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In vitro evaluation of new Polish prototypes of 4-mm-tip and 8-mm-tip nonirrigated radiofrequency ablation catheters

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Short title: In vitro evaluation of prototypes of RF ablation catheters

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**What’s New?**

Polish prototypes tested in standardized *in vitro* conditions had similar effectiveness of tissue injury formation as commercially available non-irrigated radiofrequency current ablation catheters.

Larger depth and volume of cardiac tissue lesions were created with 8-mm tip prototypes than with those with 4mm distal electrode.
Abstract

Background

Effectiveness of lesion formation during radiofrequency (RF) catheter ablation can be verified by in vitro or in vivo animal models.

Aims

The aim of this in vitro study was to compare prototypes of the first Polish RF ablation catheter with commonly used catheters of different manufacturers.

Methods

The samples of porcine left ventricle were ablated (50W/50°C/60s temperature-controlled settings) using commercially available 4-mm (4mmTC) and 8-mm tip (8mmTC) non-irrigated ablation electrophysiological catheters as well as with new prototypes. Parameters characterizing RF delivery were collected during energy applications, and subsequently lesion dimensions were measured and compared statistically.

Results

Initial impedance and impedance drop during energy delivery were significantly different between studied catheters within both groups (4mmTC and 8mmTC). Maximal temperatures on catheters were similar between competitors for 4mmTC (P = 0.26), but different for 8mmTC (P < 0.001). Lesion volumes were similar between manufacturers within both groups of catheters. Prototypes with longer tip created lesions of larger depth (5.8 (0.4)mm vs. 4.7 (0.4)mm; P < 0.001) and volume (239.4 [217.9 - 255.5]mm³ vs. 173.7 [156.1 - 186.4]mm³; P < 0.001) than prototypes with standard distal electrode length.

Conclusions

Our experiments revealed that RF catheters of the same tip length but made by different manufacturers, despite demonstrating distinct physical parameters during energy applications,
create tissue lesions of similar volume. Tested prototypes of Polish producer performed similarly to commercially available catheters. Lesions created with Polish prototypes with 8mm distal electrodes had larger depth and volume than those done with catheters of shorter tip.

**Key words:** cardiac tissue, catheter, lesion, radiofrequency ablation
Introduction

Radiofrequency (RF) catheter ablation is widely used and effective method for invasive arrhythmia treatment [1]. The main role of ablation catheters is to deliver energy resulting in thermal injury of cardiac tissue. There are two well-known mechanisms of heat production during RF energy application: resistive heating and thermal conduction. Resistive heating is a rapid process of conversion of electromagnetic energy into mechanical energy of ions. The tissue surrounding the catheter works as a resistor for high density current resulting in heat production, which injures tissues at distance less than 2 mm from catheter tip. The thermal conduction is connected with heat transfer due to tissue temperature gradient. It is a slower process influencing deeply located layers of tissues (above 3 mm), which depends on time of RF energy application. Persistent myocardial tissue necrosis resulting from thermal damage is a crucial point of cardiac ablation [2, 3]. The rise of tissue temperature to above 50°C is required to produce irreversible thermal injury and loss of cellular excitability [4]. The isotherm of irreversible myocardial injury with hyperthermic ablation is likely to be 50°C to 56°C. Non-irrigated catheters with 4-mm-tip and 8-mm-tip as well as those with open-irrigated systems for tip cooling proved effectiveness in in vitro and in vivo animal models [5]. During these studies the thermal injury was assessed based on measurement of the heart tissue lesion [6-8]. However, there is scarce published data which compares parameters characterizing RF application and size of lesion created by catheters of different competing manufacturers [9]. The aim of our study was to test the first Polish ablation catheters prototypes and to compare them to commonly used ablation catheters.

Methods

Unique transparent experimental container was constructed by local engineering company (Figure1). An aqueous solution containing 30% glycerol and 0.9% NaCl was
prepared to approximate physical and chemical blood features: viscosity, density and electrical conductibility. Porcine hearts were obtained at a local abattoir from healthy pigs approximately six months of age. Left ventricle wall pieces approximately 5x5cm in size with smooth endocardial surface were prepared not later than 3 hours from slaughter. Thereafter the samples were placed and fixed on the plate in the central part of the container.

Subsequently, the blood imitating fluid was poured into and was pumped continuously with speed of 0.5m/s directly on heart sample area were RF application was to be performed. The catheter with constant weight pressure 10g (0.1N) was positioned by special tube system to set the tip of electrode perpendicularly to the cardiac sample surface. An ablation generator Biosense Webster Stockert 70 ST-0829 delivered radiofrequency energy to the catheters on temperature-controlled mode (50W/50°C). The neutral electrode was submerged in solution closing electrical circuit. Each RF application lasted 60 seconds except those with steam-pop phenomenon. In such cases, when audible ‘pop’ occurred the RF application was stopped and repeated on a new sample of the heart. Only one application on one sample of heart tissue was performed. Initial impedance and maximum impedance drop during energy delivery expressed in absolute measures and in percentage were recorded. Thereafter following measurements (given in mm) characterizing the size of the tissue lesion were taken with digital caliper (Figure 2): maximal diameter of lesions at (1) sample surface and on (2) cross-section, (3) maximal depth, (4) depth on the level of maximal lesion diameter. Lesion volume, expressed in mm$^3$, was calculated for an oblate ellipsoid as described elsewhere [7, 8]. RF applications with catheters positioned parallelly to the tissue were not performed because standardization of catheter pressure on tissue in parallel positions were not reliable.

The RF applications were performed with two types of non-irrigated catheters, which differed with length of the distal (ablative) electrode. One group of the catheters had distal electrode 4mm long (4-mm tip catheters, 4mmTC) and the second group – 8mm (8-mm tip catheters).
catheters, 8mmTC). Commercially available RF electrophysiological catheters made by three different manufacturers were compared to prototypes elaborated, constructed and produced by Polish company Hagmed (Rawa Mazowiecka, Poland), as governmental initiative for medical technology development. The 4mmTC prototypes were compared to Blazer II 4mm (Boston Scientific, Marlborough, MA, USA) and Marin RF MC (Medtronic, Minneapolis, MN, USA), whereas the 8mmTC prototypes to: Blazer II XP (Boston Scientific, Marlborough, MA, USA) and Celsius DS ( Biosense Webster Inc., Johnson and Johnson Medical NV/SA, Waterloo, Belgium) [Figures 2 and 3]. Prototypes manufactured by Hagmed, both 4mmTC and 8mmTC, had a golden tip (99% of gold), and distal electrodes of catheters made by competitors consisted of platinum/iridium alloy.

Statistical analysis was performed using Statistica software (ver. 13, StatSoft Inc., OK, USA). Continuous variables were tested for the normality with Shapiro-Wilk test and presented as mean and standard deviation if normally distributed, otherwise as median and interquartile range. Categorical variables were given as numbers and percentages. The t-Student test and Wilcoxon-Mann-Whitney test were applied if two groups were compared, accordingly to data distribution. In case of comparison between three groups analysis of variance (ANOVA) was used for normally distributed data, otherwise Kruskal-Wallis H test was applied; additionally, to confirm where differences occurred between groups post-hoc test were run adequately. The chi square test and Fisher’s exact test were used to compare categorical data accordingly. P-values less than 0.05 were considered statistically significant.

Our study did not include any experiments on animals either humans, additionally all animal tissue samples were commercially obtained, therefore bioethical committee approval was not required.

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Results

In total 114 RF applications with studied catheters were performed. No dysfunctionality of tested devices was disclosed. Incidentally (2.8%; 2/68) steam-pop phenomena were observed during RF applications done with 4mmTC, which was not recorded in experiments with 8mmTC. The number of effective RF applications was similar between catheters of different manufacturers regardless of a tip size.

Parameters, especially impedance, that characterize physical properties of tested catheters were different between competitors in 4mmTC group as well as for 8mmTC. Among 4mmTC the highest initial impedance was observed for Medtronic Marinr (median [IQR]: 175.5 [165.0-188.0]Ω, $P < 0.001$), whereas similar values were registered for Blazer II and Hagmed 4mmTC prototype (median [IQR]: 144.0 [138.0 - 148.0]Ω vs. 146.5 [137.0 - 167.0]Ω; $P = 0.24$). In a group of 8mmTC initial impedance was also different between manufacturers (Table 2, $P < 0.001$), and the highest values were observed for Blazer Prime XP (mean (SD): 146.1 (11.4)Ω vs. Celsius DS – 127.3 (19.0)Ω vs. Hagmed – 112.9 (21.3)Ω). Impedance drop observed during RF applications measured in absolute values as well as percentage of initial impedance were different between catheters provided by competitors in both groups (Table 2).

Maximal power delivered was not different between producers in both types of catheters, 4mmTC as well as in 8mmTC (Tables 1 and 2). However, more power was delivered via 8mmTC than with 4mmTC (median [IQR]: 34.1 [29.9 - 39.2]W vs. 28.7 [24.8 - 33.6]W; $P < 0.001$). Maximum temperature recorded on catheter was similar for all 4mmTC reached approximately 40 - 41°C (Table 2). Contrastingly, in a 8mmTC group the highest temperatures were noted during applications with prototypes provided by Hagmed (mean (SD): 43.0 (2.5)°C vs. Biosense Webster – 38.5 (1.8) °C vs. Boston Scientific – 39.8(1.5)°C, $P = 0.001$).
Depth of tissue lesions created with Hagmed 4mmTC was smaller (mean (SD): Hagmed 4.7 (0.4)mm vs. Medtronic – 4.9 (0.4)mm vs. Boston Scientific – 4.9 (0.4)mm; \( P = 0.04 \)), while no difference was noted in an 8mmTC group (Table 2). An opposite situation was observed for maximal lesion diameter, which was similar between 4mmTC of different manufacturers, and varied within 8mmTC group. Nevertheless, in both types of catheters tissue injury volumes were similar between producers (Tables 1 and 2). Bigger lesions formation was observed for Medtronic Marinr catheters (median [IQR]: 184.1 [163.3 - 198.9]mm\(^3\) vs. Hagmed – 167.6 [156.6 - 179.9]mm\(^3\) vs. Boston Scientific 166.6 [148.3 - 185.4]mm\(^3\); \( P = 0.08 \)), however the difference was not statistically significant.

Analysis focused on Hagmed prototypes revealed that 8mmTC had significantly lower initial impedance (median [IQR]: 109.0 [97 - 130] vs. 146.5 [137.0 - 167.0]; \( P < 0.001 \)), lower absolute impedance drop (median [IQR]: 21.8 [11 - 38] vs. 33.5 [29 - 44]; \( P < 0.001 \)) as well as percentage decrease of impedance (median [IQR]: 21.2 [16.5 - 22.3] vs. 24.7[19.7 - 30.6]; \( P = 0.03 \)) during RF application than those with standard 4mm distal electrode. Maximum power delivered was higher in 8mmTC group (median [IQR]: 36.5 [33.8 - 39.1]W vs. 29.8 [25.9 - 32.3]W; \( P < 0.001 \)), but maximum temperatures reached during RF applications were similar in both types of catheters. Tissue lesions created with Hagmed 8mmTC were significantly deeper (mean (SD): 5.8 (0.4)mm vs. 4.7 (0.4)mm; \( P < 0.001 \) and had considerably larger volume (median [IQR]: 239.4 [217.9 - 255.5]mm\(^3\) vs. 173.7 [156.1 - 186.4]mm\(^3\); \( P < 0.001 \)), but were similar in diameter (median [IQR]: 10.5 [10.4 - 10.9]mm vs. 10.4 [10.2 - 10.7]mm; \( P = 0.08 \)).

**Discussion**

Our study revealed that catheters of the same size of distal electrode but made by different producers despite showing significant difference in physical parameters, especially
in impedance, created lesions of similar volumes. Tested prototypes of Polish producer performed similarly to commercially available catheters. Moreover, we demonstrated that prototypes with longer distal electrode created deeper and bigger tissue injury than those of standard tip length.

Confronting results from studies performed in distinct laboratory conditions seems to be methodologically improper and/or difficult for interpretation. Notwithstanding this, some researchers used for experiments same catheters as we did (Marinr Medtronic, MN, USA or Blazer II, Boston Scientific, USA) [9-11]. Unfortunately, only the authors of two papers [10, 11] reported values of catheter impedance, which were similar (90-170Ω) to observed in our study. Additionally, in the experiment of Petersen et al. [12] who also used Marinr catheters, analogous relation in power delivered to sample was described (4mmTC – 33W; 8mm – 60W; with generator settings 75W). Aforementioned concordance of our experimental data with published by others proves that our findings are reliable and therefore comparable to external observations.

Surprisingly, we could not find many studies, which directly compared electrical properties and tissue lesion formation of RF ablation catheters of the same type but made by different manufacturers. All non-clinical data that we found [9] compared catheters of different producers but of different types, i.e. standard 4mm tip vs. long 8mm tip vs long 10mm tip vs. irrigated catheters. Therefore, it seems that equivalency of catheters manufactured by different companies is generally assumed. We proved that despite of different physical characteristics (impedance), catheters of the same type but different producers may create tissue lesions similar in size. From the theoretical point of view [2] lesion volume depends on power delivered via catheter. In our study power delivery was not different between catheters of the same type but different manufacturing. This relation between power delivery and tissue lesions was also observed experimentally by others [6, 9-
11]. However, only single reports on more complex relations can be found [12], probably due to distinct experimental conditions.

Golden-tip electrodes were introduced into clinical practice relatively recently, and due to higher thermal conductivity than platinum/iridium (Pt/Ir) alloy used in standard catheters were deemed as more effective in lesion formation [6, 13]. In our study we could not confirmed this observation as golden-tip catheters performed similarly to standard Pt/Ir ones. The most probable explanation for this discordance is laboratory methodology mainly due to distinct experimental chamber, fluid composition, generator settings, catheter orientation and catheter pressure to the sample tissue. All aforementioned factors might had resulted in smaller lesions with standard Pt/Ir catheters than those recorded in our study (depth: 4.6mm vs 2.9mm [13] vs. 3.5mm [6]). Outwardly, in case of high cooling with fluid flow approximately 0.5m/s and perpendicular catheter orientation, which both provides relatively efficient energy transfer to the tissue, differences between golden-tip catheters and standard Pt/Ir appeared to be insignificant. Nevertheless, head-to-head testing of golden-tip catheters manufactured by different producers could bring additional information, and not including such comparison in our experiments is important limitation of the study.

Length of catheter distal electrode, which delivers RF energy to cardiac tissue and its influence on lesion size was a matter of debate and often misinterpretation [2]. As tested prototypes of non-irrigated catheters were manufactured in two versions with short (4mm)-tip and long (8mm)-tip we performed comparative analysis between them, which disclosed lower initial impedance, higher delivery of power and bigger lesion creation with longer tip catheter. These findings go along with majority of published data [7, 10, 12], however some authors argued that longer tip catheters did not provoke formation of bigger lesions [14, 15]. Our results fit well to deliberations of Wittcamp et al. [2], who suggests that lesions created with
longer tip catheters may be bigger due to higher energy transmission resulting from more efficient catheter convective cooling by blood (fluid) flowing around the tip.

Laboratory conditions that we provided were focused on reproducibility of the experimental environment and the highest rate of successful applications. The tests were performed with standardized composition of blood-imitating liquid, constant temperature, constant flow of fluid directly on ablation area and equal catheter pressure on the cardiac tissue. Interestingly, in our experiment we observed relatively low rate (3%) of steam-pops, which created important problem for us during early phase of setting our laboratory routine as well as reported by others [6, 9, 11, 13]. We managed to overcome this inconvenience mainly due to use for experiments only very fresh porcine hearts (< 2-3 hours from slaughter), selecting only smooth parts of left ventricle and cooling the catheter and RF area with relatively high constant flow of fluid jet (0.5m/s). All aforementioned factors altogether with a fact that recorded lesions sizes were comparable to in vivo experiments [11, 14, 16] suggest that our results might be taken into consideration as reliable guidance for clinical practice, nonetheless, still are limited with in-vitro fashion of our study. Additionally, a performance of new prototype tested in our study could be confronted with irrigated RF catheters which are often used in complex ablation procedures [17].

Conclusions

Our in vitro experiments revealed that RF catheters of the same tip length but made by different manufacturers, despite demonstrating distinct physical parameters during energy applications, create tissue lesions of similar volume. Tested prototypes of Polish producer performed similarly to commercially available catheters. Lesions created with Polish prototypes with 8mm distal electrodes had larger depth and volume than those done with prototypes of shorter tip as well as in other manufacturers.
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Table 1. Parameters characterizing RF application and lesion size for catheters with 4mm distal electrodes.

| Parameter                        | Hagmed              | Medtronic           | Boston Scientific  | P-value |
|----------------------------------|---------------------|---------------------|--------------------|---------|
| Initial impedance, Ω             | 146.5 [137.0-167.0] | 175.5 [165.0-188.0] | 144.0 [138.0-148.0] | < 0.001 |
| Impedance drop, Ω               | 33.5 [29.0-44.0]    | 27.0 [17.0-38.0]    | 22.5 [20.5-28.0]    | 0.004   |
| Impedance drop, %                | 25.4 (8.8)          | 15.9 (10.9)         | 16.3 (4.2)          | 0.002   |
| Maximal catheter temperature, °C | 41.0 [39.0-45.0]    | 40.0 [38.0-43.0]    | 41.5 [39.5-44.0]    | 0.26    |
| Maximum power delivered, W       | 50 [39-45]          | 50 [49-50]          | 50 [49-50]          | 0.11    |
| Lesion depth, mm                 | 4.7 (0.4)           | 4.9 (0.4)           | 4.9 (0.4)           | 0.04    |
| Lesion maximum diameter, mm      | 10.4 [10.2-10.7]    | 10.6 [10.2-10.8]    | 10.4 [9.8-10.6]     | 0.68    |
| Lesion volume, mm³               | 167.6 [156.6-179.9] | 184.1 [163.3-198.9] | 166.6 [148.3-185.4] | 0.08    |

The values are given as mean (SD) or median [IQR].
**Table 2.** Parameters characterizing RF application and lesion size for catheters with 8mm distal electrodes.

| Parameter                         | Hagmed       | Johnson&Johnson | Boston Scientific | P-value |
|-----------------------------------|--------------|-----------------|-------------------|---------|
| Initial impedance, Ω              | 112.9 (21.3) | 127.3 (19.0)    | 146.1 (11.4)      | < 0.001 |
| Impedance drop, Ω                 | 22.8 (8.0)   | 16.5 (4.2)      | 28.9 (6.5)        | < 0.001 |
| Impedance drop, %                 | 19.8 (4.6)   | 13.1 (3.6)      | 19.5 (4.5)        | < 0.001 |
| Maximal catheter temperature, °C   | 43.0 (2.5)   | 38.5 (1.8)      | 39.8 (1.5)        | < 0.001 |
| Maximum power delivered, W        | 36.1 (6.4)   | 34.6 (6.4)      | 33.9 (7.1)        | 0.64    |
| Lesion depth, mm                  | 5.8 (0.4)    | 5.7 (0.4)       | 5.5 (0.4)         | 0.14    |
| Lesion maximum diameter, mm       | 10.6 (0.4)   | 11.1 (0.5)      | 10.7 (0.3)        | 0.01    |
| Lesion volume, mm³                | 241.3 (30.6) | 245.7 (30.7)    | 250.0 (26.6)      | 0.72    |

The values are given as mean (SD).
Figure 1. The transparent experimental container.
Figure 2. Measurement of tissue lesion by digital caliper.
Figure 3. The distal portion of prototypes (4-mm tip and 8-mm tip) manufactured by Hagmed company (Rawa Mazowiecka, Poland).
Figure 4. Handles with connection ports of prototypes (4-mm tip and 8-mm tip) manufactured by Hagmed company (Rawa Mazowiecka, Poland).