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## Use of the new contact force sensing ablation catheter dramatically reduces fluoroscopy time during atrial fibrillation ablation procedures

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## ABSTRACT

**Objectives:** To study the impact of contact force (CF) sensing on fluoroscopy, procedure, left atrial (LA) and ablation times and number of ablations during atrial fibrillation (AF) ablation.

**Background:** Catheter ablation is an effective treatment for symptomatic AF. Recently a new ablation catheter providing real-time CF has been approved for use.

**Methods:** A nested case-control study was performed comparing radiofrequency ablation of AF using the irrigated CF-sensing ThermoCool SmartTouch catheter versus open-irrigated ThermoCool SF catheter (Biosense Webster, Inc., Diamond Bar, California). Demographic and procedure data were obtained and student t-test was used to compare data between groups.

**Results:** Thirty consecutive adult patients were included with 15 patients in each group. Mean fluoroscopy time was significantly lower in CF group ( $19.4 \pm 8$  vs  $40.7 \pm 8$  min,  $p < 0.0001$ ). LA time was significantly lower in CF group ( $151.7 \pm 44$  vs  $185.7 \pm 35$  min,  $p = 0.01$ ). There were no significant differences in procedure time between CF and SF groups ( $204 \pm 37$  vs  $207 \pm 36$  min) and ablation time ( $121 \pm 32$  vs  $122 \pm 37$  min). When patients who only underwent pulmonary vein isolation (PVI) were compared, fluoroscopy time was significantly lower in CF group ( $18 \pm 9$  vs  $37.8 \pm 5$  min,  $p < 0.0001$ ) as was LA time ( $141.4 \pm 39$  vs  $171.8 \pm 30$  min,  $p = 0.04$ ). Fluoroscopy time was also significantly lower in CF subgroup with additional ablation ( $20.9 \pm 7$  vs  $44.9 \pm 10$  min,  $p < 0.001$ ).

**Conclusion:** Use of CF-sensing catheter significantly reduced fluoroscopy and LA times during AF ablation with similar acute efficacy.

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### 1. Introduction

The prevalence of atrial fibrillation (AF) in the developed world is approximately 1.5–2% of the general population and its incidence is expected to dramatically increase in the future [1]. Catheter ablation of AF is now recognized as a Class I indication for treatment of symptomatic AF refractory to at least one membrane active anti-arrhythmic drug [2]. Ablation of AF, while effective, can sometimes be a time consuming procedure with significant fluoroscopy exposure for the patient and physician. Until recently, the surrogate markers for tissue contact during pulmonary vein isolation (PVI) with or without additional lesion formation were

electrogram diminution and impedance changes during ablation, but there was no direct quantitative way to ensure adequate tissue contact to maximize effective lesion formation. With the development of the Biosense Webster Smart touch force sensing ablation catheter this deficiency has been overcome. Good electrode-tissue contact with objective measurement of contact force (CF) by use of an irrigated CF-sensing catheter has been demonstrated to be safe and effective in RF ablation procedures [3]. We conducted this study to assess the real-world impact of contact-force sensing on procedure and fluoroscopy times during radiofrequency (RF) ablation of AF.

### 2. Methods

The Institutional Review Board at Einstein Medical Center, Philadelphia, approved the study protocol. This was a retrospective study that included patients who had undergone RF ablation of AF at Einstein Medical Center between August 2012 and August 2014.

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Thirty consecutive patients were included in the study. The first 15 patients who underwent RF ablation of AF with the ThermoCool SmartTouch catheter were included in the CF group, while the last 15 patients who underwent RF ablation of AF with the ThermoCool SF Catheter were included in the SF group. Inclusion criteria included patient age >18 years, at least one documented episode of symptomatic paroxysmal or persistent AF, non-responsiveness to at least one anti-arrhythmic drug therapy (Class I, Class III or atrio-ventricular nodal blocking agents) and previous AF ablation within the last two years at Einstein Medical Center, Philadelphia.

Demographic and procedural data were obtained from the electronic database. Procedure time was defined as the time interval in minutes between insertion of the first diagnostic catheter to the removal of the last diagnostic catheter after ablation. Left atrial time was defined as the time interval in minutes between the first transseptal puncture and removal of the last diagnostic catheter from the left atrium after ablation. Ablation time was defined as the summed duration of the individual ablation times in minutes.

### 2.1. CF sensing Catheter/CF sensing technology

The ThermoCool SmartTouch catheter (Biosense Webster, Inc., Diamond Bar, California) is a 7.5 Fr CF sensing catheter and has a 3.5 mm tip electrode with 6 small holes (0.4 mm diameter) around the circumference for saline irrigation. The catheter tip electrode is mounted on a precision spring, which permits micro-deflection, which is measured by three magnetic sensors located proximal to the spring. The system calculates the associated magnitude and angle of CF based on the micro-deflection, which is displayed both continuously and as the average value (over 1 s) on an electro-anatomical mapping system (CARTO XP, Biosense Webster, Inc.) [4].

The ThermoCool SF Catheter (Biosense Webster, Inc) is a non-CF sensing, open irrigation catheter with an 8 Fr tip electrode, 3.5 mm in length with 56 very small holes (diameter 0.0035") positioned around the entire electrode. It contains an embedded thermocouple for monitoring electrode temperature during RF ablation.

### 2.2. AF ablation procedure

All procedures were performed under general anesthesia with mechanical ventilation. A decapolar catheter was inserted transvenously and positioned in the coronary sinus. Intracardiac echocardiography was performed using a 9 Fr linear phased array ultrasound catheter (AcuNav, Biosense Webster Inc., Diamond Bar, CA), which was advanced into the right atrium to guide the *trans-septal* procedure, (puncture) monitor ablation catheter position and development of any pericardial effusion during the procedure. Double *trans-septal* procedure (puncture) was performed after intravenous heparin bolus administration to maintain activated clotting time >350 s. Two long 8.5 Fr sheaths (Agilis, St Jude Medical, Inc. and SL1, St Jude Medical, Inc.) were introduced into the left atrium (LA). Electroanatomic shell of the LA and the pulmonary veins (PV) was created using a PentaRay NAV catheter (Biosense Webster Inc., Diamond Bar, CA) and a magnetic-based electro-anatomic mapping system (CARTO System, Biosense Webster Inc., Diamond Bar, CA). A circular electrode catheter (Lasso, Biosense Webster, Inc.) was inserted into the LA for recording pulmonary vein (PV) potentials. The ThermoCool SmartTouch or ThermoCool SF mapping/ablation catheter was inserted through the second *trans-septal* sheath. To calibrate the CF sensor to 0 g (baseline non-contact value), the CF-sensing catheter was positioned centrally in the LA chamber without endocardial contact, confirmed by fluoroscopy and intracardiac echocardiography. Pulmonary vein antrum isolation by a circumferential lesion set was performed in

all 30 patients with confirmation of entrance and exit block. The peak contact force in the ThermoCool SmartTouch group did not exceed 40 g, and a minimum contact force of 5–10 g was targeted. Additional ablation was performed at the operator's discretion. It included ablation of complex fractionated atrial electrograms, LA linear ablation lesions and cavotricuspid isthmus ablation in cases of inducible atrial flutter. Isoproterenol infusion was used post-ablation to identify dormant foci.

### 3. Statistical analysis

Data are reported as mean  $\pm$  SD for continuous variables and as number and percentage for categorical variables. Student t-test was used to compare continuous variables and the chi-square test was used to compare categorical variables. A 2-tailed p-value <0.05 was considered significant in advance.

### 4. Results

Thirty consecutive patients were included, 15 patients had AF ablation using ThermoCool SmartTouch catheter and 15 had AF ablation using ThermoCool SF catheter. Baseline characteristics of the two groups are described in Table 1.

Six subjects in the ThermoCool SmartTouch group underwent PVI alone. Nine patients underwent additional ablation: 5 had additional focal non-PV ablation targeting complex fractionated electrograms while the remaining 4 underwent focal and linear ablation. Eight subjects in the ThermoCool SF group underwent PVI alone. Two patients underwent additional focal non-PV ablation targeting complex fractionated electrograms, while 5 underwent additional focal and linear non-PV ablation. Acute success described as achievement of entrance and exit block at all pulmonary veins and maintenance of sinus rhythm was achieved in all patients in both groups. There were no acute post-procedural complications in both groups.

A comparison between the mean procedure, fluoroscopy, ablation and left atrial times and the average number of ablations in the ThermoCool SmartTouch versus the ThermoCool SF group is presented in Table 2. Mean fluoroscopy time ( $19.4 \pm 8$  vs  $40.7 \pm 8$  min) and left atrial time ( $151.7 \pm 44$  vs  $185.7 \pm 35$  min) were significantly lower in the ThermoCool SmartTouch group. There were no significant differences in procedure time and ablation time between the two groups: procedure times; (ThermoCool SmartTouch  $204 \pm 37$  min vs ThermoCool SF  $207 \pm 37$  min); ablation times (ThermoCool SmartTouch  $121 \pm 32$  min vs ThermoCool SF  $122 \pm 37$  min).

A comparison between the mean procedure, fluoroscopy, ablation and left atrial times and the average number of ablations in the subsets of patients who underwent PVI alone and those who underwent PVI plus additional ablation is presented in Table 3.

There was significant fluoroscopy time reduction noted early on within the first five cases with CF sensing catheter as compared to non-CF sensing group (ThermoCool SmartTouch first 5  $27.64 \pm 6.3$  min vs ThermoCool SF  $40.7 \pm 8$  min) (Table 4). Also, fluoroscopy time was significantly lower in the last five patients compared to the first five patients in the CF-sensing group (ThermoCool Smart Touch last 5  $14.96 \pm 7.8$  min vs ThermoCool Smart Touch first 5  $27.64 \pm 6.3$  min) (Table 5).

When AF patients who only underwent PVI were compared, fluoroscopy time and left atrial time were significantly lower in the ThermoCool SmartTouch group (Fig. 1, Fig. 2). Fluoroscopy time was also significantly lower in the ThermoCool SmartTouch subgroup with additional focal or linear ablation (Fig. 1).

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