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ORIGINAL RESEARCH

Safety and efficacy of transcatheter cryoablation of septal accessory pathways with three-dimensional mapping without fluoroscopy in children

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Abstract

In this study, we analyzed the success rate of cryoablation for septal accessory pathways in pediatric patients using a three-dimensional mapping method. 102 pediatric patients underwent septal accessory pathway ablation, with cryoablation performed for an average of 4 minutes in each application using a 6 or 8-mm cryoablation catheter with three-dimensional mapping. The mean age and weight of the patients were 11.3 ± 5.4 years and 35.6 ± 14.3 kg, respectively. Most patients (70.6%) had a manifest accessory pathway, while 29.4% had a concealed one. The locations of the accessory pathways were anteroseptal (37.3%), midseptal (22.5%), and posteroseptal (40.2%). The successful ablation effect time was 8.9 ± 7.3 seconds. Two patients experienced early recurrence on the day after the procedure, but the second procedure was successful in both cases. Throughout the course of the procedure, nodal rhythm manifested in five individuals, representing 4.9% of the sample; incomplete right bundle branch block was observed in four patients, accounting for 3.9% of the cohort; prolongation of the PR interval occurred in four cases, making up 3.9% of the total; and second-degree atrioventricular block was identified in two patients, constituting 1.9% of the study population. These electrocardiographic (ECG) changes returned to normal the following day, except for two patients with right bundle branch block, whose ECG findings returned to normal within the first month. The mean follow-up period was 56.71 ± 29.5 months, during which recurrence was observed in two patients with manifest preexcitation in the first and third months after the procedure. However, a second ablation procedure was successfully performed in these patients, and no second recurrence was detected during the follow-up period. Cryoablation with electroanatomic mapping system is a safe and effective procedure with high success rates in pediatric patients with septal and perinodal accessory pathways.

Keywords

Three-dimensional mapping; Cryoablation; Septal accessory pathway; Children

1. Introduction

The successful use of cryoablation for treating septal tachycardia substrates [1, 2], including atrioventricular (AV) nodal reentrant tachycardia and septal accessory pathways, has been increasing in recent years due to its safety [3]. Cryoablation offers advantages such as reversibility of lesions during cryomapping, decreased risk of thrombus formation, and increased catheter stability, especially when the arrhythmia substrate is close to the AV node or bundle of His [3]. However, catheter ablation of septal accessory pathways can be challenging due to the adjacent conductive tissue, and it carries a higher risk than in other locations [4, 5]. There is a high risk of permanent damage due to its proximity to the conductive tissue, especially in radiofrequency ablations. Additionally, in the accessory pathways localized in the posteroseptal region, difficulties are seen during ablation due to the coronary arteries' proximity and complex structure [6].

While radiofrequency ablation is the preferred method for accessory pathway ablation, cryoablation is preferred for septal and perinodal pathways due to its lower risk of permanent conduction disturbances, especially in childhood cases [1]. The cryomapping feature of cryoablation catheters is effective in reducing these possible risks, and a three-dimensional mapping system provides a comprehensive model of the heart structure. Furthermore, it significantly reduces radiation exposure for both the patient and the operator, especially in childhood ablations [7, 8].

The study aims to analyze the success rate, complications, recurrence rates, and follow-up results of septal accessory pathway cryoablation using a three-dimensional mapping method with zero fluoroscopy.

2. Materials and methods

2.1 Patient population

This study involved 102 consecutive patients who underwent an electrophysiological study and a transcatheter cryoablation procedure for a septal accessory pathway at Dr. Siyami Ersek Research and Training Hospital, Department of Pediatric Cardiology, between September 2014 and May 2021. The study included patients with atrioventricular re-entrant tachycardia or asymptomatic Wolff-Parkinson-White syndrome with high-risk criteria.

2.2 Cryoablation

The CryoConsole cardiac cryoablation system (Freezer Xtra, Medtronic, Minneapolis, MN, USA) was used for the cryoablation procedure. The temperature was reduced to −30 °C during cryomapping and to −80 °C during cryoablation. Lesion ablation was performed for between 240 and 360 seconds. A 6-mm or 8-mm tipped cryoablation catheter (Freezor Max, Medtronic Inc., Minneapolis, MN, USA) was used for the procedure. Lesions were given in a range of 1 to 5 times in each procedure. Atrioventricular conduction time and the degree of preexcitation were closely monitored during both cryomapping and cryoablation to prevent undesired permanent damage. If there was prolonged atrioventricular conduction time or more evident preexcitation, the procedure was immediately stopped at that location, and cryomapping was performed in another region. Cryoablation was resumed when tachycardia stopped or preexcitation disappeared during cryomapping.

2.3 Electrophysiological study and ablation

The patients discontinued antiarrhythmic medications at least five half-lives before the procedure. The procedures were all performed by the same electrophysiologist under deep sedation without endotracheal intubation. Pacing catheters were inserted via the right and left femoral veins. Heparin was used only in patients with a left-sided pathway location. An electro-anatomic mapping system (EnSite Nav X TM system, Abbott, St. Paul, MN, USA) was used to define anatomical and electrical landmarks (Fig. 1). The superior vena cava, inferior vena cava, and His region were marked with a quadripolar catheter. A decapolar catheter was placed in the coronary sinus, and the quadripolar catheter was placed at the apex of the right ventricle.

Basic measurements were taken to assess the forward and backward conduction properties of the accessory pathway. An electrophysiological study was conducted to evaluate risk and test for the induction of atrioventricular re-entrant tachycardia in each patient. Induction of atrioventricular re-entrant tachycardia was tested at baseline and, if necessary, after isoproterenol injection. High-risk factors in patients with obvious preexcitation included an accessory pathway effective refractory period of $\leq$250 milliseconds and/or the shortest preexcited RR interval during atrial fibrillation. The location of the accessory pathway was determined using both bipolar and unipolar recordings during sinus rhythm and/or atrioventricular re-entrant tachycardia. Mapping of the accessory pathway was performed using diagnostic catheters with four poles. The early points were marked, and the signals were controlled with the cryoablation catheter at the exact location.

Protocols involving two or three extra stimuli and burst stimulation from the high right atrium and/or coronary sinus were used to induce tachycardia. If necessary, the same protocol was repeated with sympathomimetic agents. The study evaluated the features of ventriculoatrial conduction, accessory pathway effective refractory period, and shortest preexcited RR distance in atrial fibrillation.

Cryoablations for concealed accessory pathways were performed during tachycardia or ventricular pacing (Fig. 2). Ventricular pacing was used only in posteroseptal region ablations, far away from the rapid pathway and His region. Cryoablation was stopped if the accessory pathway conduction did not disappear after 15 seconds. There were no transient or permanent blocks with a maximum of 15-second cryoablation lesions. After the retrograde conduction of the accessory pathway disappeared, ventricular pacing was stopped, and the procedure continued by following the atrioventricular conduction time in sinus rhythm.

The time to success was measured from the start of cryomapping. Sinus rhythm ablation was performed in all patients with manifest preexcitation. Fluoroscopy was not used in any of the procedures. All patients were monitored for at least 30 minutes after ablation to evaluate whether ventriculoatrial conduction was via the accessory pathway. Additionally, in cases of adenosine unresponsiveness, it was assessed whether preexcitation was repeated with adenosine, and the ablation procedure was continued if tachycardia was induced or preexcitation appeared.

2.4 Follow-up

After the procedure, all patients were hospitalized overnight after the procedure. The day after, they underwent ECG and echocardiographic evaluations. Electrocardiographic data were recorded during each follow-up visit, which occurred at 1, 3, 6, 9 and 12 months in the first year and then every six months thereafter. The presence of preexcitation or atrioventricular tachycardia detected through ECG, Holter monitoring, or event recorders was considered a recurrence.

2.5 Statistical analysis

The statistical analysis was conducted using SPSS 22.0 (IBM Corporation, Armonk, NY, USA). The Shapiro-Wilk test was used to assess normal distribution, and Levene's test was performed to examine the homogeneity of variance. Mean and standard deviation were used to present quantitative data, while categorical data were presented as numbers (n) and percentages (%). Differences between outcomes were analyzed using the Mann-Whitney U test for quantitative data and the Chi-square test for categorical variables.

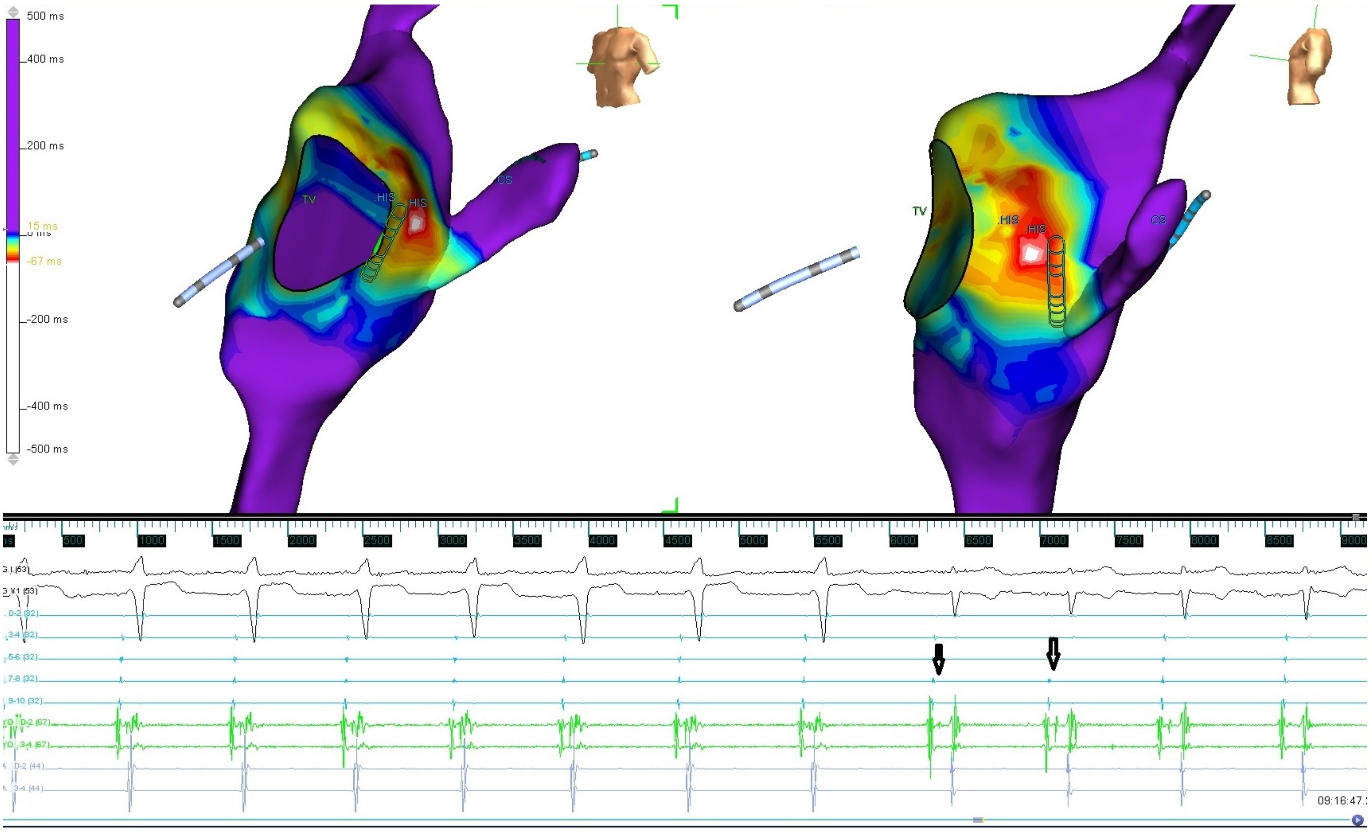

FIGURE 1. The delta mapping in sinus rhythm of a patient with a manifest parahisian accessory pathway is shown. The earliest activated region was the parahisian region. A mechanical bump has been shown in the accessory pathway, while the 6-mm-tipped cryoablation catheter comes to the early activation area detected with the diagnostic catheter. His signal after the mechanical bump is indicated by arrows. Successful cryoablation was applied to the same location. TV: Tricuspid valve; HIS: His bundle; CS: coronary sinus.

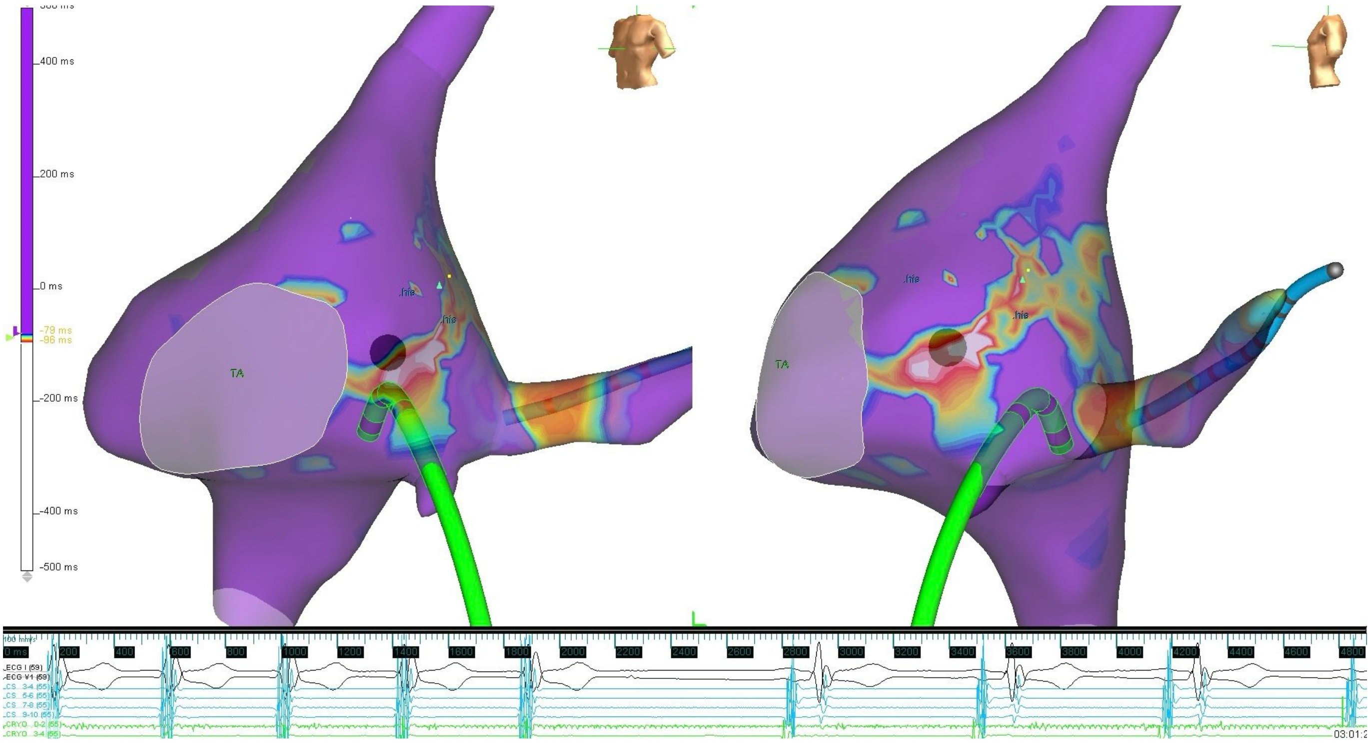

FIGURE 2. The moment when the concealed accessory pathway-dependent tachycardia stops during cryoablation is shown. TA: Tricuspid annulus; His: His bundle.

3. Results

A total of 102 patients underwent cryoablation, with 52 (51.0%) of them being female. The average age and mean weight were 11.3 ± 5.4 years (range: 0.8–18 years) and 35.6 ± 14.3 kg (range 8–88 kg), respectively. The demographic characteristics and procedural details of the participants can be found in Table 1. Among the patients, two had Ebstein's anomaly, and one had an ostium secundum type atrial septal defect. Furthermore, 68.6% of the patients experienced supraventricular tachycardia attacks, while the remaining cases were identified during routine examinations. None of the patients had a history of syncope or cardiac arrest. 72 patients (70.6%) had manifest preexcitation, and 30 patients (29.4%) had a concealed accessory pathway. Of these, 38 (37.3%) were anteroseptal, 23 (22.5%) midseptal, and 41 (40.2%) posteroseptal. Four patients (3.9%) had a history of unsuccessful ablation performed at other health centers (three with Wolff-Parkinson-White syndrome and one with a concealed accessory pathway). An additional accessory pathway originating from the right anterior, middle cardiac vein, or mitral lateral annulus was present in three (2.9%) patients. An 8-mm tipped catheter was used for ablation of the posteroseptal region in patients weighing more than 30 kilograms, and a 6-mm catheter for all remaining patients.

Twelve patients with manifest preexcitation were asymptomatic. Patients without a documented atrioventricular reentrant tachycardia, in whom tachycardia was induced during the procedure, and asymptomatic patients with manifest preexcitation who were evaluated as carrying high risk were also ablated. All the remaining patients with manifest preexcitation and all the patients with a concealed accessory pathway had previously experienced a documented atrioventricular reentrant tachycardia attack. The average procedural time and the average number of total cryoablation lesions for each subject were 126.4 ± 64.2 minutes and 3.3 ± 1.4, respectively. In successful procedures, the mean duration of the disappearance of preexcitation or time to the end of the tachycardia attack was 8.9 ± 7.3 seconds. There was no significant difference in terms of success and complications between procedures performed during sinus rhythm versus during tachycardia ($p > 0.05$).

The ablation time was 360 seconds in the 16 patients with a posteroseptal accessory pathway and six patients with an anteroseptal accessory pathway. Ten patients received a single 240-second lesion, and three of them (30%) experienced recurrence. In contrast, only one out of 21 patients (4.8%) who received two lesions of 240 seconds experienced recurrence. There was a significant difference in recurrence between patients who received a single lesion of 240 seconds and those who received two lesions of 240 seconds ($p < 0.01$). No recurrences were observed in patients who received three or more lesions.

No major complications occurred during the procedures. In one patient with manifest preexcitation in an anteroseptal location, the first procedure was unsuccessful. However, after a request from the family, the procedure was repeated two months later and was successful. During the procedures, nodal rhythm developed in five patients (4.9%), incomplete right bundle branch block developed in four patients (3.9%), prolonged PR in four patients (3.9%), and second-degree atrioventricular block, which reverted to sinus rhythm during the procedure, in two patients (1.9%). Most of these ECG changes returned to normal the next day after the procedure. Although the right bundle branch block that developed in two patients during the procedure persisted the day after, both returned to normal at the first-month follow-up. The acute success rate was 99%.

The mean follow-up period was 56.71 ± 29.5 months. Early recurrence was observed in two (1.9%) the day after the procedure, one with a manifest and one with a concealed accessory route. Additionally, recurrence was observed in two patients with manifest preexcitation in the first and third months following the procedure. A second ablation procedure was successfully performed in patients with recurrence, and no second recurrence was detected during the follow-up period in any of the patients.

4. Discussion

This study demonstrated that catheter cryoablation, guided by electro-anatomical mapping, is safe and effective for patients with manifest and concealed septal accessory pathways. None of the patients experienced permanent conduction system disturbance, and only four patients had recurrences, all of whom were successfully treated with a second ablation procedure. There were no observed difficulties or potential complications related to the feasibility of cryoablation in the pediatric age group. Cryoablation is considered an alternative to radiofrequency ablation for both children and adults [9]. Bravo *et al.* [6] found radiofrequency ablation to be more effective in septal accessory pathway ablations. However, due to the lack of reported permanent blocks with cryoablation, it is preferred in our practice. The reversible conduction block in cryomapping, the ability to operate during tachycardia, and catheter stability are the features that make cryoablation with three-dimensional mapping useful [10].

Radiofrequency catheter ablation has been extensively utilized for numerous years. However, there exists a potential risk of atrioventricular block, especially in regions proximal to the atrioventricular node or his bundle. This risk is significantly greater in the midseptal and anteroseptal areas compared to the posteroseptal region [11]. Radiofrequency ablation has the potential to induce a permanent atrioventricular block [11]. In both cryomapping and cryoablation procedures, halting the lesion can reverse conduction delays when prolonged AV conduction time or increased preexcitation is detected. Nonetheless, radiofrequency ablation may lead to lasting damage, particularly in the septal region. Moreover, based on our observations, the likelihood of perforation in structures like the coronary sinus and pulmonary vein is very low, as the formation of thrombus at the catheter tip is less common in cryoablation.

Catheter stability plays a critical role in perinodal and anteroseptal ablations. Abrupt catheter displacements resulting from unintended blood flow or valve movements can lead to permanent adverse effects on the conduction system. A notable benefit of the cryoablation catheter is its ability to securely adhere to the tissue, ensuring stability throughout the ablation

TABLE 1. Demographic and procedural data of the subjects.

Demographics and procedural proceedings	Results
Age, years, mean ± SD, (range)	11.3 ± 5.4 (0.8–18)
Weight, kg, mean ± SD, (range)	35.6 ± 14.3 (8–88)
Gender, n, female/male	52/50
Additional cardiac pathology, n	3 (2 Ebstein's anomaly, 1 secundum type ASD)
Patient with prior ablation, n	4 (3 WPW, 1 Concealed accessory pathway)
Manifest preexcitation, n (%)	72 (70.6)
Antegrade, n (%)	17 (16.7)
Bidirectional, n (%)	55 (53.9)
Concealed accessory pathway, n (%)	30 (29.4)
Localization	
Anteroseptal, n (%)	38 (37.3)
Midseptal, n (%)	23 (22.5)
Posteroseptal, n (%)	41 (40.2)
Acute success, %	99
Total recurrence rate, %	3.90
Cryoablation catheters	
6-mm catheter, n (%)	94 (92.6)
8-mm catheter, n (%)	8 (7.4)
Cryomapping number, mean ± SD (range)	6.00 ± 3.2 (1–15)
Cryoablation number, mean ± SD (range)	3.30 ± 1.4 (1–5)
Time to effect in ablation, second, mean ± SD, (range)	8.90 ± 7.3 (5–22)
Procedural time, minute, mean ± SD, (range)	126.40 ± 64.2 (75–255)
Follow-up period, month, mean ± SD, (range)	56.71 ± 29.5 (5–84)
Fluoroscopy time	0
Permanent Atrioventricular block	0

ASD: atrial septal defect; WPW: Wolff-Parkinson-White syndrome; SD: Standard deviation.

process. This enhanced stability significantly enhances the success rate of the procedure and mitigates potential complications [12]. In contrast, achieving such stability with a radiofrequency catheter, even with extended sheaths, proves to be challenging. Notably, in our experience with cryoablation, we observed no discernible differences in success rates or complication rates when performing the procedure during sinus rhythm as opposed to during tachycardia.

Swissa *et al*. [13] found that in their study of 55 patients, the overall recurrence rate was 14.9%. They also noted that ablation during supraventricular tachycardia is linked to high recurrence rates. However, it is important to note that they did not utilize three-dimensional mapping in their study. Three-dimensional mapping allows for clearer localization of the catheter, enabling the operator to identify early activation points. This method is advantageous as it can help in marking the region more accurately, potentially increasing the success rate of the procedure. Additionally, using fluoroscopy to recognize the displacement of the ablation catheter may be challenging and could lead to inadequate lesions, ultimately decreasing the success rate of the procedure.

In cryoablation, the time it takes for the treatment to take effect is crucial. Our study showed that in patients who did not experience a relapse, the time to effect was less than 9 seconds. In a study by Drago *et al*. [14], no recurrences were reported in patients who lost accessory communication within an average of 8.2 seconds after reaching −30 °C in cryomapping among 30 patients. They observed a higher recurrence rate in patients with longer times to effect. Therefore, a shorter time to effect indicates the correct location of the accessory pathway.

Due to the limited extent of lesions produced by cryoablation, the loss of accessory pathways in areas where the lesions are not precisely placed occurs over a longer period. Consequently, recurrence is a common issue in these cases. While there is no significant discrepancy in the depth of tissue penetration between lesions created by radiofrequency ablation and cryoablation, it is understood that the radiofrequency catheter causes more disruption to the tissue, leading to the high recurrence rates observed in cryoablation procedures [15]. Cryoablation yields precise and clearly defined lesions with a smaller volume compared to radiofrequency ablation. Furthermore, the radiofrequency catheter, being more mobile than the cryoablation catheter, results in larger lesions due to its scavenging effect during the ablation process. To address this challenge, 8-mm cryoablation catheters are now utilized. Given that the posteroseptal region contains deeply situated accessory pathways with numerous epicardial extensions, we employ an 8-mm tipped catheter for patients weighing over 30 kilograms, while a 6-mm catheter is used for all others in this region.

Furthermore, a 360-second ablation time may be more beneficial for posteroseptal regions where the tissue is thicker, and the accessory pathway is more prominent. As far as we know, there is no information in the literature specifically addressing the impact of a longer ablation time in these patients. Drago *et al*. [16] reported a 100% success in patients with manifest preexcitation, while the success rate in the concealed accessory pathway group was 80% in the same study. In our research, we observed a lower recurrence rate from cryoablation. One of the main contributing factors to our low recurrence rate may be the application of more lesions and extending the ablation time up to 6 minutes in appropriate locations.

In our study, we did not observe any differences in the results of ablations performed during tachycardia for patients with manifest preexcitation. We completed the ablation process by applying an average of three lesions. For patients with an anteroseptal accessory pathway, we strategically applied the lesions to minimize the His signal and closely monitor the atrioventricular conduction time. The use of the three-dimensional mapping method in our patients may also explain the low recurrence rates. Furthermore, a study by Swissa *et al*. [13] indicated that increased experience with cryoablation is a significant factor in reducing recurrence rates. No permanent block was reported with cryoablation in studies. Cryoablation has specific features, such as creating a reversible loss of function to predict the effects of ablation (cryomapping) and the adherence of the catheter tip to tissue with freezing, which avoids the risk of displacement. These features may minimize the risk of complications.

No instances of perforation have been reported so far, as deep lesions do not occur during cryoablation. Cryoablation can be successfully performed via the coronary sinus route for ventricular arrhythmia originating from both the ventricular summit and posteroseptal accessory pathways [17, 18]. However, reaching the middle cardiac vein with a cryoablation catheter can sometimes be challenging. It's worth noting that we did not observe permanent atrioventricular block in any of our patients. All 1st and 2nd-degree blocks, as well as complete right bundle branch blocks we observed after the procedure, had regressed at follow-up. While 3D mapping systems offer advantages over conventional methods, there is a learning curve for those new to this technique. The duration of this learning curve can vary depending on the frequency of procedures to achieve increased success rates.

The use of three-dimensional mapping reduces radiation exposure and helps identify early activation areas during the mapping process. Marking these early activation sites has a positive impact on the success and duration of the procedure. Real-time display of atrioventricular conduction time during the procedure prevents irreversible conduction loss. The combination of three-dimensional mapping and cryoablation is highly effective, particularly in perinodal ablations, with high acute success and low recurrence rates. Exposure to radiation is known to increase the risk of various malignancies. Children are particularly vulnerable to ionizing radiation. Recent advancements in electroanatomic mapping systems have significantly reduced radiation exposure, making them safe for use in pregnant women and pediatric patients [19].

5. Study limitations

This study was subject to various limitations, including the retrospective design and relatively brief follow-up periods which posed significant constraints. Furthermore, the lack of a historical control group consisting of similar patients who underwent RF ablation impeded our ability to make a direct comparison between cryoablation and RF ablation. Despite these limitations, our results align with previously reported outcomes of RF ablation, showcasing a high level of safety and efficacy.

6. Conclusions

Radiofrequency ablation of septal accessory pathways carries inherent risks, as it has the potential to result in irreversible AV block and conduction disturbances. Cryoablation, on the other hand, can be meticulously administered across all areas. When coupled with the advanced technique of three-dimensional mapping, cryoablation emerges as an exceptionally effective and secure approach for managing septal accessory pathways.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

ŞB—designed and performed the research and critically revised the manuscript. ŞG—analyzed the data, performed the research and wrote the manuscript draft. SE—performed the statistical analysis, wrote and revised the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

All procedures performed were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Ethical approval was obtained from the Dr. Siyami Ersek Research and Training Hospital ethics committee (Appr.no: 2021-09/03 January 2021). Informed written consent from parents was obtained from all participants in the study.

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CONFLICT OF INTEREST

All authors declare no conflict of interest in connection to the submitted article.

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