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ORIGINAL ARTICLE / ÖZGÜN MAKALE

The effectiveness of the flip technique in vertical ductal stenting

Vertikal duktal stentlemede flip tekniğinin etkinliği

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ABSTRACT

Background: In this study, the flip technique was compared with the classical method in terms of procedural success and procedure time during ductal stent implantation (DSI) via the carotid artery in patients whose pulmonary blood flow is dependent on the vertical type of ductus arteriosus (DA).

Methods: Between January 2019 and June 2023, 40 patients (24 males, 16 females; mean age: 15.9±15.4 days; range, 1 to 68 days) with vertical ductus-dependent pulmonary circulation who underwent patent DA stent implantation via the carotid artery were included in the study. Patients were divided into two groups: those who underwent the flip technique (Group 1) and those who did not undergo the flip technique (Group 2). Data were retospectively compiled by reviewing patient files and catheter images.

Results: Demographic findings were similar in the groups. The distribution of the DA in terms of tortuosity index was also similar in the groups. The procedure was successful in 18 (90%) patients in Group 1 and 20 (100%) patients in Group 2. There was no procedure-related mortality in both groups. The frequency of procedure-related complications was similar. Procedure duration was 53.6±18.4 min in Group 1 and 41.5±9.1 min in Group 2; the difference was significantly lower in Group 2 (p=0.028). The shorter follow-up in Group 2 was attributed to the flip method starting to be used later in the clinic. During follow-up, stent dilatation was required in two patients in Group 1 and one patient in Group 2, and a second stent implantation was needed in one patient in Group 2. No significant difference was observed between the two groups in terms of reintervention.

Conclusion: The success rate of DSI using the carotid artery access is high with both the classical and the flip method in patients with vertical DA. However, the use of the flip technique could be preferred in terms of operator habituation, ergonomic use of the catheter, guidewires, and shorter procedure time.

Keywords: Carotid artery access, duct-dependent pulmonary flow, ductal stent implantation, flip technique.

ÖZ

Amaç: Bu çalışmada, pulmoner kan akımı duktus arteriozusun (DA) vertikal tipine bağlı olan hastalarda karotis arter yoluyla duktal stent implantasyonu (DSİ) sırasında “flip” tekniği, işlem başarısı ve işlem süresi açısından klasik yöntemle karşılaştırıldı.

Çalışma planı: Çalışmaya Ocak 2019 - Haziran 2023 tarihleri arasında pulmoner dolaşımı vertikal duktus bağımlı olan ve karotis arter yoluyla patent DA stent implantasyonu yapılan 40 hasta (24 erkek, 16 kadın; ort. yaş: 15.9±15.4 gün; dağılım, 1-68 gün) alındı. Hastalar iki gruba ayrıldı: flip tekniği uygulanmayanlar (Grup 1) ve flip tekniği uygulananlar (Grup 2). Veriler, hasta dosyaları ve kateter görüntüleri incelenerek retrospektif olarak derlenmiştir.

Bulgular: Demografik bulgular gruplar arasında benzerdi. Duktus arteriozus dağılımı tortuozite indeksi açısından gruplar arasında benzerdi. İşlem Grup 1’de 18 (%90) hastada ve Grup 2’de 20 (%100) hastada başarılı oldu. Her iki grupta da işleme bağlı mortalite yoktu. İşlemle ilişkili komplikasyonların sıklığı benzerdi. İşlem süresi Grup 1’de 53.6±18.4 dk, Grup 2’de 41.5±9.1 dk idi; bu fark Grup 2’de anlamlı olarak daha düşüktü (p=0.028). Grup 2’deki daha kısa takip süresi flip yönteminin klinikte daha geç kullanılmaya başlanmasına bağlandı. Takip sırasında Grup 1’de iki hastada ve Grup 2’de bir hastada stent dilatasyonu gerekirken Grup 2’de bir hastada ikinci stent implantasyonu gerekti. Reintervensiyon açısından iki grup arasında anlamlı bir fark gözlenmedi.

Sonuç: Vertikal DA’lı hastalarda karotis arter girişi kullanılarak yapılan DSİ’nin başarı oranı hem klasik hem de flip yöntemi ile yüksektir. Ancak operatör alışkanlığı, kateter ve kılavuz tellerin ergonomik kullanımı ve daha kısa işlem süresi açısından flip tekniğinin kullanımı tercih edilebilir.

Anahtar sözcükler: Karotis arter girişi, duktus bağımlı pulmoner akımı, duktal stent implantasyonu, flip tekniği.

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There are several ways to secure pulmonary blood flow in patients with ductus-dependent pulmonary blood flow. The first and immediate one is prostaglandin E1 infusion.[1-3] Other methods are aortopulmonary shunt operations and ductal stent implantation (DSI).[4-6] Less commonly, palliative pulmonary balloon valvuloplasty and right ventricular outflow tract stent implantation could also be performed in these patients.[7,8] Formerly, DSI was limited in securing pulmonary blood flow in patients with multiple pulmonary flow sources or patients having short straight ductus.[9] However, improved materials and increased operator experience yielded a high success rate, and it is on its way to becoming the first choice for all kinds of duct-dependent pulmonary circulation (DDPC) patients.[10-12] Several studies have emphasized that using the carotid artery or axillary artery in vertical ducts increases the success of DSI.[13-19] Frequent use of the carotid pathway, which is not very ergonomic for interventional cardiologists, has forced them to search for new techniques.[15,20] Flip technique is one of them.

This study aimed to compare the clinical results of the flip technique and classical technique in patient underwent DSI by using carotid artery.

PATIENTS AND METHODS

Between January 2019 and June 2023, 40 patients (24 males, 16 females; mean age: 15.9±15.4 days; range, 1 to 68 days) with vertical ductus-dependent pulmonary circulation who underwent patent ductus arteriosus (DA) stent implantation via the carotid artery were included in the study. Patients were divided into two groups: those who underwent the flip technique (Group 1) and those who did not undergo the flip technique (Group 2). Data were retospectively compiled by reviewing patient files and catheter images. The morphologic definition of DA was based on the classification of DA by Roggen et al.[13] Patients without type 3 duct morphology or who underwent DSI via noncarotid artery access were excluded.

The tortuosity index was calculated according to the definition of Qureshi et al.[14] The preprocedural, procedural, and postprocedural characteristics of these patients were evaluated retrospectively. For patients diagnosed with DDPC, the primary approach applied in our center is to start prostaglandin E1, followed by DSI. Patients in whom additional surgical intervention was required due to the need for unifocalization, anomalies of pulmonary venous return, or septectomy were exceptions for DSI. Patients having arterial duct (AD) as a single source of pulmonary blood flow or those with branch pulmonary artery stenosis were not considered a contraindication. The carotid artery was used as the access route in all patients if they had type 3 DA. Out of about 90 patients who underwent DSI for DDPC in our clinic, only patients with type 3 DA morphology who underwent the procedure through the percutaneous carotid artery were included in this study.

The first 20 patients (Group 1) were placed classically on the procedure table during the intervention, while the remain 20 patients (Group 2) underwent the flip technique described by Bauser-Heaton et al.[15] (Figure 1).

In all patients, cardiac pathology and DA type were defined by detailed echocardiography before the procedure. All procedures were performed under general anesthesia with endotracheal intubation directed by an anesthesiologist. All patients were completely monitored during catheterization (pulse oximetry oxygen saturation, continuous electrocardiogram, and invasive arterial pressure), and precautions were taken to prevent hypothermia by using a suitable heater for babies during the procedures. For calibration purposes, a 4-F (French) National Institutes of Health (NIH) catheter was nasogastrically or orogastrically inserted before starting the procedure (Figure 2). After the patient was intubated, a 4-F radial sheath was inserted into the carotid artery with the Seldinger technique on the designated side under ultrasonography guidance

Figure 1. An image of the flipped patient (top right) on the examination table and the position of the operator and auxiliary personnel during the intervention.

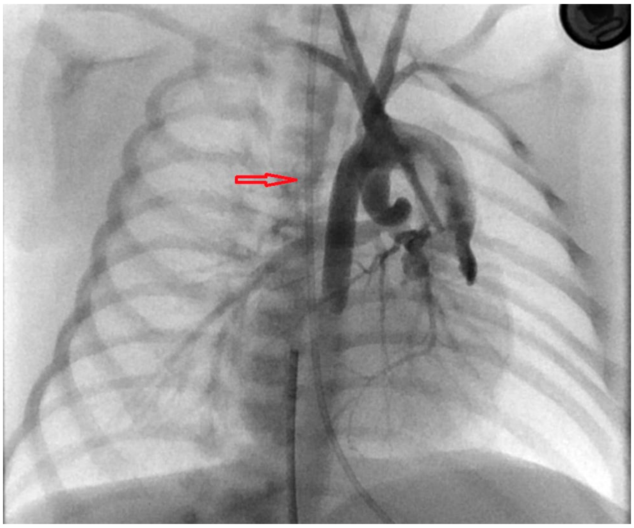

Figure 2. National Institutes of Health catheter swallowed via orogastric route for calibration (showed with the red arrow).

using a 21-G (Gauge) needle and an appropriate guide. In Group 1, the operator managed the procedure on the right cranial side of the patient. In Group 2, the patients were inverted on the craniocaudal axis on the procedure table. Afterward, they were intubated in the same position, and a 4-F radial sheath was inserted into the carotid artery in the same way as in Group 1 under ultrasonographic guidance. The patient's view was inverted on the endoscopy screen (Figure 3), and the operator was positioned on the right side of the table throughout the procedure.

After vascular access was established, arterial blood gas and invasive blood pressure measurements were performed to assess baseline status of patients. Detailed information about ductal anatomy was obtained by performing angiography in the lateral 90° and left anterior oblique or cranial left anterior oblique position using the radial sheath sidearm for the contrast medium injection. Right anterior oblique radiography was performed if needed.

Afterward, an open-end catheter was placed in the arterial duct (AD) ampulla, and the AD was passed through by using a 0.014-inch floppy coronary guidewire. A 0.014-inch extra support wire was also passed through the AD to the pulmonary artery both to straighten the AD (buddy wire) and to carry the stent. In the cases where the AD presented multiple turns and a complex morphology, reimaging was performed following the additional support wire, and the measurements were repeated accordingly. Later, coronary bare-metal stents (Ephesos II; Alvimedica, Istanbul, Türkiye) selected over the additional support wire in all cases were introduced into the duct through the short sheath without using a long sheath. The floppy wire was retrieved after ensuring that the stent had been advanced to the appropriate position in the AD. After confirming the location of the stent with manual contrast injections from the side arm of the short sheath, the stent implantation was performed by inflating the balloon with an indeflator. The balloon was carefully removed after implantation. In ducts with high tortuosity index and those that did not straighten despite the use of additional support guide wire, the

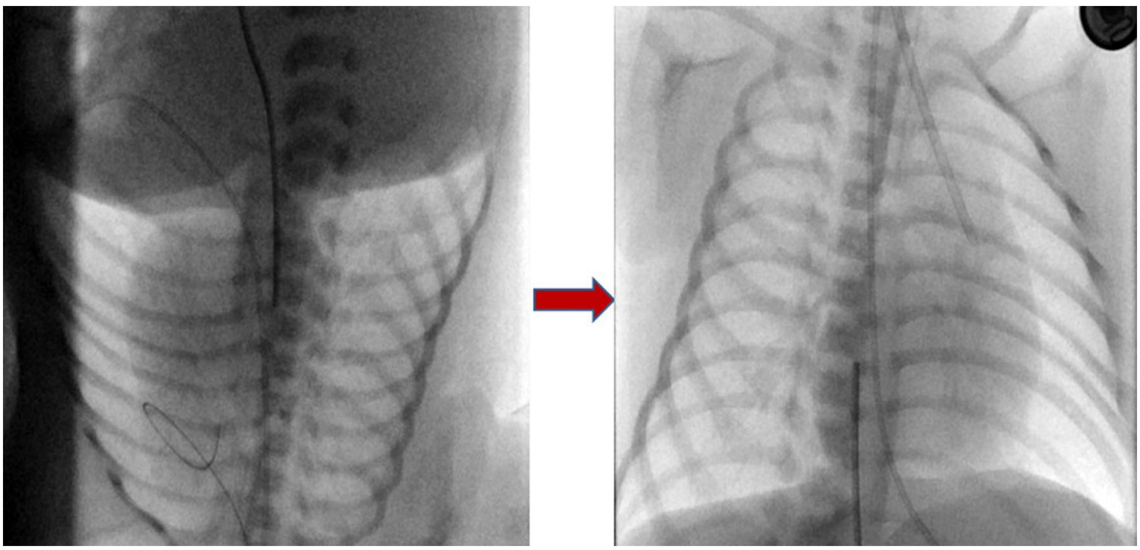

Figure 3. Inverted patient image on the monitor screen.

procedure was completed by using multiple stents by telescopic method starting from the pulmonary end. A control injection was made to evaluate both the status of the stent and the flow, and when it was ensured that the position and flow were acceptable, the guide wire was carefully removed, and the procedure was terminated.

To compare the advantages and disadvantages of each technique, the duration between the insertion of the carotid artery sheath and removal of that sheath at the end of the procedure was accepted as the procedural time.

The procedure-related complications and the inotropes used were recorded in patient files. Arterial blood gas analysis was performed immediately after entering the vessel assigned for the procedure and just before exiting the vessel at the end of the procedure.

The stent diameters were preferred according to the body weight of the patients. The procedure was performed using coronary stents with a diameter of 3.5 mm in patients weighing 2.5-3.0 kg and stents with a diameter of 4-4.5 mm in patients weighing 3.0-5 kg. The lengths of the stents to be used were decided to be 2-3 mm longer than the measured ductal length so that both the aortic and pulmonary sides of the AD were covered.[16]

After entering the artery, 50 U/kg heparin was administered, and the heparin infusion was continued at the rate of 20 U/kg/h on the first day and 10 U/kg/h on the second day for patients in whom the procedure was completed successfully. Additionally, acetylsalicylic acid at a dose of 3-5 mg/kg was started on the first postprocedural day. Carotid artery Doppler examination was performed in all patients before discharge.

Study variables

After dividing the patients into two groups according to the method used in DSI, Group 1 (nonflipped) and Group 2 (flipped) were compared retrospectively. The data used for comparing the two groups included age, body weight, sex, cardiac pathology, hospital stay, and procedural time. Furthermore, pH and lactate levels measured in the arterial blood gas analyses following the procedure, inotropic use during and after the procedure, success rate of the procedure, and the complications encountered were included.

The angiographies of all patients were reviewed retrospectively, and the definition of type 3 DA was based on the classification of Roggen et al.[13] The tortuosity index definition was based on the classification of Qureshi et al.:[14] type 1 (straight), type 2 (single turn), and type 3 (multiple turns).

Statistical analysis

Data were analyzed using IBM SPSS version 26.0 software (IBM Corp., Armonk, NY, USA). The conformity of the data to normal distribution was evaluated by the Shapiro-Wilk test. Parametric continuous variables were expressed as mean ± standard deviation, and nonparametric data were expressed as median (min-max). The chi-square test was used to evaluate categorical variables in paired groups. The Mann-Whitney U test was used for intergroup comparisons in nonparametric continuous variables. The Kruskal-Wallis test was used in the evaluation of multiple groups, and the Tamhane test was used as a post hoc test. A p-value <0.05 was considered statistically significant.

RESULTS

The demographic and clinical characteristics of the patients are listed in Table 1. There was no statistically significant difference between the groups in terms of demographic characteristics. The intervention-related characteristics are presented in Table 2.

The success rate of the procedure was 38 (95%) in the total population and 20 (100%) in the flip group. There was no significant difference between the groups in terms of success rate, metabolic status indicators during the procedure (pH, lactate, and inotrope requirement), and complication rates. Procedure time was shorter in favor of Group 2; 53.6±18.4 *vs*. 41.3±9.7 min (p=0.028). Follow-up time showed a significant difference in favor of Group 1; 14.8±11 *vs*. 6.6±5.0 months (p=0.015). No procedure-related mortality was observed. Procedure-related complications included one stent migration and one acute stent thrombosis in each group, with an additional left pulmonary artery jailing in Group 2.

During the follow-up period of Group 1, palliation was performed in nine patients, correction operations were performed in six patients, four patients were in the waiting period, and one patient died during the waiting period. In Group 2, palliation was performed in nine patients, while nine patients were in the waiting period. Two patients in this group died of infection independent of the procedure.

Table 1. Demographic data, anatomical diagnosis, and ductal morphology

	Group 1		Group 2		
Variables	n	Mean±SD	n	Mean±SD	*p*
Age (day)		14.9±17.6		17.9±13.6	0.25
Weight (g)		3,248±454		3,377±625	0.49
Sex					NS
Female	7		9		
Male	13		11		
Physiology					NS
UV	8		12		
BV	12		8		
Diagnosis					NS
PA+VSD	10		8		
PA+IVS	2		0		
dTGA+VSD+PS	2		2		
AVSD+PA	2		7		
Others	4		3		
Tortuosity index					NS
I	3		6		
II	12		10		
III	5		4		

SD: Standard deviation; UV: Univentricular; BV: Biventricular; PA: Pulmonary atresia; VSD: Ventricular septal defect; IVS: Intact ventricular septum; dTGA: d transposition of great arteries; PS: Pulmonary stenosis; AVSD: Atrio ventricular septal defect; NS: Non significant; * Statistical significance.

Table 2. Comparison of the findings of the two groups

	Group 1 (n= 20)			Group 2 (n= 20)			
Variables	n	%	Mean±SD	n	%	Mean±SD	*p*
Procedural success (%)		90			100		0.48
Procedural time (min)			53.6±18.4			41.3± 9.7	**0.028**
Cumulative stent length (mm)			15.8±3.6			19.3± 5.7	**0.022**
Stent diameter (mm)			3.89±0.26			3.75±0.47	0.301
Number of stents							NS
1	16			12			
2	2			7			
3	1			1			
Complications:							NS
Stent migration	1			1			
Acute stent thrombosis	1			1			
Pulmonary artery jailing	0			1			
Post procedural pH			7.33±0.96			7.38±0.79	0.14
Post procedural lactate			2.40±0.69			2.30±0.56	0.84
Inotrop use	2			1			NS
Hospital stay (day)			7.0±8.6			4.8±0.9	0.301
Follow-up (month)			14.8±11			6.6±5	0.015
Reintervention	3			1			0.60

SD: Standard deviation; NS: Non Significant.

DISCUSSION

Ductal stent implantation was first initiated by Gibbs et al.[5] in 1992 as a less invasive alternative palliation method. In the past three decades, the success rate of DSI has increased to over 90% thanks to the quality of materials provided by improved technology and the increased operator experience in this field.[6,8,9,17] Nowadays, it is the first choice in some clinics for palliation of patients with DDPC. It is also the first option for palliation of patients with DDPC in our clinic.

In addition to the experience of the operating center and the operator, ductal origin and morphology are the most important factors affecting the success of this procedure. The most appropriate access route to the origin of the duct and its anatomy is known to affect the success rate of DSI.[13,14,18-21] In different pathologies, AD morphology is complicated and varies in terms of origin, length, and tortuosity. In recent years, there have been various studies to develop a morphological classification for the AD in patients scheduled for DSI.[13-15] Roggen et al.[13] presented a morphological classification of the DA according to its origin from the aorta and its attachment to the pulmonary artery in patients with ductus dependent pulmonary circulation, and six different types were defined. Qureshi et al.[14] introduced a tortuosity index based on the turns in DA, and the AD was classified into type 1 (straight), type 2 (single turn), and type 3 (multiple turns). With a more detailed description of the anatomy and morphology of the DA and increased experience in the use of access routes appropriate to the type and morphology of the ductus, a more liberal approach has replaced the restrictive approach previously used in DSI.[9,12]

Many studies have reported low success rates for DSI via the classical femoral route in vertical ducts with a high tortuosity index.[11,14,17] It is recommended to perform the stenting procedure via the carotid artery or axillary artery route in such cases.[16,19] These alternative routes allow the practitioner to directly visualize the DA and to complete the procedure with fewer complications.[20] In our practice, we decide the route after the echocardiographic examination of ductus anatomy. In cases where we decide to use the carotid artery route, we perform the sheath placement process under ultrasound guidance in the safest way. The carotid cutdown technique has not been reported to be superior to the percutaneous direct puncture.[22]

However, the carotid artery way has some disadvantages, including the fact that its use is an unusual catheterization method in pediatric cardiology, as well as the differences in how the operator is positioned with regard to the patient and the operating table during the procedure. When using the femoral artery or vein, the direction of advancing the catheter is from bottom to top as usual, whereas when the carotid artery is used, it is advanced from top to bottom. It is more difficult for the operator on the side of the patient to advance the catheter from top to bottom. Furthermore, most of the sterile area of the table is located lower than the head. In some cases, the operator can move to the patient's head side, and an additional sterile table could be prepared. Thus, the scene at this position is not just across the operator but on the left side. However, with the flip technique described by Bauser-Heaton et al.,[15] it is possible to overcome these disadvantages. With this technique, the patient is placed on the catheterization table in the usual position. After induction of anesthesia and endotracheal tube placement, the patient is rotated 180°in the craniocaudal axis but remains in supine position. Following patient rotation, the endotracheal tube position is fluoroscopically reconfirmed, and the tube is secured to the contralateral side of the carotid artery to be intervened. The fluoroscopic images are digitally reconstructed for conventional visualization.[15]

We apply the flip technique by slightly modifying the description above; the patient is taken directly to the catheter table in a 180° rotated position (Figure 1). In this position, after induction of anesthesia and endotracheal intubation, we fix the tube as above. A 4-F NIH catheter is inserted nasogastrically or orogastrically into the stomach to be used for calibration purposes while hand injections are given through the side arm of the sheath (Figure 2). The fluoroscopic images are digitally reconstructed for conventional visualization (Figure 3). After covering the patient with a sterile catheter drape, we insert a 4-F sheath into the targeted carotid artery using the percutaneous Seldinger method under ultrasound guidance.

The present study allowed the comparison of two groups of 20 patients each with similar demographic characteristics. All the patients were considered to be more appropriate for the carotid artery route. The procedure was performed using the conventional method until 2021 when we used the flip technique for the first time in our center. After the first case, when we realized its more ergonomic and procedure-facilitating features, we subsequently preferred the flip method in all patients we used the carotid artery.

The technique allows the operator and ancillary staff to perform the procedure in the position they are familiar with. It does not cause any orientation problems. It creates enough space on the catheter table for the material used. It allows the first operator alone to perform the difficult manipulations. After crossing the patent DA with the guide wire, the possibility of loss of guide wire position is minimized. All these advantages increase the success of the procedure and shorten the procedure time significantly.

The results showed that the DSI success rate was 18 (90%) in Group 1 and 20 (100%) in Group 2 (Table 1). The difference in success was not significant (p=0.48). It has been reported that the use of the carotid artery significantly increases the success rate in cases of vertical DA.[13,16,22] Considering that our DSI success rate was 93.5% in the patient group in which we used the carotid artery in our previously published study, it can be said that the flip technique does not have a dramatic effect on success.[16] The most important finding in this study was that the procedure time was significantly shorter in favor of the flip method, with 53.6±18.4 min in Group 1 and 41.3±9.7 min in Group 2, as in the studies of Bauser-Heaton et al. (p=0.028).[15]

Complications included one stent migration and one acute stent thrombosis in both groups and one left pulmonary artery jailing in Group 2. There was no procedure-related mortality. Two patients from Group 1 died during the follow-up period. There was no difference between the groups in pH and lactate values in arterial blood gases immediately after the procedure (p=0.14 and p=0.81, respectively). Inotropes were temporarily used in one patient in each group during the procedure. There was no difference between the hospitalization periods of the patients (p=0.3). The follow-up time showed a significant difference, with 14.8±11 months in Group 1 and 6.6±5 months in Group 2 (p=0.015). This was explained by the fact that the flip method was started to be used later in the clinic.

The most important disadvantage of the flip technique is that if intracardiac interventions are to be performed, such as septostomy, it is necessary to turn the patient to the normal position. Another disadvantage is that older installed devices may not be suitable for these modifications. Adaptation of medical staff to an unusual patient position is also a concern.

In conclusion, the application of the flip technique during carotid artery approaches allows the operator to perform the procedure in a familiar position, creates sufficient space on the catheter table for the material used, and facilitates maintenance of the guidewire passed through the patent ductus arteriosus. The use of the flip technique is preferred for operator friendliness, ergonomic handling of the catheter and guidewire, and shorter procedure time.

Ethics Committee Approval: The study protocol was approved by the Health Sciences University Gazi Yasargil Training and Research Hospital Clinical Research Ethics Committee (date: 13.10.2023, no: 557). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from the parents and/or legal guardians of the patients.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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