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Catheter-tissue contact force values do not impact mid-term clinical outcome following pulmonary veins isolation in patients with paroxysmal atrial fibrillation.

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Contact force catheter in PV ablation

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ABSTRACT

Purpose. Catheter-tissue contact is critical for effective lesion creation in radiofrequency catheter ablation (RFCA). In a multicenter prospective study, we assessed the relationship between catheter contact force (CF) during RFCA for paroxysmal atrial fibrillation (AF) and clinical recurrences over a mid-term follow-up.

Methods. All patients underwent RFCA for paroxysmal AF by antral pulmonary vein (PV) isolation, aiming at entry and exit conduction block in all PVs. A new open-irrigated tip catheter with CF sensing (SmartTouch™, Biosense Webster Inc. CA) was used. All patients were followed for at least 12 months and the relationship between CF and clinical outcomes assessed.

Results. One year follow-up was available in 92/95 of the patients enrolled. Acute PVI was achieved in 100% of the veins. Mean CF during RFCA was 12.2±3.9 g. Mean Force Time Integral (FTI) was 733±505 gs. Following the 3-month blanking period, 17 (18%) patients experienced at least 1 atrial tachyarrhythmia relapse. There was no statistical difference in mean CF (13±3.4 g vs 12±4 g, p=0.32) and mean FTI (713±487 gs vs 822±590 gs, p=0.42) between patients with and without arrhythmias recurrences. Recurrences were recorded in 22% of patients achieving a mean FTI value below the median of 544 gs and in 15% of patients with a mean FTI value above the median (p=0.64).

Conclusions. RFCA with CF data during PV isolation for paroxysmal AF improves physician's knowledge on catheter-tissue contact. In the present dataset, however, higher CF values did not impact mid-term clinical RFCA outcome.

Key words: catheter ablation, atrial fibrillation, contact force

INTRODUCTION

The creation of a durable radiofrequency (RF) lesion depends on several parameters, including catheter tip electrode size, temperature, orientation, RF pulse duration, power, blood flow, and catheter to tissue contact (1-4). The wide diffusion of open irrigated catheters (5-8) has reduced the role of temperature in monitoring RF lesion formation. Recently development of new contact force (CF) sensor catheters has alowed measurement of the tip to tissue CF during the RF ablation procedure. Optimization of electrode-tissue contact during RF catheter ablation for pulmonary veins (PV) isolation impacts on procedure parameters by significantly reducing procedure and fluoroscopy times, without increasing acute complications (9-11). Preliminary data suggest a potential benefit of real-time CF sensing technology in reducing atrial fibrillation (AF) recurrence during the first year after PV isolation (11,12). The aim of this multicenter prospective study was to assess the relationship between catheter CF during RF catheter ablation for paroxysmal AF and clinical recurrences during a mid-term follow-up.

METHODS

Patients' selection. As previously described (10) this multicenter prospective study enrolled 95 patients in 9 Italian centres (see the Appendix) for a 3-month period. Patients aged between 18 and 90 years with documented symptomatic AF episodes refractory to drug therapy (Class I or III drugs) and self-terminating within 7 days were included.

This study followed the principles outlined in latest update of the Declaration of Helsinki and all patients signed informed consents.

Ablation procedure and contact force measuring. Detailed ablation procedure and CF measuring has been previously described (10). Briefly, after transseptal catheterization, 3D electroanatomic maps of the left atrium and PVs were reconstructed using a nonfluoroscopic navigation system (CARTO 3®, version 2, Biosense Webster Inc., Diamond Bar, California, USA) (7,13). Maps were acquired during AF or sinus rhythm using respiratory gating. Fast anatomic mapping or imaging

integration with a pre-acquired computed tomography or magnetic resonance scan was used, according to operators' preference. RF pulses were delivered using the 3.5-mm Thermocool SmartTouch™ (Biosense Webster, Inc., Diamond Bar, CA, USA) in power control mode. RF power was set between 30 and 35 W depending on different left atrial sites and the catheter tip was irrigated by saline at a flow rate of 2 mL/min during mapping and of 30 mL/min during ablation. RF was delivered up to 60 seconds or until local electrogram amplitude was reduced > 80% to produce a circumferential lesion around the proximal part of each PV's ostium or around ipsilateral PVs according to anatomy. The lesion around the PV ostium was created by sequential point-by-point application of RF energy or by continuously dragging the catheter, according to operators' preference. A circular decapolar or duodecapolar mapping catheter (LASSO®, Biosense Webster Inc, Diamond Bar, CA, USA) was used to confirm PV electrical isolation with demonstration of entry and exit block. Resumption of left atrium to PV conduction was evaluated for 30 minutes after ablation. In case of reconnection, PVs were newly isolated targeting the residual electrical breakthroughs.

Operators involved in this study had previous experience in the use of Thermocool SmartTouch™ catheter in a 6-month period prior to study commencement, and they were encouraged to navigate the catheter with a limited use of fluoroscopy.

The real time visualization of the CF values, during both the mapping and ablation phase, was available. During RF delivery, it was recommended to make every effort to reach and maintain a displayed CF value between 10 and 40 g.

For all ablation sites, CF data were recorded and exported after the procedure for off-line analysis. During each RF application maximum, minimum, and mean CT values, obtained by averaging values sampled every 50 ms, were stored and subsequently analysed. Force Time Integral (FTI) expressed in g*s and defined as the integral of the CF-time curve during the ablation period in which the catheter was located in the segment of interest was also calculated and analysed.

Follow-up. After discharge patients were followed for 12 months, with a clinical visit and a 12-lead electrocardiogram scheduled at 1, 3, 6, and 12 months. In addition, a 24-hour Holter monitoring was obtained at 3 and 12 months. Moreover, patients were instructed to obtain an ECG in the event of palpitations. No antiarrhythmic medication was prescribed following ablation.

If there was documented recurrence of symptomatic AF and the patient required antiarrhythmic drug therapy, a previously ineffective but tolerated class 1 or class 3 (sotalol) drug was the preferred option.

Ablation was deemed successful in the absence of symptomatic or asymptomatic atrial tachyarrhythmias lasting more than 30 seconds identified on surface ECG or on Holter monitoring, off antiarrhythmic drug therapy. As early relapse of atrial tachyarrhythmias within the first 3 months after RF ablation may be a transient phenomenon, this transition period was excluded from the final analysis (14).

Statistical analysis. Normally distributed continuous variables were expressed as mean (±SD) and compared by unpaired Student's *t* test. Skewed variables were expressed as median (25-75 quartiles) and compared by the runk-sum test. Normality was assessed by the Shapiro-Wilk test. Categorical variables were presented as counts and percentages, and compared by Chi square test (Pearson, Yates or Fisher's exact test as appropriate). The actuarial probability of freedom from AF after ablation was calculated using the Kaplan-Meier method . Differences between the curves were tested for significance by the log-rank statistic. A p value <0.05 was considered statistically significant.

RESULTS

Procedural data. Complete one year follow-up was available in 92/95 (97%) patients; three patients were lost after 6 months of follow-up. All patients underwent successful ablation achieving acute PV isolation in 100% of the veins. Overall procedure time, fluoroscopy time, and ablation time were 138±67, 14.3±11.2 and 34±20 min, respectively. Mean CF during ablation was

12.2±3.9 g. Mean FTI was 733±505gs. Three groin haematoma were observed. No stroke/TIA, pericardial effusion, or cardiac tamponade were reported within 30 days from the procedure.

Clinical outcome. Following the 3-month blanking period, 17 (18%) patients experienced at least 1 episode of atrial tachyarrhythmia. In Table I are summarized the clinical characteristics of the study population, there was no statistical difference between patients with and without arrhythmias recurrences with the exception of an higher prevalence of recurrences among females. Comparing radiofrequency energy applications between the group of patients with and the one without recurrences, there was no statistical difference in mean CF (13±3.4 g vs 12±4 g, respectively; p=0.32) and mean FTI (713±487 gs vs 822±590 gs, respectively; p=0.42). In Table II are reported the percentages of CF values 5-10g, 11-20g, and 21-30g, in patients with and without AF recurrences percentage. There was no difference in the percentage of CF values among patients with and without AF recurrence when the suggested minimum value of 10 g was achieved. Similarly, there was no statistically significant difference in the median value of mean CF [12 (9.8-22) g vs 11.1 (6.7-23.7) g, p=0.64] and FTI [520 (361-2065) gs vs 561 (143-2724) gs, p=0.51] values in patients with vs those without recurrences. Arrhythmias recurrences were recorded in 22% of patients achieving a mean FTI value below the median of 544 gs against 15% of patients with a mean FTI value above the median (p=0.64). Figure 1 shows the Kaplan–Meier survival curve of patients free arrhythmia recurrences during the 12-month follow-up according to FTI quartiles. No statistically significant difference was observed among the four groups (p=0.43).

DISCUSSION

Main findings. In this multicenter study on the use of a new technology which allows visualization of CF values and CF direction, performed with operators not blinded to CF values, higher catheter-tissue CF values, achieved during PV isolation for paroxysmal AF, did not significantly impact mid-term clinical outcome.

Previous studies. Preliminary experience of RF catheter ablation in patients with AF by means of catheters able to assess catheter-tissue contact, by means of optical fibers, impedance measurement, and magnetic sensors, have shoved how higher FTI and mean CF values during ablation allow reduction of both procedural and fluoroscopy time (9-11), without increasing complications. Moreover, CF data allowed the identification of key areas where CF was poor, related to higher probability of acute and sub-acute reconnection (15,16). Availability of real time CF information during PVI has been associated with a significantly lower acute and 3-month PV reconnection rate. In the TOCCATA study (12) 32 patients with paroxysmal AF underwent PV isolation by using a RF ablation catheter with a CF sensor integrated at its tip, and they were followed for 12 months. All patients treated with an average CF of < 10 g (5 of 5 patients) experienced recurrences, whereas 80% of the patients treated with an average CF of > 20 g (8 of 10 patients) were free from AF recurrence at 12 months. The analysis of the average force-time integral showed that 75% of the patients treated with < 500 gs were recurrent whereas only 31% of the patients treated with > 1000 gs had recurrences at 12 months. The authors, based on this small population, concluded that CF during catheter ablation for AF related to RFCA clinical outcome. Marijon et al (11) first demonstrated the benefit of CF technology use in reducing AF recurrence during the year following PVI, when compared to a non-CF catheter. Sixty patients with symptomatic paroxysmal AF were enrolled in this prospective trial, comparing circular antral catheter ablation using either the CF catheter used in the present study (CF group) or a non-CF open-irrigated catheter (control group). The incidence rates of AF recurrence were 10.5% (95% CI, 1.38–22.4) in the CF group, and 35.9% (95% CI, 12.4–59.4) in the control group (p= 0.04). After adjustment of potential confounders, the use of CF catheter was found to be associated with a lower AF recurrence (OR 0.18, 95% CI 0.04–0.94, p= 0.04).

Present study. For the first time in a multicenter experience, our data demonstrates that CF improves physician's knowledge on Catheter-tissue contact reducing procedure and fluoroscopy

times, but not significantly impact on mid-term clinical outcome. Only a trend towards a better outcome in patients with mean FTI values above the median value was observed.

Many factors might explain the discrepancy of our results compared to previous published data. 1) Although there is a growing evidence that catheter–tissue CF is a major determinant for RF ablation lesion size and quality, Olson et al.(4) demonstrated equivalent ablation lesion size with RF energy delivered with intermittent tissue contact over a longer period of time when compared to lesions created with constant catheter contact. This hypothesis seems to be confirmed by the findings (9,11) that CF guided ablation decreased RF time as compared with ablation performed with standard catheters. Also in our experience (10) optimization of electrode-tissue contact during RF catheter ablation for PV isolation significantly reduced procedure and fluoroscopy times. In fact, increasing RF energy duration in case of low or unknown contact may lead to similar clinical results. 2) In our study operators were not blinded to the CF value and, during RF delivery, it was recommended to make the maximum effort to reach and maintain a displayed CF value between 10 and 40 g. In fact, mean CF during ablation was 12.2±3.9 g, higher than that (< 10 g) predicting poor outcome in previous studies (Reddy et al (12)). 3) One of the advantages of CF technology is the possibility to visualize real time direction and orientation of the catheter's tip enabling immediate recognition of catheter dislodgement/sliding (11). This feature is independent from CF value and unmeasurable in a routine clinical setting.

Limitations.

The number of patients enrolled in each centre was limited and this might increase the range of data variability, and the bias of operators' dependent outcome. However, this observational prospective study is the largest to date available and provides a representative picture of the real-life scenario of the use of CF sensing for AF ablation. Larger cohorts are needed to confirm or exclude the trends observed in the present study.

Another potential limitation of the study was the different techniques used to perform PVI. Infact the lesions around the PV ostium were created by sequential point-by-point application of RF

energy or by continuously dragging the catheter, according to operators' preference. We did not evaluated the interlesion distance with both approaches. Recently, Park et al (17) demonstrated that acutely durable PV isolation can be achieved when RF lesions are delivered with a mean CF > 10 g and an interlesion distance < 5 mm.

Conclusions. RFCA with CF data during PV isolation for paroxysmal AF improves physician's knowledge on Catheter-tissue contact. In the present dataset, however, higher CF values did not impact mid-term clinical RFCA outcome. Further studies randomly comparing implementation or not of CF data on RFCA outcome are therefore needed.

Conclict if interest disclosure: dr. Roberto De Ponti is a consultant of Biosense Webster; dr Emanuele Bertaglia is a consultant of Biosense Webster, St. Jude Medical, and Boston Scientific; none for the other authors.

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Appendix

Participating centers (listed in alphabetical order):

Ospedale Sant'Anna, Ferrara (Matteo Bertini, Lina Marcantoni, Claudio Pratola); Ospedale Morgagni, Forlì (Alberto Bandini, Paolo Golia); Casa di Cura Montevergine, Mercogliano (Francesco Solimene, Giovanni Donnici); Casa di Cura Mediterranea, Napoli (Assunta Iuliano, Giuseppe Stabile); Policlinico Casilino, Roma (Leonardo Calò, Ermenegildo De Ruvo, Luigi Sciarra); Ospedale Sandro Pertini, Roma (Antonello Castro, Marialuisa Loricchio); Azienda Ospedaliera Santa Maria Nuova, Reggio Emilia (Nicola Bottoni, M Iori, F Quartieri); Città della Salute e della Scienza, Department of Medical Sciences, University of Turin (Matteo Anselmino, Federico Ferraris, Fiorenzo Gaita); Ospedale di Circolo e Fondazione Macchi, University of Insubria, Varese (Roberto De Ponti, Raffaella Marazzi, Lorenzo A Doni).

Table I. Clinical characteristics of study population

	Study Population (92 pts)	**Recurences Group (17 pts)**	**No recurences Group (75 pts)**	**P**
Mean age (years)	58±11 (range 24-82)	58±13	58±10	0.83
Male sex	84%	65%	88%	0.02
Left atrium diameter (mm)	40±5 (range33-55)	39±7	41±5	0.39
Left ventricle ejection fraction (%)	58±8 (range 40-65)	60±2	58±9	0.34
Body mass index > 30	5%	0%	6%	0.33
Previous stroke/TIA	4%	0%	5%	0.33
Heart disease	51%	47%	52%	0.71
Hypertensive	46%	41%	47%	0.68
Ischemic	7%	0%	8%	0.23
Valvular	4%	6%	4%	0.73
Dilated cardiomyopathy	4%	0%	5%	0.33
Diabetes	7%	0%	8%	0.23

Table II. Percentage of mean CF values in patients with and without AF recurrence.

	A 5g < CF ≤ 10 g	B 11g < CF ≤ 20g	C 21g < CF ≤ 30 g
No AF recurrence (75 pts)	38.7 %(29)	54.7% (41)	6.6% (5)
AF recurrence (17 pts)	6 % (1)	88% (15)	6% (1)

Pts= patients; CF= contact force; A vs B p=0.024, B vs C p=1; A vs C p=0.31.

FIGURE LEGENDS

Figure 1. Kaplan–Meier survival curve of patients free of AF during the 12-month follow-up (3-month blanking period), according to the FTI quartilies .