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CLINICAL RESEARCH

Very high-power short-duration ablation for pulmonary vein isolation utilizing a very-close protocol—the FAST AND FURIOUS PVI study

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Aims The very high-power short-duration (vHP-SD) radiofrequency (RF) ablation concept of atrial fibrillation (AF) treatment by pulmonary vein isolation (PVI) aims for safer, more effective, and faster procedures. Utilizing conventional ablation, the 'close protocol' has been verified. Since lesion formation of vHP-SD ablation creates wider but shallower lesions we adapted the close protocol to an individualized and tighter 'very-close protocol' of 3–4 mm of inter-lesion distance (ILD) at the anterior and 5–6 mm at the posterior aspect of the left atrium using vHP-SD only. Here, we evaluated the safety and efficacy of vHP-SD ablation for PVI utilizing a very-close protocol in comparison with standard ablation.

Methods and results A total of 50 consecutive patients with symptomatic AF were treated with a very-close protocol utilizing vHP-SD (vHP-SD group). The data were compared with 50 consecutive patients treated by the ablation-index-guided strategy (control group). The mean RF time was 352 ± 81 s (vHP-SD) and 1657 ± 570 s (control, $P < 0.0001$), and the mean procedure duration was 59 ± 13 (vHP-SD) and 101 ± 38 (control, $P < 0.0001$). The first-pass isolation rate was 74% (vHP-SD) and 76% (control, $P = 0.817$). Severe adverse events were reported in 1 (2%, vHP-SD) and 3 (6%, control) patients ($P = 0.307$). A 12-month recurrence-free survival was 78% (vHP-SD) and 64% (control, $P = 0.142$). PVI durability assessed during redo-procedures was 75% (vHP-SD) vs. 33% (control, $P < 0.001$).

Conclusions PVI solely utilizing vHP-SD via a very-close protocol provides safe and effective procedures with a high rate of first-pass isolations. The procedure duration and ablation time were remarkably low. A 12-month follow-up and PVI durability are promising.

Keywords Atrial fibrillation • High-power short-duration • Pulmonary vein isolation • Radiofrequency • Acute efficacy

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What's new?

- Here, we evaluated the safety and efficacy of very high-power short-duration ablation for PVI utilizing a very-close protocol in comparison with standard ablation.
- The first-pass isolation rate was 74% (vHP-SD) and 76% (control, $P = 0.817$). Severe adverse events were reported in 1 (2%, vHP-SD) and 3 (6%, control) patients ($P = 0.307$). A 12-month recurrence-free survival was 78% (vHP-SD) and 64% (control, $P = 0.142$).
- PVI durability assessed during redo-procedures was 75% (vHP-SD) vs. 33% (control, $P < 0.001$).
- PVI solely utilizing vHP-SD via a very-close protocol provides safe and effective procedures with a high rate of first-pass isolations.

Introduction

Catheter ablation-based pulmonary vein isolation (PVI) has shown high procedural success and long-term follow-up rates for the treatment of paroxysmal atrial fibrillation (PAF) and persistent atrial fibrillation (PersAF).[1] Recently, novel single-shot systems have shown excellent acute and long-term success rates with decreased procedure time compared with radiofrequency (RF)-based three-dimensional (3D)-mapping and point-by-point PVI.[2] Nevertheless, single-shot systems have several limitations because they are mainly designed for PVI only. Furthermore, the adaptability to different PV anatomies is narrowed. 3D-mapping and point-by-point-based PVI received several improvements by implementing contact force (CF) sensing and ablation index (AI)-guided RF ablation shortening procedure time and improving safety and patients outcome.[3,4] Recently, high-power short-duration (HP-SD) with a maximum of up to 50 W and very HP-SD (vHP-SD) with a maximum of 90 W have been evaluated and were found to shorten the procedure duration.[5,6] The novel QDOT Micro ablation catheter (Biosense Webster, Inc., Diamond Bar, CA, USA) has been developed allowing for real-time assessment of catheter-to-tissue interface temperature and therefore allows temperature-controlled ablation.[7] This strategy aims to create shallower but wider lesions in a very short time by reducing conductive heating and increasing resistive heating at the same time. Additionally, collateral tissue damage might be reduced.[8] Utilizing conventional RF ablation the 'close protocol' with an inter-lesion distance (ILD) of 6 mm has been introduced and verified.[9] Since the lesion formation of vHP-SD ablation creates wider but shallower lesions, we adapted the close protocol to an individualized and tighter 'very-close protocol' of 3–4 mm ILD at the anterior aspect and 5–6 mm at the posterior aspect of the left atrium using vHP-SD only. Here, we thought to evaluate the safety, efficacy, and follow-up of vHP-SD ablation for PVI utilizing a novel vHP-SD catheter utilizing a very-close protocol in comparison with conventional CF sensing AI-guided RF ablation.

Methods

Inclusion and exclusion criteria

Since September 2020, 50 consecutive patients with symptomatic, drug-refractory PAF, or short-standing PersAF (duration ≤3 months) presented for PVI and were treated with the QDOT Micro catheter (vHP-SD group). A total of 50 consecutive previous patients treated with conventional CF-sensing AI-guided PVI served as the control (control group). The patients were prospectively and consecutively enrolled. Exclusion criteria were prior left atrial (LA) ablation attempts, LA diameter of >60 mm, severe valvular heart disease, or contraindications to post-interventional oral anticoagulation. Transoesophageal echocardiography was performed in all patients prior to PVI to rule out intracardiac thrombi and to assess the LA diameter. No further pre-procedural imaging was performed. In patients on vitamin K antagonists, the procedure was performed under therapeutic INR values of 2–3. In patients on new oral anticoagulants, the morning dose on the day of the procedure was omitted. All patients gave written informed consent and all patient information was anonymized. The study was approved by the local ethics board (Lübeck ablation registry ethical review board number: WF-028/15) and performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Intraprocedural management

The detailed intraprocedural management for 3D-mapping and AI-guided PVI has been described in previous studies from our group.[10] In brief, the procedure was performed under deep sedation using midazolam, fentanyl, and propofol. Three ultrasound-guided right femoral vein punctures were performed and three 8F short sheaths were inserted. Prior to transseptal puncture (TSP), one diagnostic catheter was introduced and positioned inside the coronary sinus. Double TSP was performed under fluoroscopic guidance using a modified Brockenbrough technique with 8.5F transseptal sheaths and puncture needle (SL1 sheath and BRK-1 TSP needle, St. Jude Medical, Inc., St. Paul, MN, USA). Pulmonary vein (PV) angiography was performed to identify the PV ostia. Both sheaths were continuously flushed with heparinized saline (10 mL/h). After TSP heparin, boluses were administered targeting an activated clotting time of >300 s.

Ablation procedure

3D electroanatomic LA reconstruction (CARTO 3 V7, Biosense Webster) was performed via fast anatomical mapping with a multi-electrode mapping catheter (Pentaray or Lasso Nav, Biosense Webster). For the LA voltage map, the bipolar voltage reference interval was set between 0.05 and 0.5 mV. After PV angiography, the ipsilateral PVs were tagged according to 3D-mapping and PV angiography. During PVI, a multi-electrode spiral mapping catheter was positioned inside the ipsilateral PVs. All procedures in both groups have been performed by two highly experienced operators only (R.R.T and C.-H.H.).

The vHP-SD ablation group

In the vHP-SD group, the QDOT Micro catheter was utilized. For all applications, vHP-SD ablation (90 W, 4 s; QMODE+ mode) was performed. The target temperature of the temperature-controlled ablation was 60°C based on the hottest surface thermocouple.[7] The irrigation flow rate delays the energy application for a minimum of 2 s before and 4 s after each RF application. A switch to conventional QMODE was always possible by changing the ablation mode. For all cases, a very-close protocol was utilized aiming to perform vHP-SD only. For anterior lesions an ILD of 3–4 mm and for posterior lesions an ILD of 5–6 mm was predefined (*Figure 1*). The rationale of this proceeding for the anterior aspect was derived from pre-clinical animal studies where a double application of 90 W for 4 s caused a further tissue temperature rise and a 40% deeper lesion formation. The target CF range was 10–25 g. In the case of CF of <10 g, a CF of 5 g was acceptable to start the application. In the case of CF of <5 g, another catheter position was utilized to achieve a stable and continuous contact with CF of >5 g. The final lesion set after vHP-SD-based PVI is shown in *Figure 2*. An S-shaped temperature probe (CIRCA S-CATH, Circa Scientific, Englewood, CO, USA) was advanced into the oesophagus to monitor the oesophageal temperature (Teso) in all cases of the vHP-SD group. The intraluminal Teso cut-off was set at 38.5°C. During the procedures, special attention was drawn to audible pops and all catheters were checked for charring after removal.

Conventional ablation

In the control group, conventional CF-sensing AI-guided ablation was used. Ablation was performed with a Thermocool Smart-touch surround flow catheter (Biosense Webster) in a power-controlled mode. Energy application was limited to 40 W. Target range for CF was 10–40 g. Target AIs were 550, 450, and 380 for the anterior, roof, and posterior segments of the LA, respectively.[10] The ILD was set to 5–6 mm. In the case of previously known

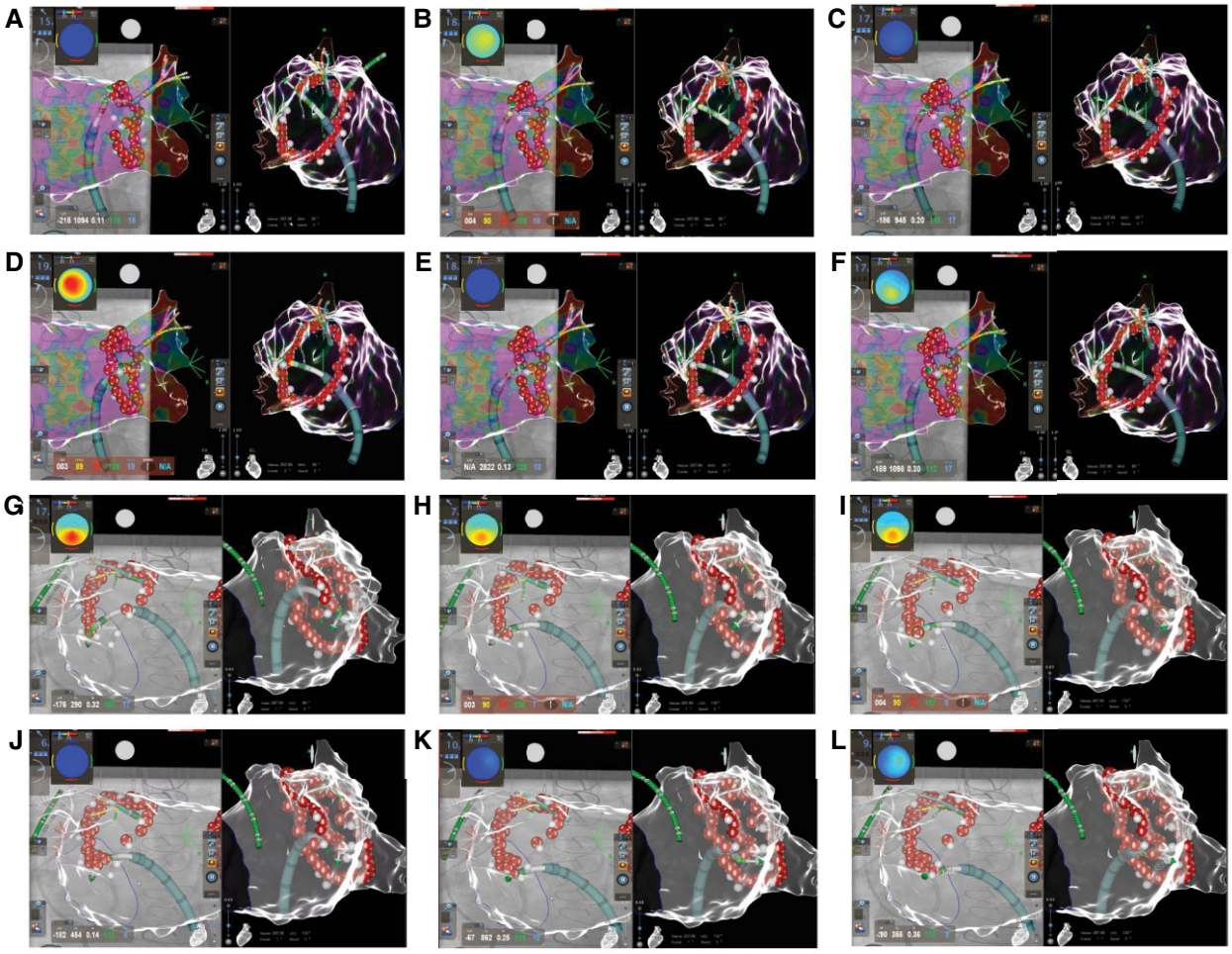

Figure 1 QDOT micro catheter in QMODE± utilizing the very-close protocol: *A–F*: posterior aspect: three-dimensional electroanatomic reconstruction (CARTO 3, UNIVIEW module, Biosense Webster) of the left atrium in right anterior oblique (left) and right lateral (right) view. Please note the deployment of very high-power short-duration applications by 90W/4 s. At the posterior area an ILD of 5–6 mm was targeted. *G–L:* anterior aspect: Three-dimensional electroanatomic reconstruction (CARTO 3, UNIVIEW module, Biosense Webster) of the left atrium in posterior anterior (left) and left lateral (right) view. Please note the deployment of very-high power short duration applications by 90 W/4 s (QMODE+ mode, red–white tags) at the anterior aspect of the left pulmonary veins. At the anterior area an ILD of 3–4 mm was targeted.

or periprocedural typical atrial flutter, cavotricuspid isthmus ablation was performed in both groups.

Postprocedural care

A figure-of-eight suture and a pressure bandage were used to prevent femoral bleeding. The pressure bandage was removed after 4 h and the figure-of-eight suture on the next day. Following ablation, all patients underwent transthoracic echocardiography immediately post procedure, after 2 h and at Day 1 after the procedure to rule out a pericardial effusion. New oral anticoagulants were re-initiated 6 h post ablation. Anticoagulation was continued for at least 3 months and continued thereafter based on the patient's CHA_2DS_2-VASc score. Previously ineffective antiarrhythmic drugs or a new antiarrhythmic drug were prescribed and continued for 3 months post ablation. All patients were treated with proton-pump inhibitors for 6 weeks. Following a 3-month blanking period, patients completed outpatient clinic visits, including ECG and 72 h-Holter ECG at 3, 6, and 12 months. In addition, regular telephone interviews were performed. Additional outpatient clinic visits were immediately initiated in cases of symptoms suggestive of arrhythmia recurrence.

End points

Primary end point

The primary endpoint was defined as freedom from documented AF/atrial tachycardia (AT) recurrence 12 months after PVI, including a 90-day blanking period. Recurrence was defined as any ECG-documented atrial tachyarrhythmia lasting for at least 30 s, including AF, AT, and atrial flutter. Patients completed outpatient clinic visits at 3, 6, and 12 months including ECGs and 24 h-Holter ECGs. In addition, regular telephonic interviews were performed.

Secondary end points

The secondary end points were acute procedural success defined as the ability to confirm electrical isolation with a circular mapping catheter, procedural parameters (e.g. procedure time, LA dwelling time, fluoroscopy time), number and duration of RF applications, number of first-pass isolations as well as periprocedural complications. Periprocedural complications were defined according to the latest guidelines. Only adverse events adjudicated as possible, probable, or definitely related to the ablation procedure were mentioned as safety events. An adverse event was considered serious if it resulted in permanent injury or death, required an intervention for treatment, or required hospitalization for more than 24 h. All other safety events were defined as minor complications.

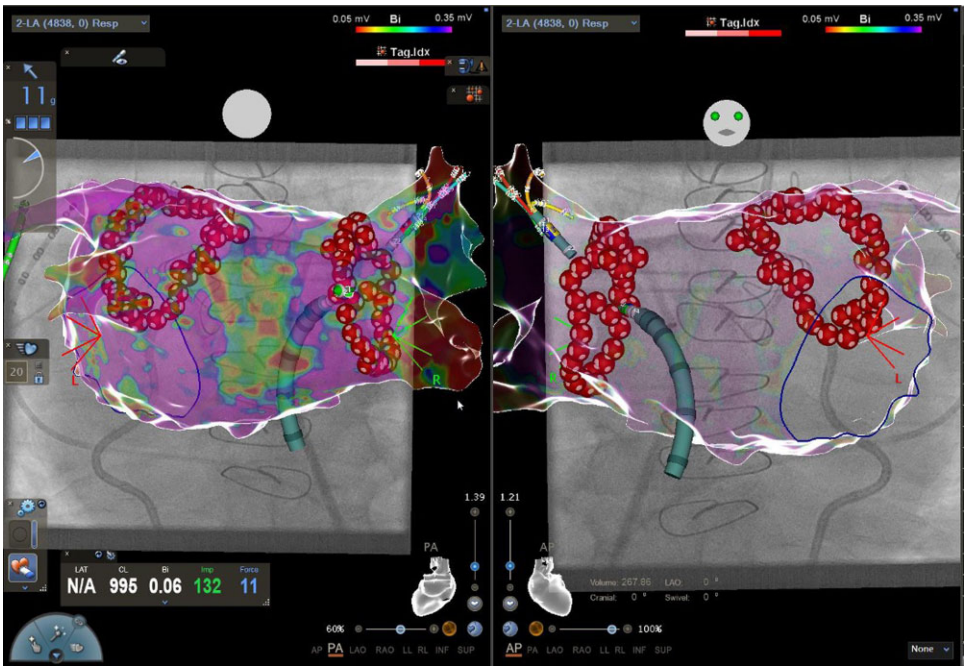

Figure 2 Final lesions set. Three-dimensional electroanatomic reconstruction (CARTO 3, UNIVIEW module, Biosense Webster) of the left atrium in posterior anterior (left) and anterior posterior (right) view. Please note the two circles of very-high power short duration applications by 90 W/4 s (QMODE+ mode, red–white tags) encircling the right and left pulmonary veins.

Second ablation procedure

Patients with AF or atrial tachycardia (AT) recurrence during the follow-up and suitable for a repeat-PVI were scheduled for a second ablation procedure using a 3D-mapping system. The techniques for mapping and RF-based PVI have been previously described. The procedures were performed as per institutional standards. Typically, LA electroanatomic reconstruction was performed using a multipolar mapping catheter. Each individual PV was evaluated for electrical reconnection using the mapping catheter recordings. When non-isolated PVs were identified, an RF-based, point-by-point PVI was performed as per institutional standards. For the treatment of AT high-density mapping utilizing a 3D-mapping system and a multipolar mapping, a catheter was conducted to identify the AT mechanism followed by deployment of standardized ablation lines as previously described.

Statistical analysis

Continuous variables are presented as median with interquartile range [first quartile (Q1), third quartile (Q3)]; they were compared using the Wilcoxon Mann–Whitney test. Categorical variables are presented as absolute and relative frequencies; they were compared using the χ^2 test or Fisher's exact test (in case of small-expected cell frequencies). All *P*-values are two-sided and a *P*-value <0.05 was considered significant. Recurrence-free survival was estimated with the Kaplan–Meier method. All calculations were performed with the statistical analysis software SAS (SAS Institute Inc., version 9.3, Cary, NC, USA).

Table 1 Baseline patient characteristics

Variable	VHP-SD	Control	*P*
Patients	50	50	
Age, years	67 ± 10	66 ± 10	0.774
LA volume, mL/m^{2a}	33 ± 10	37 ± 7	0.142
Duration of AF, months	28 ± 37	19 ± 27	0.263
Female gender	16 (32)	19 (38)	0.529
Paroxysmal AF	26 (52)	24 (48)	0.689
Congestive heart failure	7 (14)	10 (20)	0.424
Arterial hypertension	28 (56)	29 (58)	0.840
Diabetes mellitus type 2	6 (12)	2 (4)	0.140
Coronary artery disease	12 (24)	10 (20)	0.629
Previous TIA/Stroke	3 (6)	5 (10)	0.461
CHA_2DS_2-VASc score			
0	8 (16)	9 (18)	0.790
1	10 (20)	5 (10)	0.161
2	9 (18)	15 (30)	0.249
3	12 (24)	10 (20)	0.629
≥4	11 (12)	11 (32)	0.999

Values are counts, *n* (%), or mean (±SD).
AF, atrial fibrillation; LA, left atrium.
[a]Per body surface area.

Results

Patient characteristics

One hundred patients with PAF or PersAF were prospectively enrolled in this study. A total of 50 consecutive patients underwent vHP-SD-based PVI utilizing the QMODE+ ablation mode. The data were compared with 50 consecutive previous patients with PVI by conventional CF-sensing AI-guided ablation. Patient baseline characteristics are shown in *Table 1*. No demographic differences were detected between the groups.

Table 2 Procedural details

Variable	vHP-SD	Control	P
Number of patients	50	50	
Number of PVs	200	200	
Total number of isolated PVs	200 (100)	200 (100)	0.999
FAAVI	37 (74)	38 (76)	0.817
Total procedure time, min	59 ± 13	101 ± 38	<0.0001
Total procedure time, min (PVI only)	56 ± 10	98 ± 35	<0.0001
Total LA dwelling time, min	41 ± 9	73 ± 33	<0.0001
Total fluoroscopy time, min	7 ± 3	12 ± 6	<0.001
Total amount of contrast agent, mL	50 ± 13	54 ± 28	0.364
Total radiofrequency time, s	352 ± 81	1657 ± 570	<0.0001
Total number of applications	88 ± 20	83 ± 31	0.314
Mean application duration, s	4 ± 0	19 ± 6	<0.0001
Mean contact force, g	15 ± 3	18 ± 3	0.212
Mean power/application, Watt	90 ± 0	32 ± 4	<0.0001
Total delivered power/lesion, Joule	331 ± 111	565 ± 212	<0.001
Teso Temp. > 38.5°C, *n*	18 (36)	—	—
Teso Temp. > 38.5°C, *n*/patient	0.6	—	—
Max Teso, °C	42 ± 2	—	—
Cavotricuspid isthmus block, *n*	13 (26)	13 (26)	0.999
Periprocedural complications			
Severe adverse events	1 (2)	3 (6)	0.307
Cardiac tamponade	0	1 (2)	0.787
Severe bleeding	1 (2)	2 (4)	0.558
Phrenic nerve injury	0	0	0.999
Stroke or TIA	0	0	0.999
Minor complications	3 (6)	2 (4)	0.553
Minor bleeding	2 (4)	2 (4)	0.553
Pericardial effusion	1 (2)	0	0.787
Transient air embolism	0	0	0.999
Clinical apparent oesophagus injury	0	0	0.999
Charring on catheter tip	0	0	0.999

Values are counts, *n* (%) or mean (±SD).
PV(s), pulmonary vein(s); PVI, pulmonary vein isolation; FAAVI, first-attempt all veins isolated; LA, left atrium; min, minutes, s, seconds; g, grams.

Procedural characteristics

Procedural data are summarized in *Tables 2*, *3* and *Figure 3*. All procedures were performed by two experienced operators. Only patients with PVI or PVI plus CTI block were included in this study. All PVs were successfully isolated in either group. With 74% (vHP-SD) and 76% (control), a similar rate ($P = 0.817$) of first-pass isolations was observed in both groups (first attempt all veins isolated, FAAVI). For right PVs, the rate of first-pass isolation (first-attempt vein isolated, FAVI) was significantly higher in the vHP-SD group (96%) than in control patients (76%), $P = 0.004$. For left PVs, no difference in FAVI was observed (78% vs. 72%; $P = 0.488$). Significantly shorter procedure times 59 ± 13 min vs. 101 ± 38 min ($P < 0.0001$), LA dwelling times 41 ± 9 min vs. 73 ± 33 min ($P < 0.0001$), and fluoroscopy times 7 ± 3 min vs. 12 ± 6 min ($P < 0.0001$), were observed for the vHP-SD group. For procedures with PVI only (excluding all patients with additional CTI block, $n = 13$ in each group), the procedure times were 56 ± 10 min vs. 98 ± 35 min ($P < 0.0001$). CTI block was achieved by Qmode+ only in all patients ($n = 13$). In one patient with a repeat procedure, the CTI was checked and was found to be blocked after QMODE+ only.

While the total number of applications ($P = 0.314$) and mean CF ($P = 0.212$) were similar in both groups, the total ablation time 352 ± 81 min vs. 1657 ± 570 s ($P < 0.0001$) and mean application duration 4 ± 0 min vs. 19 ± 6 s ($P < 0.0001$) were significantly shorter in the vHP-SD group. Despite a higher mean power per application in the vHP-SD group 90 ± 0 min vs. 32 ± 4 W ($P < 0.0001$), the total delivered energy per lesion was significantly lower 331 ± 111 J vs. 565 ± 212 J ($P < 0.001$). The QMODE+ ablation mode was exclusively used for all procedures in the vHP-SD group. No switch to QMODE was necessary to achieve PVI. No differences were observed between the groups with regard to catheter maneuverability and catheter stability along the targeted PVs. After discharge, all patients received antiarrhythmic drugs post ablation for 3 months.

Table 3 Procedural details—individual pulmonary vein

Variable	vHP-SD	Control	P
Right-sided PVs	50	50	
Total ablation time, s	172 ± 53	802 ± 308	<0.0001
Total number of applications	43 ± 13	42 ± 19	0.899
Mean application duration, s	4 ± 0	19 ± 6	<0.001
Mean contact force, g	17 ± 4	20 ± 5	<0.001
Mean power/application, Watt	90 ± 0	32 ± 4	<0.0001
Total delivered power/lesion, Joule	329 ± 17	565 ± 212	<0.001
FAVI	48 (96)	38 (76)	0.004
Left-sided PVs	50	50	
Total ablation time, s	182 ± 51	831 ± 375	<0.0001
Total number of applications	46 ± 13	44 ± 19	0.463
Mean application duration, s	4 ± 0	18 ± 14	0.001
Mean contact force, g	14 ± 4	16 ± 3	<0.001
Mean power/application, Watt	90 ± 0	32 ± 5	<0.0001
Total delivered power/lesion, Joule	334 ± 6	543 ± 231	<0.001
FAVI	39 (78)	36 (72)	0.488

Values are counts, *n* (%), or mean (±SD).
PV(s), pulmonary vein(s); FAVI, first-attempt vein isolated; s, seconds; g, grams.

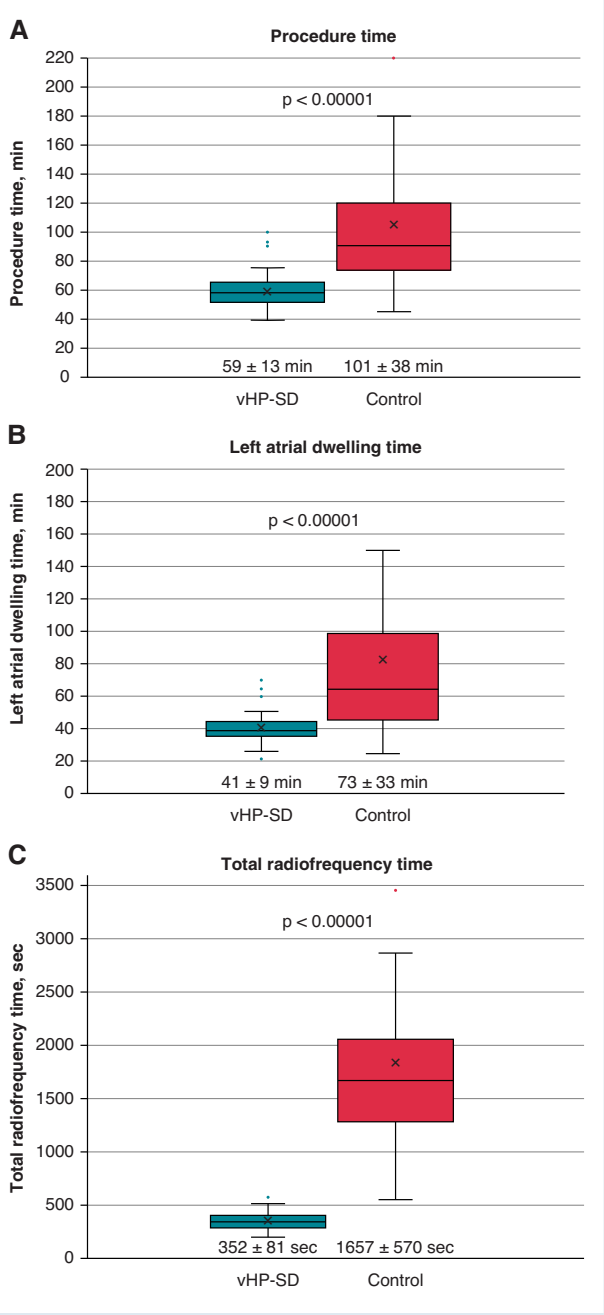

Figure 3 Periprocedural data: periprocedural duration: (*A*) procedure time; (*B*) left atrial dwelling time; (*C*) total radiofrequency time, vHP-SD group compared with the control group.

Safety

No differences in terms of serious adverse events or minor complications were observed. One groin bleeding requiring blood transfusion was observed in the vHP-SD group (2%) and two patients with groin bleeding (one surgical intervention and one blood transfusion) were observed for the control group (4%, $P = 0.558$). In the control group, one patient suffered from a cardiac tamponade which was detected after finalizing the procedure (2%). The patient was successfully treated via epicardial puncture and aspiration. There were no further severe adverse events such as stroke, phrenic nerve palsy, or atrioesophageal fistula in either group. Concerning minor complications, one patient of the vHP-SD group experienced an asymptomatic pericardial effusion not requiring epicardial puncture or any further intervention (2%). Two patients of each group (4%/4%) experienced minor bleeding of the groin, not requiring intervention or blood transfusion. There were no documented steam pops and no catheter tip charring was detected in either group. An oesophageal temperature probe was utilized only in the vHP-SD group. A Teso >38.5°C was detected in 18 (36%) patients solely at the posterior part of the left PVs. The mean maximum Teso was measured at 42 ± 2°C.

Follow-up and clinical success

In a total of 89/100 patients (89%), 12-month follow-up was available [rate of loss to follow-up was not different between the groups (vHP-SD: $n = 5$ vs. control: $n = 6$, $P = 0.749$)]. The rate of 12-month AF/AT-free survival after a 90-day blanking period was vHP-SD: 78% vs. control 64% ($P = 0.142$ *Figure 4A*). The mean time to recurrence was 344 ± 178 and 359 ± 188 days.

Concerning patients with PAF 12-month AF/AT-free survival after a 90-day blanking period was vHP-SD: 83% (20/24) vs. control 67% (15/21), ($P = 0.334$), and vHP-SD: 71% (14/21) vs. control 61% (14/23), ($P = 0.670$) or PersAF, respectively.

The findings during repeat procedures are summarized in *Table 4* and *Figure 4B*. A total of 16 patients (vHP-SD group = 7, control group = 9) received a repeat procedure and verification of PVI due to recurrence of AF, atrial tachycardia, typical flutter, or LA appendage closure (*Table 4*). The median time to reintervention was 12 (9, 16) months for the vHP-SD group and 14 (12, 20) months for the control group ($P = 0.516$).

Discussion

This study aims to assess efficacy, procedural characteristics, safety, and follow-up during PVI utilizing solely the vHP-SD mode of the QDOT

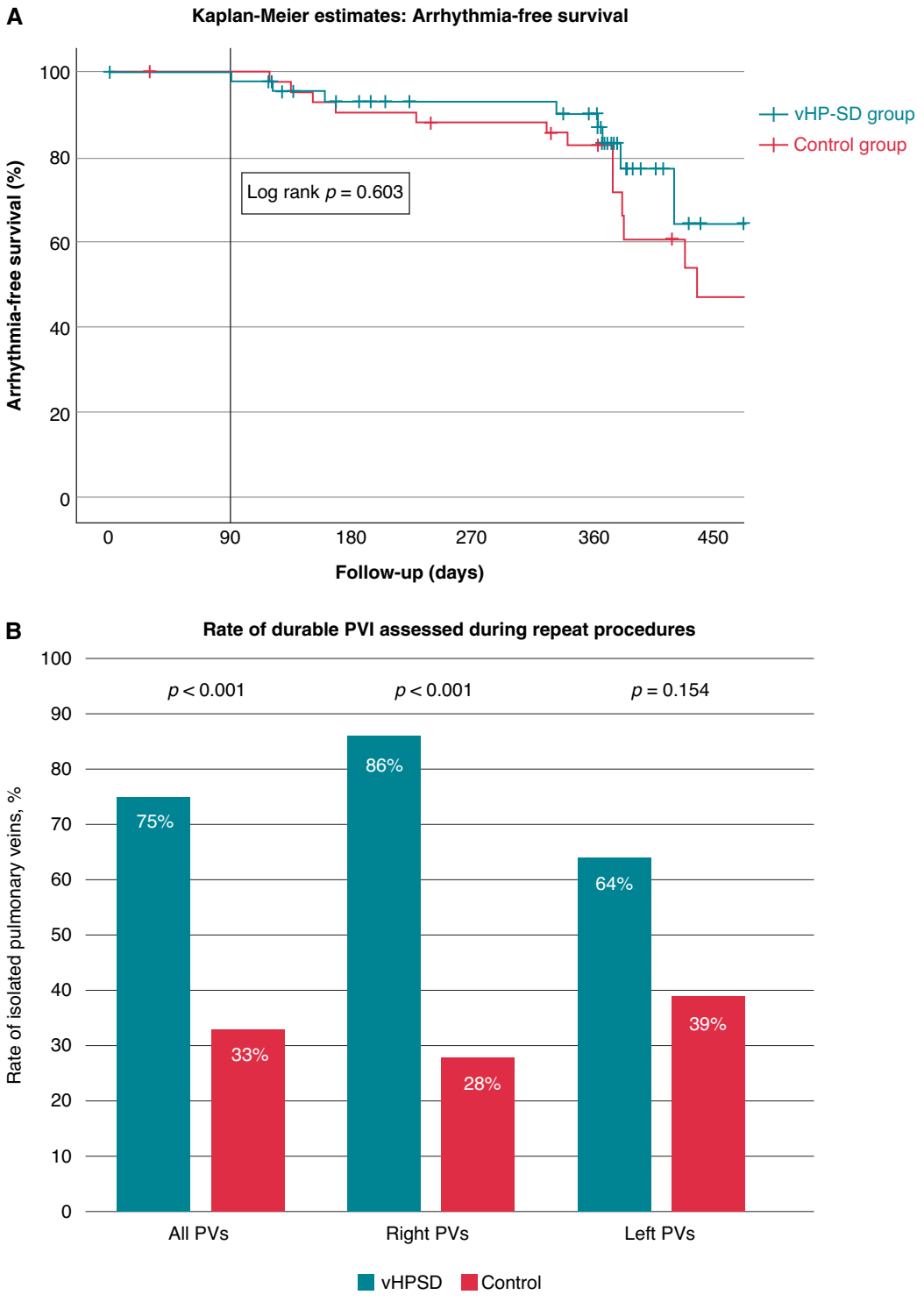

Figure 4 12-month follow-up and findings of repeat procedures. (*A*) Kaplan–Meier estimates with 12-month follow-up after the index PVI utilizing very-high power short duration applications by 90 W/4 s (QMODE+) only and the control group. No statistical differences were found concerning 12-month freedom from atrial tachyarrhythmias. (*B*) Comparison of pulmonary vein durability assessed during repeat procedures of $n = 7$ (very high-power short-duration group) and $n = 9$ (control) patients. All four PVs were found to be isolated in 57% of very high-power short-duration group and 0% of control group patients.

Table 4 Finding during repeat procedures

Variable	vHP-SD	Control	P
Patients	7	9	
AF recurrence	3	7	0.152
Atrial tachycardia/typical flutter	2/1	2/	0.377
PV isolation verified during LAA closure	1	0	0.565
Time to repeat procedure, months	12 (9, 16)	14 (12, 20)	0.516
PVs	28	36	
Patients with durable complete PVI	4 (57)	0 (0)	<0.01
Isolated PVs	21 (75)	12 (33)	<0.001
Isolated right PVs	12 (86)	5 (28)	<0.001
Isolated left PVs	9 (64)	7 (39)	0.154
CTI block (index procedure)	1	3	
CTI block verified (repeat procedure)	1 (100)	2 (67)	0.572
Ablation strategy during repeat procedure			
Reisolation of not isolated PVs	7 (100)	24 (100)	
Box-lesion	2	0	
Mitralisthmus line	1	1	
LAA isolation	1	0	
CTI block	3	2	

Values are counts, *n* (%), mean (±SD), or median (interquartile range) as appropriate.
AF, atrial fibrillation; CTI, cavotricuspid isthmus block; LAA, left atrial appendage; PV(s), pulmonary vein(s); PVI, pulmonary vein isolation.

Micro catheter by utilizing a very-close protocol. The data were compared with standard CF-guided ablation. The major findings are

(1) All PVs could be isolated utilizing vHP-SD only, with no necessity to switch the ablation mode to moderate power.
(2) A higher first-pass isolation rate was observed for right-sided PVs compared with control while the overall rate was similar.
(3) RF time, procedure time, and LA dwelling time were significantly reduced utilizing vHP-SD only.
(4) The rate of periprocedural complications were low and no differences were observed between the groups.
(5) During repeat procedures a higher rate of durable PVI was observed for vHP-SD.
(6) The long-term outcome was promising and similar between the groups.

Although the number of single-shot devices for PVI are increasing, the gold standard remains RF-based ablation. The advantages for single-shot devices are shorter procedure times, learning curves, and safety aspects. Recently, the HP-SD concept of RF-based PVI with increased power and shorter duration was introduced and efficacy and safety were shown in previous studies in a power-controlled ablation mode.[11]

A further improvement of performance was recently shown for the vHP-SD concept utilizing 90Watts for 4 s in a temperature-controlled mode which was recently realized by the QDOT Micro catheter. The six thermocouples of this catheter enable precise temperature measurement and power modulation to avoid tissue overheating, collateral damage, catheter tip charring, and steam pops.[12]

The concept of RF ablation utilizing the 'close protocol' has been verified by different groups and was found to be effective and safe.[9] However the lesion formation of vHP-SD ablation creates wider but shallower lesions. Therefore, we suggested an adapted, individualized, and tighter 'very-close protocol' of 3–4 mm ILD at the anterior aspect and 5–6 mm at the posterior aspect of the left atrium using vHP-SD only to achieve safe and fast PVI. The present study shows that PVI utilizing the QMODE+ ablation mode provides similar acute success and periprocedural complications rates when compared with the standard CF-sensing AI-guided PVI. The rate of first-pass isolation was relatively high and comparable between the groups. Utilizing the 'very-close protocol' PVI was achieved by QMODE+ only. This observation is different from the study by Reddy *et al.* They reported a necessity of conventional ablation in 26.9% of patients and 5% of PVs.[7] The reason for this discrepancy might be the fact that an individualized 'very-close protocol' was utilized aiming for a QMODE+ only strategy.

With the QDOT Micro catheter, a switch to conventional ablation mode (QMODE) is always possible, yet it was not necessary in any of our cases to achieve PVI. In our study, no charring, no steam pops, and no clinical apparent oesophageal injuries occurred, suggesting an excellent safety profile of the QMODE+ ablation mode. The fact that the application duration and consequently the total RF ablation time was massively reduced utilizing the QMODE+ translated into significantly reduced median LA dwelling times and a shorter median procedure time.

For PVI only (excluding all patients with additional CTI block, $n = 13$ in each group), the procedure times were 56 ± 10 vs. 98 ± 35 min ($P < 0.0001$). With a mean procedure time of <60 min, the vHP-SD strategy offers short procedure times comparable with single-shot devices.[13,14,15] Although a comparable procedure time of 55.6 ± 6.6 min for PVI only was reported for the 50 W HP-SD protocol by Chen and colleagues.[16] With a total mean RF time of 352 s, this was massively reduced compared with the control group (1657 s). With potentially similar or even faster PVI compared with balloon-based ablation, the ability to set further ablation strategies as well as an excellent safety profile, vHP-SD has the potential for an ideal ablation tool. With a total of 75% durable isolated PVs and 57% of patients showing all four PVs durable isolated this rate was unexpectedly high compared with 33 and 0% for the control group. Data on PV durability for the cryoballoon showed 56–69% durable isolated PVs while all four PVs were shown to be isolated in 21–26% of patients.[17,18] Utilizing point-by-point RF ablation via the close protocol, Pooter *et al.* showed PVI durability of all four PVs in 62% of patients.[19] Additionally, prior studies reporting on cryoablation or conventional RF showed durability percentages ranging from 0 to 33%.[20] Our observation is strengthening the high efficacy of the QMODE+ only strategy utilizing a very-close protocol. The 12-month follow-up is promising and comparable with recent findings of single-shot devices.

Limitations

This study is the first prospective analysis on 1-year follow-up of vHP-SD only-based PVI in comparison with standard AI-guided PVI. It is a non-randomized analysis resulting in potential biases. Although we are presenting single-center experience with a relatively small number of patients, consecutive patients where prospectively evaluated and all procedures were performed by two highly experienced operators. A Teso probe was provided in all patients of the vHP-SD group. Yet, no post-ablation endoscopy analyses were performed. Therefore, no data on subclinical oesophageal injury are available and especially atrioesophageal fistula typically occur weeks after the procedure. The number of redo-procedures was relatively low; however, we are presenting the first data on PVI durability after vHP-SD-based PVI.

Conclusions

Here, we are reporting on the efficacy and safety of vHP-SD-based PVI utilizing a very-close protocol as compared with standard CF-sensing

AI-guided PVI. While demonstrating similar acute and long-term efficacy for PVI, the total ablation time, as well as procedural duration, were impressively low utilizing vHP-SD. The data are promising and is comparable with the data of recent single-shot catheter ablation procedures.

Author contributions

C.-H.H. contributed to concept/design, data collection, data analysis and interpretation, drafting article. M.S., S. Ș.P., B.S., M.F., S.H., B.K., H.-L.P., and K.-H.K. contributed to critical revision and approval. C.E. and J.V. contributed to data collection, critical revision, and approval. R.R.T. contributed to concept/design, data analysis, and interpretation, critical revision, and approval.

Conflict of interest: C.-H.H. received travel grants and research grants from Boston Scientific, Biosense Webster, and Cardiofocus, and Speaker's Honoraria from Boston Scientific, Biosense Webster, and Cardiofocus. R.R.T. is a consultant of Boston Scientific, Biotronik, and Biosense Webster, and received Speaker's Honoraria from Biosense Webster, Medtronic, Boston Scientific, and Abbot Medical. K.-H.K. reports grants and personal fees from Abbott Vascular, Medtronic, Biosense Webster outside submitted work. All other authors have no relevant disclosures. C.E. received travel grants and research grants by Boston Scientific, Biosense Webster, Medtronic, Abbott, and Speaker's Honoraria from Boston Scientific, Biosense Webster Medtronic, and Abbott. All other authors none declared.

Data availability

The data will not be available for other researchers due to ethical reasons.

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