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ORIGINAL ARTICLE

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Novel protocol for optimal utilization of HPSD approach for pulmonary vein isolation

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Abstract

Background: The efficiency of pulmonary vein isolation (PVI) depends on the durability of RF lesions. Recent studies documented sustained continuity of ablation lines, improvements in durability, and expected clinical outcomes through altered settings in duration and power. However, the ablation strategy has not been adapted to this new approach and different biophysics of lesion formation.

Purpose: The aim of this study was to demonstrate that by adjusting the ablation approach to the broader geometry of lesions by increasing the minimal spacing between adjacent RF, a further significant reduction of procedural time while maintaining sufficient long-term outcomes is achievable.

Methods: The presented study was a prospective, observational multi-center trial. The periprocedural data were compared with data from a consecutively collected historical cohort.

Results: In total, 196 patients were included (mean age 62 ± 11 years, male 64.3%). Procedural duration, RF time, and LA dwelling time were significantly shorter in the HPSD group compared with the standard group (73 ± 26 min vs. 98 ± 36 min, $p < .001$; 14 ± 7 min vs. 33 ± 12 min, $p < .001$; and 59 ± 21 min vs. 77 ± 32 min, $p < .001$, respectively). Mean AF-free survival in the first year of follow-up was 304 ± 14 days in the HPSD group versus 340 ± 10 days in the standard group (log-rank $p = .403$). There were no statistically significant differences in the complication rates between the groups.

Conclusion: Increasing the minimal distance between individual application points simplifies AF ablation and further reduces procedure time without negative effects on efficacy and safety. Larger studies are needed to optimally utilize this approach.

KEYWORDS
ablation, atrial fibrillation, high-power short duration, pulmonary vein isolation

1 | INTRODUCTION

Pulmonary vein isolation (PVI) has been established as the cornerstone for the invasive treatment of atrial fibrillation (AF).[1,2] Successful ablation outcome requires durable lesion formation, which is the predominant goal of catheter ablation of AF.[3] Creating a durable RF lesion depends on the RF power delivered, the duration of RF energy delivery, the degree of catheter tissue contact, and catheter stability.[4] Lesion geometry especially lesion depth and lesion diameter are highly dependent on these parameters. Recent studies documented improvement in durability and expected clinical outcomes through increased power settings (45–70 W). Simultaneous reduction of RF application time has led to the elimination of initially observed complication rates.[5–9] This new concept of high-power short-duration (HPSD) approach consistently results in shorter procedural times, reduced fluoroscopy dose, and decreased total RF energy delivery.[5–7] However, the ablation strategy has not been adapted to this new approach and its different biophysics of lesion formation. Bourier et al.[10] demonstrated that HPSD RF applications result in similar lesion volumes compared with standard RF applications, but with different lesion geometry, showing a larger maximum diameter and a smaller lesion depth. These differences are caused by increased resistive heating and decreased conductive heating which is outweighed by using standard ablation with 30–40 W.[11,12]

To fill this knowledge gap, we proposed a modified protocol for better utilization of this technique based on the previously proposed CLOSE approach.[13] The aim of this study was to demonstrate that using this approach may lead to a significant reduction of procedural times and complication rates in comparison to the conventional power setting while maintaining similar or better long-term outcomes.

2 | MATERIALS AND METHODS

2.1 | Study design

The present study was a prospective, observational multi-center trial in a cohort of 196 patients referred for AF ablation. All patients underwent HPSD ablation (50 W for maximum of 13 s on the anterior wall and 11 s on the posterior wall) according to the prespecified ablation strategy. The periprocedural data, as well as the long-term outcomes of study patients, were compared with data from the consecutively collected historical cohort.

2.2 | Patient population

One hundred ninety-six consecutive patients ($n = 196$) with paroxysmal or persistent AF who underwent initial PVI for standard clinical indication were enrolled in this study at ablation centers in Europe. The patients with a history of prior PVI or longstanding persistent AF lasting >1 year as well as patients undergoing left-sided ablation beyond PVI, that is, low-voltage isolation, rotor, or fractionated potential ablations were excluded from the study. Moreover, patients with low-voltage areas (local amplitude below 0.5 mV) detected during contact mapping were also excluded. The further inclusion and exclusion criteria are summarized in Table S1. The study and data collection were conducted in accordance with the regulation of the local ethic committees.

2.3 | The ablation procedure

The ablation procedure with a goal of wide-area circumferential ablation with en-bloc isolation of ipsilateral pulmonary veins was conducted in deep sedation in accordance with the center-specific protocol. For this study, a 3D mapping system (EnSite Precision, Abbott) tool was used. At the beginning of the procedure, a voltage map in sinus rhythm was acquired as previously described by Kosiuk et al.[14] For ablation, the TactiCath SE catheter with irrigation at 30 mL/h and the HPSD 50 W protocol was used. The lesion formation was controlled by the ablation period of 13 s for the anterior and 11 s for the posterior regions. In case of reaching the target LSI of maximum 6.5, the impulse was terminated. The catheter was preirrigated for 1 s and postirrigated for 2 s at a flow of 17 mL/min for every RF application. The generator (Ampere Generator, Abbott) was set to power control mode.

The lesion formations were automatically visualized (AutoMark, Abbott) in accordance with the study protocol (described below). The PV isolation was examined by a round of "pace and ablate" along the ablation line, as previously reported,[4,15,16] while entrance and exit blocks were verified using a circular mapping catheter (Adviser SE) or high-resolution multipolar catheter (HD-Grid). The verification of the entrance/exit block was defined as an intraprocedural endpoint. The periprocedural management (i.e., anticoagulation strategy, echocardiography screening, etc.) was left to the discretion of the physician with the exception of antiarrhythmic drugs that were discontinued at discharge.

In this multicentric study, the ablation setting (power and duration of individual impulses) in the standard group was at the discretion of the individual operators. The standard distance between two neighboring ablation lesions was 4 mm. Patients underwent close protocol ablation.

2.3.1 | Lesion visualization protocol

For the current study, prespecified setting for automatic lesion visualization (Automark) was proposed. The minimal cutoff lesion index (LSI) was set to 4.5 with a gradual increase to 6.0. Increasing values of LSI were color-coded (Figure S1). The ablation markers correlating with ablation sites were presented as 3D spherical markers with a diameter of 8 mm. (Figure 1).

Similar to the previously described CLOSE protocol, the operators were supposed to ensure that the lesion continuity was

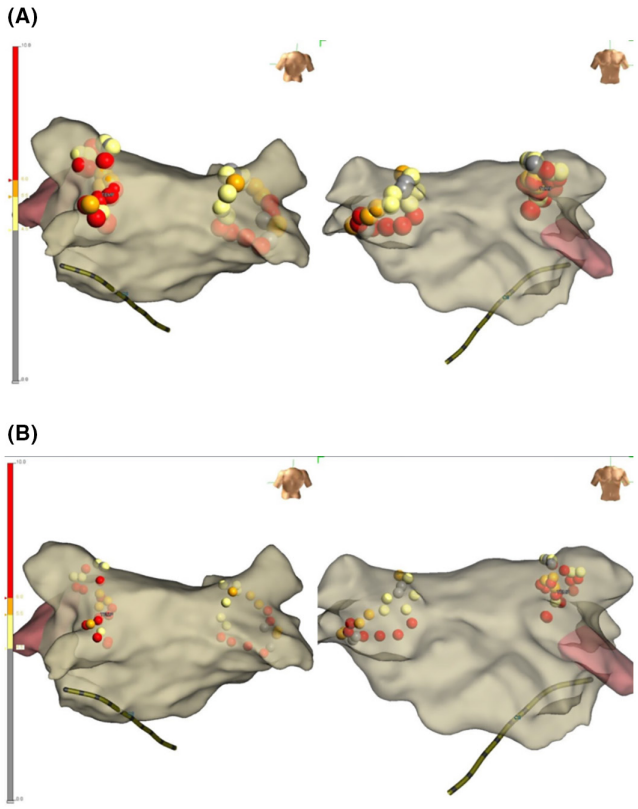

FIGURE 1 Examples of the same circumferential PVI with lesions visualized with (A) setting of the novel protocol and (B) conventional system setting.

visualized by markers.[13] The ablation points with an LSI below 4.5 had to overlap, whereas the lesions above this value could be adjacent. The visualization of catheter movement response rate (EnGuide Responsiveness) was left at the default setting.

2.4 | Follow-up

The blanking period was defined as the first 3 months postablation. Patients were followed-up at 6 and 12 months after ablation. The control visit was including ECG recording, clinical evaluation, and Holter-ECG monitoring. Recurrence was defined as any AF, atrial tachycardia, or flutter (AT or AFL) lasting >30 s during the follow-up after the blanking period. In the case of AF-recurrence and a repeat ablation after the blanking period, only the initial ablation results were used for outcome analysis.

2.5 | Outcome measurements

For the standardization of the study outcome, the following definitions were proposed: (1) procedural time was defined as the time point from the placement of the first catheter to the withdrawal of the last catheter and was extracted from the recordings of the EP system; (2) LA dwelling time was defined as the time from the placement of a mapping catheter in the left atrium to withdrawal; (3) periprocedural complications were defined as typical intervention-related complications occurring within 30 days after the procedure.

2.5.1 | Statistical analysis

Continuous variables were expressed as mean and standard deviation (SD). Categorical variables were reported as frequencies and percentages. The Kolmogorov-Smirnoff test was used to analyze the distribution of continuous variables. Parametric variables were compared by means of paired Student's *t*-test and nonparametric by Wilcoxon test. The procedural times were analyzed with a Student's *t*-test. Although nominal data such as recurrence and complication rate were studied by means of the Chi-square model, respectively, Kaplan–Meier curves were calculated for AF-free survival for both groups, and the log-rank test was used to compare event distribution between both groups. A two-tailed *p*-value of less than .05 was considered statistically significant. Statistical analysis was adjusted for all significant differences in baseline characteristics by use of regression models. Analysis was performed with SPSS v 20.0 (SPSS Inc.).

3 | RESULTS

3.1 | Study population

Patient demographics and clinical characteristics, including cardiovascular risk profile, are summarized in Table 1. A total of 196 consecutive patients (mean patient age 62 ± 11, male 64.3%) were

TABLE 1 Demographic and clinical baseline characteristics ($n = 196$).

	HPSD group ($n = 98$)	Standard group ($n = 98$)	*p* value
Age	64 ± 11	60 ± 12	.009
Male	58 (59.2%)	66 (67.3%)	.235
Persistent type of AF	41 (41.8%)	52 (53.1%)	.116
CHA2DS2-VASc score	2.6 ± 1.5	1.9 ± 1.4	.001
Heart failure	15 (15.3%)	6 (6.1%)	.038
Arterial hypertension	85 (86.7%)	65 (66.3%)	.002
Diabetes mellitus	22 (22.4%)	13 (13.2%)	.094
Prior stroke/TIA/ Thromboembolism	6 (6.1%)	7 (7.1%)	.775
CHD/PAD	15 (15.3%)	13 (13.3%)	.685
AAD Class Ic	23 (23.5%)	20 (20.4%)	.605
AAD Class III	21 (21.4%)	28 (28.6%)	.248
Digitalisglykosid	2 (2%)	0 (0%)	.157
Oral anticoagulants	98 (100%)	98 (100%)	n/a
Antiplatelet drug	5 (5.1%)	5 (5.1%)	1.000

Abbreviations: AAD, antiarrhythmic drugs; AF, atrial fibrillation; CHD/PAD, coronary heart disease/peripheral arterial disease; HPSD, high-power short duration; n/a, not applicable; TIA, transient ischemic attack.

included in two groups ($n=98$ patients HPSD group and $n=98$ patients standard group). Patients in the HPSD group were significantly older (64±11 years vs. 60±12 years, $p=.009$). Concomitant cardiovascular comorbidities and thromboembolic risk described as CHA_2DS_2-VASc score were more severe in the HPSD group (mean CHA_2DS_2-VASc score in the HPSD group of 2.6±1.5 vs. 1.9±1.4, $p=.001$). Persistent type of AF was documented in 41.8% in the HPSD group and 53.1% in the standard group ($p=.116$). Antiarrhythmic drugs Class Ic were administrated prior to ablation in 23.5% of the patients in the HPSD group and 20.4% of patients in the standard group ($p=.605$). Class III antiarrhythmic drugs were used in 21.4% of patients in the HPSD group and 28.6% of patients ($p=.248$) in the standard group.

3.2 | Procedural data

Procedural data are summarized in Table 2. Complete PVI was achieved in all patients, however, single-pass isolation was significantly more common in the HPSD group. In the subgroup of patients with available data regarding first-pass isolation was more frequently observed in the HPSD group. In detail, the presence of first-pass isolation of left veins was observed in 72.3% in the HPSD group versus 27.9% in the standard group ($p=.002$) and for right veins in 67.9% in the HPSD group versus 32.1% in the standard group ($p=.032$).

Total procedure duration was significantly lower in the HPSD group compared with the standard group (73±26 min vs. 98±36 min, $p<.001$). Correspondingly, RF time was significantly shorter in the HPSD group (14±7 min) compared with the standard group (33±12 min), ($p<.001$). Furthermore, the LA-dwelling time was significantly shorter in the HPSD group (59±21 min) compared to the standard group (77±32 min), ($p<.001$). Of note, these differences persisted when stratified by AF subtype. When stratified by type of AF, the procedure duration, RF time and LA dwelling time remained significantly shorter in the HPSD group: for persistent AF, 70±24 min versus 99±32 min, $p<.001$ for procedural time, 13±4 min versus 33±13 min, $p<.001$ for RF time and 59±23 min versus 77±28 min, $p=.002$ for LA dwelling time. In the paroxysmal AF group, 75±27 min versus 97±40 min, $p=.001$ for procedural time, 14±8 min versus 33±12 min, $p<.001$ for RF time, and 60±20 versus 76±35, $p=.003$ for LA dwelling time. Consistent results were also observed regardless of the number of TSP used during the procedure. In the HPSD group, the procedure duration, RF time, and LA dwelling time were significantly shorter both in the case of single and double TSP (single TSP: 74±28 min vs. 98±31 min, $p<.001$; 14±8 min vs. 35±15 min, $p<.001$; 60±24 min vs. 78±27 min, $p<.001$ and double TSP: 71±22 min vs. 98±41 min, $p<.001$; 13±4 min vs. 32±9 min, $p<.001$; 59±16 min vs. 75±36 min, $p=0.008$).

TABLE 2 Procedural data.

	HPSD group ($n=98$)	Standard group ($n=98$)	p value
Procedure duration, min	73±26	98±36	<.001
RF time, min	14±7	33±12	<.001
LA dwelling time, min	59±21	77±32	<.001
RF applications (sessions)	73±25	25±23	.001
First Pass Isolation left veins (*n*, %)	27 (27.6%)	10 (10.2%)	.003
First Pass Isolation right veins (*n*, %)	19 (19.4%)	9 (9.2%)	.041
Sensitherm esophageal probe (*n*, %)	12 (12.2%)	12 (12.2%)	1.000
Double TSP	40 (40.8%)	49 (50%)	.198

Abbreviations: AF, atrial fibrillation; HPSD, high-power short duration; LA, left atrium; TSP, transseptal puncture.

3.3 | Follow-up results

In all patients, acute procedural success defined as PVI with entrance and exit block was achieved. Due to the coinciding global pandemic of COVID-19, 114 patients (58%) were lost during the follow-up. However, provided data documented no significant difference in the freedom of AF between study groups (log-rank $p=.403$). Time to first recurrence is shown in the Kaplan–Meier curves (Figure 2). In detail, 88.5% of the patients in the HPSD group and 73.2% of the standard group showed freedom from AF during the total follow-up. In the first year of the follow-up, mean AF-free survival was

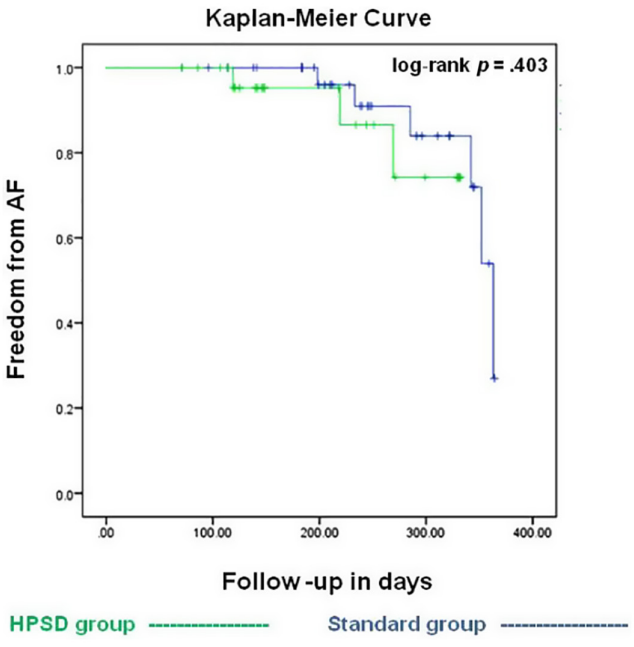

FIGURE 2 Kaplan–Meier curve of AF-free survival. Freedom from AF Kaplan–Meier survival analysis demonstrating the primary outcome of freedom from AF in the first year of follow-up following pulmonary vein isolation for atrial fibrillation (combined paroxysmal and persistent) following an HPSD or standard strategy. HPSD, high-power short duration.

estimated at 304 ± 14 days in the HPSD group versus 340 ± 10 days in the standard group (long-rank $p = .403$). In comparison between the groups, HPSD was not associated with recurrence of AF in adjusted Cox regression analysis (hazard ratio with HPSD, 0.255; 95% CI 0.051–1.283; $p = .097$).

3.4 | Complications

Overall, the major and minor complications rates were low and similar in any of the groups (2 vs. 2, $p = 1.0$). In the standard group, 2 (2%) groin complications occurred, one arteriovenous fistula and one pseudoaneurysm. No groin complications were detected in the HPSD group. In the HPSD group, two patients ($n = 2$, 2%) developed pericardial effusion, which required pericardial drainage. In study centers performing continuous thermal monitoring of the esophagus, no differences were observed between groups in regard to temperature increase during ablation.

4 | DISCUSSION

This is the first in man, multi-center study demonstrating that a novel modified method of visualization of HPSD ablation lesions leads to significantly shortened procedure times without negative influence on efficacy and safety.

Despite the development of new technologies, pulmonary vein reconnection remains the main cause of AF recurrence in long-term follow-up.[17] Although recently a new concept of the application of RF energy has been proposed, the PVI procedure has not changed. Physicians are still focusing on point-by-point isolation with high accuracy aiming for minimal spacing between two adjacent lesions. This results in time-consuming adjustments of the catheter movement intending a precise allocation of the ablation points within a desired line by retaining close spacing in between. However, such an approach is no anymore dictated by the biophysics of the lesion formation. Bourier et al.[10] showed that high-power short-duration lesions lead to significantly larger lesion diameters of up to 8 mm with less lesion depth (4 mm after 6 s at 50 W) compared with standard ablation lesions.

It is important to notice that the difference between our findings and previous reports can be explained by different energy settings and mainly long-lasting RF application time, that is, 11/13 s versus 5 or 7 s in other studies. Therefore, our results cannot be translated to other approaches or even different RF generators or catheters.

In our novel protocol for optimal utilization of HPSD ablation, we have adapted these differences and proposed a visual representation of lesion sets with a diameter of 8 mm (instead of 4 mm as previously).[18] This approach could potentially reduce overtreatment and simplify the PVI procedure. Due to the increase in minimal distance between individual applications, the operator can more freely accept small deviations in the position of the ablation points as well as reduce the number of RF applications needed to achieve full circumferential PVI. The present study clearly demonstrates this paradigm shift in optimal visualization of the ablation lesion. Regarding first-pass isolation, our results proved that an 8 mm distance is optimal for both quick and effective PVI. Our data also reveal, that through this novel modified method of visualization of HPSD ablation lesions the procedural time, LA dwelling time as well as RF time, can be significantly reduced.

One of the mechanisms explaining our findings can be the reduction of tissue edema due to catheter instability. HPSD RF delivery is thought to destroy tissue, mostly through local resistive heating, which occurs early during an RF application. It avoids the distant conductive heating tissue damage that predominates later during long RF applications, which also might induce more edema and provoke early PV reconnection during the follow-up period.[19] Compared with traditional parameters, such as monitoring loss of pacing capture during RF delivery[15] and/or observing a drop in the impedance,[16] LSI enables actual tracing of lesions maturation and defining optimal endpoints for RF impulse allocation. As LSI reliably depicts the transfer of energy from the catheter into the target tissue by monitoring catheter stability over time as well as catheter-tissue contact and power settings, it is an optimal aggregated parameter to guide the distribution of such short and highly effective RF applications.

It should be emphasized that despite the higher complexity of patients treated with HPSD, as indicated by CHA_2DS_2-VASc score, the results remain in favor of our approach. Moreover, higher comorbidity indices of the HPSD group resulting from selection bias for AF ablation during the pandemic might be responsible for the more severe, although statistically negligible, nature of complications in this group as it was described previously by Koeanig et al.[20]

Further randomized studies are required to secure the safety and efficiency of this novel method and to assure the optimal protocol for individual HPSD ablation approaches.

5 | CONCLUSION

Increasing interlesion distance between ablation points when performing high-power short duration further reduces procedural time without an effect on long-term efficacy and safety. Larger studies are needed to optimally utilize this approach.

5.1 | Limitations

The main limitation of the study results from the concomitant global COVID-19 pandemic. This resulted in a limited availability of follow-up data in the study. Furthermore, it was also reflected in the patient's collective. More patients with preexisting comorbidities as well as in acute conditions were treated in the global COVID-19 pandemic situation and involved in the study. The present study was a nonrandomized study with the inherent limitations of the observational analysis. Since the purpose of the study was to test the predefined HPSD protocol, the results could not be directly applied

to other HSPD settings. During the study, all clinically relevant complications were protocolized. However, nonmanifest events such as silent cerebral lesions or nonsevere esophageal tissue alteration detectable by means of endoscopy were routinely not assessed during this study.

AUTHOR CONTRIBUTIONS

Jedrzej Kosiuk, Hayarpi Manukyan, and Guido A. Matschuck designed and directed the project, contributed to the design and implementation of the research, the analysis of the results, and to the writing of the manuscript. Nandor Szegedi, Nikola Pavlović, Herman Blessberger, Lucas Fiedler, Konstantin Krieger, Šime Manola, Vivien K. Nagy, Franz Xaver Roithinger, Zoltán Salló, Clemens Steinwender, and László Gellér processed the experimental data, performed the analysis, drafted the manuscript and designed the figures, and collected the data.

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CONFLICT OF INTEREST STATEMENT

Nikola Pavlović—proctoring fees: Abbott, Biosense Webster, and Medtronic. Šime Manola—proctoring fees: Abbott, Biosense Webster, and Medtronic.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author, [Hayarpi Manukyan], upon reasonable request.

ETHICS STATEMENT

This study protocol was reviewed and approved by the Ethics Committee of the Medical Faculty of the Johannes Kepler University Linz (approval number 1196/2020).

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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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