Catheter–tissue contact force for pulmonary veins isolation: a pilot multicentre study on effect on procedure and fluoroscopy time

Giuseppe Stabile1*, Francesco Solimene2, Leonardo Calò3, Matteo Anselmino4, Antonello Castro5, Claudio Pratola6, Paolo Golia7, Nicola Bottioni8, Giuseppe Grandinetti9, Antonio De Simone10, Roberto De Ponti11, Serena Dottori12, and Emanuele Bertaglia13

1Laboratorio di Elettrofisiologia, Clinica Mediterranea, 80122 Napoli, Italy; 2Clinica Montevergine, 83013 Mercogliano (AV), Italy; 3Policlinico Casilino, 00169 Roma, Italy; 4Città della Salute e della Scienza, 10126 Torino, Italy; 5Ospedale Sandro Pertini, 00157 Roma, Italy; 6Ospedale Sant’Anna, 44121 Ferrara, Italy; 7Ospedale Moragni, 47121 Forlì, Italy; 8Azienda Ospedaliera Santa Maria Nuova, 42123 Reggio Emilia, Italy; 9Fondazione Macchi-University of Insubria, 21100 Varese, Italy; 10Clinica San Michele, 81024 Maddaloni (CE), Italy; 11Ospedale di Circolo e Fondazione Macchi-University of Insubria, 21100 Varese, Italy; 12Biosense Webster Italia, 00040 Pomezia (RM); and 13Clinica Cardiologica, Dipartimento di Scienze Cardiologiche, Toraciche e Vascòlari, Università di Padova, 35122 Padova, Italy

Introduction

Catheter ablation (CA) has become a well-established option for management of drug refractory atrial fibrillation (AF).1,2 Although several ablation approaches have been developed, a recent HRS/ EHRA/ECAS Expert Consensus3 recommends ablation strategies that target the pulmonary veins (PVs) and/or PV antrum as the cornerstone for most AF ablation procedures, the goal being complete electrical isolation of all PVs. One of the major limitations 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.4,5 In this setting, optimization of electrode–tissue contact may have a two-fold benefit. First, by achieving a satisfactory contact at the electrode–tissue interface, RF delivery to the tissue is optimized with less energy dissipated into the circulating blood pool and creation of more predictable and reliable lesions.5 This may affect...
Contact force measuring

The Thermocool SmartTouch™ catheter is a 7.5 F catheter with a precision spring connecting the distal 3.5 mm irrigated electrode and the catheter shaft. The spring allows small amounts of tip deflection. Sensors monitor the location signals of the transmitter coils embedded in the tip electrode and detect the micromovement of the spring. Therefore, microdeflections of the tip are translated by the system into CF values, sampled every 50 ms. Since the precision spring provides information on both lateral and axial movements in response to tissue-electrode contact, direction of CF is also given. This catheter is specifically designed for integration into the CARTO 3® system. On the system screen, direct visualization of CF values averaged on 500 ms time interval (in grams), CF direction, and instant variations of CF values over time in a real-time graphic are shown (Figure 1). After catheter insertion and initialization, the CF value was zeroed for the first time before mapping initiation, when the catheter tip was in the centre of the LA. During the procedure the CF value was re-zeroed every time it was required by the system.

Operators involved in this study had previous experience in the use of Thermocool SmartTouch™ catheter in a 6-month period prior to study commencement. Since the CF value is a reliable marker of catheter contact with heart structures, the operators were encouraged to navigate the catheter with a limited use of fluoroscopy. They were allowed to view in real-time the CF values, during both the mapping and ablation phase. During RF delivery, it was recommended to make every effort to reach and maintain a displayed CF value between 10 and 40 g. According to previous studies, values in this range proved to be safe and effective.

For all the 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 were stored and subsequently analysed. Mean CF value were calculated by averaging CF value sampled every 50 ms during each RF application. Force time integral (FTI) expressed in gram seconds 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.

Statistical analysis

Normally distributed continuous variables were expressed as mean (± SD) and compared with unpaired Student’s t-test. Skewed variables were expressed as median (25–75 quartiles) and compared with the rank-sum test. Normality was assessed by the Shapiro–Wilk test. Categorical variables were presented as counts and percentages, and compared with $\chi^2$ test (Pearson, Yates, or Fisher’s exact test as appropriate). A $P$ value < 0.05 was considered statistically significant.

Results

Study population

Ninety-five patients were included in the study. Their clinical characteristics are shown in Table 1.
Pulmonary vein isolation and contact force data

In our study population, image integration was used in 34 of 95 patients without any statistically significant influence on procedural and fluoroscopy time. At the end of the procedure all the target PVs were persistently isolated. Overall procedural time was $138.0 \pm 67.0$ min with a fluoroscopy time of $14.3 \pm 11.2$ min. Ablation time was $33.8 \pm 19.4$ min, and mean CF values during RF applications were $12.2 \pm 3.9$ (range 6.7–23.7) g. A similar value of mean CF was observed during ablation of the right PVs as compared with that of the left PVs ($12.5 \pm 4.3$ vs. $11.7 \pm 4.7$ g, respectively; $P = 0.14$). However, although the difference reaches marginal statistical significance, the percentage of time during which the CF was $<5$ g was lower during right as compared with left PV ablation ($22 \pm 14$ vs. $27 \pm 16$%, respectively; $P = 0.04$). The average of the minimum and maximum CF values were $3.3 \pm 2.2$ (range 0.4–10.7) and $39.4 \pm 13.6$ (range 18–79.6) g, respectively. As shown in Figure 2A, the average CF during the entire ablation time was quite variable in different patients. However, 34.7% of the patients had a CF between 10.01 and 12.5 g and 29.5% between 7.51 and 10 g.

Contact force values were well correlated with FTI (unadjusted $r^2 = 0.519$, $P < 0.001$). Figure 2B shows a similarly variable distribution in different patients of FTI during the entire ablation time. Figure 3 shows the box and whiskers plot of the CF values during ablation in the nine centres. Interestingly, in seven of the nine centres, the range of the median values was minimal, within 4 g, varying from 12.48 to 8.64.

**Effect of contact force on procedural parameters**

The analysis of FTI during ablation showed a median value of 543 gs: 48 patients with FTI below the median value had an average value of $394 \pm 100$ gs, while the 47 with FTI above had an average value of

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**Table I** Clinical characteristics of the study population

| Characteristic                        | Value               |
|---------------------------------------|---------------------|
| Mean age (years)                      | $58 \pm 11$ (range 24–82) |
| Male sex                              | 83%                 |
| Left atrium diameter (mm)             | $40.5 \pm 5$ (range 33–55) |
| Left ventricle ejection fraction (%)  | $58 \pm 8$ (range 40–65) |
| Body mass index > 30                  | 5%                  |
| Previous stroke/TIA                   | 4%                  |
| Heart disease                         | 51%                 |
| Hypertensive                          | 45%                 |
| Ischaemic                             | 7%                  |
| Valvular                              | 4%                  |
| Dilated cardiomyopathy                | 4%                  |
| Diabetes                              | 6%                  |

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**Figure 1** CARTO™ 3 system screen showing a reconstruction of the LA in posteroanterior view (top left) and left lateral view (top right) with a decapolar circular mapping catheter and an ablation catheter placed at the ostium of the left superior PV. The dashboard on the left-hand side shows the value of CF (16 g), while the arrow on the catheter icon shows the CF direction. The real-time graph of the CF vs. time is also shown (blue line in the bottom right pane). Surface electrocardiogram and intracavitary electrograms from the coronary sinus catheter and circular mapping catheter before ablation are also shown (bottom left).
When these two groups are compared, patients with FTI below the median required significantly longer procedure (158.0 ± 74.0 vs. 117.0 ± 52.0 min, respectively; P = 0.004) and fluoroscopy (17.5 ± 13 vs. 11 ± 7.7 min, respectively; P = 0.007) times when compared with patients with FTI above the median value. Moreover, as shown in Figure 4, patients with a mean CF during ablation >20 g required significantly shorter procedural time as compared with patients in whom CF was <10 g (92.0 ± 23.0 vs. 160.0 ± 67.0 min, respectively; P = 0.01). In the former group, a non-significant trend towards shorter fluoroscopy (9.2 ± 5.1 vs. 15.3 ± 10 min, respectively; P = 0.2) and ablation (25 ± 10.1 vs. 36.3 ± 23.7 min; respectively; P = 0.26) times was noted as compared with the latter group.
Complications
Four groin haematomas were observed. No stroke/transient ischaemic attack, pericardial effusion, or cardiac tamponade were reported within 30 days from the procedure.

Discussion
Main findings
Optimization of electrode–tissue contact during radiofrequency catheter ablation (RFCA) for PV isolation affects procedural parameters by significantly reducing procedural and fluoroscopy times, without increasing acute complications. Monitoring of catheter–tissue CF during PV ablation shows a wide range of values in different patients with a significantly shorter time of poor contact during right as compared with left PV ablation.

Previous studies
First data on CF measuring were reported using a catheter able to assess catheter–tissue contact by means of optical fibres.\(^7,9\) Subsequently, two other technologies were developed for clinical use, based on impedance measurement and magnetic sensors,\(^10,11\) respectively. The TOCCATA study investigators\(^9\) reported data on clinical use of a CF sensor for CA of supraventricular tachycardia and AF. They concluded that CA using real-time CF technology was safe for the treatment of supraventricular tachycardia and AF: high CF values may occur not only during catheter manipulation but also during ablation, suggesting that measuring the CF may provide additional useful information to the operator for safe catheter manipulation. With the same technology, Kumar et al.\(^12\) characterized the CF at different anatomical sites during antral PV isolation for AF. Monitoring of catheter–tissue CF during RF ablation demonstrated that there was significant variability in CF both within and between different PV anatomical sites. For left PVs, the highest CF areas were the superior and inferior quadrants, while the lowest CF were the carina and anterior quadrants. For right PVs, the areas of highest CF values were the anterior and inferior quadrants and the lowest CF was the carina. Furthermore, CF at any right PV quadrant was consistently higher than the corresponding left PV quadrant, except at the left superior quadrants where the right and left PVs had similar CF.

More importantly, data on ablation using CF sensing showed a strong linear relationship between the number of lesions with low average CF or FTI and the time to achieve acute PV isolation, confirming that catheter–tissue CF is an important determinant of procedural duration and ablation efficacy.\(^8,13\) Moreover, acute PV reconnection was strongly associated with low values of CF and FTI.\(^12\) Availability of real-time CF information during PVI was in this series associated with a significantly lower acute PV reconnection rate.\(^12\) Recently, Neuzil et al.\(^14\) showed that minimum CF and minimum FTI values are strong predictors of gap formation.

Finally, in a single-centre non-randomized study, Martinek et al.\(^10\) found that the CF sensing technology using the Thermocool SmartTouch\(^\text{TM}\) catheter was able to significantly reduce ablation and procedural times in PV isolation. Energy delivery was substantially reduced by avoiding RF delivery in areas with insufficient tissue–electrode contact.

Present study
For the first time in a multicentre experience, our data demonstrates, that optimal CF values during CA of AF significantly improve the procedural parameters. In fact, during ablation, patients with an FTI above the median value had shorter procedural and fluoroscopy time and, similarly, patients with a mean CF value during ablation >20 g had shorter procedural time.

As already reported by Kumar et al.\(^12\) optimal CF may be easier to obtain and maintain during right as compared with left PV ablation. In our study, the time with poor CF values (<5 g) was significantly shorter for right than for left PV ablation.

In our study, the mean CF value during ablation is slightly lower than the one reported in a previous study\(^14\) (12.2 ± 3.9 vs. 17.2 ± 3.5 g in our study and the previous one, respectively). The value of CF during ablation is very close to the value of 10 g, which has been considered critical for clinical success in the TOCCATA study,\(^15\) in which patients who received ablation with a mean CF below this value experienced AF recurrences. The difference between our and previous data is possibly due to different technology used. Data on follow-up will clarify if the value of 10 g is critical also using the Thermocool Smart Touch technology. In our study, we found that patients with a mean CF during ablation >20 g required significantly shorter procedural time as compared with patients in whom CF was <10 g. However, the small sample size and, above all, the lack of randomization and clinical outcome data does not, to date, allow conclusive recommendations concerning optimal CF values. Interestingly, while the mean value of CF during ablation shows wide inter-patient variability, the range of variation of this parameter is within 4 g in seven of the nine centres. This leads us to hypothesize that this value could be more patient-specific rather than operator-specific. This seems apparently in contrast with a previous report,\(^3\) which showed a wide range of CF values corresponding to the subjective feedback of ‘good contact’ defined by the operator. However, contrary to the previous study,\(^3\) in our study, the operators had already completed the learning curve of the use of the CF catheter and were not blind to the CF values.

Finally, no complication related to ablation and/or catheter manipulation was observed. Although lack of randomization does not allow a definitive conclusion, the safety profile of this CF catheter seems at least comparable with that of the conventional open-irrigated tip catheter. The low value of fluoroscopy time suggests that CF sensing could have been useful to minimize the use of fluoroscopy to manipulate the catheter without affecting procedural safety.

Limitations
First, the number of patients enrolled in each centre is small and this might increase the range of data variability, mainly due to the involvement of multiple operators. However, this observational prospective study may provide a representative image of the real-life scenario in the use of CF sensing for AF ablation.

Secondly, since this was designed as a pilot study to investigate initially the effect of CF measurement on acute procedural parameters during RFCA of AF, we did not include data on long-term clinical outcome.
Thirdly, CF was computed by averaging values sampled every 50 ms during each RF application; however, bias introduced by ablation strategy (point by point vs. dragging) may not be completely excluded.

Fourthly, several parameters may affect CF: operators’ attitude and expertise, use of steerable sheaths, site of transseptal puncture, individual anatomy of the LA, rotation of the heart, etc. Moreover, the direction of the force vector and the thickness of the tissue are other important variables that could play a major role in creation of a transmural and durable lesion. Although in our study we did not evaluate all these variables and their relationship with CF, our findings show that better the contact is shorter the procedural and fluoroscopy times are. This is potentially of great clinical relevance.

Conclusion

Contact force measurement is useful in CA aiming at isolation of PVs for AF. Achievement of a higher FTI and mean CF values during ablation allows reduction of both procedural and fluoroscopy time.

Acknowledgements

The authors thank Lidia Visigalli, BS, and Serena Dottori, BS, from Biosense-Webster, Italy, for their technical support.

Conflict of interest: R.D.P. is a consultant of Biosense Webster; E.B. is a consultant of Boston Scientific and Biotronik; all the other authors have no conflicts to declare. S.D. is an employee of Biosense Webster Italia.

Appendix

Participating centres (listed in alphabetical order)

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

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