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***Original Article** / Özgün Makale*

Right ventricular outflow tract stenting during neonatal and infancy periods: A multi-center, retrospective study

Yenidoğan ve infant döneminde sağ ventrikül çıkım yoluna stent yerleştirilmesi: Çok merkezli, retrospektif çalışma

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ABSTRACT

Background: The aim of this study was to evaluate the outcomes of right ventricular outflow tract stenting for palliation during the newborn and infancy periods.

Methods: Between January 2013 and January 2018, a total of 38 patients (20 males, 18 females; median age 51 days; range, 3 days to 9 months) who underwent transcatheter right ventricular outflow tract stenting in three centers were retrospectively analyzed. Demographic characteristics, cardiac pathologies, angiographic procedural, and clinical follow-up data of the patients were recorded.

Results: The diagnoses of the cases were tetralogy of Fallot (n=27), double outlet right ventricle (n=8), complex congenital heart disease (n=2), and Ebstein's anomaly (n=1). The median weight at the time of stent implantation was 3.5 (range, 2 to 10) kg. Five cases had genetic abnormalities. The median pre-procedural oxygen saturation was 63% (range, 44 to 80%), and the median procedural time was 60 (range, 25 to 120) min. Acute procedural success ratio was 87%. Reintervention was needed in seven of patients due to stent narrowing during follow-up. During follow-up period, seven cases died. Total correction surgery was performed in 26 patients without any mortality. While a transannular patch was used in 22 patients, valve protective surgery was implemented in two patients, and the bidirectional Glenn procedure was performed in two patients.

Conclusion: Based on our study results, right ventricular outflow tract stenting is a form of palliation which should be considered particularly in cases in whom total correction surgery is unable to be performed due to morbidity.

Keywords: Infant, newborn, palliation, right ventricular outflow tract, stent.

ÖZ

Amaç: Bu çalışmada yenidoğan ve infant döneminde palyasyon amaçlı sağ ventrikül çıkım yoluna stent uygulanan olguların değerlendirilmesi amaçlandı.

Çalışma planı: Ocak 2013 ve Ocak 2018 tarihleri arasında, üç merkezde, sağ ventrikül çıkım yoluna transkateter yoldan stent yerleştirilen toplam 38 hasta (20 erkek, 18 kadın; medyan yaş 51 gün; dağılım 3 gün-9 ay) retrospektif olarak incelendi. Hastaların demografik özellikleri, kardiyak patolojileri, anjiyografi işlem ve klinik izlem verileri kaydedildi.

Bulgular: Tanılar Fallot tetralojisi (n=27), çift çıkışlı sağ ventrikül (n=8), kompleks doğumsal kalp hastalığı (n=2) ve Ebstein anomalisi (n=1) idi. Stent yerleştirme sırasında medyan ağırlık 3.5 (dağılım, 2-10) kg idi. Beş olguda genetik anormallikler mevcuttu. İşlem öncesi medyan oksijen satürasyonu %63 (dağılım, %44-80) ve medyan işlem süresi 60 (dağılım, 25-120) dk. idi. Akut işlem başarısı %87 idi. Takip döneminde stent daralması nedeniyle yedi hastaya tekrar girişim uygulandı. Takip döneminde, yedi olgu kaybedildi. Hastaların 26'sına mortalite olmaksızın tam düzeltme ameliyatı yapıldı. Yirmi iki hastada transanüler yama kullanılırken, iki hastada kapak koruyucu tam düzeltme ve iki hastada çift yönlü Glenn operasyonu gerçekleştirildi.

Sonuç: Çalışma sonuçlarımıza göre, sağ ventrikül çıkım yoluna stent yerleştirilmesi, özellikle morbidite nedeni ile tam düzeltme ameliyatı yapılamayan olgularda akla gelmesi gereken bir palyasyon çeşididir.

Anahtar sözcükler: Infant, yenidoğan, palyasyon, sağ ventrikül çıkım yolu, stent.

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Right ventricular outflow tract (RVOT) obstruction may coexist with congenital heart diseases such as tetralogy of Fallot (TOF), right ventricular (RV) hypoplasia, and double outlet right ventricle (DORV). Under these circumstances, cyanosis due to systemic or supra-systemic RV pressure and decreased pulmonary blood flow are the main indications for treatment. Depending on the patient's cardiac pathology, intensive care conditions, the staff's experience, and the choice of treatment modality may be total correction or palliation.[1-3]

Recently, with increasing surgical experience and technical advances, the outcomes of total correction surgery cases with RVOT stenosis are relatively favorable. However, there is an important subgroup of high-risk patients who have prematurity, low body weight, insufficient development of pulmonary arteries, and systemic diseases or additional congenital anomalies. As these additional factors increase the need of cardiopulmonary bypass and can significantly reduce the success of total correction surgery, palliative methods have been increasingly used in the management of these patients.[4,5]

The main goal of palliation methods is to provide enough blood to the pulmonary artery.[6] Palliative procedures include a surgical method (aortopulmonary shunt) or a transcatheter method (stenting of the arterial duct, balloon pulmonary valvuloplasty, RVOT stenting).[6,7] In recent years, a limited number of studies has reported that transcatheter RVOT stent placement is a safe and effective alternative palliation method in patients who are not suitable for total correction or have a high risk for surgery.[6,8,9] In the present study, we aimed to evaluate the outcomes of RVOT stenting for palliation during the newborn and infancy periods and to examine the results of total correction surgery in these high-risk patients.

PATIENTS AND METHODS

Between January 2013 and January 2018, a total of 38 patients (20 males, 18 females; median age 51 days; range, 3 days to 9 months) who underwent transcatheter right ventricular outflow tract stenting in three centers were retrospectively analyzed. Two of the three centers were newly established during the study period. Therefore, the start date of the study was different for the three centers, although the termination date of the study was the same for all clinics. In addition, it was possible to follow all patients until either total repair or death. Data including demographic and clinical characteristics of the patients, echocardiographic diagnosis, procedure indication, preprocedural oxygen saturation, mechanical ventilator requirement, and inotropic support were recorded. The approach to RVOT stenosis is summarized in detail in Figure 1. A written informed consent was obtained from each parent and/or legal guardian. The study protocol was approved by the Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Each patient underwent two-dimensional and Doppler echocardiography one day before the procedure using standard imaging techniques in accordance with the recommendations of the American Society of Echocardiography.[10] The patients were on either oral propranolol hydrochloride (3 mg/kg/day - 3 dose) or intravenous esmolol (according to the patient's arterial blood pressure, 50-100 μg/kg/min infusion) until the intervention. Esmolol infusion was initiated routinely at the first center (Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital) at least a day before the procedure, and the patients were treated under esmolol infusion. Infants under esmolol infusion were routinely followed and monitored. If the heart rate dropped below 80 bpm (while sleeping) and 90 bpm (while awake), esmolol infusion rate was decreased. The rates were adjusted based on the saturation levels and heart rates. In the second center (Siyami Ersek Thoracic and Cardiovascular Surgery Training and Research Hospital), the patients were taken to the procedure after being treated with propranolol. In this center, esmolol was not used before the procedure. In the third center, (Istanbul Medipol University) no premedication was applied in the first few patients. However, in the last three cases, all patients were treated with esmolol infusion.

Catheterization procedural details

Procedural details vary among each institution. All cardiac catheter procedures were performed under general anesthesia. Except one case (right internal jugular vein), the right or left femoral vein was used as the entrance site. In addition to a pre-procedural standard antibiotic prophylaxis, all patients received 50 to 100 IU/kg of heparin with repeated doses every after 60 min. Blood pressures and heart rates were monitored. An arterial access was used to measure blood pressure and to visualize major aortopulmonary collateral arteries (MAPCAs) in all cases.

A RV angiogram was performed through a diagnostic catheter placed toward the apex of the

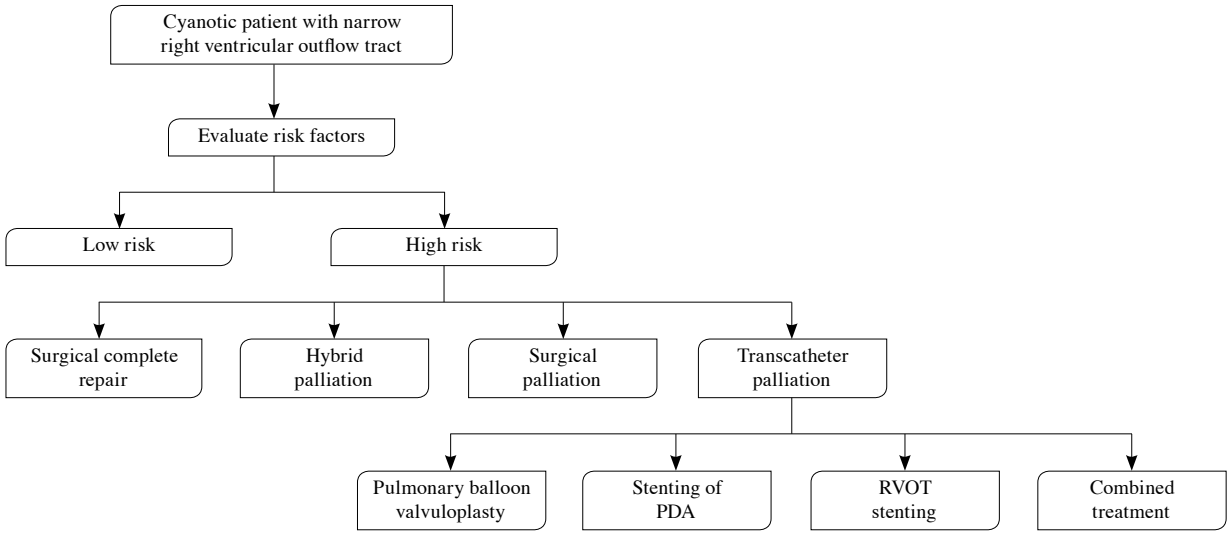

Figure 1. Approach to a cyanotic patient with narrow right ventricular outflow tract.

PDA: Patent ductus arteriosus; RVOT: Right ventricular outflow tract; Risk factors: Genetic syndrome, low birth weight or low weight at the time of procedure, general condition disorder, accompanying comorbid diseases.

RV with 20° right anterior oblique with 20° cranial and 20° left anterior oblique, and with 20° cranial angulations and a straight lateral projection. The RV, pulmonary valve annulus, anatomy of right and left pulmonary arteries, and their peripheral branches were all evaluated (Figure 2). The measurements were made after contrast injections.

The measurements were evaluated by Z-scores which were standardized according to the body surface area. The patients who were eligible for total correction were consulted by the surgical team and were operated for total repair, while those who were not eligible for full correction and needed palliation underwent RVOT stenting.[11,12]

During initial RVOT stenting procedures, all of the centers performed coronary artery injections to visualize the coronary artery anatomy and its association with RVOT. However, later, none of the centers performed the procedure, since compression of the coronary artery was unlikely to occur in a stented native outflow tract during infancy.

The Judkins catheter or guiding catheter was advanced to the right or left pulmonary artery with the aid of a 0.035" hydrophilic guide-wire from

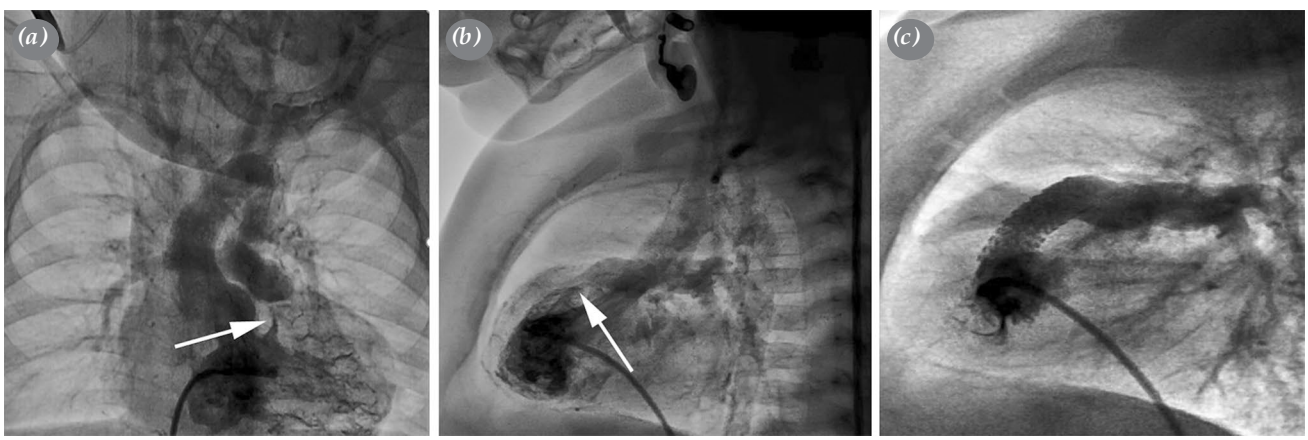

Figure 2. An angiogram of a four-month-old case weighing 6 kg. A right ventricular angiogram showing narrowing in right ventricular outflow tract, pulmonary valve annulus, right and left pulmonary artery anatomy, and peripheral arteries of pulmonary arteries. **(a)** Anteroposterior projection, **(b)** lateral projection **(c)** after 7-mm stent implantation. White arrows indicate narrowing in right ventricular outflow tract.

the antegrade pathway. An appropriate-sized wire (0.014", 0.018" or 0.035" depending on the stent size) was placed in the left/right pulmonary artery. The stents were introduced from the femoral vein, and long sheaths or guiding catheters were always used while advancing the stents. This equipment helps to minimize the potential for significant hemodynamic instability which is frequently encountered while crossing obstructed pulmonary outflow tracts. A pre-mounted stent was selected according to angiographic and echocardiographic measurements of the pulmonary valve annulus and RVOT infundibular length. The stent diameter was at least 2 mm larger than the narrowest part of the main pulmonary artery, pulmonary annulus or RVOT. The length was 1 to 2 mm longer than the narrowest part (RVOT or RVOT to main pulmonary artery length). If the length of the infundibulum and RVOT could not be fully covered with one stent, a second stent was placed in the telescopic manner.

An extreme attention was paid while removing the deflated balloon to avoid compromising the deployed stent. After stent placement, a repeat RV angiogram was performed through the long sheath with the wire remaining in the pulmonary artery. An echocardiographic evaluation was performed to confirm the adequate positioning of the stent and rule out any damage to any of the surrounding structures in the cardiac catheterization laboratory. The guidewire and the venous sheath were removed, only when the patient was entirely stable.

Statistical analysis

Statistical analysis was performed using the SPSS for Windows version 15.0 software (SPSS, Chicago, IL, USA). Continuous variables were expressed in median (min-max), and categorical variables were expressed in number and frequency.

RESULTS

A total of 38 patients with RVOT stenting cases were collected from three centers including more than eight cases from each center. Baseline demographic

Table 1. Baseline demographic and clinical characteristics of patients

Patient characteristics	n	%	Median	Range
Sex				
Male	20	52		
Female	18	48		
Median age (day)			51	3-270
<1 months	18	47		
1-6 months	18	47		
>6 months	2	6		
Median body weight (kg)			3.5	2-10
Median saturation (%)			63	44-80
Syndrome				
None	33	87.0		
Down syndrome	2	5.1		
Di George	1	2.5		
Trisomy 18	1	2.5		
VACTERL	1	2.5		
Diagnosis				
Tetralogy of Fallot	27	71.0		
Double outlet right ventricle	8	21.0		
Right atrial isomerism + complete atrioventricular septal defect + pulmonary stenosis	2	5.2		
Ebstein anomaly	1	2.6		
Prostaglandin E1	6	15		
Mechanic ventilation	5	13		
Inotropic support	3	8		
Pulmonary annulus				
Median size (mm)			4.9	3.1-7
Median Z score			-1	+1 to -2

and clinical characteristics of the patients are summarized in Table 1.

Three of the patients underwent patent ductus arteriosus (PDA) stenting during the neonatal period; however, with an increasing age, RVOT stenting was performed due to inadequate blood flow through the PDA stent and unsuitability for complete repair. In addition, four patients previously underwent pulmonary balloon valvuloplasty.

A catheterization procedure was performed in 38 cases (5 urgent and 33 elective interventions). Five patients were intubated before the procedure, and all patients received oxygen support. Inotropic support was given in three patients, and PGE1 infusion was initiated in six cases.

The median pre-procedural oxygen saturation was 63% (range, 44 to 80%), and the median procedural time was 60 (range, 25 to 120) min. Before the first catheter procedure, the median pulmonary annulus diameter was 4.9 (range, 3.1 to 7) mm with a avarage Z-score of value (-2 to +1).

In 33 of 38 patients (86%), stent placement procedures were successfully performed, whereas the procedure could not be performed in five patients of whom two were lost during the procedure or at the same day. In the remaining three cases, the modified Blalock-Taussig (mBT) shunt was performed as a rescue procedure. Two of three patients with mBT shunt had total correction, while one of them died during follow-up (Figure 3). All patients who were unable to undergo stenting (5/38 patients) or died (6/33 patients, although the procedure was successful) were the initial few patients of the newly established centers.

Coronary or peripheral stents of different types and brands were used during the procedures, according to each patient's pathology, body weight, and RVOT anatomy. The median balloon diameter was 6 (range, 4 to 8) mm, and the mean stent length was 15 (range, 12 to 20) mm. In 25 of 33 patients (76%), the stent was advanced to include the pulmonary annulus. In eight of 33 patients (24%), the stent was placed in the subvalvular region of the RVOT. If the stent did not fully cover the narrowest region in the RVOT, a second stent was placed at the same session.

The median fluoroscopy time was 25.4 (range, 6.8 to 75) min. The median saturation after

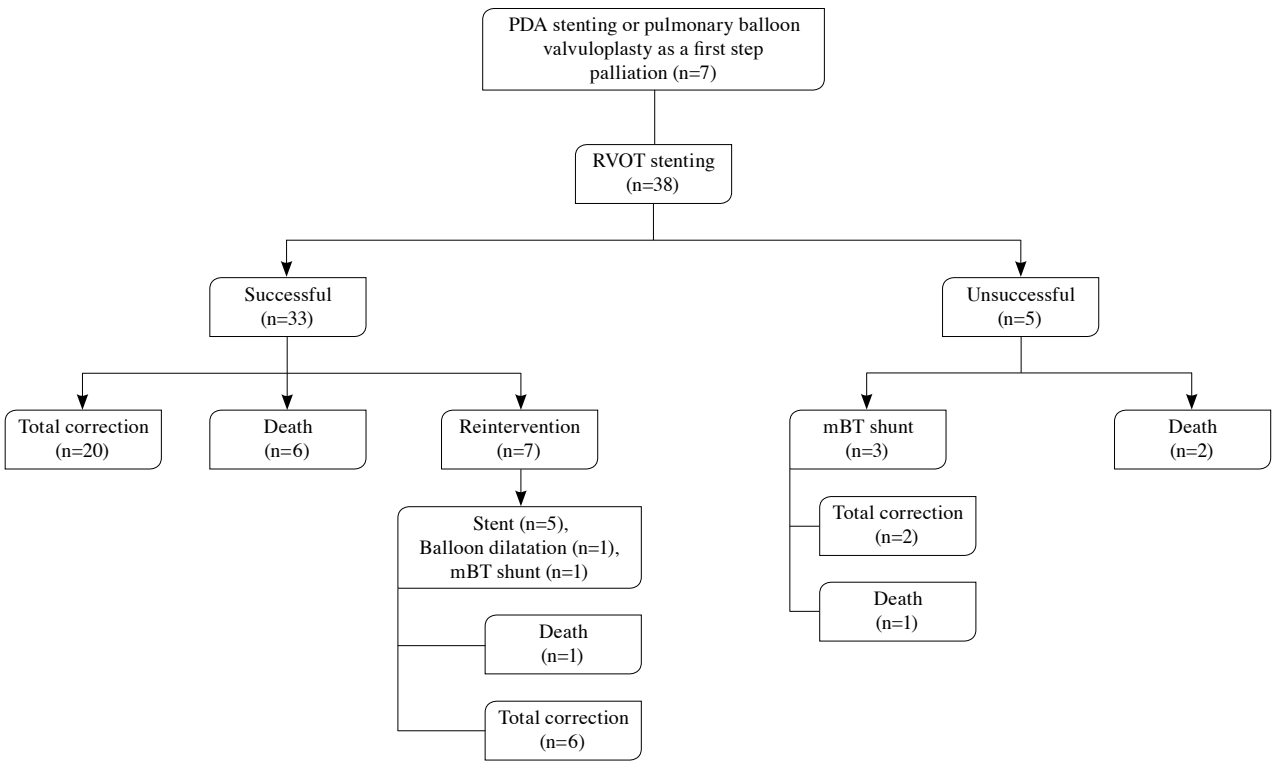

Figure 2. Follow-up data.

PDA: Patent ductus arteriosus; RVOT: Right ventricular outflow tract; mBT: modified Blalock-Taussig.

the procedure was 88% (range, 80 to 96%). Two patients had transient pulse loss, and one patient had a temporary complete atrioventricular block. Two patients died within the first 24 h after the procedure.

Clinical follow-up

The median hospitalization time was 14 (range, 3 to 90) days. Although the procedure was successful in six of the patients, they died during the same hospitalization period. One of these patients had Down syndrome. The diagnoses of the patients were TOF in three, DORV in two, and complete atrioventricular septal defect with right atrial isomerism, and pulmonary stenosis in one patient. Three of the patients were intubated and necessitated inotropic support. Among those patients, the intervention was unsuccessful in two patients, although one of them underwent mBT shunt after an unsuccessful RVOT stenting and died at the same hospitalization period. Six patients died at home after successful RVOT stenting, and one died at home after the second intervention (mBT shunt) (Figure 3).

During the follow-up period, seven of 33 patients required reintervention. The median transcatheter reintervention time for six out of seven cases was four weeks (range, 5 days to 4 months). Catheter reinterventions were done in four patients due to decreased in-stent flow and in two patients due to subpulmonic muscle hypertrophy. Second stent placement was performed in five patients, and stent dilatation with a balloon was required in one patient. An mBT shunt was performed in a patient due to ineligibility for stenting into the RVOT or total repair; however, this patient died during follow-up. Totally 10/38 (26%) patients died after the procedure during the hospitalization (Figure 3).

Surgical total correction was successfully achieved in 26 of 33 patients who underwent RVOT stenting procedure. Total correction was accomplished eight to 80 weeks after the initial RVOT stent implantation (median: 16 weeks). The timing for total correction surgery was decided according to patients' oxygen saturation, pulmonary artery growth, clinical condition, surgical correctability of the other accompanying pathologies, and patient compliance with scheduled follow-up visits (i.e., as some of the patients were living in rural areas, and they had difficulty in attending the follow-up visits). In 22 of 26 patients, total correction surgery was performed with transannular patching of the RVOT, while two patients had valve protective surgery and the other two patients underwent bidirectional Glenn anastomosis.

There was no perioperative mortality in this study. Severe postoperative right heart failure was reported in two patients of whom one patient needed extracorporeal membrane oxygenation support.

DISCUSSION

In this study, we evaluated RVOT stenting along with the clinical follow-up of these patients from three different centers. The RVOT stent procedure was successful in high-risk newborns and infants (due to low body weight, concomitant other diseases and syndromes) and made a significant contribution to the palliation process. Final total correction was achieved in 68% of the high-risk patients. To the best of our knowledge, this is the first and largest series in Turkey regarding the RVOT stenting in children.

Right ventricular outflow tract stenosis is part of congenital heart diseases such as TOF, DORV, and some complex congenital heart diseases. It causes cyanosis or spell seizures and may require early surgery. The treatment of symptomatic patients due to RVOT stenosis is a total correction surgery. With the continuing development in surgical experience and device hardware means, total correction can be obtained in all age groups, particularly in patients with TOF. In some institutions, surgery can be even performed during the neonatal period with mortality rates below 5%. The advantages of full correction during the neonatal period are prevention of further cyanosis, minimal RV hypertrophy and fibrosis, avoiding volume load of the left ventricle due to shunt, and reduced risk of arrhythmia. Disadvantages include an increased exposure of the patients to postoperative stress, longer duration of intensive care unit stay, more frequent pulmonary regurgitation due to the need for transannular patch, and more neurological damage.[13]

However, palliative methods may be required in patients with high risk due to the factors such as severe cyanosis (particularly aged less than one month), low body weight, presence of other systemic diseases, inadequate development of pulmonary vascular bed, and total correction under cardiopulmonary bypass. Palliative procedures include aortopulmonary shunt, modified Brock procedure, stenting of the arterial duct by transcatheter methods, pulmonary balloon valvuloplasty (particularly in patients with marked pulmonary stenosis), and RVOT stenting (Figure 1).[7,14,15]

When the surgical palliation options are evaluated, the mBT shunt is still the gold standard and primary treatment modality. However, this is associated with complications such as pulmonary artery distortion,

phrenic and laryngeal recurrent nerve injury, chylothorax, shunt obstruction, over circulation, and even death. At the same time, the mortality rate of mBT shunt in newborns is high.[5,16]

In a study conducted by Quandt et al.[6] including 67 TOF patients (mBT shunt, n=28; RVOT stenting, n=39), RVOT stenting resulted in better pulmonary artery growth and oxygen saturation, compared to mBT shunt. In another study, they reported that RVOT stenting could be performed safely with a lower intensive care unit hospitalization rate, shorter hospital stay, and shorter palliation time until complete repair.[8]

Transcatheter stent implantation into PDA is another palliation option; however, the ductus should be open and the position of ductus should be suitable for transcatheter stenting.[9,17,18] This method can be applied in Turkey with a high success and low mortality rate. In the present study, the first palliation method was reported in cyanotic patients with an open PDA.

Pulmonary balloon valvuloplasty palliation is another option which can be safely performed. This method has been shown to be particularly effective in patients with significant valvular stenosis, while it fails in patients with severe infundibular stenosis.[19] It has been also reported that pulmonary balloon valvuloplasty reduces the pressure gradient by a smaller amount and has less effect on pulmonary artery development compared to RVOT stent placement.[20]

Stent implantation of RVOT is a fourth palliation option. It can be used in cases with a high risk for surgical intervention, additional congenital malformations, and when a sufficient effect is not achieved using other palliation methods. The most important complications associated with RVOT stenting are stent migration, ventricular arrhythmias, fracture or collapse of the stent, and recurrent stenosis.[5,7] Also, during total repair due to the stent in the RVOT and main pulmonary artery, the risk of pulmonary valvular damage and the need for transannular patch repair is increased, which is a major disadvantage of this procedure. The success rate in the presented study was found to be 33/38 (86%), whereas success rates of 94% was reported in the literature by Bertram et al.[5] (n=35) and Stumper et al.[3] (n=52).

In our study, the acute procedure success rate was found to be 87%. The imperfect success rate was due to the learning curve, which improved over time up to 100% with the growing experience of the newly established centers. This finding indicates that the procedure can be performed with high success rates after an adequate level of experience is achieved.

On the other hand, the question of whether pre-medication before the procedure affects the success of the intervention remains statistically uncertain. Some interventional cardiologists have advocated that reducing the stenosis of the RVOT as much as possible increases the success, and beta-adrenergic receptor blockers are recommended.

In one of the centers participating in the study, the patients were treated with esmolol infusion prior to the procedure to avoid low success possibility. Although unpublished, this center observed that esmolol infusion had a positive feedback on their success gain. However, it is not possible to prove whether this is due to the increased experience of central interventional cardiologists or the drug contributes to the success of the procedure by reducing spasms in RVOT. Nevertheless, interventional cardiologists in two of the three centers have currently reported that all patients undergo esmolol infusion in routine practice.

It was reported that between 67 and 100% of the patients were delivered to total repair. The most common cause of death was non-cardiac complex pathologies. The present study suggested that the total correction surgery could be performed at a median of 16 weeks. Also, in the largest published series, the authors reported that total correction could be performed between 16 weeks and 26 weeks after the RVOT stenting procedure. However, it was reported that patients were still monitored during this period.[1-3,5] In the present study, surgical total correction was achieved in 26 of 33 cases (79%), and the median time to surgery after the intervention was 16 weeks.

Dohlen et al.,[1] Stumper et al.,[3] and Bertram et al.[5] reported the rate of reintervention as being 18%, 41%, and 52%, respectively. It was also reported that there was a need of one to three reinterventions, until surgical total correction was performed. The authors reported that reinterventions included balloon dilatation of RVOT stent, a second stent placement, or mBT shunting. In the present study, the reintervention rate was 7/33 (21%), consistent with the literature. In addition, some of these patients are still not totally repaired, suggesting that these rates may be higher than estimated.

This study was performed retrospectively including a limited number of cases. The subgroups of patients with RVOT stenosis are heterogeneous, and the three

centers performing the procedures have different experience and protocols. Another disadvantage is that a comparison was unable to be made regarding other options such as surgical shunt or total repair. Also, before surgical repair, each patient was unable to undergo control angiography and pulmonary artery growth was unable to be evaluated objectively and compared.

In conclusion, symptomatic neonates or infants who are unsuitable for total correction surgery with a narrow right ventricular outflow tract may have significant comorbidities. Application of right ventricular outflow tract stents may be an alternative palliation option in this patient population. Since patients have high mortality and morbidity rates, they should be closely monitored, and reinterventions should be applied urgently, when necessary.

Declaration of conflicting interests

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