Indian Pacing and Electrophysiology Journal 16 (2016) 83–87

Contents lists available at ScienceDirect

Indian Pacing and Electrophysiology Journal

journal homepage: www.elsevier.com/locate/IPEJ

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

Aditi Naniwadekar [a, *], Kamal Joshi [b], Allan Greenspan [b], Sumeet Mainigi [b]

[a] Division of Cardiovascular Medicine, Einstein Medical Center, Philadelphia, PA, USA
[b] Division of Cardiac Electrophysiology, Einstein Medical Center, Philadelphia, PA, USA

ARTICLE INFO

*Article history:*
Received 4 January 2016
Received in revised form
29 March 2016
Accepted 18 June 2016
Available online 20 June 2016

*Keywords:*
Contact force
Radiofrequency ablation
Atrial fibrillation

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 ± 8 vs 40.7 ± 8 min, $p < 0.0001$). LA time was significantly lower in CF group (151.7 ± 44 vs 185.7 ± 35 min, $p = 0.01$). There were no significant differences in procedure time between CF and SF groups (204 ± 37 vs 207 ± 36 min) and ablation time (121 ± 32 vs 122 ± 37 min). When patients who only underwent pulmonary vein isolation (PVI) were compared, fluoroscopy time was significantly lower in CF group (18 ± 9 vs 37.8 ± 5 min, $p < 0.0001$) as was LA time (141.4 ± 39 vs 171.8 ± 30 min, $p = 0.04$). Fluoroscopy time was also significantly lower in CF subgroup with additional ablation (20.9 ± 7 vs 44.9 ± 10 min, $p < 0.001$).
*Conclusion:* Use of CF-sensing catheter significantly reduced fluoroscopy and LA times during AF ablation with similar acute efficacy.


## 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.

* Corresponding author. Department of Cardiology, Klein Suite 303, Einstein Medical Center, 5501 Old York Road, Philadelphia, PA 19141, USA.
*E-mail address:* aditinaniwadekar@gmail.com (A. Naniwadekar).
Peer review under responsibility of Indian Heart Rhythm Society.

http://dx.doi.org/10.1016/j.ipej.2016.06.002

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 atrioventricular 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 electroanatomical 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 electroanatomic 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 ± 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 fractioned 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 fractioned 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 ± 8 vs 40.7 ± 8 min) and left atrial time (151.7 ± 44 vs 185.7 ± 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 ± 37 min vs ThermoCool SF 207 ± 37 min); ablation times (ThermoCool SmartTouch 121 ± 32 min vs ThermoCool SF 122 ± 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 ± 6.3 min vs ThermoCool SF 40.7 ± 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 ± 7.8 min vs ThermoCool Smart Touch first 5–27.64 ± 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).

**Table 1**
Demographics.

| Parameters | ThermoCool SmartTouch group (n = 15) | ThermoCool SF group (n = 15) |
|---|---|---|
| Age (years) | 60 ± 10 | 61 ± 5 |
| Male (%) | 73 | 60 |
| Hypertension (%) | 93 | 87 |
| Dyslipidemia (%) | 47 | 53 |
| Diabetes mellitus (%) | 20 | 13 |
| Coronary artery disease (%) | 27 | 13 |
| Valvular disease (%) | 7 | 7 |
| Secondary arrhythmias (%) | 33 | 33 |
| Left ventricular ejection fraction (%) | 54.6 ± 9.9 | 53 ± 10.8 |
| LA diameter (cm) | 4.4 ± 0.6 | 4.5 ± 0.6 |

**Table 2**
Mean procedure, fluoroscopy, ablation and left atrial times and number of ablations.

| Parameter | ThermoCool SmartTouch | ThermoCool SF | p value |
|---|---|---|---|
| Procedure time (mins) | 203.8 ± 37 | 206.7 ± 37 | 0.4 |
| Fluoroscopy time (mins) | 19.4 ± 8 | 40.7 ± 8 | <0.0001 |
| Ablation time (mins) | 120.6 ± 32 | 122.3 ± 37 | 0.4 |
| No. of ablations | 100 ± 14 | 97 ± 24 | 0.33 |
| Left atrial time (mins) | 151.7 ± 44 | 185.7 ± 35 | 0.01 |

PVI alone as well as patients who underwent additional focal or linear non-PV ablation. There was also a significant overall decrease in the left atrial time with the use of CF-sensing catheter. There was no significant reduction in the procedure time, ablation time or the number of ablation lesions with use of CF sensing.

The single-procedure efficacy rate of catheter ablation of drug-refractory paroxysmal AF is 60–80% twelve months after the procedure. The current incidence of major complications after catheter ablation for atrial fibrillation is between 1% and 5%. Much effort has been invested in the last fifteen years in improving efficacy but the

**Table 3**
Comparison between the subsets of patients who underwent PVI alone and those who underwent additional ablation.

| | Parameter | ThermalCool SmartTouch | ThermaCool SF | p value |
|---|---|---|---|---|
| PVI | Procedure time (mins) | 194.5 ± 21 | 192.9 ± 35 | 0.4 |
| | Fluoroscopy time (mins) | 18.0 ± 9 | 37.8 ± 5 | <0.01 |
| | Ablation time (mins) | 111.0 ± 22 | 104.0 ± 12 | 0.21 |
| | No. of ablations | 98 ± 17 | 85 ± 13 | 0.05 |
| | Left atrial time (mins) | 141.4 ± 39 | 171.8 ± 30 | 0.04 |
| PVI + CFAE | Procedure time (mins) | 214.6 ± 50 | 227.3 ± 30 | 0.2 |
| | Fluoroscopy time (mins) | 20.9 ± 7 | 44.9 ± 10 | <0.01 |
| | Ablation time (mins) | 131.6 ± 40 | 149.5 ± 45 | 0.2 |
| | No. of ablations | 102 ± 10 | 114 ± 28 | 0.3 |
| | Left atrial time (mins) | 163.4 ± 49 | 206.7 ± 34 | 0.05 |

**Table 4**
Comparison between all ThermoCool SF cases with the first five ThermoCool SmartTouch cases.

| Parameters | ThermoCool SF | ThermoCool SmartTouch first five cases | p value |
|---|---|---|---|
| Fluoro time | 40.7 ± 8 | 27.64 ± 6.3 | 0.005 |
| Procedure time | 206.7 ± 37 | 215.8 ± 44.2 | 0.692 |
| Ablation time | 122.3 ± 37 | 134.4 ± 40.2 | 0.573 |
| LA time | 185.7 ± 35 | 165.8 ± 20.7 | 0.148 |

**Table 5**
Comparison between the first five and last five cases in the ThermoCool SmartTouch group.

| ThermoCool SmartTouch | First 5 cases | Last 5 cases | p value |
|---|---|---|---|
| Fluoro time | 27.64 ± 6.3 | 14.96 ± 7.8 | 0.02 |
| Procedure time | 215.8 ± 44.2 | 202.6 ± 47.6 | 0.66 |
| Ablation time | 134.4 ± 40.2 | 114.8 ± 35.8 | 0.44 |
| LA time | 165.8 ± 20.7 | 163.4 ± 59.7 | 0.94 |

## 5. Discussion

Use of CF-sensing catheter has been proven to be safe and effective in RF ablation of AF. However, its real-world impact on fluoroscopy time and procedure time during AF ablation is largely unknown. Our study has demonstrated a significant reduction in mean fluoroscopy time with the use of a CF-sensing catheter. This reduction in fluoroscopy time was seen in patients who underwent

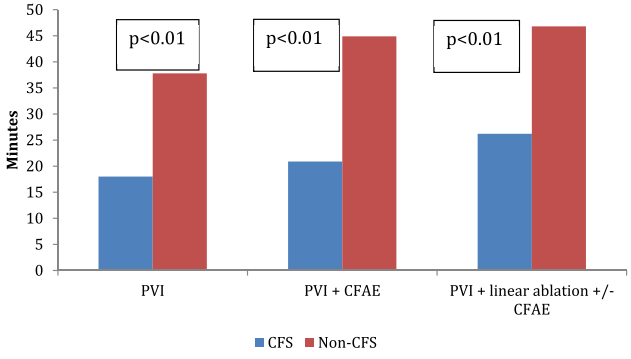


**Fig. 1.** Fluoroscopy time (minutes).

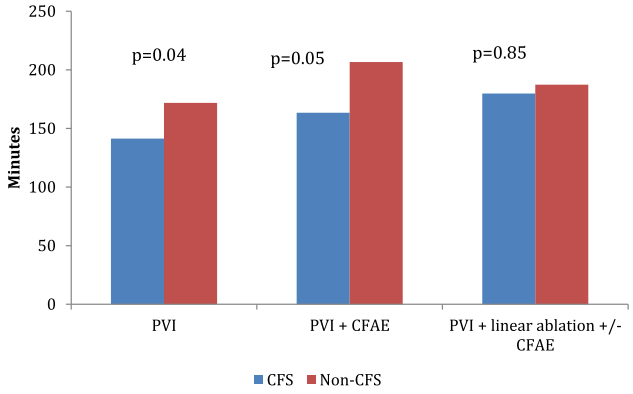


**Fig. 2.** Left atrial time (minutes).

results have so far been modest. Ability to quantify the amount of force used during ablation has the potential advantage of increasing efficacy by reducing late PV reconnection, streamlining the ablation procedure and minimizing some of these complications.

It has been shown in prior studies that contact-force is a major determinant of lesion size. An open-irrigated contact-force sensing catheter helps in selection of optimum RF power and application time to minimize the risk of steam pop and thrombus while increasing lesion size thereby ensuring effective PV isolation [5,6] The SMART-AF study demonstrated that ablation with the ThermoCool CF-sensing catheter was safe and effective for the treatment of drug refractory symptomatic PAF [3]. Another study using a different CF-sensing catheter system demonstrated that contact force during catheter ablation for AF correlated with better clinical outcomes [7].

A longer catheter dwell time in the left atrium exposes patients to thrombus or char formation on ablation apparatus, air entry with an inevitable variability in the degree of anticoagulation during the procedure [8]. We demonstrated a significant decrease in the catheter dwell time in the left atrium in the ThermoCool SmartTouch group which could potentially lead to a reduction in complications related to atrial fibrillation ablation.

Radiation exposure is an often underappreciated complication of catheter ablation procedures. X-ray exposure is associated with stochastic (cancer and genetic defects) and deterministic risks (hair loss, skin burns, cataracts, diminished fertility, bone marrow suppression etc). RF ablation for atrial fibrillation is associated with significant radiation exposure for patients and medical staff due to the length of the procedure, and patient comorbidity like obesity. The additional lifetime risk of excess fatal malignancies normalized to 60 min of fluoroscopy has been reported to be 0.07% for women and 0.1% for men [9]. Another study has estimated the average excess of fatal cancers to be 650 per million patients undergoing RF ablation requiring 1 h of fluoroscopy, and average risk for genetic defects was determined to be 1 per million births [10]. Use of 3D electroanatomical mapping systems has demonstrated reduction in fluoroscopy times [11]. Our study demonstrates further reduction of fluoroscopy time with use of a contact-force sensing catheter along with use of a 3D electroanatomical mapping system.

Reduction in fluoroscopy time was evident early on with the first 5 patients with use of CF sensing catheter as compared to use of non-CF sensing catheter. Further, there was significant reduction in fluoroscopy time in last 5 patients as compared to first five patients out of a total cohort of 15 patients in the CF-sensing group. This reflects that the learning curve for the use of the CF-sensing catheter is smooth and operator confidence builds quickly with less reliance on fluoroscopy during navigation and ablation.

The finding of our study is in agreement with the recent study by Jarman et al. where they looked at 600 patients undergoing AF ablation and demonstrated that use of CF sensing catheter was associated with reduced fluoroscopy time in multivariate analysis [12]. Zero-fluoroscopy ablation procedures with use of CF sensing catheter has been shown to be feasible [13]. With evolving technology, this could be a reality in real world practice for AF ablation in the future.

## 6. Study limitations

This was a retrospective single-center study which has inherent problems with selection bias and confounding by unmeasured variables. Our sample size was small and we did not have medium or long-term follow-up results. This may preclude quantification of the presumed risk reduction associated with use of CF catheter. We opted to enroll subjects in a 1:1 fashion to CF group and SF group. There were no acute complications noted in our study. This is likely due to the small sample size and single operator experience. We did not perform cost analysis comparing the ablation procedures with two different catheter technologies.

Our study, however, reflects real world practice outside of the clinical trial setting. Our study included both paroxysmal and persistent AF cases with different ablation strategies. However, all the procedures done in our study were performed by a single operator using identical ablation technique. Only acute procedural outcome was assessed during the study since medium term follow-up data was unavailable.

## 7. Conclusion

In this study, we demonstrated that the use of irrigated CF-sensing catheter significantly reduces fluoroscopy and left atrial times during AF ablation. Acute success is comparable to standardized techniques using non-CF sensing catheters.

## Funding

None.

## Relationships with industry

None.

## References

[1] Camm AJ, Lip GY, De Caterina R, et al. 2012 focused update of the ESC Guidelines for the management of atrial fibrillation. An update of the 2010 ESC Guidelines for the management of atrial fibrillation. Eur Heart J 2012;33:2719–47.
[2] Calkins H, Kuck KH, Cappato R, et al. 2012 HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation: recommendations for patient selection, procedural techniques, patient management and follow-up, definitions, endpoints, and research trial design. Heart Rhythm 2012;9:632–96.
[3] Natale A, Reddy VY, Monir G, et al. Paroxysmal AF catheter ablation with a contact force sensing catheter results of the prospective, multicenter SMART-AF trial. J Am Coll Cardiol 2014;64:647–56.
[4] Perna F, Heist EK, Danik SB, et al. Assessment of catheter tip contact force resulting in cardiac perforation in swine atria using force-sensing technology. Circ Arrhythm Electrophysiol 2011 Apr;4(2):218–24.
[5] Yokoyama K, Nakagawa H, Wittkampf FHM, et al. Novel contact force sensor incorporated in irrigated radiofrequency ablation catheter predicts lesion size and incidence of steam pop and thrombus. Circ Arrhythm Electrophysiol 2008;1:354–62.
[6] Thiagalingam A, D'Avila A, Foley L, et al. Importance of catheter contact force during irrigated radiofrequency ablation: evaluation in a Porcine *ex vivo* model using a force-sensing catheter. J Cardiovasc Electrophysiol July 2010:806–11.
[7] Reddy VY, Shah D, Kautzner J, et al. The relationship between contact force

and clinical outcome during radiofrequency catheter ablation of atrial fibrillation in the TOCCATA study. Heart Rhythm 2012;9:1789–95.
[8] Dewire J, Calkins H. Update on atrial fibrillation catheter ablation technologies and techniques. Nat Rev Cardiol October 2013;10:599–612.
[9] Lickfett L, Mahesh M, Vasamreddy C, et al. Radiation exposure during catheter ablation of atrial fibrillation. Circulation 2004;110:3003–10.
[10] Perisinakis K, Damilakis J, Theocharopoulos N, et al. Accurate assessment of patient effective radiation dose and associated detriment risk from radiofrequency catheter ablation procedures. Circulation 2001 Jul 3;104(1):58–62.
[11] Stabile G, Scaglione M, del Greco M, et al. Reduced fluoroscopy exposure during ablation of atrial fibrillation using a novel electroanatomical navigation system: a multicentre experience. Europace 2012;14:60–5. http://dx.doi.org/10.1093/europace/eur271.
[12] Jarman JW, Panikker S, Das M, et al. Relationship between contact force sensing technology and medium-term outcome of atrial fibrillation ablation: a multicenter study of 600 patients. J Cardiovasc Electrophysiol 2014 Dec 27. http://dx.doi.org/10.1111/jce.12606 [Epub ahead of print].
[13] Kerst G, Weig HJ, Weretka S, et al. Contact force–controlled zero-fluoroscopy catheter ablation of right-sided and left atrial arrhythmia substrates. Heart Rhythm 2012;9:709–14.