tional heparin was administered when necessary. The activated clotting time was evaluated every 30 min. The CFC catheter was injected in the LA through an 8.5F sheath and the CFC sensor in the tip electrode was cal-ibrated after positioning the catheter tip in a free floating position in the LA cavity.

2.4. Contact force sensing radiofrequency ablation

The CFC (Biosense Webster Inc., Diamond Bar, CA, USA) [3,11] is an externally irrigated catheter with a 3.5 mm tip electrode. The tip electrode is armed with a contact force sensor which measures both contact pressure and vector of tip deflection. The cathe-ter system is fully integrated within the 3D electro-anatomical mapping system (CARTO 3™, Biosense Webster Inc., and Diamond Bar, CA, USA). PVI was performed by delivering RF energy in a point-by-point style to the PV antrum making contiguous circular ablation lesions. RF energy was applied in a temperature-control method with a temperature setting of 43 °C. RF energy was applied at 30 W with a flow rate of 15 ml/min or at 40 W by a flow rate of 30 ml/min, dependent on site of ablation. The endpoint of the ablation procedure was PV isolation, as recognized by entrance and exit block or dissociation of PV potentials.

Fig. 1. Example of right upper pulmonary vein orientation quantity in the transverse and frontal planes. This figure displays the PV orientation amount in the transverse and frontal plane of the RUPV. In panels A and B, the allocation of the RUPV in this patient in the transverse plane is showed. The angle between the PV direction and the sagittal plane ref erence is 98°, as is displayed in panel A. The median RUPV direction in the transverse plane is 103° as can be appreciated from table 2, classifying this RUPV to the dorsal RUPV orientation group. In panels C and D, the allocation of the RUPV of this patient in the frontal plane is showed. The angle between the PV direction and the sagittal plane reference is 62°, as is presented in panel C. The median RUPV direction in the frontal plane is 77°, as can be appreciated from table 2, classifying this RUPV to the caudal RUPV orientation group. Combining the frontal and transverse plane, the RUPV of this patient is considered to the dorsal–caudal RUPV orientation group. PV: pulmonary vein; RUPV: right upper pulmonary vein.

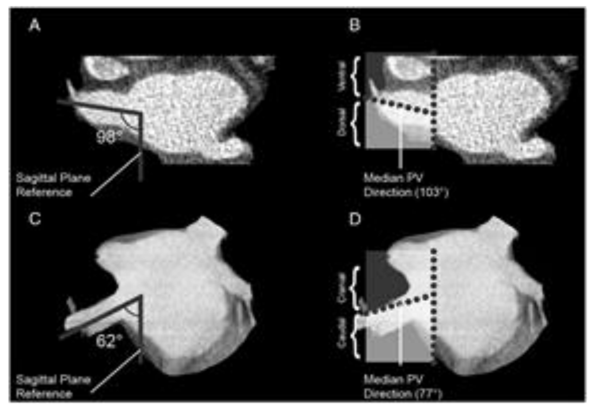

Figure 1

Table 1

Baseline characteristics

	Total (n = 60)
Gender female (%)	23%
Age (years)	59.3 (±9.1)
BMI (kg/m^2)	26.9 (±3.5)
AF duration (years)	5.1 (±5.4)
Paroxysmal AF	88%
Failed AADs (range)	1.1 (0–3)
LA dimension in PSLAX (mm)	42.2 (±5.3)
LVEF (%)	58.9 (±3.8)
Hypertension	38%
Previous TIA/stroke	12%
Coronary artery disease	0%
Diabetes	2%

Data are presented as percentages or means their SD or ranges where appro-priate; BMI: body mass index; AF: atrial fibrillation; AAD: anti-arrhythmic drugs; LA: left atrium; PSLAX: parasternal long axis view; LVEF: left ventricular ejection fraction. P-values: comparison between AF free and AF recurrence groups.

2.5. Follow-up

A blanking period of 3 months was defined after PVI. Patients visited the outpatient clinic at 3, 6, 12, 18 and 24 months after PVI, including Holter ECG, event recorder monitoring and loop recorder monitoring in selected cases. Patients were immediately referred to the emergency room in case of symptoms. 3 months after PVI, an attempt was made in all patients to cease anti-arrhythmic drugs (AADs).

2.6. Study endpoints

The primary endpoint of our study was AF free survival, defined as patients without AF/atrial flutter/atrial tachycardia recurrence after a blanking period of 3 months. AF recurrence was defined as an ECG showing the characteristics of AF, or on a 30 s telemetry strip, in accor-dance with European Heart Rhythm Association AF ablation guidelines [1]. Ablation points with a contact force b10 g were assessed separately, based on a study that showed adequate lesions are applied with a mean contact force N10 g [12].

2.7. Statistical analysis

Continuous variables were expressed as mean with standard devia-tion in case of normal distribution or median with interquartile range when variables were not normally distributed. Differences in mean contact force among PV orientation configurations was assessed with a Kruskal–Wallis test in case of continuous data and a Chi-square test in case of categorical data. A univariate and multivariate Cox proportional hazard model was used to govern predictors of AF free survival. Statistical analysis was performed using IBM SPSS statistics version 20 (IBM inc., Armonk, NY, USA). A p-value of ≤0.05 was consid-ered statistically significant.

3. RESULTS

Our study population consisted of sixty consecutive patients. Baseline characteristics are displayed in Table 1. There were 6 common PVs (2.6%), which were excluded from analysis. No LA thrombi were found during preoperative transesophageal echocardiography or CT scans. Table 2 describes the characteristics of the PV orientation in all patients.

3.1. Pulmonary vein isolation results

In 234 out of 234 PVs (100%), acute PV isolation after CFC ablation was confirmed. After a median follow up of 12.3 (interquartile range: 8.3–16.1) months, AF free survival was 57.6% after a single CFC PVI without the use of class I or III AADs.

3.2. Contact force data

Mean contact force was 15.0 g ± 10.9 for the left upper PV (LUPV), 13.5 g ± 9.7 for the left lower PV (LLPV), 17.9 g ± 10.0 for the right upper PV (RUPV) and 15.6 g ± 9.8 for the right lower PV (RLPV). PV ori-entation was not associated with contact force for the LUPV (p = 0.236), LLPV (p = 0.491), RUPV (p = 0.143) and RLPV (p = 0.718), as is displayed in the supplemental Table 1. Furthermore, no association was found between PV orientation and the number of lesions with a mean contact force b10 g, as displayed in supplemental Table 2.

3.3. Association with AF free survival

In univariate analysis, none of the baseline characteristics were associated with AF free survival. Moreover, PV orientation was also not associated with AF free survival, as is also displayed in Fig. 2. Table 3 displays the univariate analysis. Of note, mean contact force was not associated with AF free survival, but the number of ablation points with a mean contact force b10 g was significantly associated with AF free survival. However, in multivariate analysis, only AF duration was associated with AF free survival.

Data are presented as absolute median or percentages, ± their SD where appropriate

Pulmonary vein	Median angle	Ventral–caudal	Dorsal–caudal	Ventral–cranial	Dorsal–cranial
Left upper	Transverse: 97.1° (±32.0) Frontal: 139.0° (±19.7)	28%	24%	22%	26%
Left lower	Transverse: 62.1° (±17.6) Frontal: 86.4° (±19.4)	26%	26%	24%	24%
Right upper	Transverse: 103.0° (±14.9) Frontal: 121.8° (±11.4)	28%	23%	22%	27%
Right lower	Transverse: 55.5° (±16.2) Frontal: 77.1° (±14.8)	20%	32%	30%	18%

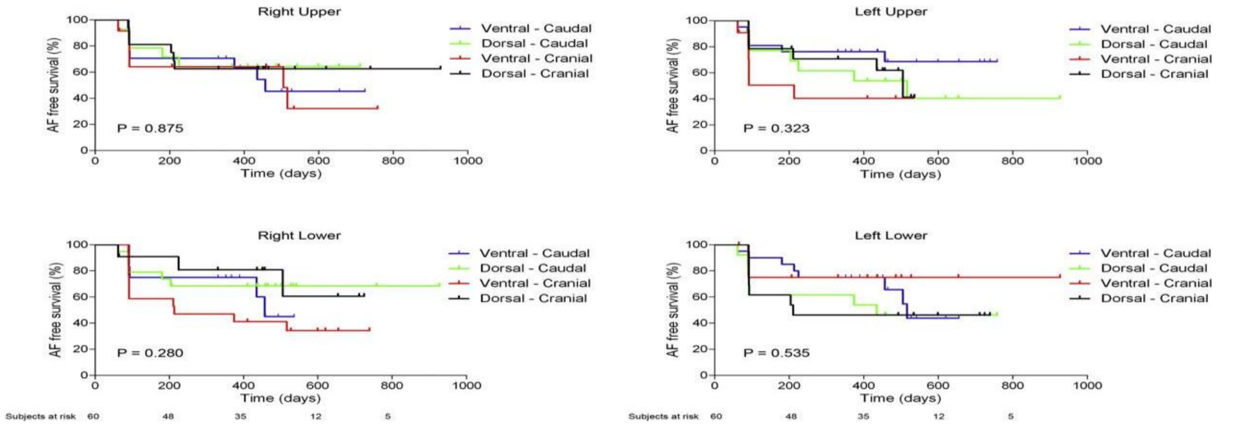

Fig. 2. Association of pulmonary vein orientation and atrial fibrillation free survival. This figure displays the association between PV orientation and AF free survival for all four PVs. There is no significant association between PV orientation and AF free survival. P-value between pulmonary vein orientation groups. AF: atrial fibrillation; PV: pulmonary vein.

4. DISCUSSION

This study displays that in patients undergoing PVI with the CFC ablation system, PV orientation does not disturb contact force and is not associated with AF free survival. These results suggest that durable PV lesion sets can be delivered independent of PV alignment with the CFC ablation system. PV orientation assessment does not appear to be necessary in patients undergoing CFC PVI.

4.1. Pulmonary vein anatomy and atrial fibrillation free survival

In a study of 100 patients who experienced RF catheter ablation, a smaller LA size and an atypical right-sided PV anatomy were related with an increased AF free survival after PVI [7]. In another study of 118 patients who underwent RF catheter ablation, the nonappearance of common PV trunks was associated with an increased AF free survival [13]. How-ever, none of these studies assessed the association amongst PV.

Table 3 Univariate and multivariate analysis of AF free survival.

Univariate analysis	p-value	Hazard ratio	95% CI	Multivariate analysis	p-value	Hazard ratio	95% CI
Female gender	0.882	1.072	0.428–2.687	Ablation points with mean contact force b10 g	0.333	1.017	0.983–1.053
Age	0.560	0.988	0.947–1.030	AF duration (per year)	0.017	1.128	1.021–1.246
BMI	0.605	1.031	0.918–1.158				
Paroxysmal AF	0.115	0.452	0.169–1.212				
AF duration (per year)	0.062	1.053	0.997–1.112				
Failed AADs	0.907	1.032	0.607–1.755				
LA dimension	0.468	1.028	0.954–1.107				
LVEF	0.645	1.028	0.913–1.159				
Hypertension	0.976	0.988	0.440–2.216				

Mean contact force	0.305	0.890	0.711–1.112
Ablation points with mean contact force b10 g	0.042	1.036	1.001–1.072
LUPV orientation	0.547		
Ventral–caudal[a]	0.643	0.755	0.230–2.481
Dorsal–caudal[a]	0.712	1.229	0.412–3.665
Ventral–cranial[a]	0.326	1.765	0.568–5.488
LLPV orientation	0.641		
Ventral–caudal[a]	0.819	0.884	0.308–2.536
Dorsal–caudal[a]	0.800	1.146	0.399–3.287
Ventral–cranial[a]	0.285	0.478	0.123–1.852
RUPV orientation	0.876		
Ventral–caudal[a]	0.671	1.258	0.436–3.628
Dorsal–caudal[a]	0.928	0.947	0.289–3.103
Ventral–cranial[a]	0.521	1.450	0.467–4.505
RLPV orientation	0.299		
Ventral–caudal[a]	0.536	1.574	0.374–6.618
Dorsal–caudal[a]	0.793	1.204	0.301–4.820
Ventral–cranial[a]	0.137	2.644	0.735–9.513

Univariate and multivariate analysis of the association between patient, procedural and PV characteristics and AF free survival after CFC PVI. BMI: body mass index; AF: atrial fibrillation; AAD: anti-arrhythmic drugs; LA: left atrium; PSLAX: parasternal long axis view; LVEF: left ventricular ejection fraction. LUPV: left upper pulmonary vein; LLPV: left lower pulmonary vein; RUPV: right upper pulmonary vein; RLPV: right lower pulmonary vein. CFC: contact force sensing catheter ablation system. P-values between AF free and AF recurrence groups.

4.2. Contact force sensing catheter system characteristics

The CFC permits contact force guided RF ablation of AF. Previous studies found an association between pressure–time curves logged with the CFC and AF free existence, indicating that contact force sensing may assist in the application of durable lesion sets [14,15]. The present study is in line with these results, showing that the number of lesions with a contact force b10 g was associated with a diminished AF free survival. Hypothetically, pressure-guided ablation should let the operator to identify inadequate lesions and apply additional ablations when deemed necessary.

4.3. Pulmonary vein orientation and AF free survival

AF reappearances are generally regarded as reconnection between the PV and the LA allowing electrical reconduction [16,17]. Consequently the durability of the practical circumferential lesions are essential in preventing AF recurrences. Hypothetically, the influence of PV orienta-tion may be negated by allowing the operator to identify inadequate catheter-tissue contact due to PV location, and increase catheter– tissue contact accordingly, resulting in durable lesion sets.

4.4. Limitations

With respect to interpreting our data, the succeeding limitations should be considered. This is a single center study with a limited number of patients. The patient cohort was limited to those having no or minimal structural heart disease and a normal left ventricular function.

5. CONCLUSION

This study showed that in patients undergoing PVI with the CFC ablation system, PV orientation does not affect contact force and is not linked with AF free persistence. PV orientation assessment does not appear to be necessary in patients undergoing CFC PVI.

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