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Safety and efficacy of cryoablation without the use of fluoroscopy

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Abstract

Background: *Development of electroanatomical systems make it possible to perform ablations without the use of fluoroscopy. The aim of this study was to evaluate the efficacy and safety of cryoablation procedures without the use of fluoroscopy.*

Methods: *The study group consisted of 45 patients (14 female; age 36 ± 15 years) treated with cryoablation using the EnSite electroanatomical system: 10 with ventricular extrasystoly from the right ventricle, 6 with the arrhythmogenic site near the left coronary artery, 17 patients with Wolff-Parkinson-White syndrome (WPW), 2 patients with atrioventricular nodal reentrant tachycardia (AVNRT) type 2, 7 patients with AVNRT type 1, 3 patients with atrial tachycardia.*

Results: *In 38 of the 45 patients (84%) cryoablation procedure was performed without the use of fluoroscopy. Cryoablation efficacy was 78.9%. In 5 patients unsuccessful cryoablation was fallowed by radiofrequency applications. Finally, efficacy reached 92.1%. There were no deaths. In 1 patient a small adverse event — right bundle branch block was observed after ablation of para-Hisian accessory pathway. No other adverse events were observed. In the long term follow-up efficacy was 89.5%.*

Conclusions: *Cryoablation using electroanatomical system without the use of fluoroscopy is a safe and efficient procedure and it is a possible alternative in most patients qualified for cryoablation.* (Cardiol J 2018; 25, 3: 327–332)

Key words: cryoablation, fluoroless ablation, electroanatomical mapping, no-fluoroscopy, cardiac arrhythmias

Introduction

Due to technological improvements in field of electroanatomical mapping (EAM) systems there is a possibility to reduce fluoroscopy. In selected arrhythmias fluoroless ablation is possible with the use of EAM system [1, 2]. Because there is no safe ionizing radiation dose, in 2005 Hirsfeld introduced a strategy of As Low As Reasonably Achievable (ALARA), involving the use of various techniques to reduce fluoroscopy [3]. This is mainly important in children [4], patients with an oncological history, and also in pregnant women [5–8]. X-rays could affect the structure of DNA, whereas fluoroscopy impairs the repair processes of DNA structure. Therefore, catheter ablation with the use of EAM (without fluoroscopy) could be safer than conventional ablation [2, 9–11].

Due to technological advancements, the amount of catheter ablations has increased and procedures have become shorter. In recent years, it was possible to perform more complex ablations with a significant reduction or even without using fluoroscopy [4–8, 12–24]. Ablation without fluoroscopy allows a reduced risk of delayed side effects from ionizing radiation. The risk assessment of X-ray should be performed individually before ablation in each patient in order to decrease the risk of delayed side effects. The most preferred method would be to perform ablation without the use of fluoroscopy, allowing for decreased risk of adverse events and increasing ablation efficacy.

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Table 1. Procedure data in study group and in reference groups.

	Study group (n = 38)	Reference group 1 (n = 70)	Reference group 2 (n = 143)	P 1	P 2
Procedure time [min]	110 ± 43	114 ± 54	80 ± 40	NS	< 0.05
Application time [min]	26.6 ± 20.5	31.6 ± 34.8	8.1 ± 10.8	NS	< 0.05
VEBs	15	10	0	NS	< 0.05
AVNRT	6	32	83	< 0.05	< 0.05
WPW syndrome	15	19	30	NS	NS
Atrial tachycardia	2	1	2	NS	NS
Atrial flutter	0	8	20	NS	< 0.05
Atrial fibrillation	0	0	8	NS	NS

AVNRT — atrioventricular nodal reentrant tachycardia; NS — non-significant; VEB — ventricular extra beat; WPW — Wolff-Parkinson-White

However, thus far there is limited data about safety procedures performed without the use of fluoroscopy [4–8, 12–25].

The aim of this study was to assess the feasibility, safety and efficacy of cryoablation without the use of fluoroscopy or limited fluoroscopy time and dose area product in various arrhythmias with the help of EAM system.

Methods

The group of patients

Fourty five patients were enrolled (14 women [F], 31 men [M], aged 36 ± 15 years) and treated with cryoablation using EAM system (EnSite NavX, St. Jude Medical), and catheter Freezor 7 F (Medtronic). These patients were treated with cryoablation using EAM system due to prior unsuccessful radiofrequency (RF) ablation (n = 16) and patients with arrhythmogenic sites localized near important anatomical and electrophysiological structures in the heart or with high risk of adverse events with the use of RF ablation (n = 29). The study had a positive opinion of the local bioethical committee.

In the present group there were 10 patients with ventricular arrhythmias (ventricular extrasystolic beats [VEBs]) of the right ventricle, 6 patients with the site of ventricular arrhythmia in a region near the left coronary artery (LCA) ostium, disqualified from RF ablation, 17 patients with Wolff-Parkinson-White (WPW) syndrome (7 patients with para-Hisian accessory pathway, 10 with septal accessory pathway), 2 patients with atrioventricular nodal tachycardia type 2 (AVNRT t2), 7 patients with atrioventricular nodal tachycardia type 1 (AVNRT t1), 3 patients with atrial tachycardia (AT). In 2 patients arrhythmogenic sites were localized in the left ventricle therefore there was a need to use fluoroscopy. 17 procedures were redo: 9 patients with WPW syndrome, 6 patients with VEBs and 2 patients with AVNRT. In patients with WPW syndrome RF ablation was not performed because the location of bundle branch or atrioventricular node being too close. In patients with AVNRT ablation, proceeding was discontinued because of a small Koch triangle and registration of His potential across a large area.

The first reference group was 70 patients (38 F, 32 M; age 44 ± 18 years) who had cryoablation without using EAM system: AVNRT — 32 patients, WPW syndrome — 19 patients, VEBs/ventricular tachycardia (VT) — 10 patients, typical atrial flutter (AFL) — 8 patients, AT — 1 patient.

The second reference group consisted of 143 consecutive patients (79 F, 64 M; age 49 ± 19 years) who underwent conventional RF ablation (without using EAM system) during the same period as patients in the study group: AVNRT — 83 patients, WPW syndrome — 30 patients, AFL — 20 patients, AT — 2 patients, ablation of the atrioventricular node — 8 patients.

The efficacy between the groups was not assessed because of the different types of arrhythmia in the study group and the reference groups. Comparison was performed only in procedural data (procedure and fluoroscopy duration, number and duration of applications) (Table 1).

Ablation

Before ablation all patients signed an informed voluntary consent form. The right atrium or right ventricle was reached through the femoral vein. Left ventricle or aorta was reached through the femoral artery. One patient with left posterolateral

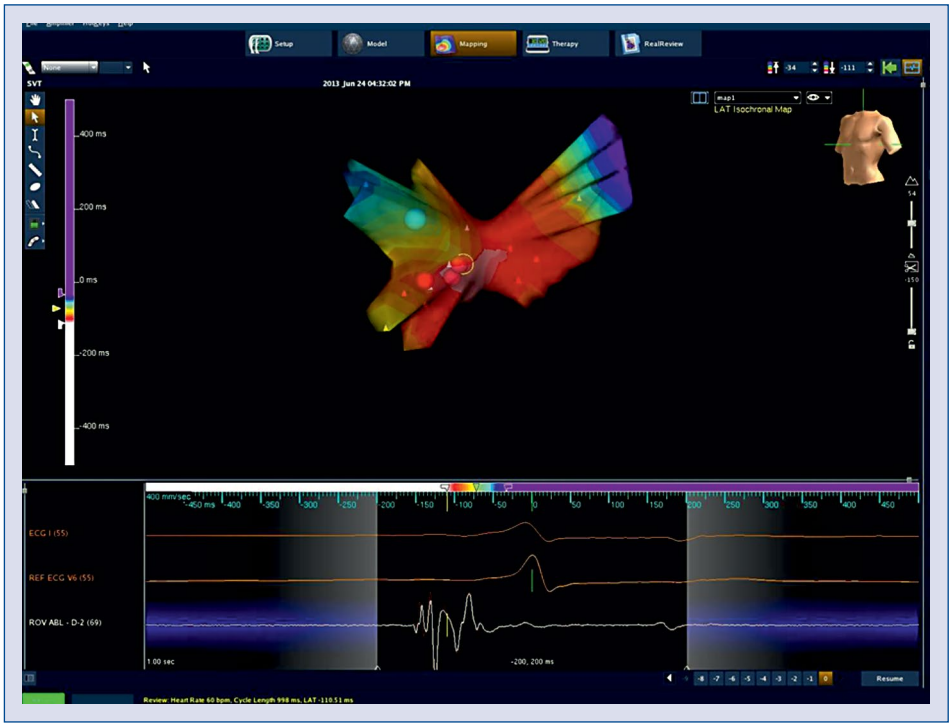

Figure 1. EnSite map of posteroseptal region of the right atrium. Series cryoapplications (red dots) near the ostium of coronary sinus in patient with Wolff-Parkinson-White syndrome and right posteroseptal accessory pathway.

accessory pathway was catheterized via patent foramen ovale (PFO).

In the study group, all catheter ablations was performed with the use of EAM system. EnSite system enables visualization of each catheter, which came into the vascular system outside the vascular sheath. It allows visualization of the veins and arteries which pass to the heart without the use of fluoroscopy (Figs. 1, 2).

After the electrophysiological study (EPS), detailed electroantomical maps of the arrhythmogenic sites were created. Then, cryomaping was performed (application of up to –30°C for up to 60 s). After safe and successful cryomapping, the cryoablation was performed (temperature decrease below –75°C during the application for at least 240 s). In 5 patients immediate efficacy of cryoablation was not achieved, therefore this method was changed to RF ablation.

After ablation, antiarrhythmic drugs were discontinued. Duration time of the procedure was measured from the local anesthesia to catheter removal from the vessels. When fluoroscopy was used, time was measured in minutes with a dose area product in cGy/cm^2. The immediate efficacy of the ablation procedure was assessed individually for each arrhythmia and its absence in the control EPS in short term follow up after ablation (at least 15 min after the last application). Long term follow-up was evaluated based on a 24-h electrocardiogram (ECG) Holter from 4 to 8 weeks after ablation. The follow-up included 6 months observation for each patient. Adverse events were divided into small and large. Small adverse events included: hematoma in the groin, arteriovenous fistula and pseudoaneurysm, bundle branch block. Large adverse events included: atrioventricular block, cardiac tamponade, death, aortic dissection, and mechanical damage of valves or large vessels.

Statistical analysis

Quantitative parameters were presented as means ± standard deviation (SD). Qualitative data were presented with numerical percentages. Groups were compared statistically with the Mann-Whitney-Wilcoxon test and were statistically significant at $p < 0.05$.

Results

In 38 of 45 patients (84%) cryoablations were performed completely without the use of fluoroscopy: 9 patients with VEBs of the right ventricle, 6 patients with VEBs with site close to the ostium

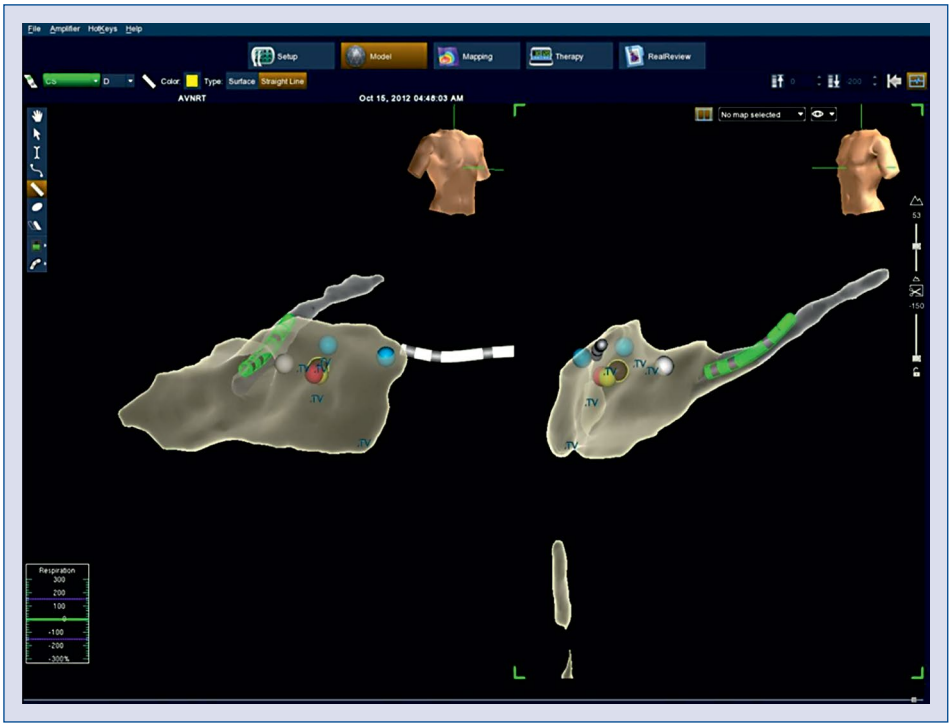

Figure 2. EnSite map of Koch triangle in patient with atrioventricular nodal reentrant tachycardia. Green catheter in the coronary sinus, white ablation catheter. Blue dots indicate site of His bundle. Brown dot indicates the place of successful cryoablation.

of LCA, 15 patients with WPW syndrome, 2 patients with AVNRT t2, 4 patients with AVNRT t1, 2 patients with AT and arrhythmogenic site close to the ostium of coronary sinus. In 8 patients the cryoablation was unsuccessful. Therefore, in 5 patients additional RF ablation was performed. In 3 patients previous RF ablation was unsuccessful: 1 patient with wide right-sided accessory pathway, 1 patient with VEBs from the ostium of LCA and 1 patient with right-sided posteroseptal accessory pathway. Due to redo procedures additional RF ablation were not performed.

In 38 patients with cryoablation without the use of fluoroscopy overall procedure time was 110 ± 43 min (the first reference group: 114 ± 54 min; NS; the second reference group 80 ± 40 min; $p < 0.05$), the average application time was 26.6 ± ± 20.5 min (the first reference group 31.6 ± 34.8 min; p = NS, the second reference group 8.1 ± 10.8 min, $p < 0.05$), the number of applications was 6.8 ± 5.2 (the first reference group 5.9 ± 7.4; NS, the second reference group 8.9 ± 8.2; NS).

In 19 patients the arrhythmogenic sites were close to important anatomical structures (13 close to the atrioventricular node or His bundle and 6 close to LCA ostium).

In 7 (15.6%) patients fluoroscopy was used because of the difficulties in catheter navigation or increased risk of adverse events (fluoroscopy time in this group was 7.6 ± 7.2; range from 1.4 to 34.7 min), dose area product was 722 ± 1371 cGy/cm^2. Fluoroscopy was used in 2 patients with left-sided accessory pathway (difficulties with catheter movements), 3 patients with AVNRT with a small Koch triangle (higher risk of atrioventricular block), 1 patient with AT and 1 patient with VEBs (difficulties with catheter stabilization). In the first reference group fluoroscopy duration was 8.5 ± 6.9 min (NS). In the second reference group fluoroscopy time was 10.6 ± 8.1 min ($p < 0.05$). In the first reference group dose area product was 1366.6 ± 1302.7 cGy/cm^2 ($p < 0.05$), in the second 647.2 ± 938.4 cGy/cm^2 (NS).

Immediate efficacy of cryoablation without use of fluoroscopy was 78.9% (30/38). After considering an additional method of RF ablation efficacy increased to 92.1% (35/38). In long term follow up efficacy was 89.5% (34/38). In the study group (patients with the use of fluoroscopy and without fluoroscopy) efficacy was 88.9% (40/45) in long term follow up. In 1 patient there was a small adverse event — right bundle branch block was

observed after ablation of para-Hisian accessory pathway. No other adverse events were observed.

Discussion

Radiation exposure related to conventional catheter ablation which carries a small but not negligible stochastic and deterministic effects on health. These effects are cumulative and potentially more harmful in younger individuals. EAM systems can significantly reduce the radiological exposure and in some cases it can completely eliminate it. This is especially important in pregnant women, patients with oncological history or diseases of the hematologic system. To date there are few reports on fluoroless ablation in pregnant women [5–7].

Ablation procedures for arrhythmias have increased in frequency and complexity over the last decade. RF ablation is still the prefered method of catheter ablation. However, in selected patients the cryoablation is safer and could be a method of choice, mainly in patients with high risk of damage of important anatomic and electrophysiologic structures in the heart during RF procedure.

Initially, EAM system allows a reduction in fluoroscopic time and dose area product [12–16, 26, 27]. In a NO PARTY multicenter randomized study which presented the use of EAM system (EnSite) to a significant reduction fluoroscopy time and dose area product in supraventricular tachycardia (SVT) compared to the conventional ablation treatment [13]. Subsequent to this, there were reports of RF ablation procedures performed entirely without the use of fluoroscopy in SVT [5, 6, 8, 17–22]. Casella et al. [13] shows that RF ablation without the use of fluoroscopy in 38 patients with supraventricular arrhythmias (AFL, WPW syndrome, AVNRT and AT) is safe and successful. In multicenter prospective registry Stec et al. [21] presented that 179 of 188 procedures were done without fluoroscopy with a success rate of 98% and no major complications. Koźluk et al. [22] presented safety and efficacy of fluoroless ablation in the left ventricle of a patient with benign and malignant VTs [6]. The most difficult ablation to do without fluoroscopy is pulmonary vein isolation [22]. Use of EAM system allows a significant reduction of this disadvantage [26, 27], the treatment, however, without fluoroscopy is only possible if PFO is present [23]. Bulava et al. [24] introduced transseptal puncture only under intracardiac echocontrol. In combination with EAM, this allows most patients to perform PVI without fluoroscopy [24]. In the study presented herein, we demonstrates the feasibility of performing safe and successful fluoroless cryoablation for various arrhythmias.

In a meta-analysis, Yang et al. [25] presented, that procedure duration with zero or near-zero fluoroscopy was not significantly different from that of conventional ablation. There were also no significant differences between both groups in success rate (direct and long-term), complications or recurrence rates.

The main advantage of cryoablation is its long reversibility (1 min), this makes it safe compared to RF ablation in patients with arrhythmogenic sites close to electrophysiological structures like atrioventricular node or His bundle. Advances in EAM systems have allowed flouroless cryoablation in various arrhythmias including redo procedures and various localization of arrhythmogenic sites.

Conclusions

1. In 38 of 45 patients (84.4%) cryoablation was performed without the use of fluoroscopy.
2. There were no significant complications in the study group.
3. Immediate cryoablation efficacy was 78.9% (with additional RF applications — 92.1%), and in long term follow up — 89.5%.

Conflict of interest: Edward Koźluk — Proctor during cryoballon ablations (Medtronic), Proctor during CARTO procedures (Johnson & Johnson), conference grants from Medtronic and Johnson & Johnson. Paid Lectures for St. Jude Medical (ABBOT).

References

1. Picano E. Informed consent and communication of risk from radiological and nuclear medicine examinations: how to escape from a communication inferno. BMJ. 2004; 329(7470): 849–851, doi: 10.1136/bmj.329.7470.849, indexed in Pubmed: 15472270.
2. Picano E, Vañó E, Rehani MM, et al. The appropriate and justified use of medical radiation in cardiovascular imaging: a position document of the ESC Associations of Cardiovascular Imaging, Percutaneous Cardiovascular Interventions and Electrophysiology. Eur Heart J. 2014; 35(10): 665–672, doi: 10.1093/eurheartj/eht394, indexed in Pubmed: 24401558.
3. Hirshfeld JW, Balter S, Brinker JA, et al. ACCF/AHA/HRS/SCAI clinical competence statement on physician knowledge to optimize patient safety and image quality in fluoroscopically guided invasive cardiovascular procedures: a report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training. Circulation. 2005; 111(4): 511–532, doi: 10.1161/01.CIR.0000157946.29224.5D, indexed in Pubmed: 15687141.
4. Bigelow AM, Arnold BS, Padrutt GC, et al. Non-fluoroscopic cardiac ablation of neonates with CHD. Cardiol Young. 2017;

27(3): 592–596, doi: 10.1017/S1047951116001554, indexed in Pubmed: 27766996.
5. Szumowski L, Szufladowicz E, Orczykowski M, et al. Ablation of severe drug-resistant tachyarrhythmia during pregnancy. J Cardiovasc Electrophysiol. 2010; 21(8): 877–882, doi: 10.1111/j.1540-8167.2010.01727.x, indexed in Pubmed: 20158563.
6. Stec S, Krynski T, Baran J, et al. "Rescue" ablation of electrical storm in arrhythmogenic right ventricular cardiomyopathy in pregnancy. BMC Cardiovasc Disord. 2013; 13: 58, doi: 10.1186/1471-2261-13-58, indexed in Pubmed: 23937302.
7. Koźluk E, Piątkowska A, Kiliszek M, et al. Catheter ablation of cardiac arrhythmias in pregnancy without fluoroscopy: a case control retrospective study. Adv Clin Exp Med. 2017; 26(1): 129–134, indexed in Pubmed: 28397444.
8. Kozluk E, Tokarczyk M, Kozłowski D, et al. Radiofrequency catheter ablation during pregnancy. Folia Cardiol. 2005; 12(5): 338–342.
9. Andreassi MG, Sagliano I, Cioppa A, et al. Chronic low-dose radiation exposure from interventional cardiology procedures induces chromosomal abnormalities in originally genetically identical twins. Int J Cardiol. 2007; 118(1): 130–131, doi: 10.1016/j.ijcard.2006.01.070, indexed in Pubmed: 16934348.
10. Beels L, Bacher K, De Wolf D, et al. Gamma-H2AX foci as a biomarker for patient X-ray exposure in pediatric cardiac catheterization: are we underestimating radiation risks? Circulation. 2009; 120(19): 1903–1909, doi: 10.1161/CIRCULATIONAHA.109.880385, indexed in Pubmed: 19858412.
11. Beels L, Bacher K, Smeets P, et al. Dose-length product of scanners correlates with DNA damage in patients undergoing contrast CT. Eur J Radiol. 2012; 81(7): 1495–1499, doi: 10.1016/j.ejrad.2011.04.063, indexed in Pubmed: 21596504.
12. Tuzcu V. A nonfluoroscopic approach for electrophysiology and catheter ablation procedures using a three-dimensional navigation system. Pacing Clin Electrophysiol. 2007; 30(4): 519–525, doi: 10.1111/j.1540-8159.2007.00702.x, indexed in Pubmed: 17437576.
13. Casella M, Dello Russo A, Pelargonio G, et al. Rationale and design of the NO-PARTY trial: near-zero fluoroscopic exposure during catheter ablation of supraventricular arrhythmias in young patients. Cardiol Young. 2012; 22(5): 539–546, doi: 10.1017/S1047951112000042, indexed in Pubmed: 22325367.
14. Miyamoto K, Tsuchiya T, Narita S, et al. Radiofrequency catheter ablation of ventricular tachyarrhythmia under navigation using EnSite array. Circ J. 2010; 74(7): 1322–1331, indexed in Pubmed: 20467153.
15. Sporton SC, Earley MJ, Nathan AW, et al. Electroanatomic versus fluoroscopic mapping for catheter ablation procedures: a prospective randomized study. J Cardiovasc Electrophysiol. 2004; 15(3): 310–315, doi: 10.1111/j.1540-8167.2004.03356.x, indexed in Pubmed: 15030422.
16. Casella M, Pelargonio G, Dello Russo A, et al. "Near-zero" fluoroscopic exposure in supraventricular arrhythmia ablation using the EnSite NavX™ mapping system: personal experience and review of the literature. J Interv Card Electrophysiol. 2011; 31(2): 109–118, doi: 10.1007/s10840-011-9553-5, indexed in Pubmed: 21365263.
17. Pachón M, Arias MA, Castellanos E, et al. No fluoroscopy for cavotricuspid isthmus-dependent right atrial flutter ablation. Heart Rhythm. 2009; 6(3): 433–434, doi: 10.1016/j.hrthm.2008.07.019, indexed in Pubmed: 18783993.
18. Álvarez M, Tercedor L, Herrera N, et al. Cavotricuspid isthmus catheter ablation without the use of fluoroscopy as a first-line treatment. J Cardiovasc Electrophysiol. 2011; 22(6): 656–662, doi: 10.1111/j.1540-8167.2010.01962.x, indexed in Pubmed: 21114703.
19. Ruiz-Granell R, Morell-Cabedo S, Ferrero-De-Loma A, et al. Atrioventricular node ablation and permanent ventricular pacemaker implantation without fluoroscopy: use of an electroanatomic navigation system. J Cardiovasc Electrophysiol. 2005; 16(7): 793–795, doi: 10.1046/j.1540-8167.2005.40774.x, indexed in Pubmed: 16050840.
20. Earley MJ, Showkathali R, Alzetani M, et al. Radiofrequency ablation of arrhythmias guided by non-fluoroscopic catheter location: a prospective randomized trial. Eur Heart J. 2006; 27(10): 1223–1229, doi: 10.1093/eurheartj/ehi834, indexed in Pubmed: 16613932.
21. Stec S, Sledź J, Mazij M, et al. Feasibility of implementation of a "simplified, No-X-Ray, no-lead apron, two-catheter approach" for ablation of supraventricular arrhythmias in children and adults. J Cardiovasc Electrophysiol. 2014; 25(8): 866–874, doi: 10.1111/jce.12414, indexed in Pubmed: 24654678.
22. Koźluk E, Gawrysiak M, Piątkowska A, et al. Radiofrequency ablation without the use of fluoroscopy — in what kind of patients is it feasible? Arch Med Sci. 2013; 9(5): 821–825, doi: 10.5114/aoms.2013.38676, indexed in Pubmed: 24273563.
23. Mühl A, Kühne M, Sticherling C, et al. Fluoroscopy-Free PVI With nMARQ(TM) in a Patient With a PFO. J Cardiovasc Electrophysiol. 2015; 26(8): 906, doi: 10.1111/jce.12635, indexed in Pubmed: 25656773.
24. Bulava A, Hanis J, Eisenberger M. Catheter ablation of atrial fibrillation using zero-fluoroscopy technique: a randomized trial. Pacing Clin Electrophysiol. 2015; 38(7): 797–806, doi: 10.1111/pace.12634, indexed in Pubmed: 25790320.
25. Yang Li, Sun Ge, Chen X, et al. Meta-analysis of zero or near-zero fluoroscopy use during ablation of cardiac arrhythmias. Am J Cardiol. 2016; 118(10): 1511–1518, doi: 10.1016/j.amjcard.2016.08.014, indexed in Pubmed: 27639689.
26. Koźluk E, Piątkowska A, Rodkiewicz D, et al. Direct results of a prospective randomized study comparing ablation with the nMARQ catheter and the PVAC catheter used with and without a 3D system (MAPER 3D Study). Arch Med Sci. 2017, doi: 10.5114/aoms.2017.68054.
27. Koźluk E, Gawrysiak M, Lodziński P, et al. The LocaLisa system as the key to shortening the procedure duration and fluoroscopy time during ablation of atrial fibrillation. Kardiol Pol. 2008; 66(6): 624–629; discussion 630, indexed in Pubmed: 18626831.