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Radiation dose is significantly reduced by use of contact force sensing catheter during circumferential pulmonary vein isolation

Giuseppe Stabile, MD[1], Antonio De Simone, MD[2], Francesco Solimene, MD[3], Assunta Iuliano, MD[1], Vincenzo La Rocca, MD[2], Vincenzo Schillaci, MD[3], Alfonso Panella, MD[1], Gergana Shopova, MD[2], Felice Nappi, MD[3], Francesco Urraro, MD[3], Giovanni Russo, MD[4], Giovanni Napolitano, MD[5], Paola Chiariello, MD[6]

[1]*Casa di Cura Mediterranea, Napoli.* [2]*Clinica San Michele, Maddaloni (CE).* [3]*Clinica Montevergine, Mercogliano (AV).* [4]*Ospedale San Leonardo, Castellammare di Stabile (NA).* [5]*Ospedale di Giugliano (NA).* [6]*Ospedale Santa Maria dell'Olmo, Cava dei Tirreni (SA), Italia.*

Abstract

The creation of a durable radiofrequency (RF) lesion depends on several parameters, including catheter tip electrode size and composition, tip orientation, temperature, RF pulse duration, power, blood flow, and catheter to tissue contact. The development of new contact force (CF) sensor catheters has allowed the measurement of the tip to tissue CF during the RF ablation procedure. Here, we describe the clinical experience obtained using CF catheters for atrial fibrillation ablation, with a specific focus on the impact of CF technology on acute procedural data (procedure and fluoroscopy time).

Introduction

Catheter ablation (CA) has become a well established treatment option for recurrent, symptomatic, drug-resistant atrial fibrillation (AF). Isolating or encircling all accessible pulmonary veins (PVs) is recognized as the cornerstone of any ablation approach.[1] One of the major limitation of CA of AF is the high rate of recurrences, during the short- and long-term follow-up, mainly due to electrical reconnection of the PVs. Therefore, more durable and transmural lesions produced by radiofrequency energy (RF) are desirable to improve the procedural outcome.[2,3] Crucial in the determining of the efficacy of RF lesion is the electrode-tissue contact. The optimization of electrode–tissue contact may have a two potential benefits.[1] First, it allow a more effective RF delivery to tissue with less energy dissipated into the circulating blood pool and creation of more predictable and reliable lesions. This may impact on both the procedure parameters and long-term clinical outcome. Second, monitoring the electrode–tissue contact may help reduce the excessive contact and the complications possibly related to catheter manipulation inside the heart. Here, we describe the clinical experience obtained using CF catheters for AF ablation, with a specific focus on the impact of CF sensing technology on acute procedural data (procedure and fluoroscopy time).

Key Words:
Atrial Fibrillation; Catheter Ablation; Contact Force.

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None.

Corresponding Author:
Giuseppe Stabile, MD
Via SS Martiri Salernitani 24,
84123 Salerno, Italia.

Contact Force Sensing In Catheter Ablation

The efficacy of RF ablation is to a large extent determined by the ability to create durable, transmural lesions. Lesion formation, including durability, is dependent on several interacting factors including catheter tip size, irrigation, stability and orientation to the myocardium, power delivery, ablation duration, and catheter-tissue CF. Yokoyama et al[4] showed a direct correlation between CF and the resulting lesion volume in a canine thigh muscle preparation. Using this catheter at constant RF power (saline irrigation) in the canine thigh muscle preparation, tissue temperature and lesion size increased significantly with increasing CF. The incidence of steam pop and thrombus also increased with increasing CF. The incorporation of real-time CF measurement in an irrigated ablation catheter helped to optimize the selection of RF power and RF application time to maximize RF lesion formation and reduce the risk of steam pop and thrombus in clinical application. Until recently, CF could not be measured directly by ablation catheters. As a result, surrogate measures of CF have been proposed, including electrogram amplitude, pre-ablation impedance and changes during ablation in electrode temperature and impedance.[5] The accuracy of these surrogate measures has not been extensively validated.

In this setting steerable sheaths have been introduced to improve CF during AF ablation.[6] Ullah et al[7] recently demonstrated that steerable-sheaths increased ablation CF, however, there were region-specific heterogeneities in the extent of increment, with some segments where they failed to increase CF.

Figure 1: A 3D reconstruction of left atrium by means of the TactiCath™ (St. Jude Medical, USA) catheter. Local contact force values are displayed

More recently, the advent of the CF sensing catheter has further evolved the technology of catheter ablation. Two irrigated CF sensing catheters are now available: the TactiCath™ (St. Jude Medical, USA) (TC) (Figure 1) and the ThermoCool® SmartTouch™ (Biosense Webster, USA) (ST) (Figure 2). The TC catheter measures the CF by micro-deformations of optical fibers, whereas the ST catheter measures micro-deformations of a precision spring connecting the catheter shaft and tip. In bench testing, both systems have a CF resolution of less than 1 gram.

The theoretically possible benefits of CF sensing technology are numerous.

Safety may be improved by reducing the risk of perforation during catheter manipulation and ablation. Although several initial experiences[8-12] comparing the CF catheters with standard open-irrigated tip catheter in AF ablation failed to demonstrate a reduction in complication rate with the use of CF sensing catheters, recently Acka et al[13] evaluated if CF catheters reduce cardiac perforations and other major complications and offer equal safety compared to the non CF catheters and magnetic navigation system, in 1.517 ablation procedures. Complications occurred in 11.3% (n=172) of the procedures. In 2.8% (n=43) a major complication occurred, 0.9% (n=13) had a perforation, 8.5% (n=129) had a minor complication and 2 patients died (0.1%). No cardiac perforation occurred in the CF group, which was significantly different from non CF procedures (0.0% vs. 1.6%; relative risk 0.76, 95% CI 0.74-0.79, P=0.031) and equal to magnetic navigation system (0.0%). This was also observed in the AF subgroup (557 patients) (0.0% vs. 3.3%; RR 0.67, 95% CI 0.63-0.72, P=0.021), and the occurrence of major complications was lower for CF versus non CF procedures (2.1% vs. 7.8%, P=0.010). They concluded that CF-guided CA is superior to non CF catheter with regard to procedural safety and avoidance of cardiac perforation. This difference was due to a reduction of cardiac perforation and major complications in the AF subgroup.

Although clinical practice is suggesting that increasing CF improves RF lesion formation, there are no studies correlating RF lesion size to CF in the beating heart. However CF sensing catheters allowed a lower incidence of acute reconnection, and less need of complementary segmentary RF applications.[14-16]

Impact Of CF On Fluoroscopy Time

Reddy et al[17] were the first to study the relationship between contact force and clinical outcome during RF catheter ablation of atrial fibrillation in the TOCCATA study. Thirty-two patients with paroxysmal AF underwent PV isolation by using a radiofrequency ablation catheter with a CF sensor integrated at its tip (TC). They failed to demonstrate any impact of CF values on procedural and fluoroscopy times, although they observed a trend towards a reduced fluoroscopy time (from 55±32 min vs 32±24 ms, p=0.25) in patients in which the mean CF was > 20 gr as compared with patients in which the mean CF was ≤ 10 gr. Similar results were reported by Wutzler et al[18] They analyzed 143 patients who underwent PV isolation. In 31 patients, PV isolation was performed by monitoring the catheter-tissue contact with a sensing catheter (TC). One hundred and twelve patients in whom conventional PVI was performed without CF information, using an open irrigated ablation catheter (CoolPath, IBI/St. Jude Medical, St. Paul, MN, USA) served as the control group. Circumferential PV isolation was performed with a 3D-Mapping-System (Ensite NavX, St. Jude Medical). A significant reduction in procedure duration was seen in the CF mapping group (128.4 ±29 min vs. 157.7 ±30.8 min, p = 0.001). There were no significant differences observed in ablation time, total ablation energy or fluoroscopy time, although all were reduced in the CF group.

On contrary using the ST catheters several study demonstrated a relevant the impact of CF technology on fluoroscopy and procedure time during AF ablation (Table I).

Martinek et al[8] assessed the impact of direct catheter force measurement on acute procedural parameters during RF CA in 50 consecutive patients with paroxysmal AF. Fifty consecutive patients with paroxysmal AF who underwent their first procedure of circumferential PV isolation were assigned to either RF CA using

(1) a standard 3.5-mm open-irrigated-tip catheter (Thermocool®, NavistarTM; Biosense Webster) or

(2) a catheter (ST) with contact force measurement capabilities. All RFA were performed using a 3-D electroanatomic mapping system with CT integration (Carto3®; Biosense Webster). Procedural data showed a remarkable decline in ablation time (RF time needed for PV isolation) from 50.5 ± 15.9 to 39.0 ± 11.0 minutes (P = 0.007) with a reduction in overall procedure duration from 185 ± 46 to 154 ± 39 minutes (P = 0.022). In parallel, the total energy delivered could

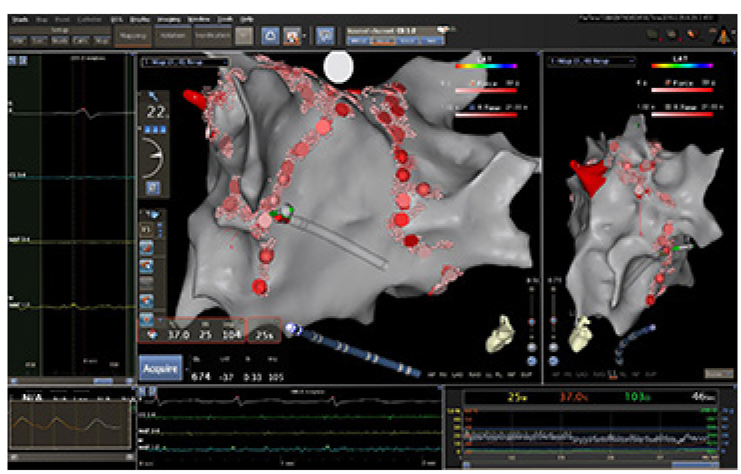

Figure 2: A 3D reconstruction of left atrium by means of the ThermoCool® SmartTouch™ (Biosense Webster, USA) catheter. Local contact force value is displayed

be significantly reduced from 70,926 ± 19,470 to 58,511 ± 14,655 Ws (P = 0.019). The number of acute PV reconnections declined from 36% to 12% (P = 0.095).

Marion et al (9) studied 60 patients with paroxysmal AF comparing circular antral CA (guided by Carto 3® System, BiosenseWebster) using either a new open-irrigated CF catheter (ST) or a non-CF open-irrigated catheter (EZ Steer Thermocool, Biosense Webster). Overall, 30 patients were enrolled in each group. Though complete PV isolation was achieved in all cases in both groups, CF use was associated with significant reductions in fluoroscopy exposure (20.1±4 vs 26.7±5 minutes, p < 0.01) and RF time (45.2±18 vs 65.4±22 minutes, p= 0.01).

Stabile et al,[19] in a multicentre prospective study, assessed the effect of direct CF measurement on acute procedural parameters during RF CA of AF. All the patients underwent the first ablation procedure for paroxysmal AF with antral PV isolation, aiming at entry and exit conduction block in all PVs, by means of a open-irrigated tip catheter with CF sensing (ST), guided by Carto 3® System (BiosenseWebster). Ninety-five patients were enrolled in nine centres and successfully underwent ablation. Overall procedure time, fluoroscopy time, and ablation time were 138.0+67.0, 14.3+11.2, and 33.8+19.4 min, respectively. The mean CF value during ablation was 12.2+3.9 g. Force time integral (FTI) analysis showed that patients achieving a value below the median of 543.0 gs required longer procedural (158.0+74.0 vs. 117.0+52.0 min, p= 0.004) and fluoroscopy (17.5+13.0 vs. 11.0+7.7 min, p = 0.007) times as compared with those in whom FTI was above this value. Patients in whom the mean CF during ablation was > 20 g required shorter procedural time (92.0+23.0 vs.160.0+67.0 min, p = 0.01) as compared with patients in whom this value was < 10 g.

Sciarra et al[10] analyzed the impact of the ST catheter and the Surround Flow (BiosenseWebster) catheter (SF) and ThermoCool (BiosenseWebster) catheter, in terms of feasibility and acute efficacy, in 63 patients with paroxysmal AF who underwent PV antral isolation, guided by Carto 3® System (BiosenseWebster). They found that the use of both ST and SF catheters obtained a reduction of fluoroscopy time (ThermoCool 34±18 min, ST 20±10 min, p<0.001; SF 21±13 min, p=0.02 vs ThermoCool) and RF time (ThermoCool 41±13 min, ST 30±14 min, p=0.013; SF 30±9 min, p<0.01 vs ThermoCoolC). The use of ST catheter resulted in a reduction of procedural time (ThermoCool 181±53 min, ST 140±53 min, p<0.001; SF 170±51 min, p=NS vs ThermoCool). The percentage of isolated PVs was comparable between groups (ThermoCool 96 % vs ST 98 % vs SF 96 %; p=NS). The percentage of deconnected PVs at 30 min was lower in ThermoCool (89 %) than in ST (95 %) and in SF (95 %) group (p<0.05).

Jarman et al[11] studied the impact of CF sensing technology on the clinical outcome of ablating AF. A total of 600 AF ablation

Table 1: Impact of CF sensing technology on on procedural and fluoroscopy time

Study	Important features	CF sensing technology	Aims and methods	Fluoroscopy time	Procedure time	Key findings
Reddy et al 17 2012	32 PAF	Optical fibers	an OIC with CF mapping capabilities	Higher CF was not associated to changes in fluoroscopy time (32±24 vs 55±32 min, p=0.25)	Higher CF was not associated to changes in procedure time (211±88 vs 188±51 min, p=0.61)	CF did not affect procedural parameters
Wutzler et al 18 2014	143 with PAF and PerAF	Optical fibers	an OIC or an OIC with CF mapping capabilities	There were no significant differences observed in fluoroscopy time, although reduced in the contact force group	Procedure duration was significantly shorter in the contact force group (128.4 ±29 min vs. 157.7 ±30.8 min, p = 0.001).	the use of CF information resulted in a shorter procedure time
Martinek et al 8 2012	50 PAF	Precision spring	a standard 3.5-mm OIC or a catheter with CF measurement capabilities	28.6 ±17.4 vs 23.6±13.1 min, p= 0.312	185±46 vs 154±39 min p= 0.022	The use of CF sensing technology was able to significantly reduce ablation and procedure times in PVI.
Marion et al 9 2014	60 PAF	Precision spring	a new OIC CF catheter or a non-CF OIC	CF use was associated with significant reductions in fluoroscopy exposure (20.1 ± 4 vs 26.7 ± 5 minutes, p < 0.01)	CF technology was associated with a significant reduction in overall procedure time	the use of CF information resulted in a shorter procedure and fluoroscopy times
Stabile et al 19 2014	95 PAF	Precision Spring	a new OIC with CF sensing	Patients in whom the mean CF during ablation was > 20 g required shorter procedural time (92±23 vs.160±67 min, p = 0.01) as compared with patients in whom this value was < 10 g.	patients achieving a FTI value below the median of 543 gs required longer procedural (158.0±74.0 vs. 117.0±52.0 min, p = 0.004) times as compared with those in whom FTI was above this value	CF affected procedural parameters, in particular procedural and fluoroscopy times, without increasing complications.
Sciarra et al 10 2014	63 PAF	Precision spring	impact of a standard OIC, SF OIC and CF catheter	ST and CF catheter obtained a reduction of fluoroscopy time (OIC 34 ± 18 min, CF 20 ± 10 min, p < 0.001; SF 21 ± 13 min, p = 0.02 vs OIC)	STc resulted in a reduction of procedural time (TCc 181 ± 53 min, STc 140 ± 53 min, p < 0.001; SFc 170 ± 51 min, p = NS vs TCc).	Both the CF and the SF OIC catheters significantly reduced radiofrequency and fluoroscopy times, as well as pulmonary veins reconnection rate at 30 min. Moreover, the CF catheter reduced overall duration of the procedure.
Jarman et al 11 2014	600 with PAF and PerAF	Precision spring	CF and non CF catheters	the use of CF catheters was associated with reduced fluoroscopy time in multivariate analysis (reduction by 7.7 (5.0-10.5) minutes; p<0.001)		Fluoroscopy time was lower when CF technology was employed in all types of AF ablation procedures
Sigmund et al 12 2015	198 with PAF and PerAF	Precision spring	3.5-mm OIC with CF measurement capabilities and a standard OIC	total fluoroscopy time could be significantly reduced from 28.5 ± 11.0 to 19.9 ± 9.3 minutes (P = 0.0001)	Procedural data showed a significant decline in overall procedure time of 34 minutes (p = 0.0001; 225.8 ± 53.1 vs 191.9 ± 53.3 minutes).	The use of CF technology was able to significantly reduce ablation, procedure, and fluoroscopy times as well as dose in RFCA of AF

PAF= paroxysmal atrial fibrillation; OIC= open-irrigated-tip catheter; CF= contact force; PVI= pulmonary vein isolation; FTI= force-time integral; SF= surround flow; PerAF= persistent atrial fibrillation procedures (200 using CF sensing and 400 using non-CF catheters) performed between 2010 and 2012 (46% paroxysmal, 36% persistent, 18% long-lasting persistent) were analyzed. First time AF ablation procedures employing CF catheter (ST) from 4 centers were matched retrospectively to those without CF catheter (ThermoCool, BiosenseWebster, and SF) in a 1:2 manner by type of AF. Among all cases, the use of CF sensing catheters was associated with reduced fluoroscopy time in multivariate analysis (reduction by 7.7 (5.0-10.5) minutes; p<0.001). Complication rates were similar in both groups.

Sigmund et al[12] assessed the impact of direct CF measurement on acute procedural parameters and outcome of RF CA for paroxysmal and persistent AF. Ninety-nine consecutive patients with paroxysmal (63.6%) or persistent AF underwent left atrial RF CA using a 3.5-mm open-irrigated-tip catheter with CF measurement capabilities (ST). For comparison a case-matched cohort with standard open-irrigated-tip catheters (ThermoCool, BiosenseWebster) was used (99 patients). Procedural data showed a significant decline in RF ablation time from 52 ± 20 to 44 ± 16 minutes (P = 0.003) with a remarkable mean reduction in overall procedure time of 34 minutes (P = 0.0001; 225.8 ± 53.1 vs 191.9 ± 53.3 minutes). In parallel, the total fluoroscopy time could be significantly reduced from 28.5 ± 11.0 to 19.9 ± 9.3 minutes (P = 0.0001) as well as fluoroscopy dose from 74.1 ± 58.0 to 56.7 ± 38.9 Gy/cm2 (P = 0.016). Periprocedural complications were similar in both groups.

Many factors justify the reduction in procedural and fluoroscopy time observed with CF sensing catheters. It may relate to increased operator's confidence during navigation, related to the confidence in the validity of geometry produced by CF sensing feedback,[20] or to the reduction in time required to complete contiguous lesions. Olson et al[21] demonstrated that the decreased lesion size due to intermittent contact can be overcome by increasing duration of ablation time. The CF sensing technology giving the feedback on the quality of catheter-tissue contact helps to reduce the number of RF pulses with intermittent or poor contact which require longer ablation times and often fluoroscopy time. Moreover avoiding ablation at sub-optimal CF may reduce late development of gaps within linear lesions, often performed during AF ablation. Finally, the reduced incidence of acute reconnection, and less need of complementary segmentary RF applications[14-16] allow a reduction in the overall procedure time and therefore also in fluoroscopy time.

Limitations

Although the great amount of the study showed a positive impact of CF sensing catheter on acute procedural data and above all procedural and fluoroscopy time, several issue remain to be clarified. The overall quality of the studies which evaluated the impact of the new CF catheters in AF ablation is poor: none of them is a randomized one, some are retrospectively, only few are multicenter studies. Second, whereas the studies using the ST catheter showed a significant reduction in the fluoroscopy time, this was not observed in the study[18] using the TC catheter. However only few patients were enrolled. Further studies using this technology are warranted to assess this issue. Third, the ST catheter has usually been compared with the Thermocool®, NavistarTM (BiosenseWEbster) catheter. Only one study[10] compared the ST with the SF, and in this case no difference on procedural and fluoroscopy times were founded.

Conclusion

CF sensing technology appears to significantly impact on short-term results with shorter procedural and fluoroscopy times, lower incidence of acute reconnection, and less need of complementary segmentary radiofrequency applications. Further randomized studies are warranted to confirm these preliminary data and to compare the CF with other technologies aiming to improve AF CA.

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