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ORIGINAL ARTICLE

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Comparison of ex vivo lesion formation for two adjacent radiofrequency applications with very high-power short-duration in various inter-lesion times

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Abstract

Background/Objectives: Very high-power and short-duration (vHPSD) ablation with QDOT MICRO™ facilitates speedy and safe ablation for pulmonary vein isolation. A brief time interval between ablating two neighboring sites with vHPSD may potentially influence the size and geometry of the lesions. This study evaluates lesion formation when delivering adjacent applications using vHPSD at various inter-lesion times (ILTs).

Methods: Radiofrequency applications were conducted by QDOT MICRO™ catheter with 90 W of strength and 4 s duration. Fresh swine heart tissue on the epicardium was ablated with 10 g of the contact force. Lesions were created using a single application (SA) and double applications (DA) of adjacent lesions with a 6 mm distance between them as measured on the 3D mapping system. The DA was performed with various ILTs, 60 s (DA-60 s), 10 s (DA-10 s), 5 s (DA-5 s), and 0 s (DA-0 s).

Results: Out of 90 lesions, 79 were analyzed. Eleven lesions were excluded for one steam pop event, seven out of the target distance, and three divided lesions of two applications. There were no significant differences in surface diameter, cross-sectional diameter, and maximal lesion depth in each application among the groups. The intermediate lesion depth was significantly more profound in groups with shorter and immediate ILT (DA-10, 5, and 0 s) compared to the group with a prolonged ILT between two applications (DA-60 s) (2.99, 3.03, 3.16 mm vs. 2.42 mm, respectively; $p < .001$).

Conclusions: Two adjacent radiofrequency applications with vHPSD in short ILT may result in deeper lesions in the middle of combined double lesions.

KEYWORDS
atrial fibrillation, catheter ablation, inter-lesion distance, inter-lesion time, very high-power short-duration

1 | INTRODUCTION

The recurrence of atrial tachyarrhythmias often occurs due to reconnection after pulmonary vein isolation (PVI),[1,2] emphasizing the need to establish a durable isolation line without gaps in the lesions. The QDOT MICRO™ and nGEN™ generator system (CARTO®3, Biosense Webster, Irvine, CA) has enabled very high-power short-duration (vHPSD: Q mode plus, 90 W of power for 4 s) radiofrequency applications, ensuring sufficient tip cooling for the temperature-controlled ablation. However, it addresses concerns regarding lesion gaps in the thickened portions of the atrial wall.[3] Some studies about various inter-lesion distances (ILDs) using vHPSD have been reported. The vHPSD protocol is comparable to a 50 W protocol in an ILD of 4 mm,[4] whereas combining protocol with 90 and 50 W within an ILD of less than 6 mm was inefficient regarding procedure time and achieving first-pass isolation.[3] Sequential applications with appropriate ILDs could be crucial for successful PVI on the first pass without gaps between neighboring lesions in various power and duration settings.[5–8]

However, excessive radiofrequency energy delivery can lead to severe esophageal complications, a highly concerning adverse event associated with PVI. In the experimental model, uninterrupted radiofrequency energy led to a more significant increase in esophageal temperatures compared to point-to-point applications.[9] Tissue heat capacitance plays a role in the accumulation of radiofrequency-induced heating from consecutive lesions. This is clinically observed as luminal esophageal temperatures continue to rise after radiofrequency current, mainly when consecutive lesions are delivered in proximity.[10]

On the other hand, no reports have thoroughly investigated the impact of inter-lesion time (ILT) between neighboring sites. Repetitive applications at the same location with short ILT can create deeper lesions in ex vivo models.[11] A brief interval between ablating two neighboring sites with vHPSD may potentially influence the lesion's geometry. Thus, this study aims to assess lesion formation when delivering adjacent radiofrequency applications using vHPSD at “immediate,” “short,” and “prolonged” time intervals.

2 | METHODS

2.1 | Ex vivo experimental model

The experimental procedure was conducted based on previously established settings,[12–14] 90 W in strength with 4 s duration with 60 degrees Celsius in catheter temperature limit, although catheter types and radiofrequency application methods differed. The equipment used in the present experiment included a 3D mapping system (CARTO®3, Biosense Webster, Irvine, CA), an nGEN™ generator, an nGEN™ pump, and a QDOT MICRO™ temperature-controlled catheter. Fresh swine heart tissue was secured to a rubber plate affixed to the bottom of the perfused normal saline pool, with temperature control maintained at 37 degrees Celsius through a regulated system, even after periodic replacement of the solution. The QDOT MICRO™ catheter was inserted into a plastic pipe and positioned perpendicular to the tissue with 10 g of the contact force. The ablation was conducted on the smooth surface of the epicardium. We periodically replaced the saline to prevent any unexpected changes in the fluid composition that could affect the study's outcome. The general impedance in the saline pool was maintained between 80 and 100 Ω.

2.2 | Temperature feedback system

During radiofrequency ablation, real-time temperature feedback was utilized with a QDOT MICRO™ catheter equipped with vHPSD.[15] The surface electrode temperature was continuously measured from the thermocouples embedded within the ablation electrode. To prevent surpassing the established temperature limit of 60°C, automatic adjustments were made, involving either a reduction in delivered power, an increase in irrigation flow rate, or both.

2.3 | Lesion creation protocol

Radiofrequency lesions were created using a single application (SA) and double applications (DA) of adjacent lesions with a 6 mm distance between them as measured on the 3D mapping system. The DA was performed with ILTs of 60 s (DA-60 s), 10 s (DA-10 s), 5 s (DA-5 s), and 0 s (DA-0 s). The SA lesions and those with DA-60 s, DA-10 s, DA-5 s, and DA-0 s were meticulously arranged in a row in one flesh mass unless there were obstructions such as blood vessels or fascia. The QDOT MICRO™ radiofrequency application has specific attributes that require a 2 s delay for irrigation flow before application and a 4 s delay after, which were eventually included in the designated intervals. In the DA-0 s group, some radiofrequency applications were unsuitable for lesion evaluation due to delayed catheter manipulation. They were distinguished into other groups according to the actual ILT.

2.4 | Lesion formation measurement

Radiofrequency lesions were defined based on a distinct boundary surrounding the lesion and observable changes in the tissue color. We measured the lesion's maximum surface diameter, cross-sectional diameter, and maximum depth in the SA group, drawing upon previous reports.[16,17] In the DA groups, as overlapping lesions characterized the lesion geometries, we evaluated the maximum surface diameter, the cross-sectional diameter encompassing double applications, the maximum lesion depth in each application, and the depth between double applications (as depicted in Figure 1). Lesions that did not overlap in the first and second applications or steam pops were excluded from the study's measurements.

2.5 | Statistical analysis

The statistical analyses were performed using SPSS ver.24 software (IBM, Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation. Categorical variables were presented as numbers and proportions. A one-way ANOVA and ad hoc Tukey multiple comparisons were used to detect the differences and interactions between radiofrequency parameters, including the power, CF, local impedance drop, and ILT of two adjacent lesions and lesion formation characteristics. A probability value <.05 was considered statistically significant.

3 | RESULTS

Of the initial 90 lesions, our investigation focused on 79. We excluded one lesion due to steam-pop occurring during the initial RF application in the DA-5s group. For lesions with inappropriate ILD, four lesions (two in DA-10s group and two in DA-5s group) had an ILD of less than 5.5mm, potentially resulting in deeper-than-expected lesions in the intermediate region. An additional five lesions (one in DA-10s, one in DA-5s, and three in DA-0s) had an ILD of more than 6.5mm, which could be associated with shallower-than-expected lesions in the same region. Among these five lesions, two (one in DA-5s and one in DA-10s) were nonoverlapping lesions. The one remaining isolated lesion, attributed to the relatively wide ILD (6.4mm) in the DA-10s group, was also excluded. In total, eleven lesions were excluded from the analysis.

We considered the impact of power titration and increased irrigation flow on suppressing catheter temperature rise exceeding the limit on the lesion geometry. However, there were no significant differences in mean ablation power, mean contact force, impedance drop, and delivered total energy among DA groups, except for a decrease in the mean contact force and initial impedance only in the second ablation of DA-5s compared with that of DA-60s (Data S1). Furthermore, no increases in irrigation flow rate were observed during the experiment. The distance between DA sites determined by the CARTO system was also comparable in DA groups. The actual mean ILT for each group was 66.9s for DA-60, 16.7s for DA-10s, 11.8s for DA-5s, and 8.4s for DA-0s, including the additional 6s by the nGen system for irrigation waiting time as described in the Method section.

3.1 | Characteristics of lesion formation

The actual cross-sectional lesion geometry and corresponding measurement data are presented in Figures 1 and 2 and Table 1, respectively. There were no significant differences in surface diameter, cross-sectional diameter, and maximal lesion depth among the DA groups in each application. However, it was noted that the intermediate lesion depth was significantly deeper in groups with shorter and immediate ILTs (DA-10s, 5s, and 0s) compared to the group with a prolonged ILT between two applications (DA-60s). On the other hand, there were no statistical differences in the intermediate depth among groups of DA-10s, 5s, and 0s.

FIGURE 1 Actual lesion geometry and measurement method. (A) Actual lesion geometries resulting from single (SA) and double applications (DA) are depicted within a continuous tissue mass. The time intervals between two radiofrequency applications in each group were 60s (DA-60s), 10 (DA-10s), 5 (DA-5s), and 0 (DA-0s). (B) The measurement method used for assessing radiofrequency lesions is shown. A combination of two adjacent applications characterizes overlapping lesions. The evaluation includes the maximum surface diameter (a), the maximum cross-sectional diameter (b) of the lesion resulting from the combined applications, the maximum lesion depth for the first (c) and second (d) radiofrequency applications, and the intermediate lesion depth between them (e). The inter-lesion distance between the first and second radiofrequency applications was fixed at 6mm.

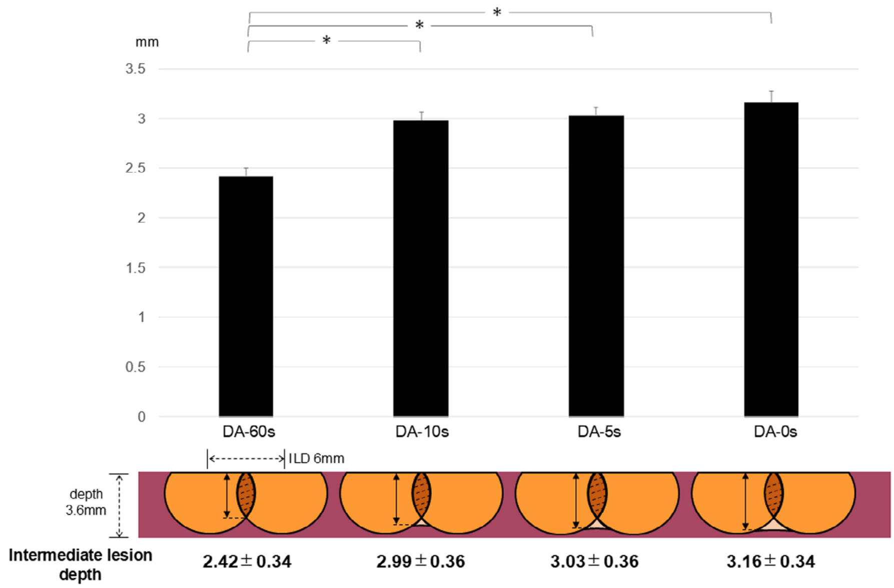

FIGURE 2 Intermediate lesion depth in groups with double applications. Significantly deeper inter-lesion depths were observed in the groups with inter-lesion time (ILT) shorter than 10 s (DA-10, 5, and 0 s) compared to the group with a prolonged ILT (DA-60 s). No statistical significance was found among the DA-10, 5, and 0 s groups. (*$p < .001$) ILD, inter-lesion distance.

4 | DISCUSSION

The present experiment demonstrates the size and geometry of vHPSD radiofrequency lesions at varying ILTs between ablating two neighboring sites. Shorter ILTs between the first and second ablations (DA-10 s, 5 s, and 0 s) yield deeper lesions at the intermediate region, although there were no statistical significances among the DA-10 s, 5 s, and 0 s groups. These lesion depths are comparable with the maximum lesion depth in the SA group in the present study, measuring approximately 3 mm, and are compatible with a previous report.[17] Except for intermediate depth, no significant differences were observed among DA groups regarding lesion measurements.

The time-dependent conductive heating can extend lesions deeper and potentially create transmural effects in conventional radiofrequency applications. The formation of deeper lesions in shorter ILTs suggests the occurrence of thermal latency affected by the initial radiofrequency application in the myocardial tissue between two adjacent application sites.[18] The impact of thermal effects on surrounding tissue using vHPSD is considered less significant than low-power and long-duration ablation.[19] Nevertheless, an in vivo experimental model reported thermal latency exceeding 50°C at a depth of 3 mm below the ablation catheter for 14 s after ablation.[16]

Our pursuit primarily involves establishing a durable isolation line without lesion gaps. This goal has been discussed regarding optimal power settings, application durations, ILD, and related factors. Prior investigations have highlighted the significance of consecutive applications employing a brief ILD to achieve PVI on the first pass successfully.[5,6] Notably, potential lesion gaps in radiofrequency applications in the setting of 90 W were reported to be larger than those of 50 W.[8] Nevertheless, appropriate ILTs between neighboring applications were not fully discussed. Drawing insights on the present study, we propose that the prompt ILTs between the initial and subsequent applications for catheter manipulation could potentially yield enduring radiofrequency lesions, facilitate a concise procedure timeline, and prevent the need for extra applications.

Previous studies have indicated that the myocardial thickness at the left atrial posterior wall is estimated to be less than 3 mm based on the pathological measurement and computed tomographic images.[20–23] Additionally, repetitive radiofrequency applications to the same site, with or without a 60 s interval, resulted in a deep lesion of 3 mm or greater in vHPSD.[11] Barbhaiya et al. demonstrated that when lesions were consecutively placed less than 20 mm apart within 60 s, at a setting of 50 W and 6 s, an additive temperature increase was observed in the esophageal lumen.[10] These reports emphasize that the residual heating effect on the esophagus is a significant concern during PVI with vHPSD. Therefore, careful consideration must be given to the tissue undergoing radiofrequency application to prevent adverse events, particularly for the left atrial posterior wall. Although there have been no reported incidents of esophageal injury in endoscopic assessments in vHPSD protocol for PVI,[24] our experiment suggests that consecutive applications with short ILD and immediate ILT may lead to unexpected lesion depth in the overlapping region, possibly due to cumulative heating effects.

Our study had several limitations. The experiment used an ex vivo model, specifically swine heart tissue, resulting in excessively stable contact force due to the tissue's nonbeating and smooth surface nature. All the tissues were ablated perpendicularly, which is not a practical scenario. Different catheter angles, such as oblique or parallel orientations, can create wider superficial diameters on formations due to the distribution of irrigation flow holes.[25,26] Furthermore, an examination of the conditions under which steam-pop occurred (during the first application in DA-5 s) revealed no significant differences in saline temperature, mean contact force, or impedance drop compared to other applications. Therefore, we suspect that the swine heart tissue may have influenced the outcome. For instance, despite our efforts to avoid this, ablation may have been performed near blood vessels or fibrous tissue, leading to a rapid temperature increase even with the irrigation flow. Additionally, our study aimed to identify the relationship

TABLE 1 Lesion measurements.

	Single application (SA) $N=18$	Double application with 60 s interval (DA-60s) $N=18$	Double application with 10 s interval (DA-10s) $N=14$	Double application with 5 s interval (DA-5 s) $N=21$	Double application with 0 s interval (DA-0 s) $N=8$
Time interval from 1st to 2nd application (Including irrigation flow latency), s	–	66.9 ± 1.0	16.7 ± 0.8	11.8 ± 0.9	8.4 ± 0.9
a. Surface diameter, mm	6.53 ± 0.67	12.00 ± 0.72	12.00 ± 0.98	12.44 ± 0.92	11.88 ± 0.75
b. Cross-sectional diameter, mm	7.08 ± 0.60	12.53 ± 0.59	12.28 ± 1.02	12.84 ± 0.90	12.94 ± 1.02
c. Lesion depth 1st application, mm	3.26 ± 0.47	3.56 ± 0.34	3.66 ± 0.37	3.51 ± 0.37	3.59 ± 0.33
d. Lesion depth 2nd application, mm	–	3.53 ± 0.33	3.69 ± 0.40	3.65 ± 0.34	3.61 ± 0.34
e. Intermediate-lesion depth, mm	–	2.42 ± 0.34	2.99 ± 0.36[a]	3.03 ± 0.36[a]	3.16 ± 0.34[a]

Abbreviation: RF, radiofrequency.
[a]<0.05 for double applications with 60 s interval (DA-60s).

between ILD and ILT of two adjacent applications rather than directly implementing our experimental lesion depth in clinical situations. Secondly, although we monitored the feedback temperature with the QDOT™ catheter, limited to 60°C, we did not measure the intra-tissue temperature. Consequently, we could not evaluate the correlation between temperatures recorded by the catheter thermocouples and the ablated tissue in this experimental model. Further research on the impact of lesion formation between two adjacent lesions using the vHPSD system should be warranted.

5 | CONCLUSIONS

Two adjacent radiofrequency applications with vHPSD in short ILTs may result in deeper lesions in the middle of combined double lesions. While this could facilitate the formation of continuous lesions, it is crucial to acknowledge the possibility of inadvertently ablating deep lesions in areas where such depth should be avoided.

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DATA AVAILABILITY STATEMENT

Data available on request from the authors.

ETHICS STATEMENT

The ethical committee of Tsukuba Clinical Research and Development Organization (T-CReDO) waived the need for ethics approval because this research was neither a clinical study nor an animal experiment.
Approval of the Research Protocol: No human participant was involved in this study.
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Registry and the Registration No. of the Study/trial: N/A.
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CONSENT

N/A.

CLINICAL TRIAL REGISTRATION

N/A.

PERMISSION TO REPRODUCE MATERIAL FROM OTHER SOURCES

N/A.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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