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# Acute Procedural Results and Mid-Term Outcome of Electroanatomical Guided Pulmonary Vein Isolation: A Single Center Observational Study Comparing A Real-Time Contact Force Sensing Versus Standard Tip Irrigated Ablation Catheter -

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## ABSTRACT

The additional benefit of real time Contact Force (CF) measurement during Pulmonary Vein Isolation (PVI) to improve procedural parameters and clinical outcome is unclear. We prospectively assessed the impact of real time CF measurement on acute procedural parameters, procedural related complications and mid-term outcome.

One hundred consecutive patients (73 males) with paroxysmal (78%) or persistent (22%) Atrial Fibrillation (AF) who underwent PVI with CARTO® 3 Electro-Anatomical Mapping (EAM) system (Biosense Webster Inc.) were consecutively assigned to either Radio Frequency (RF) ablation using the 3.5mm open-irrigated-tip Navistar®Thermocool® catheter (50 patients, standard group) or the SmartTouchTM catheter with CF measurement capabilities (50 patients, CF group). PVI endpoint was set as validation of entry and exit block. Significant reduction in fluoroscopy time (57 ± 16min vs. 29 ± 16min) and a trend in reduction of procedural related complications (10% vs. 2%) was reported in CF group patients. No differences in mid-term risk of AF recurrence were observed between the two groups (8% in the CF group vs. 10% in the standard group at 12 months respectively. Log Rank test p=0.376). However, in CF group patients with higher (>13.5g) mean time-weighed CF resulted in a lower risk of 12 month follow-up AF recurrence (18% vs. 0%; p=0.041). In conclusion, our study confirm the procedural and technical improvement related to real time CF monitoring during PVI and show an halving of the fluoroscopy time in a large cohort of patients.


**Keywords:** Catheter ablation; Radiofrequency ablation; Atrial fibrillation; Contact force; Pulmonary vein isolation.

## INTRODUCTION

Pulmonary Vein Isolation (PVI) has now become the main approach in Atrial Fibrillation (AF) rhythm control interventional strategies [1]. However, long-term experiences have emphasized the relatively high recurrence rate over time [2-5] with the large majority of recurrences related to PV reconnection [5]. In this context, catheter ablation with tip tissue sensing Contact Force (CF) appears crucial for adequate lesion formation [6-11]. The CF catheters have optical fibers that emit wavelengths. When the catheter tip touches tissue, the optical fibers bend. Catheter's software calculates the changes in the wavelengths between the optical fibers and translates this information into a measurement of how much pressure is being applied to the heart tissue. Insufficient CF 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 [7,12-13]. We prospectively assessed the impact of real time CF measurement on acute procedural parameters during Radio Frequency (RF) circumferential PVI using either a new open-irrigated RF ablation catheter (ThermoCool®SmartTouch™, Biosense Webster Inc., Diamond Bar, CA, USA) with real time CF measurement between the catheter tip and the beating heart wall, or a control open-irrigated non-CF catheter (Navistar®ThermoCool®,Biosense Webster, Inc, Diamond Bar, CA, USA).

## METHODS

### Patient population

In our prospective, non-randomized, single-center, observational study, 100 consecutive patients (73 males) with paroxysmal (78%) or persistent (22%) AF who underwent their first PVI procedure guided by CARTO® 3electro-anatomical system (Biosense Webster Inc., Diamond Bar, CA, USA) were consecutively assigned to either RF ablation using

(1) The Navistar®ThermoCool®(50 patients, standard group) or

(2) The ThermoCool®SmartTouch™ (50 patients, CF group).

Enrollment criteria included

(1) First PVI for documented symptomatic paroxysmal or persistent AF that was refractory to at least one antiarrhythmic drug or not tolerated drug therapy;

(2) Left Ventricular Ejection Fraction (LVEF) ≥ 50%;

(3) Participants capable of complying with the study requirements including all specified follow-up visits. Exclusion criteria comprehend history of heart surgery, severe valvular disease or prosthetic valve, known severe coronary artery disease, atrial and/or ventricular thrombosis, and hyperthyroidism.

PVI was performed by two experienced operators (AP and LR). All subjects provided written informed consent prior to the procedure.

### Endpoints

The primary procedural endpoint was represented by PV electrical isolation validated with entry and exit block using a combined anatomical and electrophysiological approach. The primary mid-term endpoint was indicated by the rate of AF recurrence, defined as at least one AF episode >30s documented either in baseline ECG or Holter ECG recordings or clear AF-related symptoms (palpitations, tachyarrhythmias). The first 3 months post-procedure were considered as blanking period. Secondary endpoints addressed both efficacy and safety and included: RF delivery time required for complete PVI; overall fluoroscopy time; occurrence of major complications such as cardiac tamponade or pericardial effusion (both hemodynamically significant and non-significant); stroke; severe PV stenosis; esophageal fistula; major bleeding requiring surgery or transfusion and death during the first 3 months post-procedure.

### Procedural details

All patients underwent Computed Tomographic (CT) scanning of the left atrium 24 hours prior the procedure to assess PV anatomy. A double trans-septal puncture was performed under both fluoroscopic and transesophageal echocardiographic guidance to introduce ablator and Lasso® (Biosense Webster Inc., Diamond Bar, CA, USA) catheters. The ablation catheter used (CF or non-CF) was chosen by the operator on the basis of his preference and availability (the SmartTouch catheter was subject to a temporary manufacturer recall). A CF range during ablation of 5-40g was targeted. RF energy was delivered for at least 20 seconds at a location with the aim of each ablation being a reduction in local bipolar electrogram amplitude by > 90% or until the amplitude was < 0.1mV. The sheaths in the 2 groups were left in the right atrium as our routine. Patients received

intravenous heparin to maintain an activated clotting time between 250 and 300 seconds. The Lasso® catheter was used to collect left atrial geometry using Fast Anatomical Mapping (FAM). Left atrial reconstruction was integrated with the pre-acquired CT allowing catheters navigation into the real anatomy.

Circumferential PVI was performed by systematic RF application around the PV antra without additional adjunctive left atrial ablation. Power was limited to 30W in anterior, superior and inferior sites (flow rate 30mL/min) and 25W in all posterior sites (flow rate, 30mL/min). Temperature was limited to 45°C for each lesion. Power was not adjusted according to CF. Effective PVI was tested by both entrance and exit block (bidirectional block), with a waiting period of 20 minutes after last RF application. In the event bidirectional disconnection was not achieved, PVI was completed to eliminate all points of residual PV connection (Figure 1).

### Follow up

Echocardiography was performed in all cases the day after procedure. After pre-discharge evaluation, systematic follow up was performed for each patient every 3 months. 12-lead ECG and 24-hour Holter monitoring were systematically performed at each visit. Patients were also carefully instructed on how to perform daily self-assessment of the pulse. Information collected included details of cardiac medications, NYHA functional class and history of any arrhythmias or other adverse events.

### Statistical methods

Continuous variables, when normally distributed, were presented as mean ±SD and comparisons made using the 2-sample t test. Otherwise, data were presented as the median [Inter Quartile Range (IQR)] and non-parametric Mann Whitney-U test used to assess the degree of significance. Categorical data were presented as proportions and comparisons made using Fischer's Exact test. All tests were two-tailed, and *p* values of less than 0.05 were considered to be statistically significant. Univariate and multivariate logistic regression analysis (using the forward stepwise model selection procedure) were performed to evaluate the relationship between procedural complications and the following variables: age≥ 50 years, male gender, type of arrhythmia, $CHA_2DS_2$-Vasc score and type of ablation catheter used. Only variables with *p* value <0.1 at univariate analysis were entered as covariates in the multivariate model. Survival curves were generated by the Kaplan-Meier method and compared by the log-rank test. Univariate and multivariate Cox proportional hazards analysis (using the forward stepwise model selection procedure) was used to evaluated baseline covariates independently associated with AF recurrence. Only variables with *p* value<0.1 at univariate analysis were entered as covariates in the multivariate model. Two-tailed tests were considered statistically significant at the 0.05 level.

## RESULTS

### Population characteristics

Clinical characteristics of the study population are summarized in (Table 1). No significant differences were observed between the two groups of patients regarding age (*p=0.363*), gender (*p=0.083*), number of anthiarrihythmic drugs tested before the procedure (*p=0.247*), percentage of amiodarone usage (*p=0.689*) and $CHA_2DS_2$-

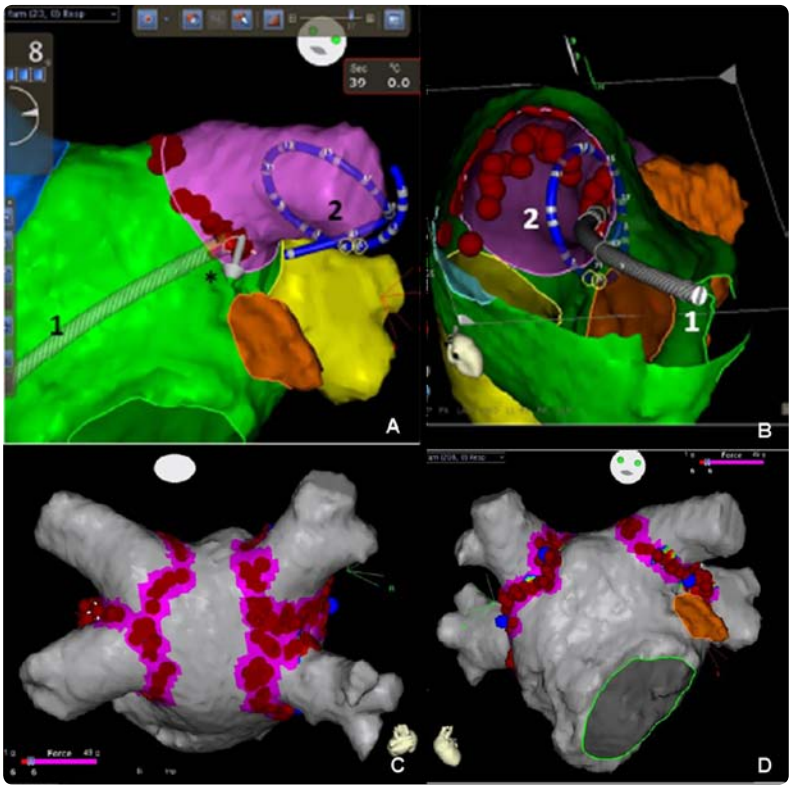


**Figure 1:** Fast anatomical mapping of the left atrium merged with Angio-TC 3D reconstruction by CARTO 3 system. The position of ablation catheter (1), Lasso catheter (2) and contact force direction (*) are shown from an epicardial view (A) and from an endocardial view (B). CARTO 3 system contact-force map showing in purple the ablation sites with contact force major than 13.5 g and in red the ablation sites with contact force less than this cut-off. Red dots represent the anatomical localization of radio-frequency energy erogation. Postero-anterior (C) and antero-posterior (D) views.

**Table 1:** Main characteristics of the study population.

| | Standard group | Contact force group | P value |
|---|---|---|---|
| N° of patients | 50 | 50 | |
| Male; n (%) | 30 (60%) | 43 (86%) | |
| Age (mean ± SD) | 61 ± 10 years | 59 ± 10 years | 0.363 |
| Lone atrialfibrillation; n (%) | 38 | 40 | 0.810 |
| $CHA_2DS_2$-VASC (mean ± SD) | 2 ± 1 | 1.5 ± 1 | 0.148 |
| Type of arrhytmia | | | 0.470 |
| - Paroxysmal AF; n (%) | 41 (82%) | 37 (74%) | |
| - Persistent AF; n(%) | 9 (18%) | 13 (26%) | |
| Antiarrhythmic drugs (mean n° ± SD) | 2 ± 1 | 2 ± 1 | 0.247 |
| Amiodaroneusage; n (%) | 23 (46%) | 26 (52%) | 0.689 |
| Common/additional PV ostia; n (%) | 2 (4%) | 8 (16%) | 0.092 |

Vasc score (*p=0.148*). Paroxysmal and persistent AF were equally distributed in the two groups (*p=0.470*). Previous known heart diseases (coronary artery disease in 11 patients and hypertensive heart disease in 8 patients) were present in 19 patients, with a normal mean left ventricular ejection fraction (60 ±4%). The $CHA_2DS_2$-Vasc score was relatively low (≤2 in 80 patients). Presence of common and/or additional PV ostia was present in 10 patients. History of typical atrial flutter was present in 36 cases (21 among CF group and 15 among control group), requiring additional cavo-tricuspid isthmus ablation, which was performed at the end of the procedure in all cases.

### Procedural results

Acute effective PVI was reached in all patients. In the CF group, the meantime-weighed CF during PVI was 13 ± 2g. The RF ablation time for PVI was essentially comparable in the two groups (33 ± 10min in CF group *vs.* 30 ± 8min in the standard group, *p=0.082*). Conversely, in CF group there was just a slight increase in the overall procedural time (165 ± 27 in the CF group *vs.* 153 ± 28min in the standard group, *p=0.043*). In addition, the fluoroscopy exposure time for PVI and cavo-tricuspid isthmus ablation was significantly lower in the CF group (29 ± 16 *vs.* 57 ± 16min, *p<0.0001*) despite a higher number of patients requiring cavo-tricuspid isthmus ablation in the CF group (Table 2).

### Complications

We observed procedural-related complication in 6 patients (Table 2). Immediate post-procedural complications included 2 access-related complications (arterio-venous fistula, one in both groups), which were treated conservatively. Of note, there was only one case of pericardial effusion at echocardiography on the following day, which was treated conservatively. We observed also a case of ischemic stroke without relevant sequelae, a case of transient ischemic attack manifested with diplopia, and a case of permanent lesion of right phrenic nerve. All of these complications were observed in the standard group (*p=0.116*). Table 3 shows the results of the univariate and multivariate logistic regression analysis performed to determine the independent risk factors for procedural complications. At multivariate analysis no one of the baseline covariates were independently related to the risk of procedural complications.

### Follow up

The mean follow-up period was 12 ± 10 months. Antiarrhythmic drugs, including amiodarone, were stopped after 3 months. Overall, the rate of AF recurrence was 10% at 12 months without a significant difference between the two groups (8% *vs.* 10% at 12 months respectively in the CF group and in the standard group, Log Rank test *p=0.376*) (Figure 2A). Splitting the curves according to the type of arrhythmia, we didn't observe a significant differences in AF recurrence (Figure 2B-C). Table 4 shows the results of univariate and multivariate Cox proportional hazard analysis performed to determine the factors independently associated with recurrence of AF at follow-up between the two groups. At multivariate analysis no one of the baseline covariates were independently associated with the risk of recurrence. However, in the CF group the risk of AF recurrence was significantly related to mean time-weighed CF during procedure (Figure 3) with a risk of recurrence of 18% at 12 months follow-up when mean CF was equal to or less than 13.5g and a recurrence of 0% when CF was major than the stated cut-off (*p=0.041*).

## DISCUSSION

Our study confirms the procedural improvements due to the use of CF sensing ablation catheter over standard open-irrigated-tip catheter in the setting of PVI. Particularly we observed an halving of the fluoroscopy time (57 ± 16 *vs.* 29 ±16min respectively in standard group and CF group, *p<0.0001*; (Table 2)) with a consequent improving trend in patient safety. In particular, we think that the availability of a CF datum, could have improve the confidence and the awareness of the operators in the 3-dimensional electroanatomical mapping system, without the continuous need to have recours to the fluoroscopy during the ablation. In contrast to what observed in other studies [14], we reported a slight increase in overall procedural time (153 ± 28 *vs.* 165 ± 27min respectively in the standard and

**Table 2.** Procedural data.

| | Standard group | Contact force group | P value |
|---|---|---|---|
| **Overall procedural time (mean ± SD)** | **153 ± 28 min** | **165 ± 27 min** | **0.043** |
| RF ablation time (mean ± SD) | 30 ± 8 min | 33 ± 10 min | 0.082 |
| Time-weighed mean contact force (mean ± SD) | - | 13 ± 2 g | - |
| **Fluoroscopy time (mean ± SD)** | **57 ± 16 min** | **29 ± 16 min** | **P < 0.0001** |
| Complications | 5 (10%) | 1 (2%) | 0.116 |

**Table 3.** Univariate and multivariate logistic regression analysis to determine the independent correlates of procedural related complications risk.

| | Univariate | | Multivariate | |
|---|---|---|---|---|
| | OR (95% CI) | P value | OR (95% CI) | P value |
| Age (≥ 50 years) | 1.0 (0.96-1.15) | 0.313 | | |
| Male gender | 0.1 (0.02-0.68) | 0.017 | 0.2 (0.03-1.02) | 0.053 |
| Type of arrhythmia | | | | |
| - Paroxysmal AF | 1.8 (0.20-15.36) | 0.614 | | |
| - Persistent AF | 0.6 (0.07-5.35) | 0.654 | | |
| $CHA_2DS_2$-Vasc ≥ 2 | 2.1 (0.44-9.99) | 0.346 | | |
| Type of ablationcatheter | | | | |
| - Standard (Navistar) | 6.7 (0.77-57.70) | 0.084 | | |
| - CF sensing(Smart Touch) | 0.1 (0.02-1.29) | 0.084 | 0.2 (0.03-2.28) | 0.216 |

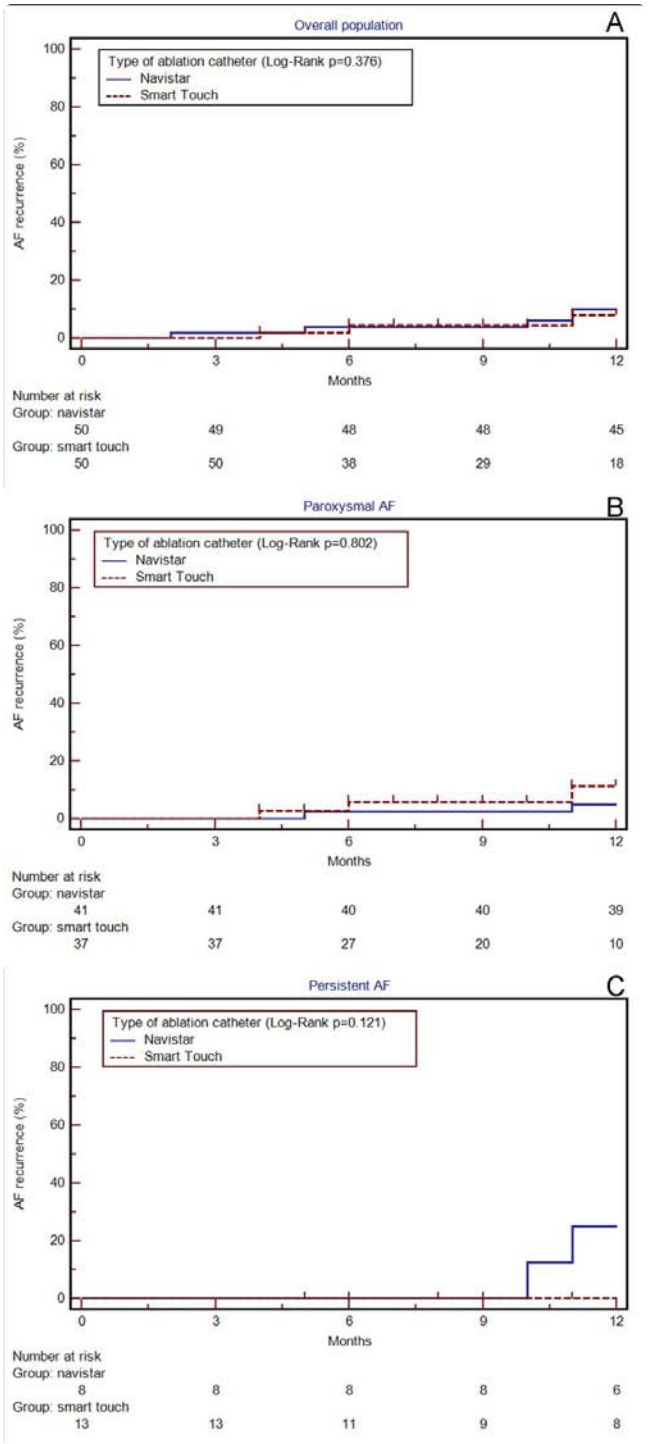


**Figure 2:** Kaplan-Meier survival curves with regard to AF recurrence according to the type of ablation catheter used for PVI in the whole population (A) and in patients with paroxysmal (B) or persistent (C) AF. The first 3 months were considered as blanking period. The number at risk is indicated under the curve.

CF group, *p=0.043*; (Table 2)), probably related to the fact that this new technology was used by relatively short time in our experience and the operators needed to become confident with the continuous real time monitoring of CF. We didn't observe any difference in RF ablation time (30 ± 8 *vs.* 33 ± 10min respectively in the standard and CF group, *p=0.082*; (Table 2)).

**Table 4.** Univariate and multivariate Cox proportional hazards analysis of baseline covariates in relation to the outcome.

| | Univariate | | Multivariate | |
|---|---|---|---|---|
| | HR (95% CI) | P value | HR (95% CI) | P value |
| Age (≥ 50 years) | 3.1 (0.41-23.05) | 0.277 | | |
| Male gender | 0.2 (0.09-0.7) | 0.006 | 0.3 (0.12-1.02) | 0.060 |
| Type of arrhithmia | | | | |
| - Paroxysmal AF | 1.1 (0.32-3.94) | 0.849 | | |
| - Persitent AF | 0.5 (0.13-2.40) | 0.429 | | |
| $CHA_2DS_2$-Vasc ≥ 2 | 3.9 (1.25-11.91) | 0.019 | 2.5 (0.74-8.52) | 0.137 |
| Type of ablationcatheter | | | | |
| - Standard (Navistar) | 1.8 (0.48-6.70) | 0.384 | | |
| - CF sensing(Smart Touch) | 0.6 (0.15-2.07) | 0.384 | | |

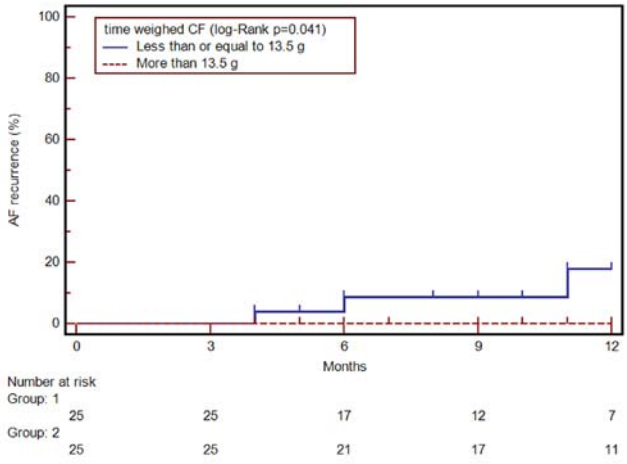


**Figure 3:** Kaplan-Meier curve showing the risk of AF recurrence according to the mean time-weighed force applied during PVI in the CF sensing catheter subgroup of patients. The first 3months were considered as blanking period. The number at risk is indicated under the curve.

Safety and effectiveness of CF sensing catheters have been evaluated in ex-vivo models, in-vivo experimental studies and more recently in humans [6,7,10,15] showing a good safety profile by avoiding application of extreme force. Likewise, in our study only one patient (2%) experienced a procedural related complication in the CF group *vs.* 5 (10%) in the standard group (*p=0.116*). Due to the limited number of patients and the relatively low frequency of complications, the difference in complication incidence between the two groups does not reach statistical significance, but we can state that the safety of the CF sensing catheter is not less than safety of the standard irrigated catheter. At univariate analysis male gender and the use of the CF catheter seemed to be related to lower risk of complications, but neither was independently associated with them at multivariate analysis (Table 3).

In literature there are other studies that evaluated the impact of different CF technology in mid-term outcome [14-20]. In the study by Reddy et al. [15] there was not a control group and the observations were limited to the relationship between the applied CF by the Tacti-Cath Set (Endosense SA, Geneva, Switzerland) and the recurrence of AF, finding that a mean CF less than 10g was strictly

associated with AF recurrence in the first 12 months after procedure and that arrhythmia control was best achieved when ablation lesions are placed with an average CF of >20g. Our findings confirmed the notable relationship between mean time-weighed CF and risk of AF recurrence (HR of 0.5 with a 95% CI between 0.26 and 0.80, *p=0.045*). Kaplan-Meier survival curve for AF recurrence comparing patients with low and high time-weighed CF during procedure is shown in [Figure 2] (18% *vs.* 0% of AF recurrence at 12 months follow up with a cut off for time-weighed CF of 13.5g, log-rank *p=0.041*). The study by Marijon et al. [16] for the first time demonstrate the benefit of CF technology in reducing AF recurrence during the first year following PVI when compared to a non-CF catheter. The incidence rates of AF recurrence were 10.5% in the CF group *vs.* 35.9% in the control group (Log Rank test, *p=0.04*). Our study does not confirm this results, because we didn't find any difference between the two groups in terms of AF recurrence at 12 month follow-up after successful PVI [Figure 1]. At univariate analysis female gender and $CHA_2DS_2$-Vasc score equal or more than 2 seemed to be related with worse prognosis, but neither was independently associated with AF recurrence at multivariate analysis [Table 4]. These differences may be explained by several reasons: First of all our study is a prospective-controlled registry and not a randomized-controlled trial. Second we enrolled both patients with paroxysmal and persistent AF as they underwent their first PVI procedure. Third, Marijon et al. used an exclusive anatomical approach for PVI, reserving the combined anatomic-electrophysiological method only to patients in which complete disconnection was not achieved and this could explain the greater improvement they observed in the CF group in terms of AF recurrence. We did not observed any difference in terms of outcome not even splitting patients according to the two types of arrhythmia [Figure 1B-C]. Like in our study, Wakili et al. [17] performed PVI on 67 consecutive patients both with paroxysmal (39 patients) and persistent (28 patients) AF using a CF catheter (32 patients) or a standard ablation catheter (35 patients). The clinical outcome (freedom from AF post PVI) was similar in both groups: 62.9 vs. 62.5 % at 6 months and 59.4 vs. 62.9 % at 12 months in CF vs. standard group, respectively. Moreover, according to our results CF guided ablation resulted in a significant reduction of fluoroscopy time (51.4 ± 3.3 vs. 33.0 ± 2.7min).

Recently, Ullah et al. [20], with a randomized multicenter study involving 117 patients, confirmed our data: their results show a reduce acute pulmonary veins reconnection but not improved 12 months success rate. For explaining this lack of improvement in success rate, they thought that not only CF range, but also its duration, quality (including stability and continuity) and ablation power may be used as defined targets.

### Study limitations

Our study is a single-center, non-randomized, observational, prospective study, and for this reason it has several limitations.

First of all it is impossible to remove all possible confounders in a non randomized study. Therefore, randomized controlled studies are needed to assess whether catheter ablation with optimized CF improves long-term clinical outcome.

Second, our results may be affected by the operator's learning curve of this new technology as we used the standard catheter technology in the first half of the patients and CF measurement technology in the second half. This seems to be unlikely as all operators have many years of PVI experience with hundreds of ablations procedures each. If there may be any learning curve effect, this would be more likely in the second (CF) group as the study reflects the early phase of using this catheter in our laboratory. Assuming this, the difference between standard and CF catheter might even be larger than reported.

Third, the relationship of CF and chronic PV reconnection was not assessed in this study.

Fourth, in the follow-up for detecting AF recurrences, we have used only 12-leads ECGs and 24-hours Holter exams, but an implantable loop-recorder would have been much more sensitive.

At last, we used a threshold of at least 10 g in accordance with the literature available at the enrollment beginning time (2010), but recent evidence suggests that 20grams may be a more pertinent cut off [15-19].

## CONCLUSION

In summary, our findings confirmed procedural and technical improvement related to real time CF monitoring during PVI and suggest a potential reduction of procedural related complications. We observed an halving of the fluoroscopy time. This datum was described in only one smaller trial [17] and we have confirmed it on more patients. Compared to conventional irrigated-tip ablation catheter we did not observe a significant benefit of real-time CF sensing technology in reducing AF recurrence during the first 12 months after PVI, but adequate CF (>13.5g) during PVI prove to be related to lower risk of AF recurrences. Long-term efficacy of this new technology needs to be evaluated in larger cohorts with longer follow-up.

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