

The safety and efficacy of zero-fluoroscopy ablation versus conventional ablation in patients with supraventricular tachycardia

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KEY WORDS

ablation, radiation, supraventricular tachycardia, 3-dimensional, zero fluoroscopy

ABSTRACT

BACKGROUND A zero-fluoroscopy approach guided by a 3-dimensional navigation system is an alternative to the traditional conventional fluoroscopy-navigation approach for ablation of tachycardia.

AIMS To compare the safety and efficacy of zero-fluoroscopy ablation of supraventricular tachycardia (SVT) guided by the CARTO mapping system (CZF) alone, the EnSite zero-fluoroscopy mapping system (EZF) alone, or the conventional fluoroscopy (CF) ablation method.

METHODS From July 2015 to March 2017, patients admitted for SVT ablation were prospectively and consecutively enrolled in the CF, EZF, and CZF groups in a 1:1:1 ratio. The procedures for the CF group were performed using the traditional fluoroscopy method or the 3-dimensional mapping method. All data were prospectively recorded by independent researchers. Procedure and fluoroscopic time as well as rate of success, recurrence, and complications in the 3 groups were analyzed.

RESULTS One patient from the CZF group was moved to the CF group due to a severe venous malformation during catheter insertion. A total of 100 patients (100%) in the CF group, 100 patients (100%) in the EZF group (100%), and 99 patients (99%) in the CZF group successfully completed the electrophysiology study. There were no severe complications in any of the groups. The mean (SD) procedure time was 61.8 (36.2), 66.5 (24.2), and 65.4 (27.5) minutes in the CF, EZF, and CZF group, respectively. The median (interquartile range) fluoroscopy time of the CF group was 3.6 (2.1–8.8) minutes.

CONCLUSIONS The zero-fluoroscopy approach guided by the CARTO system is not inferior to the zero-fluoroscopy approach guided by the EnSite system or a conventional fluoroscopic approach in terms of the efficiency and safety for ablation of SVT.

INTRODUCTION Fluoroscopic radiofrequency ablation is effective in patients with cardiac arrhythmias who do not tolerate medications.¹ However, exposure to radiation during fluoroscopy may harm the patient and medical personnel.² Prolonged radiation exposure is associated with dermatitis, cataract, malignancies, and congenital malformations.³ Reducing radiation exposure in the electrophysiology laboratory requires shielding and increasing the distance from the X-ray beam.⁴ Patients get exposed to radiation several times during various examinations and therapies. Furthermore, they

often require procedures involving radiation.⁵⁻⁷ Therefore, approaches and modalities that use less or no ionizing radiation are preferred, as they are medically appropriate, acceptable, and safe for patients.⁸

The new 3-dimensional (3D) electroanatomical mapping software can help achieve a significant reduction and even complete elimination of radiation in electrophysiology laboratories for most patients, particularly for children and pregnant women.^{9,10}

The evolution of mapping and anatomic imaging is effective for fluoroscopic imaging.^{11,12} In

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WHAT'S NEW?

Zero-fluoroscopy radiofrequency catheter ablation of arrhythmia is an alternative to traditional conventional fluoroscopy in treatment of various types of tachycardia. Three-dimensional mapping systems have become an important auxiliary tool for ablation. We analyzed 3 types of procedures: conventional fluoroscopy approach, EnSite-guided zero-fluoroscopy approach, and CARTO-guided zero-fluoroscopy approach. There were no statistical differences between the groups in the immediate success rate, recurrence rate, total success rate, and procedure time. We conclude that our zero-fluoroscopy approach guided by the CARTO system is not inferior to the zero-fluoroscopy approach guided by the EnSite or conventional fluoroscopy approach in the efficiency and safety.

the past decade, there have been many reports on the use of zero-fluoroscopy (ZF) and near-ZF approaches for catheter ablation of tachycardia, particularly of right-sided tachycardia.¹³⁻¹⁷ EnSite NavX (Abbott Laboratories Ltd., St. Paul, Minnesota, United States) is an electric field-dependent mapping system, and CARTO (Biosense Webster Inc., Irvine, California, United States) is a magnetic field-dependent mapping system. Though both have similar effectiveness and safety and both reduce X-ray exposure, NavX has a significantly greater effect than CARTO.¹⁸

CARTO and EnSite mapping systems are available for cardiac catheter ablation. The mapping and ablation catheters in both systems are based on a 3D reconstruction of the heart chambers. Low-energy electromagnetic fields are used in the CARTO system. The orientation of the magnetic field allows accurate catheter localization. The CARTO system integrates the latest technologies for magnets and impedance for catheter positioning. The EnSite system uses body-surface patch electrodes to which electrical signals are transferred. Intracardiac catheters with sensing electrodes determine the position of the body-surface patch electrode, and the analysis of the voltage allows identification of the catheter location.¹⁹ The position of the catheter is estimated based on the impedance gradient in relation to a reference electrode. The minimally fluoroscopic approach with EnSite is complicated by a nonlinear impedance from the human body.²⁰ The CARTO system allows precise spatial localization of the ablation catheter and shortens fluoroscopy time during catheter ablation for atrial fibrillation as compared with the EnSite system and ablation performed without 3D mapping.²⁰ An on-site catheter can reconstruct images of the chest and abdomen from the puncture point in the femoral artery or vein to the heart and allows tracking of the catheter in vessels using an electric field principle. Due to the CARTO magnetic field, it is limited to track the catheter in vessels between the access point and the heart. In cases of catheter torsion, impaction, kinking, vessel

branches, stenosis, and malformations, tracking the catheter in the vessels is essential to enable the CARTO system to cover vessels with magnetic fields and track the catheters inside the vessels without moving the ablation catheter tip to the desired part. We assessed the feasibility and safety of changing the patch position from the upper back to the lower back and from the chest to the lower abdomen during insertion. We also assessed the feasibility and safety of changing the catheter position in the heart. Recent randomized trials show that ZF catheter ablation is effective and safe.^{20,21} To the best of our knowledge, there are no comparative studies between the CARTO and the EnSite mapping systems.

METHODS Study design A prospective analysis was conducted in 300 patients with supraventricular tachycardia (SVT) at our center. Patients were subjected to 3 different interventional approaches in a 1:1:1 ratio: conventional fluoroscopy (CF), which used X-ray imaging with one of the 3D mapping systems; EnSite system ZF (EZF), which used the EnSite 3D navigation system alone, and the CARTO ZF (CZF) system, which used the CARTO navigation system alone. All patients were numbered according to their inpatient identification numbers (TABLE 1). All operators performed ablation procedures independently in at least 75 cases. The CF, EZF, and CZF procedure was performed by 4, 2, and 2 operators, respectively. The ethics committee of the Tongji Medical College approved the study protocol in accordance with the Declaration of Helsinki.

Study population A total of 300 consecutive patients with SVT admitted to the center for ablation procedures between January 2015 and August 2017 were included in the study. Supraventricular tachycardia indicated atrioventricular nodal reentrant tachycardia and atrioventricular reentrant tachycardia, confirmed by a transesophageal electrophysiological study. The following were the exclusion criteria: 1) suspected atrial tachycardia, atrial flutter, or combined mechanism multiple tachycardia; 2) severe congenital heart diseases or a thoracic anomaly; and 3) patients with cardiac implantable devices. All patients underwent preoperative preparation, including blood tests, blood electrolyte analysis, electrocardiogram, chest X-ray imaging, and cardiac echocardiography. Antiarrhythmic agents were discontinued over 5 half-life periods before the procedure. Holter recordings were collected before and after admission, and wireless telemetry monitors were used to assess arrhythmia burden for at least 48 hours after admission and throughout the inpatient period.

TABLE 1 Baseline patient characteristics

Variable	CF (n = 101)	EZF (n = 100)	CZF (n = 99)	Total (n = 300)	P value
Age, y, mean (SD)	46.9 (16.2)	46.7 (16)	37.8 (14.5)	45.3 (15.4)	<0.001
Weight, kg, mean (SD)	65 (6)	64 (6.2)	60.5 (4.8)	63.8 (11.7)	0.816
Height, cm, mean (SD)	167.6 (6.2)	166.9 (6.1)	162.4 (24.3)	164.9 (8.3)	0.327
Male sex	45 (44.1)	40 (40)	39 (39.6)	118 (39.3)	0.851
BMI, kg/m ² , mean (SD)	23.1 (4.1)	22.9 (4.2)	22.5 (5.2)	23 (7.1)	–
3D mapping, %	100	100	100	100	–
EPS only	0	4 (4)	3 (3)	7 (2.3)	–
Ablation	101 (100)	96 (96)	96 (96)	293 (97.7)	0.104
AVNRT	63 (62.3)	66 (56)	67 (67)	196 (65.3)	0.205
AVRT	37 (37)	34 (34)	33 (33)	104 (34.6)	0.363
Left free wall	16 (16)	19 (19)	18 (18)	53 (17.6)	0.864
Right free wall	9 (9)	7 (7)	8 (8)	24 (8)	0.882
Posteroseptal	11 (11)	6 (6)	6 (6)	23 (7.6)	0.328
Parahisian	1 (1)	2 (2)	1 (1)	4 (1.3)	0.848

Data are presented as number (percentage) unless otherwise indicated.

Abbreviations: 3D, 3-dimensional; AVNRT, atrioventricular nodal reentrant tachycardia; AVRT, atrioventricular reentrant tachycardia; BMI, body mass index; CF, conventional fluoroscopy approach; CZF, CARTO zero-fluoroscopy mapping system; EZF, EnSite zero-fluoroscopy mapping system; EPS, electrophysiological study

Ablation procedures All surgical procedures included conscious sedation with local anesthesia, and our standard electrophysiology protocol was followed.

We used a low-magnetic-field CARTO3 navigation system (Biosense Webster Inc., Irvine, California, United States) alone in the CZF group, which generates a 3D image by moving the catheter along the cavity surface to record the activation time of the local endocardium for mapping and recording of the location points.

The EnSite NavX system (EnSite, St. Jude Medical Inc., St. Paul, Minnesota, United States) was used in the EZF group, which generates 3D images of the catheter, based on a low-current electric field generated by 3 pairs of nominally orthogonal skin patches on the X, Y, and Z axes.

X-ray imaging, CardioLab EP 2000 (GE Medical System, Fairfield, Connecticut, United States) was used in the CF group with or without one of the 3D mapping systems. The ablation catheters were used as usual, including NaviStar, Celsius (Biosense Webster Inc., Diamond Bar, California, United States), IBI, Safire (Abbott Laboratories Ltd., St. Paul, Minnesota, United States), or Triguy (APT Medical Inc., Shenzhen, Guangdong, China).

CARTO zero-fluoroscopy approach The fluoroscopy approach was used in the CZF group. The X-ray machine was in standby mode, and none of the catheterization laboratory staff wore lead apparel during the procedure (unless there was

a crossover to a CF approach). The CARTO system was used for catheter positioning and mapping to visualize the vessels and the heart. A coronary sinus (CS) catheter was used for reference during mapping and ablation.

Catheter insertion All catheters were placed via the femoral vein access, first inserted into the heart through vessels in the right and left anterior oblique views. Usually, the patches were placed more inferiorly, nearly at the level of the xiphoid process in caudal-cranial direction and the catheter embedded with sensors, usually the ablation catheter, was first introduced for model reconstruction when the CARTO system was used alone. The paths of vessels were recorded during catheter insertion. The 3D navigation was used to assess the proper position of the catheters in the vessels, which were rotated gently until they reached the desired position. A typical right intracardiac electrogram was observed. The left heart catheter was placed via the femoral artery. We routinely performed reoptimization after electrophysiology, when the ablation catheter entered the targeted chamber and rechecked the location of important markers such as the His bundle before ablation. All catheters were introduced into the right atrium via the femoral vein. The first catheter was placed at the right ventricular apex, the second at the His bundle, and the third in the CS, as shown in Supplementary material, *Figure S1*.

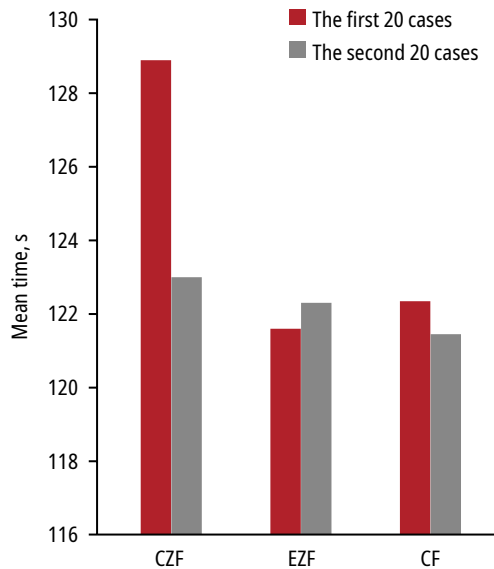


FIGURE 1 Diagram showing that the time of insertion in the coronary sinus via the femoral vein did not differ between the 3 study groups. *P* value was <0.05 for the comparison of the time taken when using the same approach during the first set of 20 cases and the second set of 20 cases.

Abbreviations: see [TABLE 1](#)

The measurement of the insertion time started when the catheter accessed the femoral vein, as shown in [FIGURE 1](#).

Mapping and ablation The electrophysiological study was diagnosed definitively using a D-curve catheter (Celsius). The right atrium was reconstructed and the tricuspid annulus was labeled with several points. Ablation endpoint results were freedom from spontaneous arrhythmia, and arrhythmia after multiple-site programmed arterial stimulation (S_1 - S_1 \ S_1 - S_2 \ S_1 - S_2 - S_3) and/or after intravenous infusion of adrenaline and ramp pacing.

EnSite zero-fluoroscopy approach Fluoroscopy was not used, X-ray imaging was set in standby mode, and staff did not wear lead apparel during the procedure. Under the guidance of the EnSite system with external skin patches set as the reference, all catheters were used via the femoral vein access for right-sided heart ablation and via the femoral artery access for left-sided heart ablation, as shown in the snap technique in Supplementary material, *Figure S2*. Initial optimization and respiratory compensation were performed. All catheters were then placed and arrhythmias ablated.

Conventional fluoroscopy approach All steps for radiofrequency ablation in the CF group, including catheter insertion via vessels, placement in the heart, electrophysiological study, mapping, and ablation were guided by X-ray plus the EnSite or CARTO 3D mapping system.

Data collection All procedures were performed by experienced operators, and the average number of ablation cases per year per operator was calculated using the records from 2 years prior to the study. All preoperative, operative, and follow-up data were gathered and stored in paper spreadsheets by independent technicians. The following data were collected: the names of the operators, assistants, and technicians; type of study; clinical and demographic variables (age, sex, body weight, height, arrhythmia type, underlying heart disease, primary or redo procedure); and procedure-related variables (procedure date, assigned group, procedure time, fluoroscopy time, number of lesions, total ablation time, immediate success rate, complications, catheter type, time from the first puncture of the skin to reach the right atrium, and time required for electrode placement in the CS and in the right ventricle, and recurrences during follow-up). All complications were validated based on our original medical records and divided into 2 types, mild or severe. The following complications were labeled as mild: large peripheral hematoma, vessel rupture, peripheral pseudoaneurysm, arteriovenous fistula, first-degree atrioventricular block, right bundle branch block, and/or left bundle branch block. The following complications were labeled as severe: sinus node injury, second or third-degree atrioventricular block, severe valve injury, cardiac rupture, cardiac tamponade, myocardial infarction, stroke, and any injury requiring thoracic surgery. Procedure time was defined as the duration from the first puncture of the skin to the complete removal of the catheter. The CF time was the total duration of the X-ray used in the procedure. All patients were monitored by continuous wireless telemetry for at least 24 hours before discharge.

Follow-up After the ablation procedure, the patients were followed at 1, 3, and 12 months post discharge by an independent technician. Echocardiography, 12-lead electrocardiogram, and 24-hour Holter monitoring were included in the assessment.

Statistical analysis Continuous data were expressed as mean with SD, or as median with interquartile range, and categorical data were expressed as numbers with percentages. The analysis of variance (ANOVA) and the Fisher exact test were used to compare the differences between the groups. Nonparametric statistics were applied when the data were not normally distributed. All analyses were performed using Statistical Package for the Social Sciences Graphpad Prism 8 (GraphPad Software, San Diego, California, United States). A *P* value of less than 0.05 was considered statistically significant.

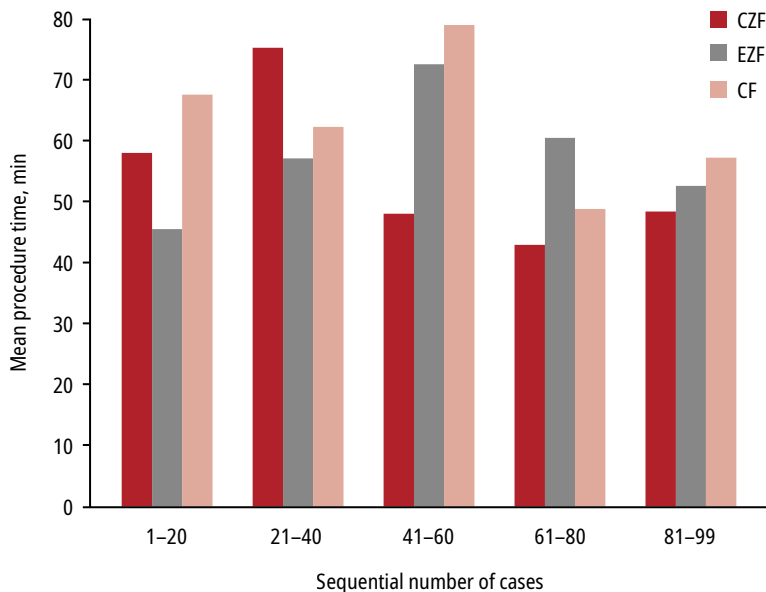


FIGURE 2 Diagram showing the learning curve in the zero-fluoroscopy (ZF) approach during the ablation of supraventricular tachycardia
Abbreviations: SVT, supraventricular tachycardia; see TABLE 1

RESULTS Baseline characteristics The baseline characteristics of the patients are presented in TABLE 1. There were 101, 100, and 99 patients in the CF, EZF, and CZF groups, respectively. There were no differences among the groups in sex or the number of redo cases. There was a difference in the mean age of the CZF group ($P < 0.01$). The mean (SD) follow-up period was 16 (2.3) months.

Operator experience The CZF approach procedures were performed by 2 operators who had experience with the EZF and CF approaches. The 2 operators and an expert in conventional fluoroscopy, but not in ZF, performed the EZF approach. The CF approach was performed by 4 experienced operators. The average number of ablations performed per year in the 2 years prior to this study was 120.

Three-dimensional mapping All 100 cases in the CF group were mapped using the EnSite or the CARTO mapping systems. All 100 cases in the EZF group were mapped using the EnSite system, and the 99 cases in the CZF group were mapped using the CARTO mapping system.

Catheter placement Right ventricle We compared the average time required for the electrode placement in the right ventricle via a femoral vein in the CF, EZF, and CZF groups, and compared the average time in the initial 20 patients and the following 20 patients. There were no differences between the 3 groups. The mean (SD) time was 21 (1.8), 22.4 (1.7), and 26.6 (2.3) seconds in the CF, EZF, and CZF group, respectively.

Coronary sinus No operator in the ECF group had previous experience with the insertion of the CS electrode via the femoral vein with CARTO before this study.

As shown in FIGURE 1, there were no differences in the EZF, CZF, and CF approaches in the first or second set of 20 patients ($P > 0.05$). We compared the average time required for the placement of the electrode in the CS via the femoral vein. The efficiency of CS electrode insertion using the ZF approaches (EZF and CZF) was not inferior to the CF approach.

Electrophysiology study For the electrophysiology study, both ZF approaches were as efficient and safe as the CF approach. Both ZF groups had an immediate success rate of 99% with no severe complications. The efficiency of CZF approach and EZF approach was similar.

Ablation procedure Fluoroscopy time In the CF group, median (interquartile range) fluoroscopic time was 3.6 (2.1–8.8) minutes in patients with SVT. A total of 99 patients (99%) in the CZF group (1 patient was moved to the CF group because of venous malformation, as shown in Supplementary material, Figure S3), and 99 patients (99%) in the EZF group completed the procedure without fluoroscopy.

Procedure time There were no differences in the average procedure time in the CZF, EZF, and CF groups when all cases were considered, as shown in FIGURE 2. The mean (SD) procedure time was 65.4 (27.5), 66.5 (24.2), and 60.99 (34.7) minutes in the CZF, EZF, and the CF groups, respectively ($P > 0.05$). The CZF approach was as efficient as the CF or EZF approach in terms of the time required for SVT ablation (TABLE 2).

Success, recurrence, and complication rates In the CZF approach, 99 out of 100 patients completed the procedure without fluoroscopy. One patient with a venous malformation was switched to the CF approach. After electrophysiology study with the ZF approach, the average fluoroscopy time in the switched case was 1.52 minutes.

All 3 approaches had a similar immediate success rate (99% for each). There was no recurrence in the CZF and ECF group with 1% recurrence in the CF group. A severe complication of pseudoaneurysm was seen in only 1 patient in the ECF group. There was no large hematoma, vessel rupture, hemothorax, new-onset left bundle branch block, myocardial infarction, stroke, or severe valve injury in any group (TABLE 3).

Learning curve in the zero-fluoroscopy approach The average procedure time for SVT ablation in the first 50 cases of CZF was similar to the next 50 cases.

TABLE 2 Comparison of the efficiency and safety of ablation in the study groups

Variable	CZF (n = 100)	EZF (n = 100)	CF (n = 100)
Procedure time, min, mean (SD)	65.4 (27.5)	66.5 (24.2)	61.8 (36.2)
Ablation time, s, mean (SD) ^a	320.4 (27.1)	306.5 (30.5)	341.7 (33.3)
Complete ZF ^b	99 (99)	100 (100)	NA
Give up ^c	0	1 (1)	0
Immediate success	99 (99)	99 (99)	100 (100)
Recurrence	0	0	1(1)

Data are presented as number (percentage) unless otherwise indicated.

a Tentative ablations of less than 10 seconds were not included.

b The patients who switched to the CF approach were excluded from the analysis.

c Some patients refused to receive ablation owing to the possible risk after electrophysiology study.

Abbreviations: NA, not applicable; others, see TABLE 1

TABLE 3 Complications in the study groups

Complication	CZF (n = 100)	EZF (n = 100)	CF (n = 100)	Total (n = 300)
Mild-moderate	1	1	0	2
Pseudoaneurysm	1	1	0	2
Arterial-venous fistula	0	0	0	0
Pneumothorax	0	0	0	0
Hemothorax	0	0	0	0
Cardiac tamponade	0	0	0	0
Severe	0	0	0	0
II–III degree of AVB	0	0	0	0
Thoracic surgery	0	0	0	0
Total	1	1	0	2

Data are presented as the number of patients in whom particular complications occurred.

Abbreviations: AVB, atrial ventricular block; others, see TABLE 1

DISCUSSION Fluoroscopy and zero-fluoroscopy

There were no differences in the rates of immediate success, complications, or recurrences between the 3 groups. A ZF approach was attempted during all procedures, and an electro-anatomical mapping made it possible to avoid fluoroscopy during ZF, EZF, and CZF. Fluoroscopy was used only in 1 patient in the CZF group to guide the catheter to the vessels. The total procedure time, fluoroscopy time, and radiofrequency time were similar. The position of important anatomical structures, such as the His bundle, should be rechecked if the ablation site is in a high-risk area. With EZF respiration, compensation should be repeated when the patient exhibits apparent changes in respiratory amplitude.

Catheter insertions and tracking The efficiency of catheter insertion by both ZF approaches (CZF and EZF) was equivalent to that of conventional fluoroscopy. Due to lack of tacking

during the passage through the vessels, the catheter was impeded in the vessel in 1 patient in the CZF group. The physician used tactile sensation to amend this issue but the pass-through failed. Therefore, fluoroscopy was used to guide the catheter. We believe that the new CZF approach is an option for operators who prefer using CARTO and have concerns with regard to fluoroscopy procedures, especially in high-risk situations such as pregnancy.

Although the ZF approach is as safe as the conventional approach, we still emphasize that all catheters should be inserted gently with only 2 fingers, the thumb and the index finger slightly holding the catheter, and with small movements, so that the resistance of the vessel to the catheter is evident and can be felt by the operator promptly if it is impeded at some point.

CARTO and EnSite mapping A ZF approach to the right atrium using the CARTO system is

feasible in most procedures.²¹⁻²⁵ With the modified CARTO vessel tracking image quality, arrhythmia ablation has similar results as with a ZF approach using the EnSite system.

Study limitations This was a single-center study with a small sample size. The selection was nonrandomized and based on operator preference. Patients in the CARTO group were younger than those in other groups. The exclusion of 1 patient after invasive electrophysiology is also a limitation.

SUPPLEMENTARY MATERIAL

Supplementary material is available at www.mp.pl/kardiologiapolska.

ARTICLE INFORMATION

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CONFLICT OF INTEREST None declared.

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