ORIGINAL ARTICLE

New Polish prototypes of 4- and 8-mm-tip nonirrigated radiofrequency ablation catheters: an in vitro study

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KEY WORDS
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ABSTRACT

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

AIMS In this in vitro study, we aimed to compare the prototypes of the first Polish RF ablation catheters with common commercially available catheters from other manufacturers.

METHODS Samples of the porcine left ventricle were subject to temperature-controlled ablation (50 W / 50 °C / 60 s), using 4- and 8-mm-tip nonirrigated ablation catheters (commercial ones as well as new prototypes). The parameters of RF delivery were collected during energy applications. Subsequently, lesion dimensions were measured and compared between catheters.

RESULTS Initial impedance and impedance drop during energy delivery differed significantly between catheters (both those with 4-mm and 8-mm tip electrodes). The maximum temperature was similar for 4-mm-tip catheters ($P = 0.26$), while it differed for 8-mm-tip ones ($P < 0.001$). No significant differences between catheters were noted for lesion volume. The 8-mm-tip prototypes created lesions of greater depth (mean [SD], 5.8 [0.4] mm vs 4.7 [0.4] mm; $P < 0.001$) and volume (mean [interquartile range], 239.4 [217.9–255.5] mm^3 vs 173.7 [156.1–186.4] mm^3; $P < 0.001$) than those with a 4-mm tip electrode.

CONCLUSIONS Our study showed that RF ablation catheters with the same length of the tip electrode created lesions of similar volume, irrespective of the manufacturer and despite showing distinct physical parameters during energy applications. The Polish catheter prototypes showed similar performance as commercially available devices. Finally, 8-mm-tip prototypes produced lesions of greater depth and volume than those with a 4-mm tip electrode.

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INTRODUCTION Radiofrequency (RF) catheter ablation is a common and effective method for invasive treatment of arrhythmia.[1] The main role of ablation catheters is to deliver energy, resulting in thermal injury of cardiac tissue. There are 2 well-known mechanisms of heat production during RF energy application: resistive heating and thermal conduction. Resistive heating involves a rapid 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 and, ultimately, tissue injury at a distance of less than 2 mm from the catheter tip. In contrast, thermal conduction involves heat transfer caused by a tissue temperature gradient. It is a slower process than resistive heating and affects deep tissue layers (>3 mm), with the depth of lesion depending on the duration of RF energy application. Persistent myocardial necrosis due to thermal damage is crucial for efficient cardiac ablation.[2,3] The rise of tissue temperature above 50 °C is required to result in irreversible thermal injury and loss of cellular excitability.[4] The isotherm of irreversible myocardial injury with hyperthermic ablation is likely to range from 50 °C to 56 °C. Nonirrigated catheters with

WHAT'S NEW?

Polish ablation catheter prototypes tested in standardized in vitro conditions show similar effectiveness in terms of lesion formation to commercially available nonirrigated radiofrequency ablation catheters. The 8-mm-tip catheter prototypes produced cardiac lesions of greater depth and volume than the 4-mm-tip catheters.

4- and 8-mm tips as well as those with open irrigated systems for tip cooling were shown to be effective in in vitro and in vivo animal models.[5-8] In those studies, thermal injury was assessed by measuring cardiac lesions. However, few studies compared the parameters of RF application and the size of ablation-induced lesions between catheters of different manufacturers.[9] Therefore, the aim of this study was to test the prototypes of the first Polish ablation catheters and to compare them with common commercially available ablation catheters from other manufacturers.

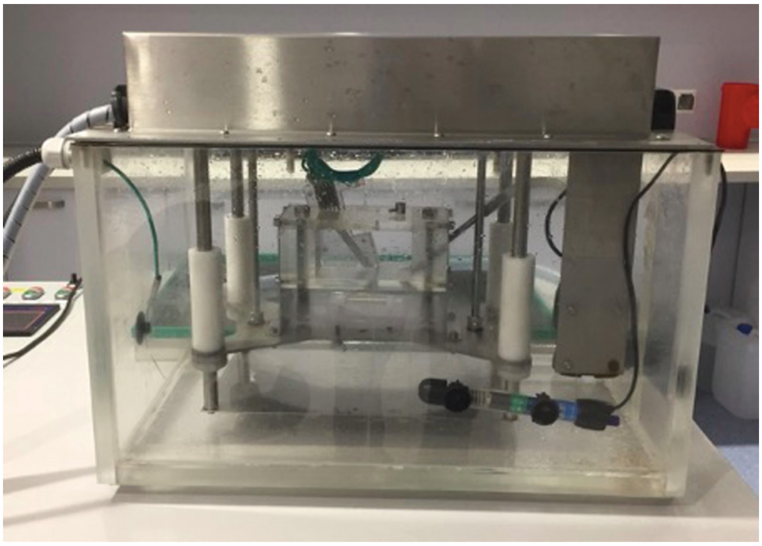

FIGURE 1 Transparent experimental container

FIGURE 2 Measurement of a cardiac tissue lesion by a digital caliper

METHODS A transparent experimental container was constructed by a local engineering company (FIGURE 1). An aqueous solution containing glycerol (30%) and sodium chloride (0.9%) was prepared to approximate the physical and chemical parameters of blood, including viscosity, density, and electrical conductivity. Porcine hearts were obtained from healthy pigs aged approximately 6 months, from a local abattoir. The samples (approximately 5 × 5 cm in size) of the left ventricular wall with smooth endocardial surface were prepared within 3 hours from slaughter. Subsequently, they were placed and fixed on a plate in the central part of the container. Then, the blood-mimicking fluid was poured into the container and was pumped continuously at a speed of 0.5 m/s directly on the site of planned RF energy application. A catheter with a constant weight pressure of 10 g (0.1 N) was positioned using a special tube system to set the tip electrode perpendicularly to the surface. An ablation generator, Biosense Webster Stockert 70 ST-0829 (Biosense Webster, Inc., Johnson & Johnson Medical NV/SA, Waterloo, Belgium), was used to deliver RF energy to catheters in a temperature-controlled mode (50 W/50 °C). The neutral electrode was submerged in the solution, closing the electrical circuit. Each RF application lasted 60 seconds, except those with the so-called steam pops. In cases when an audible "pop" occurred, the RF application was stopped and repeated on a new cardiac tissue sample. Only a single application per sample was performed. Initial impedance and a maximum impedance drop during energy delivery were recorded. Subsequently, a digital caliper was used to obtain the following parameters describing the size of the tissue lesion (FIGURE 2): maximum lesion diameter at sample surface and cross section; maximum lesion depth; and depth at the level of the maximum lesion diameter. Lesion volume was calculated for an oblate ellipsoid as described elsewhere.[7,8] Radiofrequency energy applications with catheters positioned parallel to the tissue were not performed, because the standardization of catheter pressure on the tissue in this position was not reliable.

The RF applications were performed with 2 types of nonirrigated catheters, differing by the length of the tip electrode (4 mm vs 8 mm). The prototype catheters (FIGURES 3 and 4) designed and produced by Hagmed (Rawa Mazowiecka,

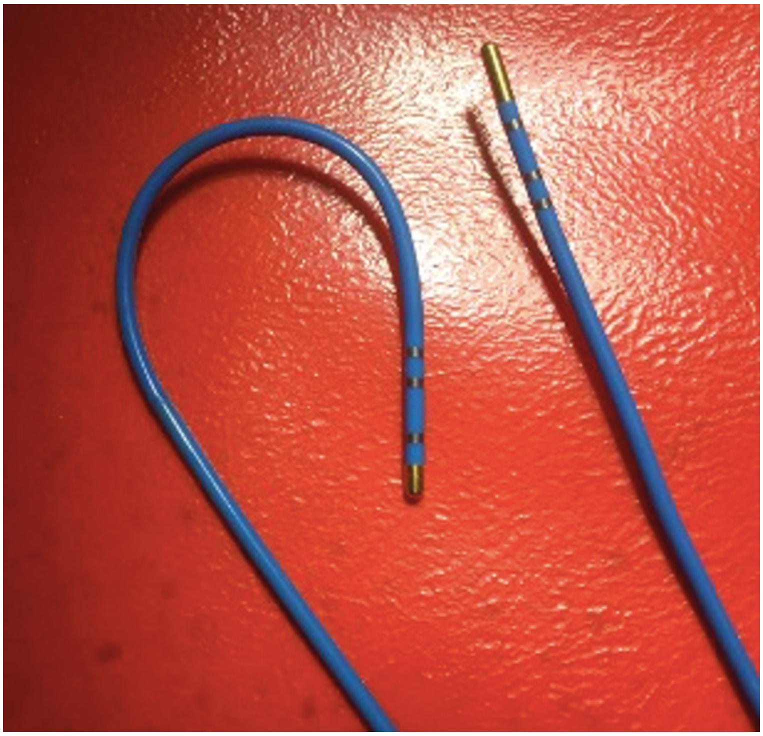

FIGURE 3 The distal portion of catheter prototypes with 4-mm and 8-mm tip electrodes manufactured by Hagmed (Rawa Mazowiecka, Poland)

FIGURE 4 Handles with connection ports of catheter prototypes (4-mm-tip and 8-mm-tip) manufactured by Hagmed (Rawa Mazowiecka, Poland)

Poland) as part of a government initiative for medical technology development were compared with commercially available RF catheters from 3 different manufacturers. More specifically, the 4-mm-tip prototype catheters were compared with Blazer II (4 mm; Boston Scientific, Marlborough, Massachusetts, United States) and RF Marinr MC (Medtronic, Minneapolis, Minnesota, United States), whereas the 8-mm-tip prototypes, with Blazer II XP (Boston Scientific) and Celsius DS (Biosense Webster, Inc.) (FIGURES 2 and 3). Both prototypes from Hagmed are gold-tip catheters (99% of gold), while those produced by the other manufacturers are equipped with a platinum-iridium electrode.

Ethical approval As we did not perform any experiments on animals or humans and all animal tissue samples were commercially obtained, the approval of a bioethics committee was not required for this study.

Statistical analysis Continuous variables were tested for normality with the Shapiro–Wilk test. Variables with normal distribution were presented as mean (SD), and those without normal distribution, as median (interquartile range [IQR]). Categorical variables were presented as numbers and percentages. The *t* test and Wilcoxon–Mann–Whitney test were applied for comparisons between 2 groups, according to data distribution. If 3 groups were compared, the analysis of variance and the Kruskal–Wallis test on ranks were used for data with and without normal distribution, respectively. Additionally, post hoc tests were used to confirm the differences between groups. The χ^2 test and Fisher exact test were applied to compare categorical data as appropriate. A P value of less than 0.05 was considered significant. The analysis was performed using the Statistica software, version 13 (StatSoft, Inc., Oklahoma, United States).

RESULTS

A total of 114 RF applications with the tested catheters were performed. No dysfunction was revealed during the study in any of the devices. Steam pops were observed in 2 of the 68 RF applications with a 4-mm-tip catheter (2.8%). No such cases were reported for applications with 8-mm-tip catheters. The number of effective RF applications was similar between catheters, irrespective of the manufacturer and the tip size.

The physical parameters of the catheters differed between manufacturers, both for the devices with 4-mm and those with 8-mm tip electrodes. Among the 4-mm-tip catheters, the highest initial impedance was noted for RF Marinr MC, while Blazer II and the Hagmed prototype showed similar initial impedance ($P = 0.24$). Detailed data are provided in TABLE 1. Initial impedance also differed between the 8-mm-tip catheters, with the highest values noted for Blazer Prime XP, followed by Celsius DS and the Hagmed prototype (TABLE 2). Impedance drop during RF applications, measured as absolute values and percentage of the initial impedance, also differed between the 4-mm and 8-mm catheters from the various manufacturers (TABLES 1 and 2).

Maximum power delivered did not differ between manufacturers either for 4-mm or 8-mm-tip catheters (TABLES 1 and 2). However, more power was delivered with 8-mm-tip catheters than with

TABLE 1 Parameters of radiofrequency energy application and lesion size for catheters with 4-mm tip electrodes

Parameter	Hagmed prototype	RF Marinr MC (Medtronic)	Blazer II (Boston Scientific)	*P* value
Initial impedance, W	146.5 (137–167)	175.5 (165–188)	144 (138–148)	<0.001
Impedance drop, W	33.5 (29–44)	27 (17–38)	22.5 (20.5–28)	0.004
Impedance drop, %	25.4 (8.8)	15.9 (10.9)	16.3 (4.2)	0.002
Maximum catheter temperature, °C	41 (39–45)	40 (38–43)	41.5 (39.5–44)	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
Maximum lesion diameter, mm	10.4 (10.2–10.7)	10.6 (10.2–10.8)	10.4 (9.8–10.6)	0.68
Lesion volume, mm^3	167.6 (156.6–179.9)	184.1 (163.3–198.9)	166.6 (148.3–185.4)	0.08

Data are presented as mean (SD) or median (interquartile range).

TABLE 2 Parameters of radiofrequency energy application and lesion size for catheters with 8-mm tip electrodes

Parameter	Hagmed prototype	Celsius DS (Biosense Webster, Inc.)	Blazer II XP (Boston Scientific)	*P* value
Initial impedance, W	112.9 (21.3)	127.3 (19)	146.1 (11.4)	<0.001
Impedance drop, W	22.8 (8)	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
Maximum 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, mm^3	241.3 (30.6)	245.7 (30.7)	250.0 (26.6)	0.72

Data are presented as mean (SD).

the 4-mm ones (median [IQR], 34.1 [29.9–39.2] W vs 28.7 [24.8–33.6] W; *P* <0.001). The maximum temperature of the catheter tip was similar for all 4-mm-tip catheters (TABLE 1). In contrast, among the 8-mm-tip catheters, the highest temperature was noted for the Hagmed prototype, followed by Celsius DS and Blazer II XP (TABLE 2).

The mean lesion depth was smaller with the Hagmed 4-mm-tip catheter than with RF Marinr MC or Blazer II (TABLE 1). However, no differences were noted between 8-mm-tip catheters (TABLE 2). In contrast, the maximum lesion diameter was similar for all 4-mm-tip catheters, while it differed between 8-mm-tip catheters. On the other hand, lesion volume was similar between catheters from different manufacturers, and this was observed for both tip sizes (TABLES 1 and 2).

The comparison of the Hagmed prototypes revealed that the 8-mm-tip catheter had lower initial impedance (median [IQR], 109 [97–130] vs 146.5 [137–167]; *P* <0.001), lower absolute impedance drop (median [IQR], 21.8 [11–38] vs 33.5 [29–44]; *P* <0.001), and lower percentage impedance drop (median [IQR], 21.2 [16.5–22.3] vs 24.7 [19.7–30.6]; *P* = 0.03) during RF application than the 4-mm-tip catheter. Maximum power delivered during ablation was higher for 8-mm than for 4-mm catheter (median [IQR], 36.5 [33.8–39.1] W vs 29.8 [25.9–32.3] W; *P* <0.001), but no differences between catheter types were observed for maximum temperature. The 8-mm-tip prototype created lesions of greater depth (mean [SD], 5.8 [0.4] mm vs 4.7 [0.4] mm; *P* <0.001) and volume (median [IQR], 239.4 [217.9–255.5] mm^3 vs 173.7 [156.1–186.4] mm^3; *P* <0.001) than the 4-mm catheter, but no differences between catheters were noted in maximum lesion diameter (median [IQR], 10.5 [10.4–10.9] mm vs 10.4 [10.2–10.7] mm; *P* = 0.08).

DISCUSSION Our study showed that catheters with the same size of the distal electrode create lesions of similar volume despite being produced by different manufacturers and despite significant differences in physical parameters, especially impedance. Moreover, the tested prototypes of catheters produced by the Polish manufacturer showed similar performance to commercially available catheters. Finally, we demonstrated that prototypes with a longer tip electrode create deeper and larger tissue lesions than those with standard electrodes.

Any comparison with studies performed under different laboratory conditions seems to be methodologically improper and the results would be difficult to interpret. Nevertheless, some investigators used the same catheters for their experiments as we did (Marinr or Blazer II).[9-11] Unfortunately, only 2 studies reported catheter impedance, and the reported values (90–170 W) were in line with those observed in our study.[10,11] Additionally, Petersen et al,[6] who also used Marinr catheters, reported similar values of power delivered to the sample (for 4-mm-tip catheters, 33 W; for 8-mm-tip catheters, 60 W; with generator set at 75 W). The similarities between studies strongly suggest that our findings are reliable and consistent with previous reports.[10-12]

Surprisingly, we were unable to identify studies that would directly compare the electrical properties and tissue lesion formation between RF ablation catheters with the same catheter tip length but produced by different manufacturers. The only nonclinical study that we found[9] compared catheters from various manufacturers but tested 5 different types of devices: with 4-mm tip, 10-mm tip single thermistor, 10-mm tip multitemperature sensor, 4-mm closed-loop irrigated tip, and 4-mm open-loop irrigated tip. Therefore, it seems that catheters produced by different manufacturers are generally assumed to be equivalent in terms of performance. We proved that despite different physical characteristics (eg, impedance), catheters of the same type but from different manufacturers create tissue lesions of a similar size. Theoretically, lesion volume depends on power delivered by the catheter.[2] In our study, power delivery did not differ between the catheters of the same type but from various manufacturers. The association between power delivery and tissue lesion was also observed in other experimental studies.[6,9-11] However, only a single report on more complex relations can be found,[12] probably due to distinct experimental conditions.

Gold-tip electrodes have been introduced into clinical practice relatively recently. Owing to higher thermal conductivity than that observed for standard platinum–iridium electrodes, they were reported to be more effective in lesion formation.[6,13] We did not confirm this observation, because gold-tip catheters in our study showed similar performance to the standard ones. The discrepancy is most likely due to differences in laboratory methodology, such as a distinct experimental chamber, fluid composition, generator settings, catheter orientation, and catheter pressure on the sample tissue. All these factors might have resulted in differences in lesion depth obtained with standard platinum–iridium catheters, with lower values reported in other studies as compared with our research (2.9 mm[13] and 3.5 mm[6] vs 4.6 mm in our study). Apparently, in the case of high cooling with a fluid flow of approximately 0.5 m/s and perpendicular catheter orientation (both providing a relatively efficient energy transfer to the tissue), differences between gold-tip and standard platinum–iridium catheters appear to be nonsignificant. Nevertheless, head-to-head testing of gold-tip catheters produced by different manufacturers should be performed to provide additional information. The lack of such a comparison in our study is a relevant limitation.

The distal electrode of the catheter is responsible for delivering RF energy to cardiac tissue. The length of the electrode and its effect on lesion size have been widely studied, with some conflicting results.[2] As the tested prototypes of nonirrigated catheters come in 2 versions, with a short (4 mm) and a long (8 mm) tip, we were able to perform a comparative analysis. The comparison showed lower initial impedance, higher power delivery, and formation of greater lesions for longer tip electrodes. These findings are in line with most published data,[7,10,12] although some authors argued that longer-tip catheters did not lead to formation of greater lesions.[14,15] In support of our findings, Wittcampf and Nakagawa [2] suggested that lesions created with a longer electrode may be larger due to higher energy transfer resulting from more efficient convective cooling by blood (fluid) flowing around the catheter tip.

When creating the laboratory setting for our study, we focused on the reproducibility of the experimental environment and the highest rate of successful applications. The tests were performed with the standardized composition of the blood-mimicking liquid, constant temperature, constant flow of the fluid directly on the ablation area, and constant catheter pressure on the cardiac tissue. Interestingly, in our study, we observed a relatively low rate of steam pops (3%), which constituted a real challenge at the initial stage of setting our laboratory routine, as also reported by other authors.[6,9,11,13] We managed to overcome this challenge mainly by using only fresh porcine hearts (<2–3 hours from slaughter), selecting only smooth parts of the left ventricle, and cooling the catheter and RF area with a relatively high constant flow of fluid jet (0.5 m/s). Considering also that the lesion sizes in our study were comparable to those reported for in vivo experiments,[11,14,16] our findings might be considered as reliable guidance for clinical practice, although the in vitro study design represents an important limitation. Additionally, the performance of the new prototype could be compared with that of irrigated RF catheters, which are often used in complex ablation procedures.[17]

In conclusion, our in vitro study demonstrated that RF ablation catheters with the same tip length, produced by different manufacturers, create tissue lesions of similar volume, although they have distinct physical parameters during energy applications. The tested catheter prototypes produced by the Polish manufacturer showed similar performance to that of commercially available catheters. Lesions created with the 8-mm-tip catheter prototype had greater depth and volume than those obtained with 4-mm-tip catheters, irrespective of the manufacturer.

ARTICLE INFORMATION

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REFERENCES

1 Zipes D. Contemporary approaches to treating arrhythmias. Nat Rev Cardiol. 2015; 12: 68-69.

2 Wittkampf FH, Nakagawa H. RF catheter ablation. Lessons on lesions. Pacing Clin Electrophysiol. 2006; 29: 1285-1297.

3 Heines DE. Biophysics of radiofrequency lesion formation. In: Huang SK, Wood MA. Catheter Ablation of Cardiac Arrhythmias. Philadelphia, United States: Saunders Elsevier; 2011: 2-19.

4 Nath S, Lynch C, Whayne JG, Haines DE. Cellular electrophysiological effects of hyperthermia on isolated guinea pig papillary muscle. Implications for catheter ablation. Circulation. 1993; 88: 1826-1831.

5 Haines DE. Direct measurement of the lethal isotherm for radiofrequency ablation of myocardial tissue. Circ Arrhythm Electrophysiol. 2011; 4: e67.

6 Petersen HH, Chen X, Pietrsen A, et al. Lesion dimension during temperature-controlled radiofrequency catheter ablation of left ventricular porcine myocardium. Circulation. 1999: 99; 319-325.

7 Kongsgaard E, Steen T, Jensen O, et al. Temperature guided radiofrequency catheter ablation of myocardium: comparison of catheter tip and tissue temperatures in vitro. Pacing Clin Electrophysiol. 1997; 20: 1252-1260.

8 Linhart M, Mollnau H, Bitzen A, et al. In vitro comparison of platinum-iridium and gold tip electrodes: lesion depth in 4 mm, 8 mm, and irrigated-tip radiofrequency ablation catheters. Europace. 2009; 11: 565-570.

9 Everett IV TH, Lee KW, Wilson EE, et al. Safety profiles and lesion size of different radiofrequency ablation technologies: a comparison of large tip, open and closed irrigation catheters. J Cardiovasc Electrophysiol. 2009; 20: 325-335.

10 Otomo K, Yamanashi WS, Tondo C, et al. Why a large tip electrode makes a deeper radiofrequency lesion: effects of increase in electrode cooling and electrode – tissue interface area. J Cardiovasc Electrophysiol. 1998; 9: 47-54.

11 Skrumeda LL, Mehra R. Comparison of standard and irrigated radiofrequency ablation in canine ventricle. J Cardiovasc Electrophysiol. 1998; 9: 1196-1205.

12 Dorwarth U, Fiek M, Remp T, et al. Radiofrequency catheter ablation: different cooled and noncooled electrode induce specific lesion geometries and averse effect profiles. Pacing Clin Electrophysiol. 2003; 26: 1438-1445.

13 Lewalter T, Bitzen A, Wurtz S, et al. Gold-tip electrodes – a new "deep lesion" technology for catheter ablation. In vitro comparison of a gold alloy versus platinum-iridium tip electrode ablation catheter. J Cardiovasc Electrophysiol. 2005; 16: 770-772.

14 Langberg JJ, Gallagher M, Strickberger SA, Amirana O. Temperature-guided radiofrequency catheter ablation with very large distal electrodes. Circulation. 1993; 88: 245-249.

15 Petersen HH, Chen X, Pietersen A, et al. Tissue temperatures and lesion size during irrigated tip catheter radiofrequency ablation. Pacing Clin Electrophysiol. 2000; 23: 8-17.

16 Leslem E, Tschabrunn CM, Contreras-Valdes FM, et al. Evaluation of catheter technology: comparison between thigh preparation model and in-vivo beating heart. Heart Rhythm. 2017; 14: 1234-1240.

17 Orczykowski M, Borowiec K, Biernacka E, et al. Ablation of atrial tachyarrhythmias late after surgical correction of tetralogy of Fallot: long term follow-up. Kardiol Pol. 2018; 76: 1097-1105.