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Operator-blinded contact force monitoring during pulmonary vein isolation using conventional and steerable sheaths ☆

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ABSTRACT

Background: We performed contact force (CF) monitoring during pulmonary vein (PV) isolation to evaluate CF according to sheath type, catheter position, and inadequate ablation.
Methods: Thirty consecutive patients (paroxysmal atrial fibrillation, 23; $CHADS_2$ score, 0.5 ± 0.7; age, 56 ± 10 years) who underwent PV isolation using a CF-sensing catheter were included. Data for operator-blinded CF, impedance, and duration of the "first touch" (first round of ablation in each PV) was collected. We compared the CF, maximum CF, force–time integral, average impedance, and impedance drop (Δ impedance) between different sheaths (Swartz™ vs. Agilis™) in 12 different catheter positions, and in inadequate first touches requiring additional ablation.
Results: A total of 1283 ablation points (Swartz™, 620 points; Agilis™, 663 points) were evaluated. The average CF was significantly higher in the Agilis™ group (17.8 ± 13.0 g) than the Swartz™ group (15.0 ± 12.4 g; $P < 0.001$), especially in the anterior, inferior-anterior, and inferior-posterior sections of the right PV, and the top of the roof, and calina of the left PV. The Δ impedance showed a mildly significant negative relationship with the average CF ($r = -0.206$; $P < 0.001$) and with the force–time integral ($r = -0.279$; $P < 0.001$). Compared to first touches, the average CF and Δ impedance were significantly smaller in inadequate first touches in the Swartz™ group, but not in the Agilis™ group.
Conclusions: CF for PV isolation was significantly different depending on the position of the catheter and the type of sheath.

1. Introduction

Contact force (CF) is definitely one of the critical factors for effective radiofrequency (RF) catheter ablation, since the mechanism of its action is determined by the local generation of heat. For obtaining a larger lesion size, a greater CF is regarded to be more important than a higher power [1]. At least 20 g of CF is not only required for achieving transmural lesions in a cavo-tricuspid isthmus ablation in a swine model [2], but the constancy of CF is also important for producing the largest lesions despite identical peak CFs [3]. Safety-wise, CF also has an important impact on the incidence of cardiac tamponade, since higher CF associated with steam pops [4] and mechanical perforation [5]. In the porcine heart, the minimum CF resulting in perforation of the atrium is only 77 g which is reduced by 23% at ablated lesions [6]. Indeed, a multicenter study showed that high transient CFs >100 g were noted in 79% of cases and 3% of those resulted in cardiac tamponade [7].

Thus, measuring CF provides additional useful information for both the safety of the patient and the procedure itself, because insufficient CF might result in an ineffective lesion, whereas excessive CF might result in complications. Knowing the characteristics of CF allows a more effective and safer atrial fibrillation (AF) ablation. Previously, the EFFICAS I multicenter study showed that minimum CF was a strong predictor of gap formation; however, the characteristics of CF using different types of sheaths were not clarified [21]. Therefore, in this operator-blinded study, we measured the CF during initial catheter ablation for AF and compared a conventional sheath with a steerable sheath in order to elucidate the characteristics of CF delivery depending on catheter positions and the use of sheaths.

2. Methods

This study was approved by our Institutional Review Board based on the ethical guidelines of the Declaration of Helsinki. All patients provided written informed consent to participate.

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2.1. Study population

A total of 30 consecutive patients with AF (paroxysmal AF, 23; persistent AF, 7; $CHADS_2$ score, 0.5 ± 0.7; age, 56 ± 10 years) who received an initial catheter ablation were included in the study. The indication for catheter ablation was decided according to the Japanese guidelines [8]. Trans-thoracic echocardiography and multi-detector computed tomography were performed to reveal the anatomy of the pulmonary veins (PVs) and the left atrium (LA) before catheter ablation. Trans-esophageal echocardiography was performed to rule out preexisting thrombi in the LA within 2 days prior to ablation. Oral anticoagulation therapy was administered to all patients for more than 1 month. Warfarin ($n = 12$) was switched to intravenous heparin administration which was terminated 4 hours prior to ablation. Dabigatran ($n = 10$) and rivaroxaban ($n = 8$) were discontinued 24 hours prior to ablation.

2.2. Ablation procedure

Patients were sedated with a continuous intravenous infusion of propofol (20–40 mL/h) and monitored with a bispectral index monitor (Aspect Medical Systems, Newton, MA) maintained at 30–60. An adaptive servo-ventilator (Teijin Pharma Ltd., Tokyo, Japan) was used to stabilize respiratory movement regardless of the presence of sleep apnea. An 8-polar electrode catheter was introduced into the right ventricle from the left femoral vein of which proximal electrodes could cover the His bundle region (Inquiry™ L1/XL1, St. Jude Medical, St. Paul, MN; or Suprime™, Nihon Kohden Corporation, Tokyo, Japan). A 14-polar electrode catheter was introduced into the coronary sinus from the right jugular vein of which proximal electrodes could cover the right atrial free wall and superior vena cava region (Inquiry™ SC1, St. Jude Medical). Both Swartz™ left 0 and 1 sheaths (St. Jude Medical) were introduced from the right femoral vein for catheter manipulation in the LA. An esophageal thermometer was placed in the esophagus (SensiTherm™, St. Jude Medical) with a cut-off of 38 °C. After the delayed phase of the right atriography revealed the LA anatomy, a double transseptal puncture was performed. Both Swartz™ sheaths were placed in the LA after the administration of 100 U/kg of intravenous heparin. In the steerable sheath group, the Swartz™ left 0 introducer, an 8 French standard sheath, was replaced by an Agilis™ sheath (St. Jude Medical), an 8.5 French bidirectional steerable sheath. The activated clotting time was measured every 20–30 minutes throughout the ablation procedure and was maintained at over 300 s. A circular mapping catheter (Inquiry™ Afocus™, St. Jude Medical) and a 3.5-mm saline-irrigated and CF sensing catheter (Navi-Star THERMOCOOL® SMARTTOUCH™, Biosense Webster, Diamond Bar, CA) were introduced. Ipsilateral superior and inferior pulmonary venographies were obtained simultaneously from both sides of the PVs. Radiofrequency (RF) energy was delivered continuously, encircling the ipsilateral superior and inferior PVs circumferentially under the guidance of the CARTO®3 system (Biosense Webster) with the 3-dimensionally reconstructed LA geometry obtained from the multi-detector computed tomography images. The RF power was cut off at 43 °C and delivered with 30–35 W at the anterior wall with a saline irrigation rate of 17 or 30 mL/min and with 20–25 W at the posterior wall with 17 mL/min saline irrigation. The catheter was maintained at the same position for the first 30 s, followed by dragging the catheter with a maximum duration of 60 s, unless ablation was terminated due to insufficient catheter stability or the temperature cut-off of the catheter or the esophagus was activated. CF cut-off was set to 70 g as a safety measure, with an alarm notifying the operator. PV isolation was confirmed by the elimination of PV potentials recorded by the circular mapping catheters without dormant conduction under a rapid infusion of 20 mg of adenosine triphosphate. A conduction block from the PVs to the LA was also confirmed by applying 25 mA output pacing from the PVs. The PV conduction block including the loss of dormant conduction was evaluated 30 min after the first completion of PV isolation, and additional ablation was performed in cases of relapses. Ablation was performed by 2 skilled physicians in our facility and both physicians were blinded to the CF during the procedure.

2.3. Data analysis

All data for CF, impedance, and duration of ablation was collected from the CARTO®3 system. Typical examples of contact force during pulmonary vein (PV) isolation by the use of Swartz™ sheath and Agilis™ sheath are shown (Fig. 1). The positions in the circumferential line around the RPV were named in clockwise fashion by dividing the RPV into 12 equal sections in the right lateral view (Fig. 2 a). The circumferential line around the LPV was named in the same manner in the left posterior-cranial view, but taking into account the following anatomical characteristics: 1, top of the roof; 2, posterior roof; 3, upper posterior; 4, mid posterior; 5, lower posterior; 6, bottom of the left inferior PV; 7, lower part of the left inferior PV; 8, upper part of the left inferior PV; 9, calina; 10, lower part of the left superior PV; 11, upper part of the left superior PV; and 12, anterior roof (Fig. 2 b). The roof was defined as the convexly curved portion of the upper LPV which was separated as anterior, top, and posterior. The posterior LPV was defined as the curved portion of the posterior wall to the bottom of the left inferior PV, which was divided into 3 sections — upper, mid, and lower. The force time integral (FTI) was calculated as the average contact force multiplied by the ablation duration in each point. A "first touch" was defined as the first round of ablation in each circumferential PV isolation line, which excluded the ablation points for covering gaps and dormant conductions, and was analyzed according to the positional information and type of sheath. An "inadequate first touch" was defined as either requiring 1) gap ablation in the first round or 2) additional ablation for spontaneous relapses or dormant conductions 30 min after the first isolation. The isolation time was defined as the time from the first ablation to the last ablation which ensured PV isolation, including ablation for gaps and dormant conductions.

Patient data of age, $CHADS_2$ score, CHA_2DS_2-VASc score, body mass index, number of antiarrhythmic drugs prior to ablation, serum creatinine level, serum HbA1c level, serum brain natriuretic peptide level, left ventricular ejection fraction and LA size measured using transthoracic echocardiography, spontaneous echo contrast and flow velocity of the left atrial appendage ostium measured using trans-esophageal echocardiography were also analyzed.

2.4. Statistical methods

Parametric data were expressed as the means ± standard deviation. The Mann–Whitney *U* test was utilized to compare parameters among groups. The relationship among the parameters was investigated by the Pearson's correlation coefficient test. The chi-square test was used to compare differences of categorical variables across the groups. The odds ratio and 95% confidence interval were also computed. A *P*-value less than 0.05 was considered statistically significant. The analyses were performed using IBM SPSS software.

3. Results

3.1. Swartz™ vs. Agilis™

Bilateral circumferential PV isolations were completed in all patients. There were no complications such as cardiac tamponade, or stroke during procedure. The comparison of patient characteristics between the Swartz™ group and the Agilis™ group is shown in Table 1. There was no significant difference in patient backgrounds between the Swartz™ and Agilis™ groups including for $CHADS_2$ score, serum brain natriuretic peptide level, LA size, and LA appendage flow velocity.

A total of 1283 ablation points for the first touch were evaluated, with 620 points in the Swartz™ group and 663 points in the Agilis™