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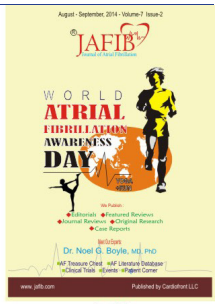

Atrial Fibrillation Radiofrequency Ablation: Safety Using Contact Force Catheter In A Low-Volume Centre

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Abstract

The tip-to-tissue contact force (CF) has been identified as a potential determinant of lesion quality during radiofrequency (RF) ablation. The aim of this paper is to report the experience of a single low-volume centre in the atrial fibrillation (AF) ablation procedure with an RF catheter capable of measuring this parameter. CF data and their possible implications on patient safety are presented.

Thirty-nine consecutive patients suffering of paroxysmal or permanent AF received percutaneous ablation with the novel catheter studied. Procedural characteristics, CF applied and safety events related to the procedure were reported.

During RF application the mean CF value was 17 ± 3 g, with a maximum mean value of 37 ± 8 g. CF value never exceeded 62 g and in the 74% of the RF applications ranged between 10 g and 30 g. No complication related to the catheter manipulation or to the energy delivered was observed.

This study of a single centre with a low level of experience in AF ablation suggests that the ability to measure CF may provide additional useful information to the operator. It ensures uniform ablations, with little variability in the catheter manipulations, and it avoids excessive contact forces increasing the patient safety.

Introduction

Catheter ablation has been proven to effectively cure atrial fibrillation (AF) and its popularity continues to escalate.[1] According to the second worldwide multicenter survey (2003-2006), catheter ablation of AF shows to be effective in 70% of the patients with an overall incidence of major complications of 4.5%.[2]

The tip-to-tissue contact force (CF) has been identified as a potential determinant of lesion quality during RF ablation.[3-6] A radiofrequency (RF) irrigated catheter with optical fibers to determine CF (TactiCath®; Endosense SA, Geneva, Switzerland) has been evaluated in human in vivo studies demonstrating the feasibility and safety of the catheter.[7-9] The recent studies TOCCATA and EFFICAS I recommend optimal CF and force-to-time integral (FTI) parameters in order to have efficient and safety ablation.[7-9] Insufficient CF and FTI may result in an ineffective lesion, whereas excessive CF may result in complications such as heart wall perforation, steam pop, thrombus formation, or esophageal injury.[3, 10, 11]

In this paper we report the experience of a single and small electrophysiology (EP) laboratory. We performed 39 consecutive AF ablation procedures with this new technology collecting the CF data during the interventional procedure and we evaluated its possible implication on patient safety. We analysed the CF information for two different techniques of ablation: the "dragging" approach and the "focal"(point by point) one. Knowledge of the CF and FTI may ensure less variability in catheter manipulations and reduce commonly related complications, overcoming the lack of important experience of the EP lab.

Key Words:

Catheter Ablation,Atrial Fibrillation,Contact Force,Force-To-Time Integral,Safe Ablation,Radiofrequency.

Disclosures:
None.

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Material And Methods

Patients

From January 2011 to July 2013 39 consecutive patients suffering of paroxysmal or permanent AF following ACC/AHA/ESC (American College of Cardiology/American Heart Association/European Society of Cardiology) guidelines,[12] who signed informed consent before the procedure, were enrolled. Patients' characteristics and cardiovascular history are given in Table 1. All the patients had more than one episode of AF, of which at least one of sustained (>30s) AF documented by the 12-lead electrocardiogram or by an implanted device within 12 months prior to enrolment; 32 patients over 39 (82%) were symptomatic to the arrhythmias. Symptom duration mean was 2.5 years (range 1.0 – 4.3). A mean of 1.5 ± 0.9 antiarrhythmic therapy drugs for patient was used. Two patients were recidivist cases by

Table 1: Baseline patient characteristics of all patients and in "dragging" and "focal" groups

Parameter	total N = 39	dragging N=11	focal N=28	p value
Age (y)				
Mean ± SD	59.8 ± 10.2	60.0 ± 9.9	59.7 ± 10.5	ns
Range	43-78	47-72	43-78	
Sex - n (%)				
Male	25 (64)	5 (45)	20 (71)	ns
Cardiovascular hystory – n (%)				
Paroxysmal atrial fibrillation	16 (41)	5 (45)	11 (39)	ns
Persistent atrial fibrillation	23 (59)	6 (55)	17 (61)	ns
Coronary artery disease	2 (5)	1 (9)	1 (4)	ns
Vascular disease	0 (0)	0 (0)	0 (0)	ns
Heart Failure	0 (0)	0 (0)	0 (0)	ns
Hypertiroidism	6 (15)	2 (18)	4 (14)	ns
Obesity	4 (10)	1 (9)	3 (11)	ns
Left atrium diameter (mm)				
Mean ± SD	40.4 ± 8.4	39.5 ± 4.9	42.0 ± 6.8	ns
Range	28-55	30-45	28-55	

standard AF ablation procedure, done without CF information in other EP lab.

CF Ablation Catheter System

The Contact Force (CF) information is obtained by the TactiCath Set (Endosense SA, Geneva, Switzerland), a system for percutaneous catheter RF ablation of atrial cardiac arrhythmias. TactiCath is a deflectable 3.5 mm electrode, 6 holes irrigation catheter and it was used with approved pump (CoolFlow Irrigation Pump M-5491-00, Biosense Webster, Diamond Bar, USA) and RF generator (Stockert Remote Control RC-1-1178, Stockert Gmbh, Freiburg, Germany).

The catheter tip has an integrated force sensor that allows, with the specific software, real-time visualization of the tip CF. It is calculated every 100 ms, displayed continuously on the screen and simultaneously recorded on a digital file for later reviews and analysis. To characterize the effect of CF applied over time, the system automatically detects the onset and the end of RF current delivery and calculates the force-to-time integral (FTI) defined as the total CF integrated over the time of RF delivery and expressed in units of gram seconds (g*s).[6]

Ablation Procedure

Patients underwent the AF ablation procedure following standard clinical practice guidelines. The mapping of the left atrium and the ablation procedure was guided anatomically by a 3-dimensional mapping system (EnSite, SJM, St. Paul, MN). The objective of each procedure was the complete disconnection of all the pulmonary veins (PVs). A circumferential diagnostic catheter was used to confirm acute PVI by bidirectional block; the integrated approach was used.[13] When the patient was at sinus rhythm (SR) at the beginning of the procedure only PVI was performed. If the patient was in AF, PVI was performed, but in case of persistence of AF, the complex fractionated atrial electrograms (CFAE's)[14] ablation was done. When AF turned into atrial left flutter, linear lesions were performed to stop the arrhythmic circuit. When right atrial flutter was documented, a linear ablation on cavo-tricuspid isthmus was performed.

The RF power setting followed the standards of the laboratory, 30 W for left PV and 25 to 30 W for the right PV. The saline irrigation flow was 2 mL/min during catheter manipulation and 30 mL/min during RF delivery.

The ablation procedures were performed with two techniques; the first 11 patients were treated with dragging lesions ("dragging" group), the following with point by point ("focal" group) technique. In both cases during the ablation the guide parameters were CF and real-time FTI. The target values were 20 g for the CF and a minimum of 450 g*s for the FTI for each new lesion, as recommended by the EFFICAS I Study.[9] The mean CF and the FTI were measured for each RF delivery; in the "focal group" this was focused on a single lesion, in the "dragging" group this was the sum of several lesions performed moving the catheter after the achievement of the FTI target (450 g*s) for each point. RF energy was not delivered if the CF was > 60g.

Average first-to-last RF delivery time, total radiofrequency time and fluoroscopy time were measured. At the beginning and at the end of the procedure cardiac rhythm of the patient was evaluated and electrical cardioversion (ECV), when performed, was reported.

Procedure Safety Monitoring

Duration of hospitalization was recorded for each patient. All the complications associated with the procedure were monitored. As suggested by Doppalapudi et al.[15] the complications were classified with the following specifications: vascular access, transeptal access, trauma from catheter manipulation, energy delivery and procedural components.

Statistical Methods

Variables were summarized by calculating the mean and the standard deviation. The non paired Student t-test was performed to compare the two ablation techniques. The results reached a level of significance when $p<0.05$. All statistical calculations were done using Excel 2007.

Results

Patients characteristics are described in Table 1, no statistical differences are present between the "dragging" and the "focal" group.

Procedural Characteristics

Procedural characteristics are described in Table 2. The acute procedural effectiveness was 100%, with PVs successfully isolated. Ad-

Table 2: Procedural characteristics of AF ablations for all patients and in "dragging" and "focal" groups

Parameter	total N = 39	dragging N=11	focal N=28	p value
Number of ablations, n	60 ± 24	31 ± 13	71 ± 16	< 0.001
Time first-to-last ablation (min)	129 ± 47	79 ± 31	149 ± 37	< 0.001
Total radiofrequency time (min)	52 ± 18	35 ± 13	59 ± 15	< 0.001
Fluoroscopy time (min)	53 ± 20	49 ± 22	55 ± 20	ns
SR at the beginning, n (%)	20 (51)	6 (55)	14 (50)	ns
AF termination during RF, n (%)	8 (21)	3 (27)	5 (18)	ns
ECV in the procedure, n (%)	11 (28)	2 (18)	9 (32)	ns
PV isolation, n (%)	39 (100)	11 (100)	28 (100)	ns
CFAEs ablation, n (%)	19 (49)	5 (45)	14 (50)	ns
Left atrial linear lesions, n (%)	11 (28)	2 (18)	9 (32)	ns
Cavo-tricuspid isthmus ablation, n (%)	6 (15)	1 (9)	5 (18)	

SR = sinus rhythm, AF atrial fibrillation, ECV = electrical cardioversion, CFAE = complex fractionated atrial electrogram, NS = statistically non-significant

Table 3: Contact force characteristics of AF ablation procedures

Parameter	total N = 39	dragging N=11	focal N=28	p value
Mean CF during ablation (g)	17 ± 3	20 ± 3	16 ± 2	< 0.001
Max CF during ablation (g)	37 ± 8	37 ± 11	36 ± 7	ns
Mean FTI during ablation (g*s)	954 ± 551	1521 ± 790	732 ± 120	< 0.001
Max FTI during ablation (g*s)	2844 ± 2034	4181 ± 3192	2319 ± 1016	0.008

Parameters are indicated as average value ± standard deviation

ditionally 19 (49%) patients underwent CFAEs ablation and in 11 (28%) linear lesions were performed (7 on the atrial roof, 2 on the mitral isthmus and 2 on the inter-atrial septum). 6 patients (15%) had also cavo-tricuspid isthmus linear lesion. All the patients were in SR at the end of the procedure. The mean number of ablations delivered for patient was 60 ± 24. The mean duration from the first to the last ablation was 129 ± 47 min, with a total mean radiofrequency time of 52 ± 18 min and a mean fluoroscopy time of 53 ± 20 min. Twenty patients were in SR at the beginning of the procedure, in 8 patients sinus rhythm was restored during RF ablation and in 11 with ECV. In the "dragging" group a significant lower number of ablations (31 ± 13 Vs 71 ± 16, p<0.001) were performed than the "focal" group, shorter first-to-last ablation (79 ± 31 Vs 149 ± 37, p<0.001) and radiofrequency (35 ± 13 Vs 59 ± 15, p<0.001) times were reported.

Contact Force (CF) Analysis

The mean and maximum values of CF and FTI applied during the ablation are shown in Table 3. The mean contact was 17 ± 3 g with a mean maximum value of 37 ± 8 g. The average FTI per ablation was 954 ± 551 g*s with a mean maximum value of 2844 ± 2034 g*s. The greatest significant between the two groups was noted when comparing the FTI parameter, "dragging" group have both mean (1521 ± 790 g*s Vs 732 ± 120 g*s, p<0.001) and maximum (4181 ± 3192 g*s Vs 2319 ± 1016 g*s, p<0.001) higher values than the "focal" one. It had been noted also a higher average CF applied in the "dragging" group (20 ± 3 g Vs 16 ± 2 g, p<0.001). In figure 1 the mean and maximum CF achieved are reported for each procedure, the first 11 are performed with "dragging" technique, the following with "focal" one. In figure 2 and 3 the relative distributions of the average CF and of the average FTI per ablation are shown for both "dragging" and "focal" groups.

Safety Monitoring

The average duration of hospitalization was 3.2 ± 2.9 days. 29 (74.4%) patients had just 2 days of hospital recovery. One complication (2.6 %) occurred, classified as related to vascular access; the patient developed a total femoral pseudoaneurysm, resolved with compression and bandage in 8 days of hospitalization. No other complication was observed.

Discussion

The objective of this paper was to report the CF information of the AF ablation procedures of a single and small EP lab and to evaluate its possible implication on patient safety.

As in the TOCCATA study[7,8] the safety of the CF catheter was confirmed, just one complication with a long hospitalization was observed (total femoral pseudoaneurysm), but it was not related to the manipulation of the catheter in the heart chamber or to the RF energy delivery. No cardiac tamponade was reported. The overall incidence of major complications (2.6 %) was comparable or slightly

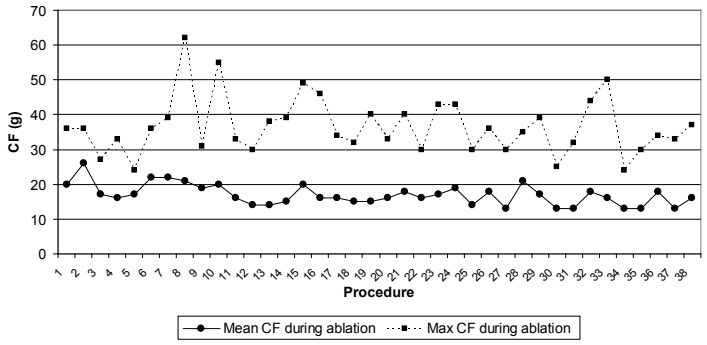

Figure 1: Average and maximum CF values for each procedure

For each AF ablation procedure the average and the maximum CF values during RF application are showed. The first 11 procedures were performed with "dragging" technique, the others with "focal" technique

lower than the one present in other AF ablation studies.[2,16]

The small sample size of this report is a limitation, this is due to the low rate of the procedures of the centre. The patients enrolled are the consecutive procedures in the period from January 2011 to July 2013.

Shah et al.[6] suggested that it may be prudent to avoid a CF exceeding 100 g during catheter ablation, in our RF application the average maximum value of CF was 37 g, with a highest value of 62 g. Sight of high values, even of short duration, may help the operator avoiding a high risk situation and be more vigilant for possible effusion.

For the long-term success of the ablation both TOCCATA[7,8] and EFFICAS I[9] showed the need to have CF > 10 g. In our study the CF was nearly 20 g for all the procedures, with a slightly higher value in the "dragging" group. This underlines how also an operator without a high level of experience is able to keep a stable catheter contact thanks to the real time contact information displayed. The majority of the ablations performed in our study (74%) have an average CF value between 10 g and 30 g. The ones with lower CF are due to the ablations where the operator lost contact and stopped it quickly. The EFFICAS I[9] suggested also to have a minimum FTI > 400 g*s for each point, in our study the average FTI with the "point-to-point" technique was 732 g*s and it was quite uniform for all the ablations (61% of the ablations with FTI between 500 and 1000 g*s). Different studies showed a high variability in CF inter-and intra-investigator,[7,8] even during a careful ablation procedure, the operators do not have tight control over CF. This study underlines how thanks to the CF information also an operator without a high level of experience can modulate the CF and perform a uniform ablation procedure increasing its efficacy and the patient safety. In addition, a point with low

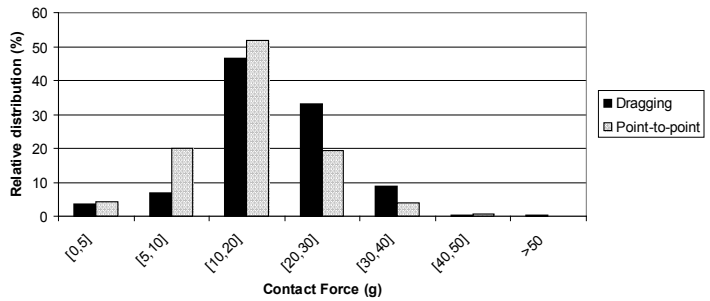

Figure 2: Distribution of CF during RF applications

Distribution of contact force (CF) during RF applications for both "dragging" and "focal" groups is displayed

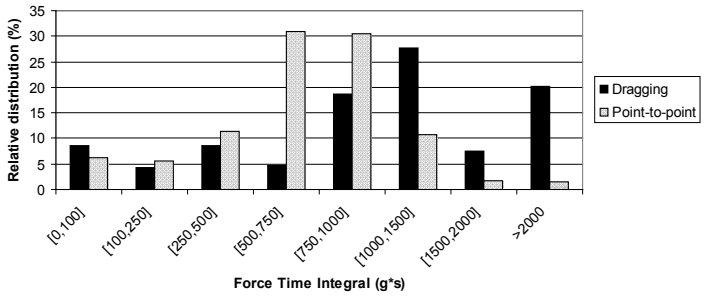

Figure 3: Distribution of FTI during RF applications

Distribution of force-to-time integral (FTI) during RF applications for both "dragging" and "focal" groups is displayed

CF because of difficulty in catheter positioning potentially could be compensated for by varying the RF power and/or duration of the RF application (FTI index). If the CF is high, the operator could decrease the RF power and/or decrease RF duration.

We monitored the data for two different techniques of ablation: the "dragging" approach and the "point by point" (focal) one. As expected, the "dragging" technique has a lower number of ablations, lower total time of the procedure and lower total radiofrequency time. It brings to a faster procedure with less energy delivered to the patient, but significant different in the fluoroscopy time was not be found. The movements of the catheter during ablation lead the operator to a higher use of the x-ray to check the ablator position. With the focal approach the operator keeping stable the catheter during ablation needs less fluoroscopy checks.

Additionally the "dragging" technique has significant higher values of FTI associated with the longer duration of each RF application.

This study reports the CF data, the acute success and the complications of the ablation procedures of a single centre, future studies should evaluated the benefit of this catheter in achieving durable PVI and in improving long-term effectiveness.

Conclusion:

This study of a single centre with a low level of experience in AF ablation suggests that the ability to measure CF may provide additional useful information to the operator during RF application. It ensures uniform ablations, with little variability in the catheter manipulations, and it avoids excessive contact forces increasing the patient safety.

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