ABSTRACT. The aim was to assess the dynamic range for contact force (CFdf) in order to achieve an effective lesion according to anatomic variables under conscious sedation. We retrospectively studied 674 radiofrequency (RF) lesions (21 procedures) at Kingston General Hospital. Consecutive patients employing a CF catheter were recruited. A force-sensing catheter was used to continuously record CF data and force–time integral (FTI) during each lesion. The CFdf represents the difference between the highest and lowest recorded contact force for each RF application. Out of 674 lesions examined, we included 438 (65%). The CFdf was significantly greater in the left atrium than in the right (36.6 ± 20.3 versus 28.7 ± 16.4, p < 0.01). Except in the cavotricuspid isthmus, the FTI lesions equal or are more than 400 g/s required higher CFdf in all anatomical locations, and these differences reached statistical difference on the right atrial free wall, left atrial posterior wall, and right pulmonary vein antrum (p = 0.011, 0.007, and <0.001). Yet, higher CFdf is an independent predictor for less successful lesions in stepwise regression model. Left atrial enlargement above 46 mm was associated with lower CFdf, CFav, and CFmax (p = 0.04, <0.001, and 0.02 respectively). This study represents the first detailed assessment of CFdf in conscious sedation patients. Significant variations in the CFdf were associated with different anatomic locations. We found that the greater the dynamic range the less likely the lesion would reach 400 g/s. Smaller atria were associated with higher dynamic ranges and greater peak and average forces.

KEYWORDS. Average contact force, dynamic range for contact force, force time integral, maximum contact force, radiofrequency ablation.

Introduction

Pulmonary vein isolation (PVI) is a common procedure for treating paroxysmal atrial fibrillation (PAF).1 Successful outcome relies on many factors including effective ablation lesion formation and prevention of ablation-related complications such as perforation. Contact force (CF), estimated in grams between the catheter tip and the myocardium, plays an important and significant role in achieving an effective ablation lesion and good size.2 While constant contact is desirable, higher forces may be potentially hazardous if the median forces exceed 60 g.3 It is recognized that catheter-tissue contact forces (CFs) will vary in the beating heart and during respiration.4 The CF–time integral (FTI) has been employed as an end point to account for this variability and inform successful lesions within the left atria. The FTI reflects duration (in seconds) of the average CF during radiofrequency (RF) application. Cardiac motion has been investigated in a bench model of a beating heart with lesion size correlating linearly with measured FTI.5 A cut-off of 400 g/s or more for FTI has been associated with a higher success rate and
recurrence of pulmonary vein reconnection less than 25% compared with low FTI. An FTI \( \geq 400 \text{ g/s} \) was previously suggested as an end point for effective lesions when contiguous lesion formation was possible.\(^6,7\)

We hypothesized that the dynamic range of forces may affect attempts to achieve 400 g/s and may be influenced by anatomic location and left atrial size, as this is a measure of stability of tissue contact. Higher peak forces have the potential for complication in addition to variable effectiveness. We investigated the dynamic range for CF (\( \text{CF}_{\text{max}} \)) at different anatomic locations in patients undergoing conventional catheter ablation procedures for symptomatic arrhythmia under conscious sedation.

**Material and methods**

This was a single-center study in consecutive patients recruited from RF procedures of PAF for PVI, cavotricuspid-dependent isthmus ablation for typical atrial flutter, and right or left atrial tachycardia. The procedure was conducted under conscious sedation using midazolam and fentanyl boluses intravenously. The procedures were performed by two expert operators with a minimum of 100 ablation procedures/year. The study protocol was reviewed and approved by the institutional ethics committee of Kingston General Hospital and Queen’s University, Ontario, Canada.

**Catheter set-up**

Various combinations of intracardiac catheters were introduced through the right femoral vein as appropriate for the procedure as follows: 1) decapoler coronary sinus (CS) catheter (St. Jude Medical, St. Paul, MN); 2) 20-pole catheter positioned along either the right atrial free wall or the tricuspid annulus; 3) His-bundle catheter; 4) spiral mapping and ablation catheter used through 8.5F SL1 sheath (St. Jude Medical, Minneapolis, MN) and Agilis steerable sheath (St. Jude Medical, Minneapolis, MN) respectively; and (5) quadripleolar catheter (St. Jude Medical, St. Paul, MN) was placed at the right ventricular apex.

**Left atrial ablation procedure**

After central venous access was obtained, a multipolar catheter was placed in the CS. One transseptal puncture was performed with standard techniques using a Brockenbrough needle and SL1 sheath (St. Jude Medical, St. Paul, MN). After left atrial access was obtained, boluses of intravenous heparin were given to maintain an activated clotting time of 300–350 s.

An irrigated CF catheter (Thermocool SmartTouch; Biosense Webster, Inc., Diamond Bar, CA) was introduced into the left atrium via a steerable sheath. The catheter uses a 3.5-mm irrigated tip electrode with location sensors at the tip that are connected by a precision spring to the shaft, housing microsensors to detect small movements of the catheter. The CARTO 3 mapping system (Biosense Webster, Inc., Diamond Bar, CA) was used to guide “point-by-point” ablation.

**Contact force and ablation procedures**

Before mapping, the catheter CF was calibrated while floating free in the right or left atrium to set the baseline value at zero; circumferential continuous point-by-point ablation lesions were placed 1–2 cm from the pulmonary vein ostia to encircle and electrically isolate the pulmonary veins guided by a circular mapping catheter. The power was adjusted between 25 W for the posterior wall and 30 W in the other regions with a catheter irrigation set at 17 and 25 ml/min with 0.9% NaCl (according to the power). The circular catheter was used to confirm electrical isolation of each vein from the left atrium. Circumferential lesions around the veins were considered complete when the circular catheter no longer recorded pulmonary vein potentials and both entrance and exit block were demonstrated.

For typical flutter, the maximum voltage-guided RF was applied until complete bidirectional block was achieved as previously described.\(^8\) RF energy was delivered at a predefined target power of 35–40 W with irrigation at 25 ml/min with NaCl 0.9%. Atrial tachycardia was performed similarly with the power determined by location. Where possible, operators aimed for a CF of between 10 and 20 g.\(^6,7\)

**Inclusion criteria for radiofrequency lesion**

We elected to select lesions when duration of ablation reached 20 s or more as previously described.\(^9\) Lesions in the epicardial region (within the CS) were excluded and also short duration RF less than 20 s.

**Data registration for RF lesions**

\( \text{CF}_{\text{df}}, \text{CF}_{\text{mean}} \) and \( \text{CF}_{\text{av}} \) for each acquired ablation point were recorded along with the voltage and local activation time. These intravenous readings were collected from the CARTO system offline after the procedure. Each point in the three-dimensional map has values for mean, maximum, minimum, and average CFs in addition to duration of the lesion. The anatomical location for each lesion was recorded as follows: a) pulmonary vein antra “1–2 cm from the pulmonary vein ostium”; b) roof of left atrium only included the line outside the antral roof regions; c) anterior wall of left atrium; d) posterior wall of left atrium; e) cavotricuspid isthmus (CTI); and f) right atrial free wall (anterolateral).

For each RF application the following data were extracted: application duration, average CF, temperature, maximum CF, minimum CF, and FTI. The \( \text{CF}_{\text{df}} \) represents the difference between the maximum and the minimum CF through the whole lesion.

**Statistical analysis**

Statistical analysis was performed with R version 3.2.1 (R foundation, Vienna University of economics and business, Austria). All continuous variables are expressed as mean ± standard deviation and medians are presented in the box plot diagrams only. Comparisons of means
were conducted using a Student’s t-test for equal variance samples or Welch’s t-test for unequal variance samples. The p-values reported are unadjusted for multiple comparisons. Data were normalized for average CF and RF duration for each application and a logistic regression analysis was performed.

Results

Study population

Twenty-one patients (17 males), mean age 57.6 years, underwent catheter ablation procedures. The patients’ demographics are detailed in Table 1. The following procedures included: paroxysmal PVI (11 patients), CTI-dependent flutter ablation (four patients), left atrial tachycardia ablation, and right atrial ablation (six patients).

Radiofrequency lesions and anatomical distributions

A total of 674 point-by-point atrial RF applications were examined; 438 RF applications (65%) met the inclusion criteria: left pulmonary vein antrum (103; 24%), right pulmonary vein antrum (128; 29%), roof of left atrium (21; 5%), anterior wall of the left atrium (60; 15%), posterior wall of the left atrium (28; 6%), CTI (18; 4%) of the right atrium, and right atrium free wall (74; 17%). Tissue CF data were collected from the anatomical locations detailed in Figure 1.

Figure 1: The radiofrequency lesion numbers according to the anatomical site. RF: radiofrequency; CTI: cavotricuspid isthmus; RA: right atrium; Rt PVs: right pulmonary veins; Lt PVs: left pulmonary veins; PVI: pulmonary vein isolation.

Impact of anatomical site on the dynamic range for $\text{CF}_{\text{df}}$

The $\text{CF}_{\text{df}}$ during ablation varied by anatomical location within the atria. The dynamic range for tissue CF during ablation varied by anatomical location within the atria. CTI lesions required lower $\text{CF}_{\text{df}}$ to achieve FTI equal or more than 400 g/s when compared with all other anatomical regions (Figure 2). The $\text{CF}_{\text{df}}$ was statistically higher in the left atrium than in the right (mean 36.6 ± 20.3 versus 28.7 ± 16.4 respectively; p < 0.01). The most striking difference in $\text{CF}_{\text{df}}$ was between the CTI and left atrium roof (21.1 ± 7 versus 34.8 ± 19.7 respectively; p < 0.01). The comparison between both left and right pulmonary vein antra $\text{CF}_{\text{df}}$ showed no significant differences (37.8 ± 24.3 versus 34.3 ± 17.9, p = 0.55) (Figure 3).

Impact of left atrial size on $\text{CF}_{\text{df}}$

The left atrial diameter had an impact on $\text{CF}_{\text{df}}$. A total of 214 points (56%) had a left atrium diameter of ≤4 mm (mild dilatation or normal). The mean of $\text{CF}_{\text{df}}$, $\text{CF}_{\text{ave}}$, and $\text{CF}_{\text{max}}$ was significantly higher in normal to mild left atrium dilatation (≤46 mm) than moderate to severe left atrium dilatation (>46 mm) (Table 2).

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Table 1: Patients’ demographics and echocardiography parameters in pulmonary vein isolation (PVI) and other procedures.

| Procedure (n) | PVI (mean ± SD) | Non-PVI (mean ± SD) | p-Value |
|---------------|----------------|---------------------|---------|
| Procedures   | 11             | 10                  | n/a     |
| Gender (F, %) | 3 (27%)        | 2 (20%)             | 0.31    |
| Age (years)  | 62.73 ± 9.46   | 51.90 ± 20.73       | 0.15    |
| Ejection fraction (%) | 58.67 ± 8.56 | 52.56 ± 12.82       | 0.25    |
| Left atrium diameter (mm) | 45.82 ± 7.90 | 37.40 ± 9.61        | 0.08    |
| Left atrium volume (ml$^3$) | 91.81 ± 27.62 | 59.10 ± 31.69       | 0.06    |
| Left atrium volume index | 39.90 ± 10.21 | 34.76 ± 11.84       | 0.39    |
| Hypertension (n, %) | 6 (28.6%) | 2 (9.5%) | ns |
| DM (n, %)    | 1 (4.8%)       | 0                   | ns      |
| IHD/CABG (n, %) | 1 (4.8%) | 2 (9.5%) | ns |

DM: Diabetes Mellitus; IHD: Ischemic heart disease; CABG: Coronary artery bypass graft surgery.
Relationship between CF_{df} and other radiofrequency parameters

The CF_{df} demonstrated excellent correlation with CF_{max} and modest correlation with average recorded values for CF (r = 0.94, p < 0.001, and r = 0.55, p < 0.001 respectively). The FTI was less well correlated with CF_{df} (r = 0.43, p < 0.001) (Figure 4).

CF_{df} and FTI ≥ 400 g/s

The ranges of CF_{df} and the percentage of successful applications achieved FTI ≥ 400 g/s are illustrated in (Figure 5a). Multivariate stepwise regression analysis using a special model including the covariates (CF_{df}, CF_{max}, CF_{av}, FTI > 400, and duration) revealed an inverse relationship between CF_{df} and FTI ≥ 400 g/s; however, higher CF_{max}, CF_{av}, and duration were significantly and independently associated with effective lesions (i.e. FTI ≥ 400 g/s) (Table 3). We elected to exclude CTI from this analysis to avoid skewing the results by relatively stable CTI lesions.

The cut-off value at CF_{df} 28 g has a sensitivity of 70% and specificity of 71% to achieve FTI ≥ 400 g/s. However, CF_{av} of 17 g and CF_{max} of 35 g have sensitivity of 76% and 70% and specificity of 89% and 79% respectively to achieve a similar target. Moreover, a duration of RF application for 28 s showed a sensitivity of 65% and specificity of 75% to achieve FTI ≥ 400 g/s (Figure 5b).

Discussion

We found that the greater the dynamic range, the less likely the lesion would reach 400 g/s FTI and the longer the duration of the application is required. There was a strong relationship with anatomic location and left atrial size.

The introduction of real time force information to ablation delivery represents a significant innovation and affords the operator valuable feedback. The CF_{df} has received very little attention compared with the mean force and FTI. Yet the dynamic range represents additional information on stability and the spectrum of forces that are applied during any given lesion to achieve the 400 g/s FTI target. There is limited information on dynamic range; recently Kumar et al. showed a critical association between ventilation and ablation effectiveness; the index for dynamic ranges of force were noted to be strongly affected by respiration phase.

This dynamic catheter behavior has implications for tip electrode stability, intermittent contact, and effectiveness of RF lesions.

FTI correlates with impedance drop, and this has a well-associated relationship.

CF_{df} and anatomical location

We anticipated some differences with CF_{df} and anatomic location in sedated patients, with observed significant differences trying to achieve effective lesions. The roof of the left atrium was observed to have a greater CF_{df} than the surrounding areas resulting in the highest peak forces observed. Higher forces and intermittent tissue contact in these regions was similarly reported by Nakagawa et al. Potential complications of high CF during ablation include steam pop and perforation, as previously reported by Ikeda et al., when the median
CF reaches 60 g. We found no complication in our cohort; nonetheless the greater the CF\textsubscript{df}, the greater the duration required to increase the probability of achieving FTI \( \geq 400 \text{g/s} \) \((p = 0.24 \pm 0.03, p < 0.01)\) in Table 2. This must be taken into context with a greater CF\textsubscript{df} being associated with poorer lesion formation (FTI \( < 400 \text{g/s} \)). The exception was the CTI where catheter stability was abundant and FTI was reached with lower dynamic ranges (Figure 2). This contrasts with the remainder of the lesions and may be due to the routine use of a support sheath and the direct approach. Our group had real time force contact information and 78.9\% were performed with a steerable sheath. Using a sheath and real time force data, excellent parameters were readily achieved in 67.1\% of ablation lesions at the CTI.

**ROC and logistic regression analysis**

Given the risk of complications with higher dynamic range and maximum force we examined the receiver operator characteristics of the various parameters (Figure 5b). Optimum lesion to achieve FTI \( \geq 400 \text{g/s} \) would require
a $CF_{df}$ limited to 35 g, a $CF_{av}$ of 17 g with a range of $CF_{df}$ at 28 g/s and duration of 28 s.

Stepwise regression analysis of our cohort confirmed lower dynamic ranges ($CF_{df}$) are independent predictors for successful lesions. Similarly, higher $CF_{max}$ and $CF_{av}$ and longer duration of RF applications are all independent variables to achieve an effective lesion. Given the risk of complications with higher dynamic range and maximum force we examined the receiver operator characteristics of the various parameters (Figure 5b).

Table 3: Data for the covariates and their coefficients, 95% CI in stepwise regression analysis.

| Coefficient | Values (g) | $\beta$ | 95% CI       | p-Value |
|-------------|------------|--------|--------------|---------|
| $CF_{av}$   | 17         | 0.23   | 0.12–0.34    | <0.01   |
| Duration    | 28         | 0.24   | 0.17–0.31    | <0.01   |
| $CF_{max}$  | 35         | 0.45   | 0.28–0.62    | <0.01   |
| $CF_{df}$   | 28         | -0.34  | -0.49 to -0.2| <0.01   |

$CF_{df}$: dynamic range of contact force; $CF_{max}$: peak forces; $CF_{av}$: average contact force readings.
Optimum lesion to achieve FTI ≥ 400 g/s would require a CF\textsubscript{max} limited to 35 g, a CF\textsubscript{av} of 17 g with a range of CF\textsubscript{df} at 28 g/s and duration of 28 seconds. Stepwise regression analysis of our cohort confirmed lower dynamic ranges (CF\textsubscript{df}) are independent predictor for successful lesions. Similarly, higher CF\textsubscript{max} CF\textsubscript{av} and longer duration of RF applications are all independent variables to achieve an effective lesion.

Gathering together a CF\textsubscript{max} at 35 g and CF\textsubscript{df} at 28 g would achieve 96.1% probability of FTI ≥ 400. A one-gram increase of CF\textsubscript{df} (i.e. only to 29g) would reduce probability success of FTI ≥ 400 to 94.6% given the fact all other parameters of duration and average forces are normalized in the same anatomical location. In other words, a one-gram increase in CF\textsubscript{df} from 28 g (best cut-off value) would decrease the probability of a successful lesion by 1.5% (95% CI, 0.76–2.6%, p<0.001)

**Left atrial size and CF\textsubscript{df}**

The left atrial size cut-off at 46 mm was chosen in our study to differentiate normal or mild dilatation from moderate to severe dilatation according to echocardiography guidelines. We observed significant differences in the forces achieved that would reduce the efficacy of ablation. While there is clear evidence that larger atria have more advanced substrates, we speculate that these mechanical difficulties with lesser CFs are responsible for the lack of efficacy in larger atria; this may be a factor in observed higher recurrence rate.\(^{14,15}\)

**Limitations**

This was a detailed analysis of several hundred lesions, nevertheless the cohort is relatively small and over-represented by PVI patients. All our procedures were performed with conscious sedation. Kumar et al.\(^{10}\) have compared catheter stability in general anesthesia patients varying ventilation with apnea. Induced apnea periods had a higher FTI and both CF\textsubscript{max} and variability index (dynamic range) were lower than during ventilation. Spontaneous ventilation has not been studied to date or compared with general anesthesia and might be expected to result in less than optimal conditions for catheter stability. We elected to include lesions at the roof performed with conscious sedation. Kumar et al.\(^{10}\) have reported higher recurrence rate.\(^{14,15}\)

**Conclusions**

This study represents the first detailed assessment of CF\textsubscript{df} in conscious sedation patients. Significant variations in the dynamic ranges of CFs were associated with different anatomic locations. We found that the greater the dynamic range the less likely the lesion would reach 400 g/s. Smaller atria were associated with higher dynamic ranges and greater peak and average forces. Attempts to mitigate large variations in force are required to improve success of ablation lesions.

**References**

1. Hussein AA, Saliba WI, Martin DO, et al. Natural history and long-term outcomes of ablated atrial fibrillation. Circ Arrhythm Electrophysiol. 2011;4(3):271–278.
2. Thiaigalingam A, D’Avila A, Foley L, et al. Importance of catheter contact force during irrigated radiofrequency ablation: Evaluation in a porcine ex vivo model using a force-sensing catheter. J Cardiovasc Electrophysiol. 2010; 21(7):806–811.
3. Ikeda A, Nakagawa H, Lambert H, et al. Relationship between catheter contact force and radiofrequency lesion size and incidence of steam pop in the beating canine heart: Electrogram amplitude, impedance, and electrode temperature are poor predictors of electrode-tissue contact force and lesion size. Circ Arrhythm Electrophysiol. 2014;7(6):1174–1180.
4. Olson MD, Phreaner N, Schuller JL, et al. Effect of catheter movement and contact during application of radiofrequency energy on ablation lesion characteristics. J Interv Card Electrophysiol. 2013;38(2):123–129.
5. Shah DC, Lambert H, Nakagawa H, Langenkamp A, Aebi N, Leo G. Area under the real-time contact force curve (force-time integral) predicts radiofrequency lesion size in an in vitro contractile model. J Cardiovasc Electrophysiol. 2010;21(9):1038–1043.
6. Kautzner J, Neužil P, Lambert H, et al. EFFICAS II: Optimization of catheter contact force improves outcome of pulmonary vein isolation for paroxysmal atrial fibrillation. Europace. 2015;17(8):1229–1235.
7. Squara F, Latcu DG, Massaad Y, Mahjoub M, Bun SS, Saoudi N. Contact force and force-time integral in atrial radiofrequency ablation predict transmurality of lesions. Europace. 2014;16(5):660–667.
8. Gula LJ, Redfearn DP, Veenhuyzen GD, et al. Reduction in atrial flutter ablation time by targeting maximum voltage: Results of a prospective randomized clinical trial. J Cardiovasc Electrophysiol. 2009;20(10):1108–1112.
9. Reichlin T, Knecht S, Lane C, et al. Initial impedance decrease as an indicator of good catheter contact: Insights from radiofrequency ablation with force sensing catheters. Heart Rhythm. 2014;11(2):194–201.
10. Kumar S, Morton JB, Halloran K, et al. Effect of respiration on catheter-tissue contact force during ablation of atrial arrhythmias. Heart Rhythm. 2012;9(7):1041–1047 e1041.
11. Ullah W, Hunter RJ, Baker V, et al. Target indices for clinical ablation in atrial fibrillation: Insights from contact force, electrogram, and biophysical parameter analysis. Circ Arrhythm Electrophysiol. 2014;7(1):63–68.
12. Wakili R, Clauss S, Schmidt V, et al. Impact of real-time contact force and impedance measurement in pulmonary vein isolation procedures for treatment of atrial fibrillation. Clin Res Cardiol. 2014;103(2):97–106.
13. Nakagawa H, Kautzner J, Natale A, et al. Locations of high contact force during left atrial mapping in atrial fibrillation patients: Electrogram amplitude and impedance are poor predictors of electrode-tissue contact force for ablation of atrial fibrillation. Circ Arrhythm Electrophysiol. 2013; 6(4):746–753.
14. Arya A, Hindricks G, Sommer P, et al. Long-term results and the predictors of outcome of catheter ablation of atrial fibrillation using steerable sheath catheter navigation after single procedure in 674 patients. Europace. 2010;12(2):173–180.
15. Wojcik M, Berkowitsch A, Zaltsberg S, et al. Predictors of early and late left atrial tachycardia and left atrial flutter after catheter ablation of atrial fibrillation: Long-term follow-up. Cardiol J. 2015;22(5):557–566.