

# Evaluation of Complications Associated with Cardiac Catheterization: A Single-center Experience

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**Cite this article as:** Yavaş Abalı Z, Nişli K, Dindar A, Eker R, Aydoğan Ü. Evaluation of Complications Associated with Cardiac Catheterization: A Single-center Experience. Trends in Pediatrics 2022;3(4):156-62

## ABSTRACT

**Objective:** The aim of this study is to evaluate complications of cardiac catheterization (CC) procedures in a pediatric cardiology center.

**Methods:** The clinical records of 781 cardiac catheterizations were reviewed to identify procedure-associated complications. Catheterizations were grouped as diagnostic or interventional procedures. A complication was classified as a major or a minor.

**Results:** Patient ages ranged from 1 day to 28.8 years (median 3.3 years). Interventional catheterizations represented 58.5% of total procedures. Patent ductus arteriosus (PDA), atrial septal defect (ASD), and aortic coarctation were the most common diagnoses in our cohort. PDA occlusion, ASD closure, pulmonary valvuloplasty, angioplasty/stenting for aortic coarctation, and aortic valve dilation were the most commonly performed interventional catheterizations. Complications were detected in 17.5% of all procedures. Major complications were 2.3% for all procedures. Decreased/absent pulses were the most common complication in all categories (8.1%). The mortality rate of cardiac catheterization procedures was 0.5%. Relative to diagnostic procedures, interventional catheterizations were associated with a greater risk of complications.

**Conclusion:** Our study's success and complication rates were similar to other studies. Complications of CC depend on the severity of the underlying congenital heart disease and the type of procedure.

**Keywords:** Cardiac catheterization, complication, patent ductus arteriosus, atrial septal defect, aortic coarctation

## INTRODUCTION

Congenital heart disease (CHD) is observed in approximately 0.8% of all live births. In the first year of life, 2-3 of 1000 newborns may be symptomatic due to CHD. CHD is usually diagnosed within the first week in 40-50% and within the first month in 50-60%. Due to advances in surgery, the number of children with CHD reaching adulthood has increased.<sup>1</sup>

Cardiac catheterization (CC) is used in cardiac diseases to determine the anatomy before surgery, evaluate the presence and size of the shunt, calculate pulmonary vascular resistance,

evaluate the response to vasodilator agents and oxygen, monitor CHD after surgery, take a myocardial biopsy, electrophysiological studies, and in transcatheter ablation. Although it is highly invasive and may have serious complications, CC and angiocardiology, which have been used for many years in the definition of cardiac anatomy and physiology, have also been widely used in therapeutic interventions with the development of technology and have been an alternative to surgical treatment in some cases.<sup>1,2</sup>

Complications of the commonly used CC procedures are important in terms of morbidity and mortality. The overall mortality rate has

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**Received:** 08.11.2022 **Accepted:** 23.11.2022

been reported as 0.1%. This rate is higher (1-2%) in newborns with critical CHD.<sup>2</sup> Morbidities such as dysrhythmia, cardiac perforation and neurological issues due to hypoxia are rare, on the other hand, minor complications such as mild bleeding, weak pulses are common and frequency varies according to the clinical condition of the patient and the experience of the clinic. Determining the complication types and frequencies and reviewing their causes will be useful in preventing complications that may develop in subsequent procedures.

Our study aimed to evaluate the complications of diagnostic and therapeutic CC procedures performed at İstanbul University, İstanbul Faculty of Medicine, Department of Pediatric Cardiology.

## MATERIALS AND METHODS

### Study Design and Patients

The patients who underwent CC between January 2007-June 2011 at İstanbul University, İstanbul Faculty of Medicine, Department of Pediatric Cardiology, constituted the study group. Demographic data and details of the catheterization procedures were obtained from the computer database, patient files, and catheterization records, retrospectively. According to the data obtained from these records, 781 catheterization procedures were performed in 708 patients.

According to body weight, groups were classified as <5 kg, 5.0-9.9, 10.0-19.9, 20.0-39.9, and more than 40 kg. Standard deviation values were calculated according to body weight reference values in children older than 6 months.<sup>3,4</sup> Cardiac diseases were grouped as cyanotic or acyanotic.<sup>1</sup> The catheterization procedure groups were grouped as diagnostic or interventional. The therapeutic procedures were defined as interventional, whereas the others were defined as diagnostic. Complications were defined as major or minor.

### Complications were defined as below:

**Absent/decreased pulses:** The condition of absent or low pulses distal to the catheter entry site after the procedure requires treatment. Pulse weakness that did not require treatment and regressed spontaneously was not considered a complication. Those requiring anticoagulant and/or thrombolytic therapy were classified as minor, and those requiring surgical thrombectomy were classified as major complications.

**Bleeding:** Bleeding that occurred from the catheter entry site and required transfusion during or after catheterization. Bleeding that did not require transfusion was not considered a complication. In the case of shock, the complication was classified as major. Patients with the coexistence of absent/decreased pulses and bleeding were considered as having local vascular complications.

**Device embolization:** Complications were considered minor if the embolized device was removed by catheterization, and major if the device was surgically removed.

**Neurological complications:** Cerebrovascular accident (CVA), convulsion, change in consciousness without the hemodynamic disorder, sensory deficit, and acute vision problems were defined as neurological problems (major in case of permanent impairment and minor in transient disorders).

**Hypertension:** A hypertensive attack that develops after catheterization was considered a complication. Hypertensive attacks requiring respiratory and circulatory support were grouped as major and others as minor.

**Infection:** Fever requiring antibiotic treatment after the CC was considered a complication. Persistent fever, sepsis, and/or infective endocarditis were considered major, while the others were classified as minor.

**Allergic reaction:** Urticaria, anaphylaxis and other allergic reactions were considered a complication. Anaphylaxis requiring respiratory and circulatory support was grouped as major and other allergic reactions were grouped as minor.

**Methemoglobinemia:** Methemoglobin value more than 10% in the blood gas analysis was defined as methemoglobinemia. Those requiring respiratory and circulatory support were grouped as major and others as minor.

**Dysrhythmia:** Dysrhythmias that regressed during the procedure were classified as minor, and those requiring long-term treatment were classified as major.

**Vascular injury:** A venous and/or arterial injury requiring surgical treatment was considered a complication. Those requiring surgery had major complications.

**Heart failure:** Defined as the need for inotropic agents due to the procedure. Inotrope requirement was considered a major complication.

**Respiratory arrest:** Respiratory arrest during and during the first 24 h after the catheterization procedure, which did not result in death was considered a major complication.

**Death:** Death due to any cause in the first 24 h after the CC procedure was considered a major complication.

### Statistical Analysis

Statistical analyses were performed using the SPSS software version 15 (LEAD Technologies Inc, 2006). Data were presented with n (%) for categorical data and mean  $\pm$  standard deviation for numerical data. Chi-square tests were used for comparison of categorical data (Fisher's exact test was used when chi-square test assumptions do not hold due to low expected cell counts). In the comparison of independent 2 groups, student t-test was used if the data were normally distributed, and Mann-Whitney U test was used if the data were non-normally distributed. Type I error was determined as 5% and a p-value was <0.05 was considered statistically significant.

## RESULTS

A total of 781 CC procedures were performed at the Department of Pediatric Cardiology in 708 patients (361 male/347 female) (twice in 47 patients and three times in 13 patients).

According to the procedural group, 58.5% (n=457) of the CCs were interventional, and 41.5% (n=324) were diagnostic. The ratio of interventional CCs was 87.1 and 56.1% in newborns and patients older than 28 days, respectively ( $p<0.001$ ).

The median age of the patients at the time of the procedure was 3.3 years (range: 1 day-28.8 years; mean  $5.0\pm5.0$  years). The ratio of newborns was 7.9%, and the ratio of patients younger than 6 months was 21.4%. Nine patients underwent catheterization on the first postnatal day (eight interventional and one diagnostic due to hypoplastic left heart syndrome).

The most common diagnoses in patients who underwent CCs were PDA (13.8%), secundum ASD (11.4%), and aortic coarctation (11.1%). In 0.9% (n=7) of CCs, no pathological findings were detected. The study group was classified as acyanotic (n=522, 66.8%) and cyanotic CHD (n=252, 32.3%).

In 17 patients, 20 CCs were performed for evaluating coronary vessels. Seven diagnostic coronary catheterizations were performed in four patients with familial hypercholesterolemia (normal in one, and varying degrees of coronary stenosis in the others). Congenital coronary anomalies were detected in eight patients on diagnostic catheterizations. A giant aneurysm in the left anterior descending coronary artery and total obstruction in the right coronary artery were observed in a patient with Kawasaki disease. Interventional catheterization (coil closure of the fistula between the right coronary artery and the right ventricle) was performed in three of these 17 patients.

Interventional procedures constituted 58.5% (n=457) of the CCs. The most common interventional catheterizations were PDA closure (n=99, 21.7%); ASD closure (n=86, 18.7%); pulmonary balloon valvuloplasty (n=83, 18.0%); angioplasty/stenting of aortic coarctation (n=75, 16.4%) and aortic balloon valvuloplasty (n=46, 10.0%). In four catheterizations multiple procedures were performed simultaneously. The success rate in all interventional catheterizations was 91.5% (n=418). When the frequent interventional catheterizations were compared, no significant difference was found between the success rates ( $p=0.503$ ). Success rates in PDA closure with a duct occluder (n=43) and a coil (n=56) were 97.7% and 98.2%, respectively. There was no significant difference between the methods in terms of success rate ( $p=0.850$ ).

Pulmonary valvuloplasty was successful in 92.8% (n=77) of the 83 patients. Although the mean age of patients ( $4.0\pm5.3$  years, n=77) who had a successful procedure was higher than the mean age of unsuccessful cases ( $0.6\pm0.9$  years, n=6), this difference was not statistically significant ( $p=0.070$ ).

## Evaluation of Complications

Complications occurred in 17.5% (n=137) of 781 CCs. The major complication rate was 2.3% (n=18). The overall mortality rate of CCs was 0.5% (n=4). The most common complication was the weakness of peripheral pulses [observed in 63 (8.1%)]. The distribution of complications is demonstrated in Table 1.

When complications were evaluated according to the type of procedure, the complication rate was significantly higher for interventional procedures ( $p<0.001$ ). The complication rates according to the type of CCs are demonstrated in Table 2.

**Table 1. Distribution of complications**

	Minor n (%)	Major n (%)	Total n (%)
Absent/weak pulses	54 (6.9)	0 (0.0)	54 (6.9)
Bleeding (+ transfusion)	11 (1.4)	0 (0.0)	11 (1.4)
Bleeding (+ weak pulses)	9 (1.2)	0 (0.0)	9 (1.2)
Device embolization	8 (1.0)	3 (0.4)	11 (1.4)
Neurological complications	7 (0.9)	2 (0.3)	9 (1.2)
Dysrhythmia	6 (0.8)	1 (0.1)	7 (0.9)
Infections	6 (0.8)	0 (0.0)	6 (0.8)
Respiratory arrest	-	5 (0.6)	5 (0.6)
Hypertension	4 (0.5)	0 (0.0)	4 (0.5)
Allergic reactions	3 (0.4)	0 (0.0)	3 (0.4)
Methemoglobinemia	3 (0.4)	0 (0.0)	3 (0.4)
Heart failure	-	2 (0.3)	2 (0.3)
Vascular damage	0 (0.0)	1 (0.1)	1 (0.1)
Other (hematuria, chest pain, cyanosis, bronchospasm)	8 (1.0)	0 (0.0)	8 (1.0)
Death	-	4 (0.5)	4 (0.5)
Total complications	119 (15.2)	18 (2.3)	137 (17.5)
No complication			644 (82.5)
Total cardiac catheterizations			781 (100.0)

**Table 2. The complication rates according to the type of the cardiac catheterization procedure**

	Diagnostic n (%)	Interventional n (%)	p-value
Complication			
(+)	34 (10.5)	103 (22.5)	<0.001
(-)	290 (89.5)	354 (77.5)	
Complication type			
Minor	30 (88.2)	89 (86.4)	0.783
Major	4 (11.8)	14 (13.5)	

In PDA closure (n=99), the complication rate was 15.2%. Complication rates were 11.6% and 17.9%, respectively, in patients who underwent “duct occluder” (n=43) and “coil” (n=56) procedures (p=0.392). The major complication rate for PDA closure was 1.0%. While no major complications were observed in PDA closure with a “coil,” major complications were observed in only one procedure with a “duct occluder” (p=0.143). The most common complication in PDA closure was device embolization (n=6, 6.1%). A major complication was observed in only one of the device embolizations.

In ASD closure (n=86), the complication rate was 9.3% (n=8). Major complications were observed in three (3.5%) patients. The most common complication was neurological complication (n=4, 4.7%) with only one considered major. Device embolization occurred in two patients during ASD closure, and both underwent surgery.

In pulmonary valvuloplasty (n=83), complications developed in 20.5% (n=17) of the patients. The major complication rate was 3.6%. Methemoglobinemia developed in two and post-procedure infections in four cases. The mean age of patients who developed complications during pulmonary valvuloplasty was significantly younger. The mean age of the patients with major complications was significantly lower than the patients with minor complications (p<0.001).

In angioplasty/stenting of aortic coarctation (n=75), complications were observed in 34.7% (n=26) of the patients, with a major complication rate of 1.3% (n=1). Neurological complications developed in this case.

In aortic valvuloplasty (n=46), the complication rate was 32.6% (n=15). A major complication was observed in one case (2.2%), who died on the 3<sup>rd</sup> postnatal day. The most common complication was absent/weak pulses (n=10) and all were minor.

In VSD closure, there was no difference in the complication rate between the muscular and perimembranous types (p=0.836). The major complication rate in the VSD closure was 16.7%. While no major complications were observed in the perimembranous type, major complications were observed in two patients with the muscular type. Also, this difference also was not statistically significant. An inferior vena cava injury occurred in one patient, and a surgical correction was performed. Device embolization occurred in three of the patients, and since none of them required surgery, these were considered minor complications.

Complications were observed in 4/10 patients who underwent pulmonary valve perforation. A major complication was detected in only one case (respiratory arrest).

The number of patients according to the interventional procedure and complication type is demonstrated in Table 3.

Overall, absent/weak pulses were the most common complication (n=63, 8.1%). Nine of the patients with absent/weak pulses had bleeding at the catheter insertion site, requiring transfusion. The second most common complication type after local vascular complications was device embolization (n=11, 1.4%). Six of

the device embolizations occurred in PDA closure, three in VSD closure, and two in ASD closure. Neurological complications were observed in nine (1.2%) cases. CVA developed in three patients (one bleeding and two infarcts). In cases with CVA, hemiplegia and central facial paresis developed, and convulsions were observed in one case. Three patients who underwent ASD closure had short-term blurred vision with normal imaging. In four cases, one with CVA, convulsions were observed after the procedure. Death occurred in four cases (0.5%) in the first 24 h after the procedure. The neonatal mortality rate is 3.2%, this rate is 0.3% for the post-neonatal period.

## DISCUSSION

Cardiac catheterization procedures were first practiced in the 1950s, and it has also been used for therapeutic purposes since the 1970s.<sup>5</sup> Pediatric CC started in the 1970s in our center and has been used for interventional purposes since 1986. Our study aimed to evaluate the characteristics and complications of CC procedures.

In the haemodynamic and anatomical evaluation of complex heart diseases, CC plays a fundamental role. However, due to advances in non-invasive imaging methods, the rate of CC for interventional purposes has also increased. In this study, more than half of the catheterization procedures were interventional. This ratio was quite similar to the rate reported by Mehta et al.<sup>6</sup> (58%). Cassidy et al.<sup>7</sup> reported the rate of interventional CCs as 14% (n=1037). In the study by Vitiello et al.<sup>8</sup>, the rate of interventional catheterization was 14% in 1987 and increased to 43% in 1993. Bergersen et al.<sup>9</sup> reported the rate of interventional catheterization as 67.4%. Considering the results of these studies, it was concluded that the rates of interventional use of CC have increased over the years.

**Table 3. The complication rates according to the interventional procure and complication type**

	Complication (+), n (%) <sup>*</sup>		Complication (-),* n (%)
	Minor, n	Major, n	
<b>PDA closure</b>	<b>15 (15.2)</b>		<b>84 (84.8)</b>
	14	1	
<b>ASD closure</b>	<b>8 (9.3)</b>		<b>78 (90.7)</b>
	5	3	
<b>Pulmonary valvuloplasty</b>	<b>17 (20.5)</b>		<b>66 (79.5)</b>
	14	3	
<b>Angioplasty/stenting of aortic coarctation</b>	<b>26 (34.7)</b>		<b>49 (65.3)</b>
	25	1	
<b>Aortic valvuloplasty</b>	<b>15 (32.6)</b>		<b>31 (67.4)</b>
	14	1	

\*p>0.05

PDA: Patent ductus arteriosus, ASD: Atrial septal defect



Patients diagnosed with CHD in the antenatal/early postnatal period using non-invasive methods can be treated early with interventional CC. In our study, patients underwent catheterization on the first postnatal day, and almost all of these were interventional procedures. Additionally, the proportion of interventional catheterization was significantly higher in newborns. Mehta et al.<sup>6</sup> reported these ratios as 6% and 18%, respectively.

The ratio of normal results in catheterization procedures was less than 1% in our study population, indicating the success of non-invasive imaging methods.

We detected that the most frequently applied interventional procedures were; PDA closure, ASD closure, pulmonary balloon valvuloplasty, angioplasty/stenting of aortic coarctation, and aortic balloon valvuloplasty. In similar studies, the most frequently performed interventional procedure was PDA closure.<sup>6,8</sup> Our success rate of PDA closure was 98%, regardless of the device type. Jang et al.<sup>10</sup> reported a success rate of 97.4% in the PDA closure with different devices in 117 patients. In a 2007 study by Wang et al.<sup>11</sup> that included patients from different age groups (n=68), the success rate of PDA closure with “Amplatzer Duct Occluder” was 97.1%. In another study by the same group, in 45 infants, the success rate of PDA closure was 97.8%.<sup>12</sup>

Complications were observed in 17.5% of the CCs in this study. The minor and the major complication ratios were 15.2% and 2.3%, respectively. Compared to other studies, complication rates were higher according to Mehta et al.<sup>6</sup> (complication rate 7.8%), but similar to those of Huang et al.<sup>13</sup> (complication rate 18.6%). In the series of Tavli et al.<sup>14</sup>, (n=230), the complication rate was reported as 14.3%. In a multicenter study by Bergersen et al.<sup>9</sup>, (3185 catheterizations when biopsy cases were excluded), the complication rate was 17.2%.

Although some differences were seen for all complications in different studies, our major complication ratio was similar to other studies. Vitiello et al.<sup>8</sup> reported this ratio as 2.0%, Mehta et al.<sup>6</sup> reported 2.2%, Cassidy et al.<sup>7</sup> reported 2.3%, and Soyulu<sup>15</sup> reported 2.7%.

We have reported that the mortality 24 h after CC is 0.5%. Vitiello et al.<sup>8</sup> reported a mortality ratio of 0.14%, Mehta et al.<sup>6</sup> 0.23%, and Bergersen et al.<sup>9</sup> reported as 0.35%. The cause of death may not be determined in patients who undergo CCs, since there are also serious cardiac pathologies that may cause death. It may not be appropriate to consider these deaths only as complications of catheterization. Depending on the severity of the cases, different mortality rates may occur between series. While our study's neonatal mortality ratio was 3.2%, Mehta et al.<sup>6</sup> reported this as 7.1%.

The complication ratio in interventional procedures was significantly higher than in diagnostic procedures in our cohort. Bergersen et al.<sup>9</sup> similarly reported high complication ratios in interventional procedures. The high ratio of interventional procedures also increases the overall complication ratio. In the

study by Vitiello et al.<sup>8</sup>, the ratio of interventional procedures was 28%, and the complication ratio in interventional procedures was 13.2%, while the overall complication ratio was 8.8%.

The ratio of major complications was also higher for interventional procedures compared to diagnostic procedures in our study. In the study of Bergersen et al.<sup>9</sup>, major complication ratios were also higher in interventional than in diagnostic procedures.

Neurological complications were most common in ASD closure and device embolization occurred in two cases. In the study of Lin et al.<sup>16</sup>, device embolization was observed in one of 33 cases and a complete AV block was observed in one case. Two device embolizations were reported by Wilson et al.<sup>17</sup> in a case series of 227 children and adults, and dysrhythmia was observed in six cases; the minor complication rate in this study was 5%. In the ASD closure procedure performed by Diab et al.<sup>18</sup> in 15 infants, minor complications were reported in 3 cases and major complications in one case.

We have detected that most of the complications in patients who underwent angioplasty/stenting of aortic coarctation were local vascular complications, and all of them were considered minor complications. In a study by Ergül et al.<sup>19</sup>, in 80 patients who underwent balloon angioplasty for coarctation of the aorta, it was reported that femoral artery occlusion occurred in 7.5% of the patients.

In cases of aortic valvuloplasty, the complication ratio was 32.6% and the major complication ratio was 2.2%. In the series of Mehta et al.<sup>6</sup>, these ratios were 30% and 9%, respectively; in the series of Vitiello et al.<sup>8</sup>, it was reported as 42% and 15%, respectively.

Local vascular complications constituted about half of all complications. All port site complications were minor complications and did not pose a serious problem, however, they cause problems such as prolonged hospitalization, extra medication, and transfusion. In the study of Vitiello et al.<sup>8</sup>, arterial thrombosis was observed approximately 30% of all complications. In the study by Mehta et al.<sup>6</sup>, the ratio of vascular complications was 32%. Vascular problems have an important place in other studies as well.

We have reported that the ratio of absent/weak pulses was higher in interventional procedures. In other studies, the incidence of thrombosis was reported to be higher in interventional procedures.<sup>6,8</sup> In our practice, a significantly higher rate of thrombosis was detected in cases of angioplasty/stenting of aortic coarctation and valvuloplasty, and this situation is also related to the arterial entry site.

Although local vascular complications were quite common in our study, the fact that most of them improved only with anticoagulant treatment indicates that the cases were mild.

Device embolization occurred in 1.4% of the cases in our study. Device embolization rates were 4% in the study by Vitiello et al.<sup>8</sup> and 2.3% in the study by Mehta et al.<sup>6</sup> In our study, the rate of surgical removal of the embolized device in ASD closure was 2.3%. In the study of Chessa et al.<sup>20</sup>, in which 417 ASD closure procedures were evaluated, this rate was 1.7%.

In the study by Szkutnik et al.<sup>21</sup>, in which 11 VSD closure procedures were evaluated, device embolization occurred in 3 cases. In our study, 3 device embolizations were detected in 12 VSD closure procedures, and none of them required surgery.

The most common neurological complications in CCs are stroke and seizures.<sup>22</sup> In our practice, neurological complications were observed in 1.2%. In the study by Mehta et al.<sup>6</sup>, the cerebral infarction rate was reported as 0.1%. Our ratio was 0.2%. In the literature, thromboembolism, intracranial hemorrhage, air embolism, drug reaction, and transient cerebral hypoperfusion are listed as causes of neurological complications.<sup>8,23</sup>

For neurological event development; young age, long procedure time, and invasiveness of the procedure have been reported as risk factors.<sup>24</sup>

Dysrhythmia was observed at a rate of 1%. In the study of Mehta et al.<sup>6</sup>, the ratio of dysrhythmia was 1.8%. In the study of Vitiello et al.<sup>8</sup>, it was 2.6% and it was the second most common complication. Huang et al.<sup>13</sup> reported the dysrhythmia rate as 9.1%.

Only one case of large vessel injury (0.13%) was reported in our practice. A wide muscular VSD closure procedure was planned in one-month-old patient, the procedure was terminated due to a vena cava inferior injury during the procedure and the patient was taken to surgery. No cases of cardiac perforation were found in our study. Myocardial/vascular injury, cardiac perforation, and tamponade were observed in 0.8% of cases in Vitiello et al.'s<sup>8</sup> study and 0.3% in Mehta et al.'s<sup>6</sup> study. Shen et al.<sup>25</sup> (n=23319) found the rate of cardiac perforation or tamponade to be 0.1%.

## CONCLUSION

Our study's success and complication rates were similar to other studies. complications of cardiac catheterizations depend on the severity of the underlying CHD and the type of procedure.

## Ethics

**Ethics Committee Approval:** This study was approved by the İstanbul University, İstanbul Faculty of Medicine Ethics Committee (2011-982-587).

**Informed Consent:** Retrospective study.

**Peer-review:** Externally peer-reviewed.

## Authorship Contributions

Concept: Z.Y.A., Ü.A., Design: Z.Y.A., Ü.A., K.N., Data Collection or Processing: Z.Y.A., Ü.A., K.N., A.D., R.E., Analysis or Interpretation: Z.Y.A., Ü.A., Literature Search: Z.Y.A., Ü.A., Writing: Z.Y.A.

**Conflict of Interest:** No conflict of interest was declared by the authors.

**Funding:** The authors received no financial support for the research, authorship, and/or publication of this article.

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