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CLINICAL EFFICIENCY AND SAFETY OF HIGH-POWER SHORT-DURATION RADIOFREQUENCY ABLATION IN TREATMENT OF PATIENTS WITH ATRIAL FIBRILLATION

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Aim. Evaluation of the clinical efficacy and safety of a high-power short-duration (HPSD) strategy for ablation index (AI) - guided pulmonary vein isolation (PVI) using different power settings.

Methods. 185 patients were scheduled for AI guided ablation. Patients were randomized into 2 groups and every group was divided into two subgroups. First group (n=95) PVI was performed with 50W. Second group (n=90) with 45 W. In Ia and IIa AI was 400-450 au (arbitrary unit) in posterior wall and 500-550 au. in the anterior wall. In Ib and IIb AI was 400-450 au in posterior wall and 450-500 au in the anterior wall.

Results. Efficacy of the PVI was 100% in all patients. Within 6 months, atrial fibrillation recurred in Ia, Ib, IIa and IIb subgroups were 5/55 (9.0%), 4/40 (10%), 6/50 (12%) μ 5/40 (12.5%) p>0,05. First-pass PVI in Ia, Ib, IIa and IIb subgroups were 53/55 (96.36%), 37/40 (92.5%), 46/50 (92%), 36/40 (90.5%) (p>0,05). There was no significant intra operative complications. The total procedure time was 55±10 min, 50±8 min, 60±10 min, 56±9 min (p>0.05).

Conclusions. HPSD ablation in patients with atrial fibrillation significantly reduces the procedure time, does not increase the incidence of intraoperative complications and is effective in the short term results.

Key words: atrial fibrillation; ablation index; high power short duration; catheter ablation; ablation index; pulmonary vein isolation; procedure time

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Atrial fibrillation (AF) stands as the most common type of cardiac arrhythmia [1]. The frequency of AF in the overall population is 1-2%, with the incidence rate increasing with age from 0.5% in the 40-50 years old to 5-15% in those aged 80 [2]. According to current recommendations for catheter ablation (CA) in patients with AF, the isolation of the pulmonary veins (PV) is a pivotal aspect of treating this arrhythmia [1]. Despite recent advancements, 20-45% of patients experience recurrences after PV isolation (PVI) [3]. According to the study by Wasmer K. et al., it was demonstrated that most patients with recurrent AF after PVI showed at least one reconnected vein during redo procedures. The primary cause of recurrences is the restoration of conduction, attributed to endurable isolation (non-transmural, intermittent radiofrequency application) [4]. Numerous approaches have been presented to enhance the outcomes of surgical treatment for AF, such as the CLOSE protocol [5] and Ablation Index (AI) [6]. CLOSE protocol represents an approach aimed at isolating the PV ostia through precise continuous (distance between points ≤ 6 mm) radiofrequency intervention, achieving target ablation index values of ≥ 400 au for the posterior wall and ≥ 500 au for the anterior wall. The Ablation Index is a marker of quality lesion formation, providing a visual representation of the lesion based on the integration of power, contact force, and time parameters, which is displayed on the CARTO® 3 system (Biosense Webster).

Throughout radiofrequency ablation (RFA), electromagnetic energy undergoes conversion into thermal energy, leading to tissue damage and temperature elevation. The temperature elevation process encompasses two stages: resistive heating, impacting surface tissues (1-2mm), and conductive heating, which facilitates the transfer of heat from surface tissues to underlying tissues [7].

In the presence of good catheter-endocardium contact (25%), only 9% of the power is effectively delivered to the endocardium. For instance, at a power level of 30 watts and optimal contact (25%) with the endocardium, merely 2.7 watts are transferred to the endocardial tissue. When applying 30 watts of power for 30 seconds, a total energy delivery of 900 joules occurs, with only 90 joules

being imparted to the endocardium. Similarly, at 50 watts for 10 seconds, only 45 joules of energy are transmitted to the endocardium. When operating at 10 watts, the catheter temperature elevates by 13°C. Consequently, at 30 watts, the temperature reaches 39°C, and at 50 watts, it rises to 65°C. The formation of an irreversible lesion necessitates a temperature exceeding 50°C [8].

During standard RFA procedures with power settings ranging from 20 to 45 watts and a duration of 20 to 60 seconds, the formation of ablation points predominantly occurs during the conductive heating phase.

High power short duration ablation (HPSD) is an approach that reduces the conductive heating phase while increasing the resistive heating phase. This results in an expanded area of lesion, facilitating the formation of transmural lesions in the atrial myocardium with irreversible tissue damage and reduced risk to surrounding structures, such as thermal injury to the esophagus [9].

Patients characteristics

	I group 50	W (n=95)	II group 45	5 W (n=90)
	a (n=55)	b (n=40)	a (n=50)	b (n=40)
Age	62.6±7.8	62.45±9.8	63.5±10.1	63.1±7.44
Female, n (%)	34 (61.81)	25 (62.5)	27 (54)	22 (55)
Male, n (%)	21 (38.18)	15 (37.5)	23 (46)	18 (45)
HTN, n (%)	32 (58.18)	21 (52.5)	31 (58)	23 (57.5)
Dyslipidemia, n (%)	10 (18.18)	2 (5)	7 (14)	3 (7.5)
BMI > 25, n (%)	53 (96.36)	39 (97.5)	48 (96)	39 (97.5)
Smoking, n (%)	37 (67.27)	26 (65)	33 (66)	24 (60)
DM, n (%)	6 (10.09)	3 (7.5)	5 (10)	5 (12.5)
CAD, n (%)	10 (18.18)	7 (17.5)	9 (18)	8 (20)
Stroke / TIA, n (%)	1 (1.8)	0	0	0
Hypothyroidism, n (%)	14 (25.45)	9 (22.5)	10 (20)	7 (17.5)
Hyperthyriodism, n (%)	3 (5.45)	1 (2.5)	2 (4)	0
Thyroid cancer, n (%)	1 (1.8)	0	0	0
CHA,DS,-VASc	4.13±1.25	3.63±1.19	4± 1.51	3.75±1.28

Note: HTN – hypertension, BMI - body mass index, DM - diabetes mellitus, CAD - coronary artery disease, TIA - transient ischemic attack

Morpho-functional characteristics

	I group 50	W (n=95)	II group 45 W (n=90)	
	a (n=55)	b (n=40)	a (n=50)	b (n=40)
LA size, mm	40±3.5	43±9.5	39.3±3.9	42±10
EF, %	59±9 58±8.5		55±10	55±9.5
ESV, ml	34.4±9.1	34±10	35.2±8.3	35±11
EDV, ml	80.3±12.1	90±9	89.3±11.2	98±8.5
RA size, mm	30±6	33±9.1	32±7	32±10
LAVI, ml/m ²	42.3±11.1	41±8.4	40.0±12	39±12.1
PASP, mmHg	26.8±7.4	25±6.5	27.3±9.7	27.5±6.5

Note: LA - left atrium; EF - ejection fraction; ESV - end systolic volume; EDV - end diastolic volume; RA - right atrium; LAVI - left atrium volume index; PASP - pulmonary artery systolic pressure.

The strategy of HPSD ablation was developed to overcome limitations of the traditional approach. However, much remains unknown regarding the safety and effectiveness of this approach. Additionally, the question for the optimal interventional treatment method for AF and the selection of the optimal RF energy for pulmonary vein isolation still require confirmation. This forms the basis for our research objective.

Aims. Evaluation of the clinical efficacy and safety of a HPSD strategy for ablation index (AI) - guided ablation using different power settings (45 and 50 watts).

METHODS

The research was a multi-center retrospective blind randomized controlled trial between 2021 and 2023. A comprehensive sample of 185 participants was enrolled in the study and categorized into 2 cohorts, each of which was further subdivided into two subgroups. Pa-

Table 1. tients were enrolled in the study after providing informed consent.

In the first group (n=95), PVI was performed with power of 50 watts in Ia subgroup (n=55) AI was 400-450 arbitrary units (au) for the posterior wall and 500-550 au for the anterior wall, in Ib (n=40) AI was 400-450 au for the posterior wall and 450-500 au for the anterior wall. In the second group (n=90), PVI was performed at a power of 45 watts, in IIa (n=50) with target AI of 400-450 au for the posterior wall and 500-550 au for the anterior wall in IIb (n=40) AI of 400-450 au for the posterior wall and 450-500 au for the anterior wall.

Inclusion criteria: Symptomatic AF or resistance to at least one antiarrhythmic drug from the first or third group of antiarrhythmic drugs.

Exclusion criteria: Left atrial thrombosis, significant coronary artery disease requiring revascularization, valvular heart disease requiring surgical correction, acute infectious diseases, severe heart failure (NYHA class IV) or left ventricular ejection fraction (LVEF) <35%, and history of stroke within the past 3 months.

Mean age of the patients in the Ia, Ib, IIa and IIb subgroups was $62,6\pm7,8$, $62,45\pm9,28$, $63,45\pm10,1$ and $63,09\pm7,44$ respectively. All patients were receiving anticoagulants. Paroxysmal atrial fibrillation (AF) was present in 72,72% (n=40), 70% (n=28), 74% (n=37) and 80% (n=32) patients in Ia, Ib, IIa and IIb subgroups respectively, Persistent atrial fibrillation (AF) was present in 27,27% (n=15), 30% (n=12), 26% (n=13) and 20% (n=8) patients in Ia, Ib, IIa and IIb subgroups. The CHA,DS,-VASc score in the in Ia,

Table 2.

Ib, IIa and IIb subgroups was 4,13 \pm 1,25, 3,63 \pm 1,19, 4 \pm 1,51 μ 3,75 \pm 1,28. Patient characteristics are presented in Table 1. LA diameter in PLAX view in Ia, Ib, IIa and IIb subgroups averaged (40 \pm 3,5) mm, (40 \pm 4,9) mm, (39,3 \pm 3,9) mm, (41 \pm 3) mm. The left ventricular ejection fraction (LVEF) was 59 \pm 9 %, 55 \pm 10, 58 \pm 8,5, μ 55 \pm 9,5 in Ia, Ib, IIa and IIb subgroups. The morpho-functional characteristics of the patients are presented in Table 2.

Before the procedure, all patients underwent transesophageal echocardiography to exclude structural heart disease and left atrial thrombosis.

Procedure

All operations were performed using the CARTO® 3 version 7 navigation system. Double transseptal puncture was performed under intracardiac echocardiography guidance. To achieve intraoperative hypocoagulation, a solution of sodium heparin was administered. Reference values of activated clotting time (ACT) were 330-350 seconds. After the septal puncture, general anesthesia was initiated. General anesthesia was preferred to reduce the risk of map disruption from patient's movement, to control respiratory movements and to prevent respiratory movements for a better catheter stability. The operation was performed without the use of X-ray equipment. Isolation performed according to CLOSE protocol standards (Figure 1) by ablation catheter (THERMOCOOL SMARTTOUCH™ Webster, USA) at 50 W and 45 W. Saline infusion was performed at a rate of 15 ml/min during RFA. Linear ablations were not performed in the left atrium. During isolation of the left pulmonary vein posterior wall (PW), RF energy was applied at each lesion until AI reached 400-450 au for a maximum of 10 seconds. On the anterior wall (AW), RF energy was applied at each point until AI reached 450-500 au or 500-550 au for a maximum of 20 seconds. If the targeted AI didn't reach at a lesion a new lesion added with a distance less than 4mm to the last lesion.

PVI was evaluated based on the following parameters: a decrease in signal amplitude from the diagnostic electrode by more than 5 times, absence of impulse con-

duction (entrance block and exit block). A diagnostic 20-pole electrode (Lasso, Biosense Webster, USA) used to evaluate the isolation.

The observation period was 6 months. Patients were examined 24 hours after the operation and all patients underwent ECG monitoring. Anticoagulation therapy resumed 6 hours after the operation. In 12 days after operation if patients presented with symptoms of chest pain, dysphagia, odynophagia, colicky abdominal pain, fever, neurologic symptoms hematemesis, and melena. Patients underwent for urgent chest CT scan with intravenous contrast for exclusion of atrio-esophageal fistula and then esophagogastroscopy was performed. In patients with recurrent AF within 3 months after RFA, cardioversion was performed, and antiarrhythmic therapy was prescribed as indicated. Antiarrhythmic therapy was discontinued after 3 months if patients did not have atrial tachycardia on Holter monitoring or ECG. Repeat ablation was performed if symptomatic AF recurred after 6 months.

RESULTS

In all patients, PVI achieved intraoperatively. Mean operation time was 55 ± 10 min, 50 ± 8 min, 60 ± 10 min, 56 ± 9 min in Ia, Ib, IIa and IIb subgroups. The first pass isolation was 53/55 (96, 36%), 37/40 (92.5%), 46/50 (92%), 36/40 (90,5%) in Ia, Ib, IIa and IIb subgroups. The PVI was confirmed 100% in all patients in all groups with a waiting time of 20 min after last RF application.

During the blinded period (3 months), AF episodes recurred in Ia 5/55 (9, 0%), Ib 3/40 (7,5%), IIa 5/50 (10%) and IIb 5/40 (12,5%) (p = 0.931). During the 6-month follow-up, AF recurred in one more patient from Ib and IIa subgroups. The success rate during 6 months in I (a,b) and II (a,b) groups was 50/55 (90,90%) , 36/40 (90%), 44/50 (88%) and 35/40 (87,5%). The electrophysiological parameters are presented in Table 3 and 4.

Contact force didn't have statistically significant difference in first and second groups. The AI was in I (a,b) and II (a,b) was 429 (424; 430) au, 416 (413; 420) au, 422 (420; 425) au, 419 (413; 424) au for posterior wall and 514 (511; 519) au, 461 (447; 465) au, 523 (518; 530) au, и 455 (453; 460)au for anterior wall. The total energy was 76325,28 J, 68440 J and 91599,48 J , 72262,89 J (P < 0,001) in I (a,b) and II (a,b) subgroups.

The follow-up period was 6 months, repeat RFA performed in 10 patients with AF, 3 patients from the Ia, 2 patients from the Ib, 3 patients from the IIa, and 4 patients from the IIb subgroups. No intraoperative complications were detected, except for one case in the Ia subgroup with the "steam pops" phenomenon, without hemopericardium. 1/55 (1,8%).

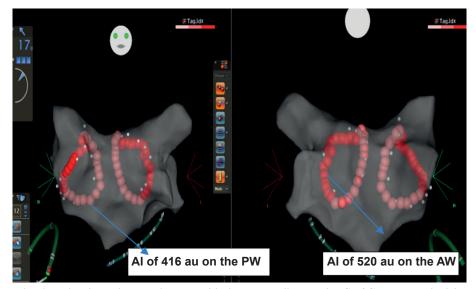


Fig. 1. Point-by-point continuous ablation according to the CLOSE protocol with distances between points <6mm, AI of 400-450 au on the posterior wall (PW) and 500-550 au on the anterior wall (AW).

Table 3.

Electrophysiological parameters

Domos de			Posterior wall				7	Anterior wall		
Farameters	Ia n=55	Ib n=40	IIa n=50	IIb n=40	d	Ia n=55	Ib n=40	IIa n =50	IIb n=40	d
Force (g), $M \pm SD$	13.36±2.42	12.34±2.48	$13.36 {\pm} 2.42 \ \ \ 12.34 {\pm} 2.48 \ \ \ 13.36 {\pm} 2.74 \ \ \ 12.29 {\pm} 1.85$	12.29±1.85	0.45*	12.41±2.70	12.41±2.70 12.78±1.52	11.0±2.19	11.0±2.19 13.23±1.66	0.040*
AI (au), Me (Q1; Q3)	429 (424;430)	416 (413;420)	422 (420;425)	419 (413;424)	**600.0	514 (511;519)	461 (447;465)	523 (518;530)	455 (453;460)	<0.0001**
Application ime (sec.), Me (Q1; Q3)	10.0 (10.0;12.2)	$ \begin{array}{c c} 10.0 & 10.6 \\ (10.0;12.2) & (10.3;11.3) \end{array} $	13.1 (11.7;13.7)	12.4 (11.8;13.1)	<0.0001**	18.8 (17.5;18.9)	18.8 13.7 20.8 15.8 17.5;18.9) (12.8;14.9) (20.6;21.1) (14.7;16.5)	20.8 (20.6;21.1)	15.8 (14.7;16.5)	<0.0001**
Max temperature (°C), $M \pm SD$	40.1±1.0	40.2±1.7	39.9±1.2	42.1±1.4	0.0001*	40.7±0.8	40.2±1.2	40.7±0.8	42.6±1.4	<0.0001*
Impedance drop (Ω), M \pm SD	10.6±1.0	9.9±2.5	8.1±1.5	10.0±1.8	0.017*	11.0±1.9	10.3±2.4	11.0±1.9	10.7±1.6	0.9*
Energy (J), Me (Q1; Q3)	502 (501;610) (533;581	559 (533;581)	588 562 (527;615) (535;588)	562 (535;588)	0.8**	938 (876;945)	705 (656;728)	935 (926;947)	709 (662;744)	<0.0001**
Total lesion points (n), Me (Q1; Q3)	23 (22;25)	23 (22;25) 29 (26;34)	25 (22;27)	27 (24;29)	0.07**	24 (22;25)	24 (22;25) 27 (26;30)	25 (22;27) 27 (24;30)	27 (24;30)	0.1**
Total ineffective lesion points(n), Me (Q1; Q3)	2 (2;3)	2 (2;2)	2 (1;2)	2 (1;2)	0.6**	2 (1;2)	2 (1;2)	3 (1;3)	2 (2;3)	0.2**

Note: * - analysis of variance is used for comparing multiple groups, and the t-Student criterion is used for pairwise comparisons; ** - the Kruskal-Wallis H test is used when comparing multiple groups, and the Wilcoxon rank sum criterion is used for pairwise comparisons

Ablation lesions studied in all patients after first RF ablation. The mean number of effective lesion points was 50±4. The ineffective lesions in thirteen patients located in the region where the posterior wall transitions to the anterior wall, which was thought to be due to anatomical variation. Recurrences occurred in 20 patients, of whom 10 underwent repeat ablation.

In patients with recurred AF, these lesions were usually pair or groups. Not all patients with ineffective lesions had AF recurrence and PV reconnection. During repeat procedures, activation mapping performed for all patients. Recurrences were identified in the pulmonary veins in only 3/10 (30%) patients, while in other patients, areas with fractionated potentials and dispersion were found outside the PV, mainly in the roof 1/10 (10%), posterior wall 2/10 (20%), and anterior wall 4/10 (40%).

Steam pops. Sometimes during the application of energy, despite careful control of the parameters, a peculiar popping sound occurs, which can lead to rupture of the heart wall with subsequent development of hemopericardium.

DISCUSSIONS

The aim of our study was to evaluate the safety and efficacy of HPSD ablation using the CLOSE protocol and AI. HPSD ablation is safe and effective, with a reduced duration and time of ablation, and overall procedure time when using 50 and 45 W. With 50 W of RF power, first pass isolation was achieved in most patients. In our study, in the first group, a contact force ≥ 10 g for up to 20 seconds was required to form an effective ablation point (reaching the required AI values) on the anterior wall, and up to 10 seconds on the posterior wall. In the second group, more time was required to achieve the required AI values. In the Ib and IIb group, as the target AI values on the anterior wall were 450-500 au, lower time was required. There was no statistically signification difference between groups in contact force and total lesions point.

On average, 57 effective ablation points (reached the required AI values) were required to achieve conduction block. In our study, the total energy was 76325,28 J, 68440 J and 91599,48 J, 72262,89 J (P < 0,001) in I (a,b) and II (a,b) groups. The delivered energy was lower in the Ib and IIb group, which can be related to a lower risk of thrombosis.

In meta-analysis Liu et al. [10] in 2021 compared the effectiveness of HPSD ablation with standard ablation. They concluded that the duration, fluoroscopy time, and overall procedure time were reduced when using HPSD. Isolation was achieved after first pass isolation in most patients. The recurrence rate of AF after isolation was lower, and the recurrence rate within 12 months was also lower.

According to the meta-analysis by Ravi et al. in 2021 [11], the effectiveness of HPSD found to be 9% higher than standard ablation (25-35 watts). In our study, recurrences of AF occurred in 20 patients. Complications such as esophageal injury, hemopericardium, or tamponade were not observed when using high power.

Bhaskaran et al. [12] noted that the use of 50 watts for 5 seconds with an irrigated catheter resulted in in vitro and in vivo lesion depths of 2.2 ± 0.0 mm and 2.3 ± 0.5 mm. This was compared to lesion depths of 2.7 ± 0.1 mm and 2.4 ± 0.8 mm when using 40 watts for 30 seconds. Both power settings led to transmural lesions in vivo, but the use of 40 watts for 30 seconds resulted in "steam pops" in 10.5% of cases. In our study, steam pops were only observed in one case in the Ia subgroup, without tamponade or hemopericardium.

According to the study by Winkle et al [13], complications of 13,974 ablations were analysed and the authors demonstrated that atrio-esophageal fistula occurs in 0.0087% (n = 1) among 11,436 ablations at a power of 45-50 watts, and 0.12% (n = 3) among 2538 ablations at a power of 35 watts over a longer time (P=0.021). The results of our study are consistent with previously published results on the effectiveness and safety of HPSD [14-19].

CONCLUSIONS

- 1. HPSD ablation in patients with atrial fibrillation reduces the duration and time of RFA to 55 ± 10 min in the Ia and 50 ± 8 min in the Ib, 60 ± 10 min and 56 ± 9 min in the IIa and IIb subgroups.
- 2. High-power isolation is effective in the short term: The effectiveness of the procedure over 6 months in I (a,b) and II (a,b) groups was 50/55 (90,90%), 36/40 (90%), 44/50 (88%) and 35/40 (87,5%) (p > 0.05).
- 3. High-power isolation is safe and not associated with a risk of intraoperative complications. Steam pops 1,8% (n=1) in Ia subgroup.
- 4. Ib subgroup presents optimal settings for achieving endurable PVI with AI 450-500 au for anterior wall, 400-450 au for posterior wall and 50-Watts power. Less ablation time (50 ± 8 min) was observed in Ib compared to other subgroups with less amount of energy delivery to myocardium (PW = 510J and AW = 650J). Ib subgroup presented similar effectiveness and safety for PVI in period of 6 months follow up compared with other subgroups.

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