

Zero-fluoroscopy strategy for catheter ablation of paroxysmal supraventricular arrhythmias: single-center study

Fluoroscopy-free catheter ablation for PSVTs: is there a learning curve effect?

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Abstract

Introduction: Data regarding the comparison of the minimal/zero fluoroscopy and the fluoroscopy-assisted approach in the treatment of paroxysmal supraventricular tachycardias (PSVTs) are limited, furthermore the impact of electroanatomic mapping systems (EAMSs) on the procedural time are controversial.

Methods: Between September 2017 and September 2018, 98 patients undergoing electrophysiologic study due to PSVT, performed by a single operator with no previous experience with the use of EAMS were included in our retrospective single-center study. 36 patients underwent an EAMS-guided (Ensite NavX/CARTO 3) procedure (Group 1), in 62 patients the procedure was performed conventionally (Group 2).

Results: In Group 1, 91.7% of the procedures were performed fluoroless. The success rate was 100% in both groups without any complication. The use of EAMS reduced radiation time (0 [0-0] vs 2.2 [0.9-3.6] min, $p<0.0001$), with longer procedure time (70.0 [55.0-99.0] vs 52.5 [40.0-76.3] min, $p=0.035$). There was no difference either in the number of RF applications (7.5 [2-13.8] vs. 7.5 [0-14.0], or in the ablation time (224.5 [78.3-394.3] vs 218 [0.0-406.5] s, $p=0.80$ each]. The analysis of the procedural time of cases with the EnSite NavX-assisted AVNRT ablations showed a trend of decreasing duration ($r=0.048$, $p=0.32$).

Conclusions: The EAMS-guided approach for the treatment of PSVTs is a feasible and safe method that reduces fluoroscopy time without influencing the number of applications, ablation time, success or complication rates. Due to the presumable learning curve effect, procedure time could be longer in the initial period although this difference disappears with the increasing experience of operators.

Introduction

Supported by its low complication and a high success rate catheter ablation is the treatment of choice for paroxysmal supraventricular tachyarrhythmias. (1) These procedures are conventionally performed fluoroscopy-guided, exposing both patients and medical staff to a significant and potentially dangerous level of ionizing radiation. Prolonged radiation exposure is known to increase the incidence of dermatitis, cataracts, and congenital defects, as well as it can increase the risk of cancer in the exposed individuals. (2–6)

The dose of radiation required during the electrophysiologic procedures can be progressively reduced by using three-dimensional electroanatomic mapping systems (EAMSs). (7) Recently the 3D mapping system guided minimally fluoroscopic approach (MFA) has become widespread, particularly in pediatric patients. (8–11) Feasibility and safety of this approach were demonstrated in a multicenter randomized trial and a multicenter prospective study as well as in multiple retrospective analyzes. (2,3, 9–16, 17–24) However, data regarding the comparison of the MFA and the conventional fluoroscopy-assisted approach in the treatment of paroxysmal supraventricular tachycardias (PSVTs) are limited, furthermore data regarding the impact of EAMS on the procedural time are controversial.

The aim of our study was to compare the conventionally performed and the EAMS-guided MFA procedures in the treatment of paroxysmal SVT.

Methods

Study design and enrolled patients

We retrospectively studied data of patients who underwent electrophysiology studies (EPS) due to paroxysmal SVTs with or without RFA for SVT performed by a single operator at our clinic between September 2017 and September 2018. We compared EAMS-guided (Group 1, n=36) with conventional fluoroscopy-guided (Group 2, n=62) procedures. In Group 1 EnSite NavX (Abbott, IL, USA; 33/36 patients) or CARTO 3 (Biosense Webster, CA, USA; 3/36 patients) systems were used. From September of 2017 we started systematically to apply MFA when using EAMS for PSVTs. There was no previous experience with MFA-guided SVT ablation in our lab, and thus data collection included the learning curve as well. Furthermore, the first operator had no former experience with the use of EAMS.

Patients with a documented PSVT or a history of PSVT were included. All patients underwent a comprehensive invasive electrophysiologic study to confirm the type and nature of their arrhythmias. Patients with implanted devices and procedures with the use of intracardiac echocardiography (ICE) were excluded. Antiarrhythmic drugs were discontinued for an interval of at least 5 half-lives. Written informed consent was obtained from all patients before the operations. The study was in accordance with the declaration of Helsinki and approved by the institutional ethical board.

Procedure protocol

After local anesthesia, mapping catheters including a decapolar catheter for coronary sinus and the ablation catheter were introduced from right femoral venous approach.

In Group 1, the Ensite NavX or CARTO 3 mapping system was used for cardiac reconstruction. Using Ensite NavX system electroanatomical map was performed by decapolar catheter (Via Cath 10, Biotronik, Germany). In CARTO 3 assisted cases the ablation catheter (Navistar, Biosense Webster) was applied for anatomical reconstruction.

Any difficulties in catheter advancement were dealt by a pullback, slight rotation with a small bend, and followed by an advancement attempt of the catheter. The corresponding anatomical features of the heart, including the inferior vena cava, superior vena cava, tricuspid valve annulus and especially the His region were carefully marked. (Figure 1.) During MFA, in case of suspected complication or difficulties of catheter movement, fluoroscopy use was left to the decision of the operator.

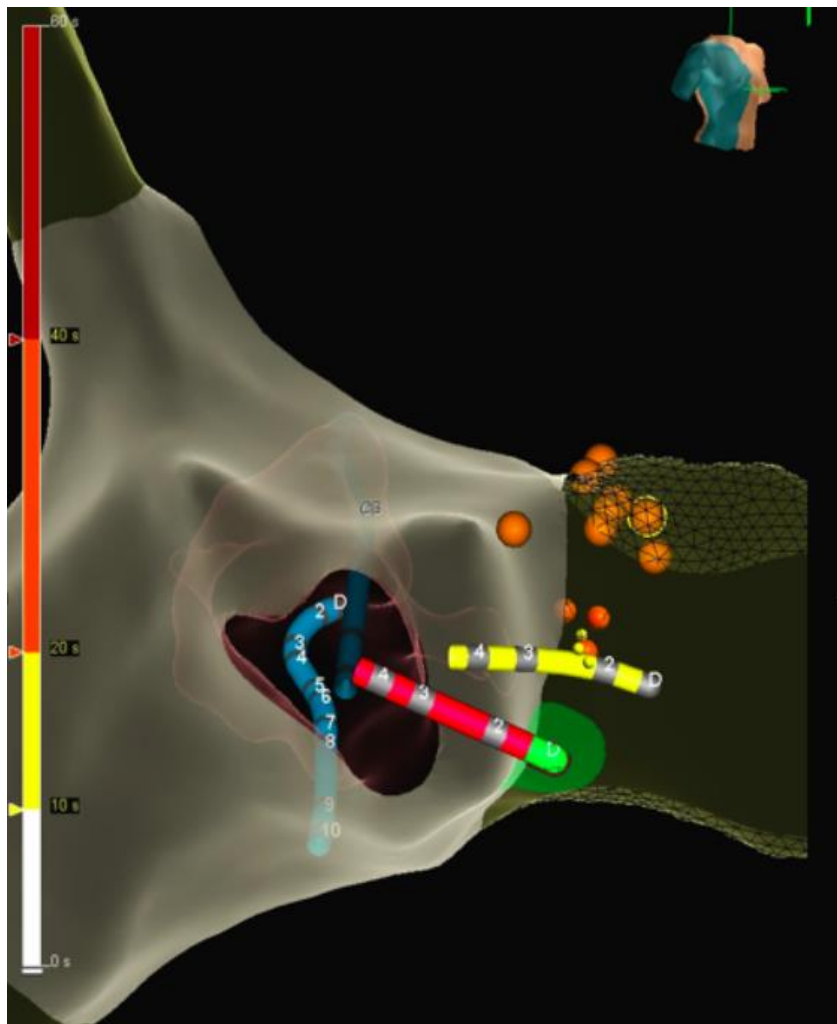


Figure 1. Electroanatomical map performed by Ensite NavX system before slow pathway ablation for AV-nodal re-entrant tachycardia (right anterior oblique view). The relevant part of the right atrium was mapped. Decapolar catheter (blue) is placed in the coronary sinus. The orange tags represent the His region. There is a quadripolar catheter in septal position in the right ventricle (yellow) during mapping in the slow pathway region with the ablation catheter (red).

After positioning all diagnostic catheters, EPS was performed using standard protocols, followed by ablation when appropriate. In cases with non-inducible tachycardia at baseline, the patient received intravenous isoproterenol. In all cases where ablation was performed, the assessment was repeatedly performed, both with and without isoproterenol. All patients underwent transthoracic echocardiogram immediately after the procedure in the EP lab to rule out pericardial effusion and structural damage.

Criteria for successful ablation

The procedural success of AV nodal reentrant tachycardia (AVNRT) ablation was defined if the arrhythmia could not be induced after a 20 min observation period and if there were no observations of >1 echo beats. Ablation of AV reentrant tachycardia (AVRT) was considered to be successful if there was no evidence of either an accessory pathway or an inducible tachycardia after at least 20 minutes of waiting period. In cases of atrial tachycardia (AT), ablation was successful if the arrhythmia could not be induced 20 minutes after the last ablation.

Follow-up

After the ablation procedure, the patients were hospitalized overnight with telemetry monitoring. The patients were discharged 24 h after the procedure. Data on symptom recurrence, ECGs and 24-hour Holter monitoring were used to assess the success rate of the ablation during the follow-up. All patients were controlled as an outpatient between 1 to 3 months and 1 year following their procedure.

Statistical analyses

Analyses were performed using SPSS 24 software (SPSS, Inc., Chicago, IL, USA). The distribution pattern of the data was evaluated using the Kolmogorov–Smirnov and Shapiro-Wilk tests. Continuous data were presented as the mean±SD or median (interquartile range, IQR), as appropriate while categorical variables are presented as absolute numbers and percentages. For comparisons, Chi-square test and Mann-Whitney U test was used as appropriate. A p value of < 0.05 was considered statistically significant.

As eligible patients were not randomly assigned to conventional or EAMS-guided MFA procedures, we intended to balance the groups to reduce potential bias associated with treatment selection. For this aim we built a propensity score (PS) matched cohort with a comparable chance for either strategy by adjusting for differences in baseline characteristics. PS was computed by using a logistic regression model for MFA versus conventional groups. Patient characteristics at presentation and clinical factors from the medical history (listed in Table 1.) were used as predictors in calculating propensity score. In the PS-matching procedure we first randomly selected a patient in the MFA group and matched with a patient from the conventional group with the closest estimated PS value. We performed a 1-to-1 matched analysis without replacement.

Results

Baseline characteristics

A total of 98 consecutive cases were analyzed, each patient underwent one procedure. Thirty-six procedures were included in Group 1 (median patient age 55 years (20-82), 38.9% men) and were compared to 62 procedures in Group 2 (median patient age 49 year (19-84), 33.9 % men). Detailed characteristics are depicted in Table 1. In Group 1, 25 AVNRT, 4 AVRT, 3 AT and 4

diagnostic EPS for suspected PSVT were included. Group 2 comprised 37 AVNRT, 5 AVRT, 2 AT and 18 EPS. At the level of individual parameters, no significant difference were found in any of the baseline characteristics or types of procedures performed in the two groups. (Table 1.) However, multiple binary logistic regression analysis identified age, AVNRT indication as well as hypertension as independent determinants associated with the use of MFA procedure ($p < 0.05$, each). Thus a PS matched non-zero fluoroscopy cohort of 36 cases with adjusted baseline characteristics was constructed. (Table 1.)

	Entire cohort			Propensity matched cohort		
	Zero (n=36)	Non-zero (n=62)	p value	Zero (n=36)	Non-zero (n=36)	p value
Clinical characteristics						
<i>Age in years</i>	47.6 ± 17.3	51.7 ± 15.5	0.22	47.6 ± 17.3	50.0 ± 15.8	0.53
<i>Male</i>	14 (38.9 %)	21 (33.9 %)	0.62	14 (38.9%)	14 (38.9%)	1.00
<i>Hypertension</i>	16 (44.4 %)	17 (27.4 %)	0.09	16 (44.4%)	11 (30.6%)	0.22
<i>Coronary artery disease</i>	3 (8.3 %)	1 (1.6 %)	0.14	3 (8.3%)	1 (2.8%)	0.61
<i>Heart failure</i>	2 (5.6%)	2 (3.2%)	0.62	2 (5,6%)	1 (2.8%)	1.00
<i>Diabetes mellitus</i>	1 (2.8 %)	6 (9.7 %)	0.26	1 (2.8%)	1 (2.8%)	1.00
Procedural parameters						
<i>EPS</i>	4 (11.1 %)	18 (29.0 %)	0.40	4 (11.1 %)	8 (22.2 %)	0.21
<i>AVNRT</i>	25 (69.4 %)	37 (59.7 %)	0.33	25 (69.4 %)	22 (61.1 %)	0.46
<i>AVRT</i>	4 (11.1 %)	5 (8.1 %)	0.61	4 (11.1 %)	5 (13.9 %)	1.00
<i>AT</i>	3 (8.3 %)	2 (3.3 %)	0.40	3 (8.3 %)	1 (2.8 %)	0.61
<i>Procedural time (min)</i>	70.0 (55.0 - 99.0)	52.5 (40.0 - 76.3)	0.01	70.0 (55.0 - 99.0)	50.0 (45.0 - 85.3)	0.09
<i>Fluoroscopy time (min)</i>	0.0 (0.0 - 0.0)	2.2 (0.9 - 3.6)	0.00	0.0 (0.0 - 0.0)	2.2 (1.0 - 3.4)	0.00
<i>Number of applications</i>	7.5 (2.0 - 13.8)	7.5 (0.0 - 14.0)	0.80	7.5 (2.0 - 13.8)	8.5 (0.8 - 17.8)	0.29
<i>Ablation time (sec)</i>	224.5 (78.3 - 394.3)	218.0 (0.0 - 406.5)	0.80	224.5 (78.3 - 394.3)	282.0 (27.0 - 553.0)	0.24

Table 1. Clinical characteristics and procedural parameters of the study population.
Values presented as absolute numbers (%) or medians (interquartile ranges)

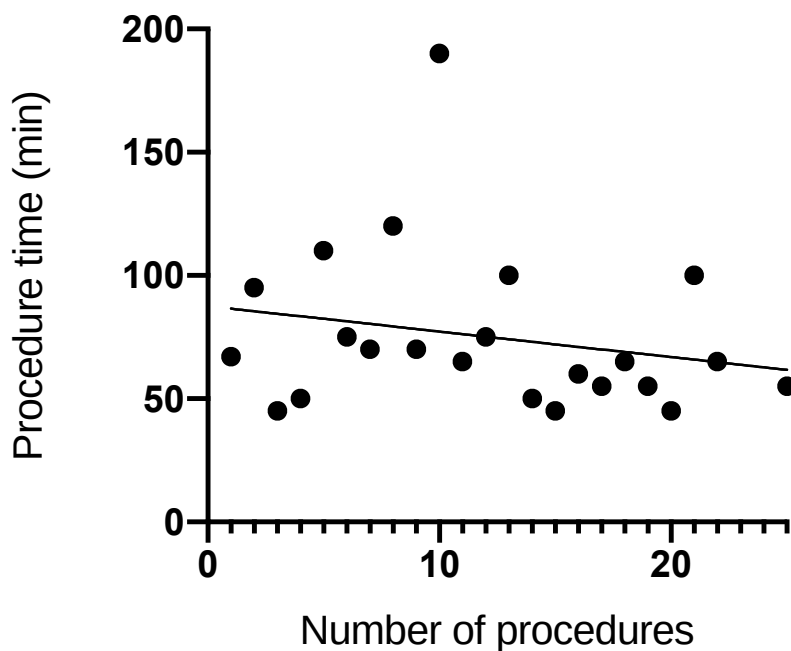
Procedural parameters, complications, procedural and long term success rate

In Group 1 fluoroscopy was used in only 3 patients (3/36, 8.33 %) as well as lead coat apron for radiation protection was worn in only 16 cases (16/36, 44.4 %). A significant reduction of fluoroscopy time in the EAMS-guided group was observed between the groups. No difference was found in the ablation time and the number of RF applications between the two groups. Procedural time was significantly shorter in the fluoroscopy-guided group. These relations remained consistent in the propensity score matched as well as in the entire cohort (Table 1.). Excluding the first 10 EAMS-guided ablation cases to allow for operator learning, the difference in procedural time disappeared (65 [55-100]) vs 62 [48-83] min, $p=0.375$). Analysis of ablation time, procedural time, showed correlation to one to another as well as to the number of ablation points applied ($p<0.01$ each). Fluoroscopy time correlated with the procedural time only in the control group and no correlation was observed between fluoroscopy time and the number of ablation points or with the ablation time in the zero-fluoroscopy group (Table 2.). The analysis of the procedural time of cases with the EnSite NavX system assisted AVNRT ablations showed a non-significant trend of decreasing duration ($r=0.048$, $p=0.32$, Figure 2.).

Table 2. Correlation of procedural parameters. Spearman correlation coefficients of the propensity score matched (n=98, above the diagonal line) and the entire cohort (n=72, below the diagonal line.) **. Correlation is significant at the 0.01 level (2-tailed).

EP Studies Zero fluoroscopy studies Control	Procedural time (min)	Fluoroscopy time (min)	Number of ablation points	Ablation time (sec)
Procedural time (min)		0.033 0.311 0.720**	0.592** 0.447** 0.773**	0.588** 0.446** 0.795**
Fluoroscopy time (min)	0.069 0.311 0.720**		0.344** 0.289 0.688**	0.312** 0.243 0.594**
Number of ablation points	0.650** 0.447** 0.773**	0.299** 0.289 0.668**		0.958** 0.947** 0.956**
Ablation time (sec)	0.644** 0.446** 0.795**	0.264** 0.243 0.594**	0.966** 0.947** 0.956**	

Figure 2. Learning curve effect in patient with AVNRT in Group 1. The analysis of the procedural time of AVNRT ablations cases assisted with the EnSite NavX system showed a non-significant trend of decreasing duration. (r=0.048, p=0.32)



The acute success rate was 100% in both groups without any complications. At follow-up with a median 10.0 (6.8-12.0) months, one single patient with AVNRT in Group 2 had a recurrence of the index arrhythmia and required a repeat procedure. This difference did not reach the level of statistical significance either in the PS matched or in the entire sample (Hazard ratio 0.32, 95% Confidence interval [0.01-8.23], $p=0.49$, and 0.56 [0.02-14.15], $p=0.73$, respectively).

Discussion

In this single-center study involving 98 cases we demonstrated that EAMS-guided zero/minimal fluoroscopy approach is a feasible method for the treatment of PSVTs that reduces radiation time without compromising success rates. However, we found significantly longer procedure time compared to the conventionally fluoroscopy-guided technique, a difference that may diminish with increasing experience.

The impact of using EAMS to minimize radiation during electrophysiologic procedures has been assessed in some earlier works of minimal and zero-fluoroscopy approaches during SVT ablation. However, these studies investigated either only AVNRT (22), or AVRT/AVNRT cases (21) or - besides AVRT/AVNRT/AT - patients with atrial flutter (AFL) were also enrolled (6,13,18,23,26), moreover, some studies included pediatric cases exclusively (21) or together with adults (13,26). Clinical presentations of atrial arrhythmias are heterogeneous. Most cases of PSVT symptoms are suggestive of paroxysmal palpitations with a sudden onset and termination. These findings uncommonly result from flutter, while cases of AVRT, AVNRT and AT is often characterized by paroxysmal episodes of tachycardia. (1) Furthermore, in the cases of isthmus-dependent atrial flutter an ablation strategy aims at a linear line created on the cavotricuspid isthmus contrary to the point-like ablations in cases of AVRT/AVNRT/AT. In

order to reduce the heterogeneity potentially induced by the different ablations strategies, we decided to restrict our analysis to dot-like ablations and thus exclude cavotricuspid isthmus ablation cases.

Medical radiation is the largest man-made source of average annual radiation exposure, representing a mean effective dose of 1.0–3.0 mSv per head per year. (27) Interventional cardiac procedures represent only 12% from all radiological examinations, however, they are responsible for delivering the highest radiation dose. (28) Due to the increasing number and complexity of interventional cardiology procedures, radiation exposure is of a notable concern for not only interventional cardiologists but for patients undergoing interventional cardiology procedures, too. Prolonged radiation exposure is known to increase the incidence of dermatitis, cataracts, and congenital defects, as well as it can increase the risk of cancer in the exposed individuals. (2–6,29) Although this risk can be reduced by applying various forms of radiation protection and the “as low as reasonably achievable” (ALARA) principle, it remains of importance. Furthermore, wearing lead aprons associate with a higher rate of work-related musculoskeletal pain. (30) As recent data show radiation protection is still not optimal in cardiac electrophysiology. (31) The risk of exposure accumulates throughout life and has a major significance in children, young and in pregnancy. (32) Thus the most effective radiation protection remains the use of no fluoroscopy under the procedures.

Previous analyses including 3 prospective and 4 prospective, randomized studies compared procedure times of MFA to fluoroscopy-guided approach in various groups of patients. Most of these studies found no difference between the two groups, though in these series operators had former experience with EAMS use for the treatment of the included arrhythmias except for 1 retrospective analysis. (5,6,13,14,16,18,20–23,25,26) In contrast, in our study where significantly higher procedural times were found, the first operator performing all cases had no

previous experience with the use of EAMS. Analyzed cases with the EnSite NavX system assisted AVNRT ablations, we found a trend of decreasing procedural time with the operator's increasing experience. In addition, after excluding the first 10 EAMS-guided ablation cases to allow for operator learning, the use of EAMS was not associated with an increase in procedural time. These findings are in line with an earlier retrospective analysis involving 184 patients who underwent radiofrequency or cryoablation due to SVT supporting that an important learning curve may be operative in this field especially in cases of operators without preceding experience with the use of EAMS. (13) In a multicenter retrospective analysis, Giaccardi et al reported a tendency of the progressive shortening of the procedural time with increasing experience. (14) Recent data show a definite reduction of dose area product (DPA) and fluoroscopy time shortly after implementation of a MFA in even those operators who are in training, while in a multicenter, prospective study total fluoroscopy time inversely correlated to the number of procedures previously performed by each operator. (16,19)

MFA with EAMS in the cases of various arrhythmias is a feasible and safe method with identical acute and long-term success and complication rates compared to conventional fluoroscopy-based technique. Use of EAMS reduces radiation exposure considerably, as well as decrease the requirement to wear lead aprons thus preventing work-related musculoskeletal pain among electrophysiologists. Due to the presumable learning curve effect, procedure time could be longer in the initial period, although this difference disappears with the increasing experience of the operators performing more and more cases.

Limitations

Our study has several limitations that have to be acknowledged. Due to its single-center retrospective, non-randomized design a limited number of patients were included. Furthermore, types of ablation catheters and differences in the mechanisms of the supraventricular

arrhythmias may have introduced substantial heterogeneity. To compensate for these, we focused our analyses on cases requiring dot like ablation as well as in the analyses of radiation duration over time only data with the EnSite NavX system were included. As we aimed to investigate the impact of EAMS guided MFA, procedures with the use of ICE were also excluded. While transseptal puncture is performed always ICE-guided in our practice, the analysis limited only for right-sided PSVTs. Multicenter studies with longer follow-up duration periods are required to validate the results.

Conclusion

The EAMS-guided zero/minimal fluoroscopy approach for the treatment of PSVTs is a feasible and safe method that reduces fluoroscopy time and does not influence the number of applications, ablation time, success or complication rates even when the operator has no previous experience with the use of EAMSs. Due to the presumable learning curve effect, procedure time could be longer in the initial period although this difference disappears with the increasing experience of operators.

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