

How often is right-power ablation equal to high-power ablation during pulmonary vein isolation under temperature control? Does the learning curve matter?

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Abstract

Introduction: The energy applied under temperature control (TC) has a more predictable effect than the one applied under power control. The currently introduced cooled-tip DiamondTemp catheter (DT) restores the ability to adjust radiofrequency (RF) power to the temperature at the electrode-tissue interface. It also enables high-power (HP) ablation procedures. Aim of the study was to assess how often ablation with TC at a 50 W nominal setting meets HP ablation criteria. We analyzed the influence of the learning curve on the results.

Material and methods: The course of 3350 applications performed using DT in 20 patients (14 M, age 55 ±13 years) with atrial fibrillation/left atrial flutter was analyzed. 24 applications with 1–2 s duration were excluded. Average (P_{avg}), minimal (P_{min}), and maximal (P_{max}) power were evaluated. The percentage of applications > 45 and > 50 W ($P_{min} > 49$ W) was assessed.

Results: From 3326 applications with the duration > 2 s only 1430 (43%) were between 3 and 10 s (excellent catheter/muscle contact). There was an insignificant trend to increase the percentage of short applications during the learning curve ($p = 0.054$). $P_{min} > 45$, > 49 or > 50 W was recorded during 3130 (94.1%), 2963 (89.1%) and 98 (1.1%) applications, respectively. $P_{avg} > 45$ or 50 W was recorded during 3230 (97.1%) and 2700 (81.2%) applications, P_{max} during 3296 (99.1%) and 3269 (98.3%) applications. The percentage of applications with P_{avg} and $P_{min} > 45/> 50$ (49) W (but not P_{max}) significantly decreased during the procedures in the second subgroup of patients.

Conclusions: P_{max} seems not to be as good a criterion for classification of application as HP. Most TC applications performed with the DT meet the criteria for HP ablation. The learning curve impacts the percentage of HP applications.

Key words: atrial fibrillation, learning curve, pulmonary vein isolation, high power ablation, temperature control ablation, DiamondTemp catheter.

Introduction

The energy applied under temperature control ablation produces a more predictable effect than energy applied only under power control [1–5]. The introduction of cooled-tip catheters resulted in a loss of the possibility of temperature control [5]. The currently implemented Dia-

mondTemp catheter (Medtronic) restores the ability to adjust radiofrequency (RF) power to the temperature at the electrode-tissue interface [6–8]. It also enables high-power (HP) ablation procedures, which have recently been shown to be safer and more effective for pulmonary vein isolation [9–14].

The detailed characteristics of the DiamondTemp catheter and application methodology with power adjustment to the temperature obtained at the tissue-ablation electrode interface were discussed in another publication [8]. From the point of view of our work, it is important that the RF current application is carried out with a nominal power of 50 W, which meets the high-power ablation criteria [8–14]. When the temperature set-point (60°C) is achieved, the generator modulates power to maintain the set temperature. Thus, lowering of the power indicates a good contact of the electrode to the tissue and is an intended effect. For this reason, the catheter is not equipped with a contact force sensor. If the pressure of the catheter on the tissue is higher and the temperature is going to the temperature set-point, the power is reduced; when the contact is poor, we do not observe a sufficient temperature rise. In high power ablation the best method for the assessment of lesion efficacy is electrogram voltage change. The duration of the application should be about 3.0–5.0 s longer than potential disappearances or its significant reduction (at least 75–80%) [6–15]. Because the amount of energy delivered depends on the temperature in the tissue adjacent to the catheter tip, the best applications are performed with energy that does not meet the high-power criteria. Therefore, ablation with the DiamondTemp catheter performed under temperature control can be defined as delivering the right power for the right duration [8]. Of course, there are also effective applications with an increase in temperature to slightly below 60°C, during which the power is not reduced.

Regardless of the applied power and the obtained temperature, the criterion of tissue damage is the disappearance or reduction of the local potential by at least 70%. If it is difficult to assess (e.g. atrial fibrillation, artifacts), the damage is reported by a decrease in impedance by at least 10%. In order to obtain permanent damage, the application is continued for 3–5 seconds from the moment the effectiveness indicator is observed. Applications lasting up to 10 s are considered optimal, while applications lasting > 15 s should be considered suboptimal.

The aim of our study was to assess how often ablation with the power optimized for temperature at a nominal setting of 50 W meets the HP ablation criteria. We also analyzed the influence of the learning curve on the above results.

Material and methods

The course of 3350 radiofrequency applications performed in 20 patients (14 M, 6 F; age 55 ± 13 years) subjected to atrial fibrillation/left atrial flutter ablation using the DiamondTemp electrode was analyzed. Patients' characteristics are presented in Table I.

As the existing HP ablation techniques are related to the application of constant power current, it has not been defined which value (average, minimum or maximum power) is crucial for the definition. As there are discrepancies in the literature, whether the HP ablation is the one performed with the power from 45 or from 50 W, the percentage of applications for both of the above values was assessed independently. Due to this, the results of our study can be related to both values. As the number of applications with $P_{\min} \geq 50$ W was small, and every smallest power fluctuation during the application reduces the P_{\min} parameter to 49 W, we assessed the value of this parameter in relation to the levels of 49 and 45 W.

As the first second of application is the time when the power is increasing, we excluded all applications ($n = 17$) with 1 s duration. We also noted that a 5–10% impedance decrease during 2 s applications ($n = 7$) was not observed, so we excluded these from our analysis. The excluded group of applications probably resulted from the unintentional pressing of the pedal or the early dislocation of the catheter.

Before the ablation procedure, all patients signed an informed consent form for the procedure. As it is a retrospective analysis of the parameters obtained during routine ablation procedures performed with a certified electrode, it was not necessary to obtain the consent of the local ethics committee.

Procedure methodology

Using the left femoral vein, the decapolar diagnostic catheter and the quadripolar diagnostic catheter were introduced into the coronary sinus and the right ventricle respectively. Using the right femoral vein access, two separate transeptal punctures were performed under pressure in the needle control or the sheath was introduced via the persistent foramen ovale. A circular mapping catheter (Advisor – Abbott) was introduced via an unsteerable sheath and the DT catheter was introduced using a deflectable sheath (Agilis – Abbott). Fast electroanatomical mapping of the left atrium and proximal part of all pulmonary veins was done using the Advisor catheter and the EnSite system (Abbott). After that, the pulmonary vein isolation was performed with the distance between neighboring ablation points

Table I. Patients characteristics. Continuous variables (age, LA diameter, EF) were presented as an average with 1 standard deviation. Because of the normal distribution the *t*-test was used; categorical variables (others) were expressed as numbers and they were compared using the χ^2 test

Factor	All patients	Patients 1–10	Patients 11–20	P-value
Age	55 ±13	51 ±13	59 ±13	0.09
Male/Female	14/6	8/2	6/4	0.33
Paroxysmal AF	13	7	5	
Persistent AF	3	0	3	
Long-term persistent AF	3	3	1	
Left Afl	1	0	1	0.14
Redo procedure	3	1	2	0.53
PVI only	14	7	7	
Left atrial lines	6	3	3	1.00
CTI ablation	1	0	1	0.30
LA diameter	42.9 ±5.7	43.6 ±6.9	42.0 ±3.5	0.31
EF	57.1 ±9.8	60.1 ±7.2	54.1 ±12.1	0.12
Lone AF	5	3	2	0.61
Hypertension	10	4	6	0.37
Dyslipidemia	3	1	2	0.53
Obesity	5	2	3	0.61
Diabetes	4	1	3	0.26
Prediabetes states	1	1	0	0.30
OSA	1	0	1	0.30
Chronic coronary syndrome	4	2	2	1.00
COPD	1	1	0	0.30
Asthma	2	0	2	0.14
Thyroid diseases	2	1	1	1.00
Stroke/TIA	1/1	0/0	1/1	0.14
Renal disease	1	0	1	0.30

AF – atrial fibrillation, Afl – atrial flutter, COPD – chronic obstructive pulmonary disease, CTI – cavo-tricuspid isthmus, EF – ejection fraction of the left ventricle, LA – left atrium, OSA – obstructive sleep apnea, PVI – pulmonary vein isolation, TIA – transient ischemic attack

< 6 mm) with nominal power of 50 W under temperature control. Target temperature was 60°C. To guide the ablation termination, we use electrogram amplitude attenuation > 75% or, if it was not clear (e.g. atrial fibrillation, artifacts), impedance reduction of at least 10%. The application was continued 3–5 s after the indicator of its effectiveness had occurred. The pulmonary vein isolation was checked and confirmed with the Advisor catheter.

Statistical analysis

Categorical variables were expressed as numbers and percentages. They were compared using the χ^2 test. Continuous variables were presented as an average with 1 standard deviation. The Shapiro-Wilk test was used to test the normality. If the normal distribution was confirmed, the *t*-test was used; if there was no normal distribution, then the Wilcoxon test was used. If there was no normal

distribution the minima and maximal value were additionally presented.

A *p*-value <0.05 was considered statistically significant.

Analyses were performed using Statistica 13.3 software.

Results

From the 3350 applications, 3326 with the duration > 2 s were analyzed. Only 1430 (43%) of them were between 3 and 10 s, which suggests excellent contact of the DiamondTemp catheter tip with left atrial wall. Comparison of the first and the second half of the patients is presented in Table II. There was an insignificant trend to increase the percentage of short applications during the learning curve (χ^2 test *p* = 0.0891).

The minimum power (P_{\min}) of 45 or 49 or 50 W was recorded during 3130 (94.1%) and 2963 (89.1%) and 98 (1.1%) applications, respectively.

The average power (P_{avg}) of 45 or 50 W was recorded during 3230 (97.1%) and 2700 (81.2%) applications, respectively and the maximum power (P_{max}) during 3296 (99.1%) and 3269 (98.3%) applications. The comparison between the first and the second half of the patients is presented in Table III. The data achieved for short applications (3–10 s) are presented in Table IV. We did not observe statistically significant differences between the first and the second subgroup of patients in P_{max} (both for 45 and 50 W). Also, the results were almost similar for all applications lasting > 2 s and for short applications (3–10 s). The percentage of applications with P_{avg} and $P_{min} > 45$ and 50 (49) W decreased during the procedures performed in the second subgroup of patients. The percentage of these applications was also lower in shorter applications (3–10 s) than in all applications > 2 s.

The percentage of applications lasting respectively > 2 s and 3–10 s, meeting high power criteria in consecutive patients, is presented in Figures 1 and 2. On the presented graphs we can observe

that a statistically significant improvement in contact and secondary to it an increased percentage of applications with reduced power result from an increase in the number of patients with applications with better parameters in patients 11–20 vs. 1–10.

Discussion

In the literature, there is a discrepancy in the definition of high-power ablation. In earlier studies, the criterion of 45 W was used [14, 16–19], in newer publications 50 W [12, 14, 18–24]. The introduction of the Qdot catheter initiated the term “very high power ablation”, for which the criterion is 70–90 W [10, 25–27], but the later issue is beyond the scope of our publication. Increasing the high-power application criterion from 45 to 50 W reduces the number of applications that meet the threshold criterion by about 5–16% (in our material for P_{avg} from 97.1 to 81.2%, for P_{min} from 94.5 to 89.1%).

To the best of our knowledge, this is the first study assessing the frequency of the high-power

Table II. The number of all applications subdivided into short applications (3–10 s) and long applications (> 10 s). P -value evaluated using χ^2 test for patients 1–10 vs. 11–20 is 0.0891

	All patients	Patients 1–10	Patients 11–20
Applications > 2 s	3326	1600	1726
Applications 3–10 s	1430 (43%)	525 (33%)	905 (52%)
Applications > 10 s	1896 (57%)	1075 (66%)	821(48%)

Table III. Comparison of the percentage of patients with different power parameters during applications lasting > 2 s. For all analyzed parameters the Shapiro-Wilk test indicated that there was no normal distribution (p -value $< \alpha$); thus the Wilcoxon test was used to compare consecutive patients 1–10 vs. 11–20. Data presented as average \pm SD (min–max)

	$P_{max} > 50W$	$P_{max} > 45W$	$P_{avg} > 50W$	$P_{avg} > 45W$	$P_{min} > 49W$	$P_{min} > 45W$
All pts	98.3 \pm 6.1 (72–100)	99.1 \pm 3.3 (85–100)	81.2 \pm 6.8 (18–96)	97.1 \pm 6.8 (91–100)	89.1 \pm 15.1 (29–100)	94.1 \pm 10.6 (82–100)
Pts 1–10	99.9 \pm 0.3 (99–100)	100 \pm 0.0 (100–100)	83.6 \pm 8.1 (67–91)	99.1 \pm 1.7 (94–100)	93.0 \pm 5.0 (85–99)	97.5 \pm 3.4 (88–100)
Pts 11–20	96.6 \pm 8.2 (72–100)	98.3 \pm 4.5 (85–100)	78.7 \pm 21.8 (18–96)	95.2 \pm 9.1 (91–100)	85.2 \pm 20.0 (29–100)	90.7 \pm 13.8 (82–100)
P -value	0.99	0.99	< 0.0001	0.0002	< 0.0001	< 0.0001

P_{avg} – average power during application, P_{max} – maximal power during application, P_{min} – minimal power during application, Pts – patients.

Table IV. Comparison of the percentage of patients with different power parameters during applications lasting 3–10 s. For all analyzed parameters the Shapiro-Wilk test indicated that there was no normal distribution (p -value $< \alpha$); thus the Wilcoxon test was used to compare consecutive patients 1–10 vs. 11–20. Data presented as average \pm SD (min–max)

	$P_{max} > 50W$	$P_{max} > 45W$	$P_{avg} > 50W$	$P_{avg} > 45W$	$P_{min} > 49W$	$P_{min} > 45W$
All patients	98.0 \pm 6.2 (72–100)	99.1 \pm 3.5 (84–100)	74.0 \pm 7.5 (16–94)	96.0 \pm 7.9 (68–100)	84.2 \pm 17.7 (28–100)	90.3 \pm 13.2 (52–100)
Pts 1–10	99.9 \pm 0.3 (99–100)	100 \pm 0.0 (100–100)	75.7 \pm 8.6 (60–89)	99.0 \pm 2.4 (92–100)	88.8 \pm 8.8 (69–97)	95.1 \pm 4.7 (88–100)
Pts 11–20	96.1 \pm 8.4 (72–100)	98.2 \pm 4.7 (84–100)	72.3 \pm 23.0 (16–94)	92.9 \pm 10.0 (68–100)	79.5 \pm 22.5 (28–100)	85.4 \pm 16.7 (52–100)
P -value	0.99	0.99	< 0.0001	< 0.0001	< 0.0001	0.0015

P_{avg} – average power during application, P_{max} – maximal power during application, P_{min} – minimal power during application, Pts – patients.

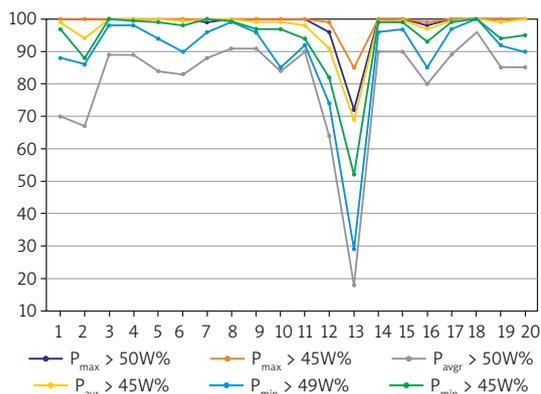


Figure 1. Percentage of applications lasting > 2 s meeting high power criteria in consecutive patients

P_{avg} – average power during application, P_{max} – maximal power during application, P_{min} – minimal power during application.

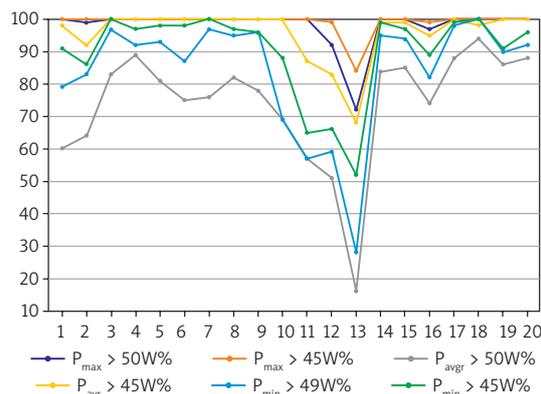


Figure 2. Percentage of applications lasting 3–10 s meeting high power criteria in consecutive patients

P_{avg} – average power during application, P_{max} – maximal power during application, P_{min} – minimal power during application.

application during ablation with the ThermoCool catheter under temperature control. The DiamondTemp catheter is the first one with which we can use high power ablation with a variable power level; thus, it is difficult to define what high power ablation means. In previous studies with ablation with a stable power level it was defined as ablation with power higher than or equal to 45 or 50 W. When using the DiamondTemp catheter the main question is which power parameter is crucial for definition: maximal, average or minimal? As a general guide, all of the above values are given in the results, although it seems that the average value best illustrates the ablation process (minimum power is the extreme instantaneous value, maximum power is usually the initial power when starting the application and almost always has the nominal power value). The confirmation that “ P_{max} ” (both > 50 W and > 45 W) is not the correct benchmark can be deduced from the observation that the threshold value is reached for almost all applications and that there are no statistically significant differences between the applications in the first and second ten patients, and the results are similar for all applications including the short applications. These restrictions do not apply to P_{avg} and P_{min} . For all four categories, a statistically significant influence of the learning curve was observed. Also, the percentage of full-power applications is lower during applications that previously achieved the desired effect (lasting 3–10 s). When the catheter tip has good contact with the atrial wall, then after a few seconds the temperature reaches 60°C and the power is reduced. In such a case P_{max} is maximal (50 W) but P_{min} and secondary to that P_{avg} are reduced. We observed this phenomenon only during 5 to 21% of applications. Also, only about 50% of applications had enough catheter contact force to meet the criteria of short application.

Because lowering of the power indicates a good contact of the electrode with the tissue and is an intended effect, the catheter is not equipped with a contact force sensor [6–8]. However, we receive this information only during the application. The information from the contact force sensor, on the other hand, is obtained before the decision to start the application is made. For this reason, the procedure performed with the DiamondTemp catheter is associated with a relatively high percentage of applications with insufficient application parameters, which results in their greater number and extension of the procedure. Fortunately, the intensity of this effect decreases during the learning curve. It seems that equipping the DiamondTemp catheter with a real time contact force sensor would shorten the learning curve during the procedures performed with it. It would also make it possible to shorten the time of procedures and reduce the number of (unnecessary) applications.

The main limitation of the study is its single-center nature. However, since this is the first analysis of this issue, we expect it to be the basis for further research. The primary aim of our study was to analyze the power parameter during left atrial ablation. A high number of applications in both categories – with good and poor contact – is enough for this analysis. The secondary aim of our study was to evaluate how the learning curve influences this parameter. We observe an insignificant trend only, probably because of the small number of patients.

In conclusion, the P_{max} value seems not to be a good criterion for classification of an application as high power. The vast majority of temperature-controlled applications performed with the DiamondTemp catheter meet the criteria for high power ablation. Pressure sensor on the catheter’s tip could reduce this effect. The learning curve influences the percentage of high-power applications.

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Conflict of interest

Edward Koźluk: proctor for Johnson & Johnson, Medtronic, Abbott; conference grants from Johnson & Johnson, Boston, Medtronic; invited speaker Medtronic. All other authors declare no conflict of interest.

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