Advances in treatment of pediatric arrhythmias

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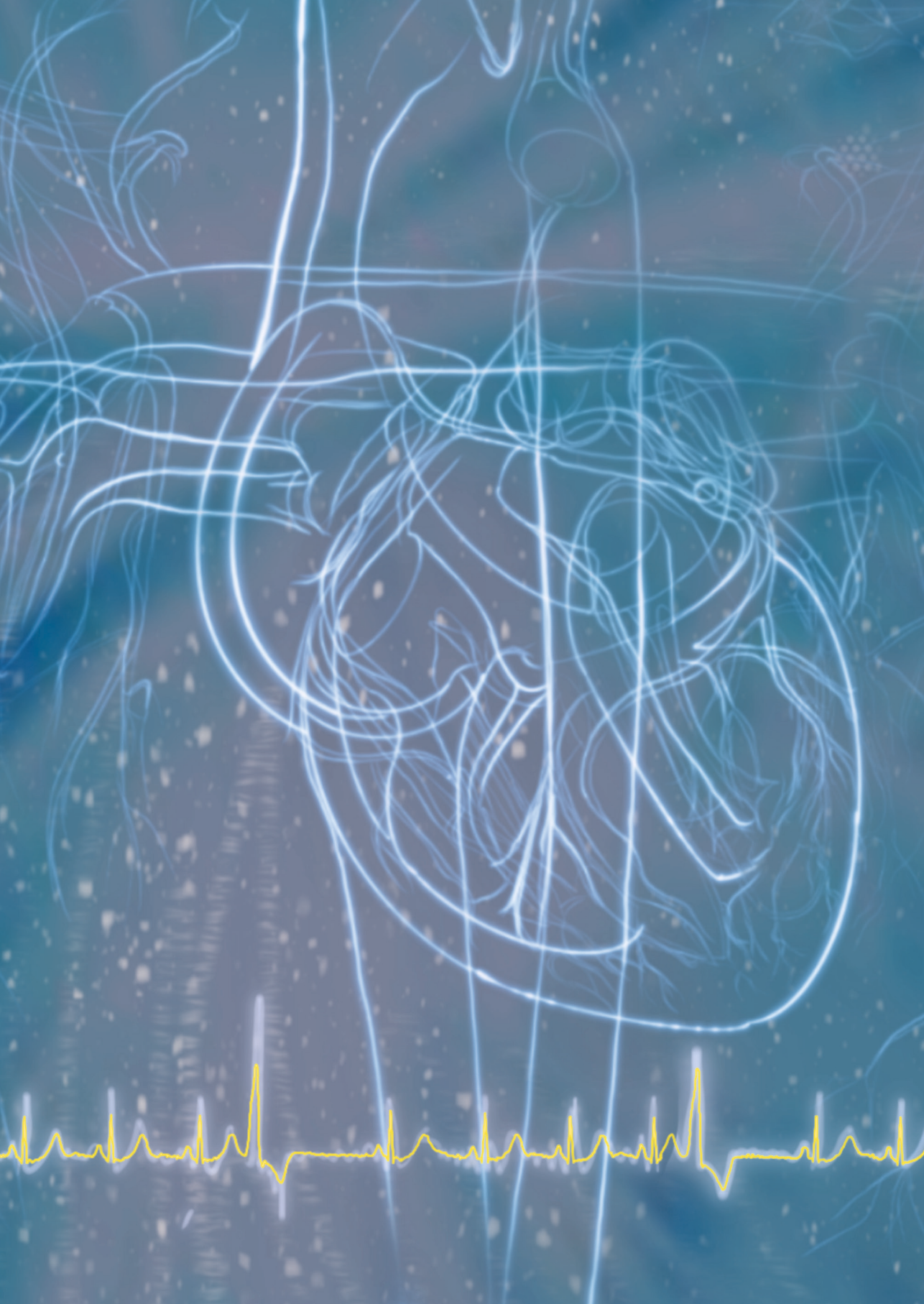
PART I

ABLATION OF SUPRA-VENTRICULAR TACHYCARDIA



2 CHAPTER

The effect of electro-anatomical mapping on the success rate and fluoroscopy time in supra-ventricular tachycardia ablation in children: single center retrospective study

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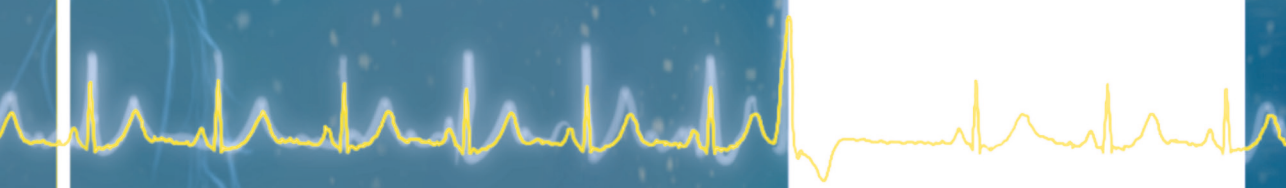

ABSTRACT

Aims

To evaluate the effect of electro-anatomical mapping (EAM) on success rate and fluoroscopy time in ablation of supraventricular tachycardia (SVT) substrates in a large group of children.

Methods

Patients referred from multiple centers in the Netherlands and who received a first ablation for SVT substrates in the Leiden University Medical Center between 2014-2020, were included in this retrospective cohort study. They were divided in procedures in patients with fluoroscopy; and procedures in patients using EAM.

Results

Outcomes of ablation of 373 electro-anatomical substrates were analysed. Acute success rate in the fluoro-group (n=170) was 95.9% compared to 94.5% in the EAM-group (n=181) (p=0.539); recurrence rate was 6.1% in the fluoro-group and 6.4% in the EAM-group (p=0.911) after a 12-months follow up. Redo-ablations were performed in 12 cases in the fluoro-group and 10 cases in the EAM-group, with a success rate of 83.3% vs 80.0%, resulting in an overall success rate of 95.9% in the fluoro-group and 92.8% in the EAM-group (p=0.216) after 12-months. Fluoroscopy time and dose area product decreased significantly from 16.00 ± 17.75 minutes (median ± interquartile range) to 2.00 ± 3.00 minutes (p=0.000), and 210.5 μGym^2 ± 249.3 to 32.9 μGym^2 ± 78.6 (p=0.000) respectively. In the fluoro-group, 4 complications occurred (2.0%) and in the EAM-group no complications occurred.

Conclusions

These results demonstrate that ablations of SVT substrates in children remain a highly effective and safe treatment after the introduction of EAM as a standard of care, while significantly reducing fluoroscopy time and dose area product

INTRODUCTION

Over the last decades catheter ablation for the treatment of supraventricular tachycardia (SVT) has been reported to be a safe and effective therapy in children with a high success rate and low complication rate.[1, 2] Catheter ablation is currently considered as an elective treatment option in children with SVT as young as 5 years of age and in those patients with asymptomatic pre-excitation in case of short AP anterograde refractory periods.[3] Data on safety and efficacy in the first large multicenter registries by the North American Pediatric Electrophysiology Society were limited to procedures using radiofrequency (RF) catheters and fluoroscopic imaging.[2, 4] Concerns that remained were the relatively long radiation exposure associated with increased risk of developing malignancies later in life and the risk -albeit small- of atrioventricular block.[5-7]

Technology has advanced since that time with the most relevant changes being the standard use of three dimensional electro-anatomical mapping (EAM) systems to reduce or even avoid fluoroscopy, and the use of cryo-energy for slow pathway modification and ablation of septal accessory pathways to reduce the risk of atrioventricular block.[1, 3, 8] Although several studies have reported the results of paediatric catheter ablations for SVT using EAM systems, there are few studies that compare these procedures with those using only fluoroscopic imaging and standard electrophysiology recordings.[8-11]

The aim of this study is to compare the safety and efficacy of RF and cryoablation performed in a large group of children, in a single center by the same operators, before and after routine use of EAM systems.

MATERIALS AND METHODS

This single-centre study evaluated all paediatric patients (0-18 years of age) referred for catheter ablation of asymptomatic pre-excitation and/or SVT from January 2014 up until December 2020 at Leiden University Medical Centre (LUMC) and their consecutive redo ablations. An official waiver of ethical approval was granted from the local ethical committee.

Patients were divided into two groups based on the year of the ablation: a group of patients who received a first ablation from 2014 till 2016 ablation and were performed with fluoroscopy, and a second group of patients who received a first ablation from 2018 till 2020 performed with EAM. The year 2017 was a transition year in which the use of EAM was introduced as a standard of care, therefore first ablations performed in 2017 were excluded. Patients in which only an electrophysiology study was performed without ablation, either because of non-inducibility of the tachycardia or in case of an unacceptable risk for damage of the AV-node in asymptomatic patients, were also excluded.

For all patients, baseline characteristics like age, sex, weight, congenital heart disease, symptoms and medication were collected. Furthermore, information on procedural outcomes, fluoroscopy time, dose area product and procedure time was collected to evaluate the result of the procedure, together with the 12 months follow-up data.

The procedure

Depending on the age of the patient, either general anaesthesia (< 16 years) or local anaesthesia with sedation was used (≥ 16 years). At the beginning of a standard procedure, two 6- and one 7-Fr sheath were inserted into the right femoral vein. Next, two quadripolar diagnostic catheters were positioned in the right ventricle and at the His bundle. A decapolar catheter was inserted into the coronary sinus. A standard electrophysiology study was performed to identify arrhythmia mechanism and target site of ablation, using standard burst pacing or extra stimulation pacing manoeuvres and standard atrioventricular (AV) ring mapping techniques. When needed, isoprenaline infusion (1–5 µg/min) was used to induce tachycardia. Following this, detailed mapping and substrate localization was performed using fluoroscopy only in the first group or using the 3D EAM system in the second group (Ensite Velocity System, St. Jude Medical, St. Paul, MN, USA, or CARTO; Biosense Webster Inc, Waterloo, Belgium). In case of a left sided pathway a transseptal puncture was performed guided by fluoroscopy and intra-cardiac echocardiography or trans-oesophageal echocardiography.

Based on substrate characteristics it was decided whether to use cryo- or radiofrequency (RF) energy; cryo-energy was typically used in AVNRT cases and in para-Hissian accessory pathways. RF ablations were performed using 7-Fr steerable RF catheter (BIOTRONIK SE & CO, KG, Berlin, Germany) in combination with the Ensite Velocity System; or, in case the CARTO system was used, mapping and ablation were performed using a 3.5mm irrigated-tip catheter (NaviStar Thermocool, Smarttouch, Biosense Webster Inc., CA, USA). During RF energy applications had a target of 30-50 W and 60 °C for a maximum of 60 seconds. The decision for an irrigated-tip catheter was made by the physician based on substrate characteristics and impedance during RF ablation. Cryoablations were performed using 7-Fr steerable catheter with a 6-mm-tip (Medtronic, Minneapolis, MN, USA), in combination with the Ensite Velocity System. During cryo energy applications had a target of -70 °C for a maximum of 240 seconds. When successful ablation was achieved, there was a waiting period of at least 30 minutes to test for possible recurrences using pacing manoeuvres, with isoprenaline and adenosine if applicable. Procedure time was measured from the moment the patient entered the catheter laboratory till they left the catheter laboratory.

Success rate

Immediate success was defined as: 1) retrograde and/or antegrade block in case of an accessory pathway; 2) maximum of 1 echobeat and non-inducibility of the tachycardia after slow-pathway ablation or modification; 3) non-inducibility of the tachycardia after ablation of a focal AT atrial focus; 4) a confirmed block line and non-inducibility after ablation of

an atrial flutter. Recurrence was defined as a documented recurrence of pre-excitation or tachycardia, or recurrence of symptoms requiring (re)start of medication. Regular follow-up consisted of an outpatient visit at our own center 3-6 months after the ablation including a 12-lead ECG, if indicated additional ECG diagnostics (Holter registration, event recording, smart watch ECG recording) and strict instruction to get in contact in case of recurrence of symptoms. Overall success is defined as the combined success of first ablations and redo ablations within 12 months.

Statistical analysis

Statistical analysis was performed using the IBM SPSS software version 25. Continuous data that was normally distributed was analysed using an independent t-test and is always presented as mean ± standard deviation. Continuous data that was not normally distributed was analysed using a Mann-Whitney U test and is presented as median ± interquartile range. To compare the categorical data between groups, Chi-square test or Fisher's exact test were performed. Categorical data is always presented as absolute count and/or percentage. A p-value of < 0.05 was considered significant.

RESULTS

Patient demographic

In the study period, 403 patients underwent a total of 425 electrophysiology procedures for asymptomatic pre-excitation or SVT. Patients in which only an EP study was performed, and no ablation energy was used, were excluded (n= 52). The cohort of patients that was included (n= 351) was divided into two groups. The fluoro-group (170 patients) consists of 182 procedures in 2014, 2015 and 2016. The EAM-group (181 patients) contains 191 procedures in 2018, 2019 and 2020.

The baseline characteristics of the cohort are presented in Table 1. Overall, the groups were similar at baseline; patients in the EAM-group were slightly older with a mean of 14.5 years vs 14.0 years (p=0.041), and medication use prior to ablation was higher in the fluoro-group (50% vs 37 %, p=.004). There were more males than females in both groups but no differences between the two groups in male – female ratio. Accessory pathways formed the largest group of substrates with 143 substrates in males and 70 in females (including redo-ablations in 9 patients). For other substrates we found a more equal distribution in males and females. Indication for ablation were based on symptoms in 90% in both groups or asymptomatic pre-excitation.

Procedural outcomes

In general, an acute success rate of first ablations of 95.2% was observed in the total cohort of patients with 95.9% in the fluoro-group and 94.5% in the EAM-group (p=.539) as presented in Table 2. Ablations of AVNRT had an acute success rate of 96.4% in the fluoro-group and 100% in the EAM-group (p=.219), ablations of accessory pathways 96.1% in the

fluoro-group vs 91.2% in the EAM-group (p=.152) and ablations of AT 88.9% in the fluoro-group vs 92.3% in the EAM-group (p=1.000).

Table 1: Baseline patient characteristics of the procedures in the fluoro-group and the EAM-group

	The fluoro-group (n=182)	**The EAM-group (n=191)**	**P-value**
Age (years) Median ± interquartile range	14.08 ± 4.87	14.58 ± 3.83	.041
Sex (n)	Male: 112 (61.5%)	Male: 117 (61.3%)	.955
Weight (kg) mean ± SD	51.85 ± 17.75	55.21 ± 15.93	.055
Congenital heart disease (n)	17	9	.079
ASD s/p surgical closure	-	1	
Tetralogy of Fallot/DORV	2	-	
ccTGA	1	-	
M. Ebstein	10	3	
Univentricular heart, s/p Fontan-type procedure	1	-	
Left heart obstructive lesions			
Left heart obstructive lesions s/p surgery	1	2	
CHD prior repair	2	2	
	-	1	
Any symptoms (n)	166 (91.2%)	171 (89.5%)	.583
Palpitations	161	160	
Syncope	12	11	
Resuscitated cardiac arrest	1	2	
Shortness of breath	23	11	
Dizziness	39	52	
Any medication (n)	91 (50.0%)	67 (35.1%)	.004
Beta-blocker	18	10	
Class IC	17	6	
Sotalol	60	46	
Amiodaron	2	1	
Calcium antagonist	1	7	
Digoxin	-	1	
Ivabradine	-	1	

The overall recurrence rate within 12 months after the first procedure was 6.1% in the fluoro-group and 6.4% in the EAM-group (Table 2). Redo procedures were not performed in all patients with a failed first ablation or a recurrence of the tachycardia, depending on the location of the electro-anatomical substrate and clinical burden of the tachycardia. In the patients who did receive a re-do procedure, the success-rate was 83% in the fluoro-group and 80% in the EAM-group. This results in overall success rate of 95.9% in the fluoro-group and 92.8% in the EAM-group (p=0.216) with an overall total of 94.3%. Ablations of AVNRT had an overall success rate of 98.2% in the fluoro-group and 93.7% in the EAM-group (p=.369), accessory pathways 95.1% in the fluoro-group vs 91.2% in the EAM-group (p=.390) and AT

88.9% in the EAM-group vs 92.3% in the EAM-group (p=1.000). The overall success rate of AFLs was 100% in both groups with no recurrences.

The procedure time was not reduced statistically, in the EAM group the procedure time was 179.00 minutes (interquartile range ± 60.00) vs of a mean of 184.50 minutes (interquartile range ± 81.50) in the fluoro-group, as is shown in Table 3. However, the fluoroscopy time differed significantly between the two groups, with a median of 16.00 minutes (interquartile range ± 17.75) in the fluoro-group and 2.00 minutes (interquartile range ± 3.00) in the EAM-group (p=.000). In accordance, the dose area product was significantly reduced from a median of 210,5 µGym^2 (interquartile range ± 249,3) in the fluoro-group to 32,9 µGym^2 (interquartile range ± 78,6) in the EAM-group (p=.000). In 24 substrates in the EAM-group no fluoroscopy was used at all.

Table 2: Procedural outcomes, acute success rate was calculated based on all performed first ablations. Recurrence data was calculated based on the first ablations that were successful.

	The fluoro-group	The EAM-group	Total	p-value
Acute success first ablations	163/170 (95.9%)	171/181 (94.5%)	334/351 (95.2%)	.539
AVNRT	54/56 (96.4%)	63/63 (100.0%)	117/119 (98.3%)	.219
Accessory pathway	98/102 (96.1%)	93/102 (91.2%)	191/204 (93.6%)	.152
AT	8/9 (88.9%)	12/13 (92.3%)	20/22 (90.9%)	1.000
AFL	3/3 (100.0%)	3/3 (100.0%)	6/6 (100.0%)	
Recurrences within 12-months	10/163 (6.1%)	11/171 (6.4%)	21/334 (6.3%)	.911
AVNRT	3/54 (5.6%)	8/63 (12.7%)	11/117 (9.4%)	.187
Accessory pathway	6/98 (6.1%)	2/93 (2.2%)	8/191 (4.2%)	.280
AT	1/8 (12.5%)	1/12 (8.3%)	2/20 (10.0%)	1.000
AFL	0/3 (0.0%)	0/3 (0.0%)	0/6 (0.0%)	
Success rate redo-ablations	10/12 (83.3%)	8/10 (80.0%)	18/22 (81.8%)	
AVNRT	4/4	4/6	8/10	
Accessory pathway	5/6	3/3	8/9	
AT	1/2	1/1	2/3	
AFL	-	-	-	
Overall success	163/170 (95.9%)	168/181 (92.8%)	331/351 (94.3%)	.216
AVNRT	55/56 (98.2%)	59/63 (93.7%)	114/119 (95.8%)	.369
Accessory pathway	97/102 (95.1%)	94/102 (91.2%)	191/204 (93.6%)	.390
AT	8/9 (88.9%)	12/13 (92.3%)	20/22 (90.9%)	1.000
AFL	3/3 (100.0%)	3/3 (100.0%)	6/6 (100.0%)	

Other procedure related parameters did not differ between the fluoro-group and EAM-group. The energy source used to perform the ablation, was cryo-energy in 30% of the procedures; 25% in the fluoro-group versus 34% in the EAM-group (p=.146). In the fluoro-group 60% of the accessory pathways were left sided versus 59% in the EAM-group (p=.386).

These required transseptal puncture with intra-cardiac echocardiography or trans-oesophageal echocardiography guidance in absence of a foramen ovale.

In total, 4 complications occurred in the fluoro-group and none in the EAM-group (Table 3). Three patients had a transient AV-block, which recovered during the procedure. One patient had a groin vessel injury that required treatment, because of a pseudoaneurysm of the right common femoral artery. He was treated with thrombin injection and no late complications occurred.

Table 3: Procedural parameters

	The fluoro-group	The EAM-group	Total	p-value
Procedure time (min)	184.50 ± 81.50	179.00 ± 60.00	183.00 ± 72.00	.386
Median ± interquartile range	(N= 182)	(N= 191)	(N= 373)	
AVNRT	181.00 ± 52.25	176.50 ± 45.75	178.00 ± 48.00	.180
accessory pathway	182.50 ± 93.75	177.00 ± 67.25	179.00 ± 85.00	.869
AT	250.00 ± 100.00	207.00 ± 79.00	232.00 ± 85.50	.071
AFL	260.00*	260.00*	260.00 ± 90.00	
Fluoroscopy time (min)	16.00 ± 17.75	2.00 ± 3.00	7.00 ± 15.00	.000
Median ± interquartile range	(N= 176)	(N= 186)	(N= 362)	
AVNRT	12.00 ± 12.25	1.00 ± 1.00	4.00 ± 11.00	.000
accessory pathway	16.00 ± 19.00	2.00 ± 5.00	8.00 ± 15.00	.000
AT	30.00 ± 16.50	3.00 ± 6.00	10.00 ± 27.00	.000
AFL	20.00*	1.00*	11.50 ± 22.25	
Dose area product (µGym²)	210.5 ± 249.3	32.9 ± 78.6	113.0 ± 213.3	.000
Median ± interquartile range	(N= 144)	(N= 159)	(N= 303)	
AVNRT	158.5 ± 194.0	24.3 ± 30.7	52.2 ± 140.0	.000
Accessory pathway	225.0 ± 243.0	57.8 ± 131.7	134.0 ± 167.6	.000
AT	599.5 ± 2345.7	51.2 ± 69.0	78.6 ± 476.9	.008
AFL	360.0*	94.0*	237.4 ± 597.0	
Major complications	4 (2.0%)	0 (0.0%)	4 (2.0%)	
Transient AV block (2nd or 3rd degree)	3	-	3	
Groin vessel injury requiring treatment	1	-	1	

* The subgroup of atrial flutter ablation procedures was too small to perform statistical analysis, therefore only the median is presented.

DISCUSSION

To our knowledge this is the largest single centre paediatric study to show that the results of ablations of SVT substrates in children remain excellent, with a high acute success rate of 94.5% and a low recurrence rate of 6.4%, while reducing the fluoroscopy time significantly by the use of EAM systems from 16 to 2 minutes, in accordance with a significant reduction

of the median dose area product from 210.5 µGym^2 to 32.9 µGym^2. Procedure time and complications decreased as well in the group using EAM, however not statistically significant. These results demonstrate that the use of EAM is safe and very effective in the treatment of ablations in children with SVT and associated with a significant decrease in fluoroscopy time and dose area product.

The baseline characteristics in the two groups of patients were the same, except for medication use prior to ablation which was higher in the fluoro-group. This might reflect that in the EAM-group ablation was more often the primary choice of treatment, instead of the start of anti-arrhythmic medication. There was no significant difference in sex distribution at baseline, however, there is a high male-female ratio in our patient population, with a total of 61.2% of the substrates found in males. Differences in male-female ratio have been previously described with accessory pathways being more common in males and AVNRT more common in females. [12, 13]

Success rate

The acute success rate in our study of 96.4% in AVNRT and 96.1% in accessory pathways in the fluoro-group is similar to results of large landmark study that used data from the Prospective Assessment after Pediatric Cardiac Ablation Cohort in 2004 (n=2761). They found an acute success rate of 97-99% in AVNRT and 92-97% in AVRT without the use of EAM (mean fluoroscopy time 38.3 +/- 33 min).[4] In the newer Multicenter Pediatric and Congenital EP Quality Initiative registry from 2019 (n = 1417), EAM was used in 95% of the procedures (mean fluoroscopy time 7.0 +/- 9.2 min) with an acute success rate of 98% in AVNRT and 95-97% in AVRT.[1] The "EUROPA" Registry with 683 patients published in 2021, showed a success rate of 94% in AVRT and 99% in AVNRT. EAM was used in 628 patients with a mean fluoroscopy time of 4.9 +/- 6.8 min.[14] In addition, there are smaller studies that report on ablation outcomes in combination with the use of EAM in paediatric populations, but often focus on only one type of arrythmia or one type of ablation energy. For example, a recent study by Jan et al. with 62 patients (< 19 years), examined the outcomes of ablations of AVNRT without any use of fluoroscopy specifically and found an acute success rate of 98% in their paediatric population.[10] Another study from Elkiran et al. focused on the outcomes of ablations of AT whilst using EAM, with an acute success rate of 87%. Their study population consisted of 39 patients; the ablation was performed without fluoroscopy in 25 out of the 39 patients and the remaining fluoroscopy time was 5.53 ± 5.22 min.[9] These studies demonstrate the possibility of completely eliminating fluoroscopy.

Recently, Anderson et al. published a study in which they compared outcomes of paediatric ablations from a previously published Prospective Assessment after Pediatric Cardiac Ablation registry in 2004 using fluoroscopy, to the more recent Catheter Ablation with Reduction or Elimination of Fluoroscopy registry in which EAM was used.[8] The acute success rate was similar in both registries, with a clear and significant reduction of fluoroscopy time (mean 38 min vs 1 min). Though this study has a large study population

(n=786), the authors conclude that there are a number of potential confounders in comparing a recent cohort to a previous registry, due to changes in treatment strategy other than the introduction of EAM. For example, in the registry published in 2004 cryo-ablation was not used, but was frequently used in the more recent registry. The strength of the present single centre study is that the only difference between the groups was the introduction of routine use of EAM. Otherwise, the two groups had similar patient characteristics and SVT substrates, and were both treated in recent years by the same two operators with the standard use of cryo-energy for AVNRT and septal pathways.

The success rates we present in this study are also comparable with the results in large studies in adults. A meta-analysis of 7693 patients, calculated an acute success rate of 90.9% for AVRTs and 94.3% for AVNRTs and complication rate of 2.8% for AVRTs and 3.0% for AVNRTs with fluoroscopy.[15] Another large study (n=3060) in adults compared a group of patients ablated with EAM only (zero-fluoroscopy) to a group ablated with a conventional fluoroscopy approach (fluoroscopy with or without EAM).[16] They found no significant difference between groups, the immediate success rate was 98.8% in the zero-fluoroscopy group and 99.2% in the conventional fluoroscopy group . The fluoroscopy time differed significantly, from 6.9 in the conventional fluoroscopy group to (per definition) 0 minutes in the zero-fluoroscopy group. However, in this study, patients were assigned to a group after they underwent transesophageal EP study and during the procedure some patients even changed groups. Razminia et al presented a single center retrospective analysis of five hundred adult patients with SVT and PVC/VT. Procedures were performed without fluoroscopy, with the use of EAM in combination with intra-cardiac echocardiography (ICE). The reported acute success rate was high, almost 100%.[17]

Limitations

Limitations of this study are its retrospective observational design in which two subsequent cohorts of patients were compared. Data on the number of applications and ablation time were not documented during the first years and therefore could not be included in this study. However, since it is a single centre study with the same two electrophysiologists in both cohorts and with no other changes in treating method than the introduction of EAM as standard of care, we do feel that this study provides clear insight in the value of EAM in reducing fluoroscopy time in a pediatric population. Another limitation of this study could be the follow-up duration of one year. Recurrences that may have occurred after 12 months, are not taken into account.

Conclusion

This study shows the results of the largest single-center study, in which catheter ablation remains a highly effective and safe treatment therapy for children with SVT substrates after the introduction of EAM as a standard of care. The fluoroscopy time and dose area product are reduced significantly, while the success rate is still high, and recurrence and complication rate remain low.

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