ORIGINAL RESEARCH

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Balloon angioplasty performed with coronary balloons in newborns with severe coarctation of aorta: a single center experience

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Abstract

Objective: Critical coarctation of the aorta (CoA) may cause severe left ventricular dysfunction and systemic hypoperfusion in the neonatal period. Surgical treatment in the neonatal period is superior to balloon angioplasty due to lower recoarctation and reintervention rates. However, surgical mortality increases in hemodynamically compromised patients. This has generated interest in emergency palliative balloon angioplasty as a bridge to surgery. The present study reports outcomes of emergency palliative balloon angioplasty performed with coronary balloons due to resource limitations, including the absence of neonatal-specific balloons and inconsistent access to pediatric cardiac centers.

Method: Records of all newborns diagnosed with critical CoA [w11.1][OÇ1.2]and undergoing coronary balloon angioplasty were retrospectively reviewed.

Results: The study included 14 critical neonates who underwent balloon angioplasty with coronary balloons. After the procedure, 13 of 14 patients with successful balloon use had left ventricular functions to return normalize within the first 24 hours. The diameter of the narrowest site increased from 1.71 to 4.34 mm ($p<0.001$), the peak-to-peak gradient decreased from 63.5±19 to 20.5±15.1 mmHg ($p=0.002$), ejection fraction increased from 42.3±9.1% to 68.3±4.7% ($p<0.001$). Circulatory disorder regressed and laboratory tests improved. After a successful balloon, 4 patients discharged from the hospital without surgery. In 5 patients, surgery was performed in better condition and all of them were discharged and no one developed recoarctation. One patient had second balloon angioplasty performed.

Conclusion: Coronary balloons can be used safely with palliative aims in newborns with high surgical mortality risk as a bridge to surgery.

Keywords: Coarctation of aorta, critical, newborn, coronary balloon

INTRODUCTION

Coarctation of aorta (CoA) is a congenital malformation causing systemic circulatory disorder due to stenosis at varying degrees in the transverse and/or descending portion of the aorta. It comprises 5-7% of all congenital heart diseases (1-4). Mild stenosis lesions are encountered such as hypertension findings in the late childhood period (5), while

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critical coarctation may cause significant systemic circulatory disruption, shock and, multiorgan failure in the neonatal period (3,5).

Previously CoA treatment was only performed with surgical methods, while balloon dilatation was added to treatment in the last three decades (6). Surgical treatment for coarctation identified in the neonatal period is superior compared to balloon angioplasty due to less recoarctation development and lower reintervention rates (1,4,7). However, in critical situations, neonates' high surgical mortality risk has increased interest in emergency palliative balloon angioplasty (3, 7-10). Additionally, special balloons produced for use in balloon angioplasty procedures in neonates may not always be accessible for various reasons in emergencies.

The aim of this study was to report outcomes of emergency palliative balloon angioplasty performed with coronary balloons due to resource constraints, including the absence of neonatal-specific balloons and lack of on-site pediatric cardiac surgery, in neonates with critical CoA.

METHOD

Records of all neonates admitted with severe systemic circulatory disorder due to critical CoA, who could not undergo cardiac surgery and received emergency palliative balloon angioplasty, were retrospectively reviewed.

Permission was granted for the study by the Hatay Mustafa Kemal University Non-Interventional Clinical Research Ethics Committee dated 27/07/2020, numbered 09/27. Informed consent was obtained from the patients' families and the necessary permission was granted by the organization. The symptoms of patients before and after treatment, examination findings and laboratory values, echocardiography and angiography data were used to research the reliability and efficacy of the palliative use of coronary balloons in neonates with critical coarctation.

Patient selection: Files of 23 patients admitted to the neonatal intensive care unit with a preliminary diagnosis of the aorta's coarctation from September 2018 to September 2020 were accessed in our hospital database. Five patients transferred to pediatric cardiac surgery centres for surgical treatment without performed angioplasty, 2 patients with interrupted aortic arc + ventricular septal defect (VSD) + patent ductus arteriosus (PDA), 1 patient with arterial intervention not performed due to prematurity and 1 patient who did not abide by critical coarctation definition (systolic dysfunction developing due to supraventricular tachycardia (SVT)) were removed from the study. The study included 14 critical neonates who underwent the balloon angioplasty procedure with coronary balloons (Figure 1).

Collection of data: The demographic data, vital signs at the time of diagnosis and after angioplasty (heart rate, respiratory rate, and upper and lower extremity blood pressure), pathological findings on physical examination (assisted respiration, hepatomegaly, oedema, diuresis), and laboratory values (hemogram, glucose, BUN, creatinine, AST, ALT, ions, albumin, uric acid, PH, PCO2, HCO3, and lactate in blood gas) were recorded for patients.

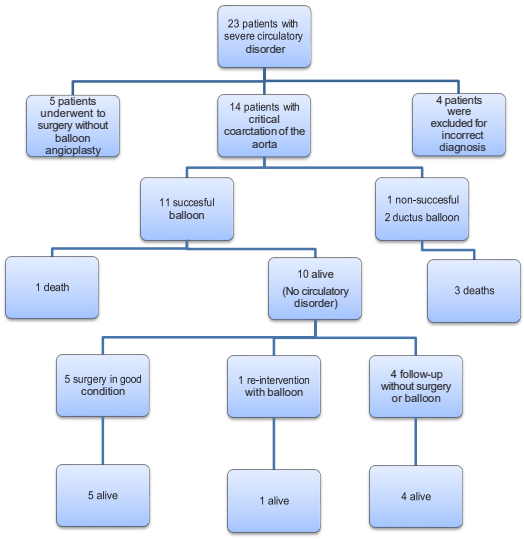


Figure 1. Flow chart illustrating selection of the patients, results of balloon angioplasty, and final outcome

Echocardiographic data: The coarctation type (tubular-discrete), aorta diameters (proximal, transverse arc, isthmus, narrowest section), gradient between proximal and distal sections, comorbid pathologies (LV systolic dysfunction, RV dilatation, bicuspid aorta valve, aorta stenosis, mitral stenosis, LV hypoplasia, VSD, PDA, systolic and diastolic pressure in pulmonary artery), diameter of narrow point after angioplasty, echo gradient and postprocedural LVEF were recorded.

Data for angiography and balloon angioplasty procedure: Sedation-analgesia, ventilation support, intervention region, local anaesthesia, type and size of sheaths and guidewires used, catheter choice, site and amount of radio-opaque agent administered, coarctation type, aorta diameters, initial and postprocedural gradient between proximal and distal sections of stricture, size of balloon used, emerging pressure values, number of balloon inflations, procedure duration, fluoroscopy duration, and complications developing during the procedure were recorded.

Postoperative care data: Status of femoral pulse, heparin infusion, blood transfusion, postoperative sedation and analgesia, antibiotics, duration on mechanical ventilator,

feeding, postoperative hypertension, postoperative pulmonary arterial pressure, use of sildenafil, duration of hospital stay, exitus, and discharge or transfer for surgery data were screened in detail.

Angiography and balloon angioplasty technique: The first 7 patients had the standard procedure performed (11). Non-compliant coronary balloons were used in all procedures. These balloons were inflated close to their burst pressure, and near-maximal inflation resulted in slight oversizing; for example, a 5-mm balloon expanded to approximately 5.6 mm. The following 7 patients had the catheter-free balloon method performed to shorten the procedure duration. In this method, the injections were administered through the sheath side connection. Then a coronary guidewire with torquer attached was passed inside the sheath alone to the coarctation region. The coronary balloon was passed above the wire within the femoral sheath. When the coarctation region was reached, the balloon's suitable position was confirmed by administering radio-opaque material through the side connection of the sheath (total dose at most 4 cc/kg). In both methods, the manufacturer's recommended pressures were not exceeded and the balloon was inflated 3-4 times for the indentation to disappear. Control injection was repeated through the side connection of the vascular sheath to check whether complications developed linked to the balloon or not. After the procedure, the distal aorta pressure was measured through the sheath side connection. Instead of proximal aorta pressure, blood pressure was measured using Doppler on the right arm.

All coarctation cases had procedure and fluoroscopy durations recorded. After the procedure, the first echocardiography investigation was repeated in the catheter room to assess patients in terms of opening of the coarctation region, gradient, and complications. Additionally, follow- up data were investigated in terms of prognosis.

Statistical analysis

All data were analyzed using the SPSS statistical program (version 21.0, IBM Corporation, Armonk, NY, USA). Descriptive data were stated using mean and standard deviation values. Comparison of values before and after catheterization was conducted with the two-sample paired t-test for data with normal distribution and the Wilcoxon test for data without normal distribution. A one-way ANOVA test was used to compare the means. The distribution of the data was investigated with the Kolmogorov-Smirnov test. P values below 0.05 were accepted as significant.

RESULTS

The study included 14 critical neonatal patients. Of these, 8 were male and 6 female, with gestational age 32-40 weeks (38.1±1.9), postnatal age 5-28 days (13.9±7.7), and body-weight 1800-4700 g (3107±596 g). Ten patients were transferred from Northern Syria in emergency conditions. Four patients were Turkish. The follow-up duration after the procedure was 10.3 months (range 4-16 months).

All patients received dual antibiotic treatment with preliminary diagnosis of sepsis when they attended the hospital. Twelve patients with respiratory failure received endotracheal intubation and mechanical ventilator support, while 2 patients had the angiography procedure performed with mask and oxygen without intubation. Table 1 shows the hemodynamic, Doppler and M-mode echocardiographic data for the patients. One patient with severe circulatory failure (case 6) had hypotensive shock findings (BP: 48/23 mmHg), while all other patients had systemic hypertension (Table 1). Apart from one case (case 2), all patients had clear hepatomegaly, right ventricular dilatation, and pulmonary hypertension findings (Table 2). Three patients had widespread oedema, while one of these had ascites in the abdomen. Among patients, 7 had discrete and 7 had long-segment coarctation. All patients had isolated coarctation of the aorta; therefore, the coarctation was juxtaductal in all cases (n=14). Accompanying cardiac findings were supra systemic pulmonary hypertension in 13/14, all were receiving diuretic and sildenafil treatment, a bicuspid aortic valve in 8/14 patients, VSD in 5/14 patients, hypoplasia of the ascending aorta in 3/14 patients, aortic valve stenosis in 3/14 patients, arcus aorta hypoplasia in 2/14 patients, PDA in 2/14 patients and, severe LV hypertrophy in 1/14 patients (Table 2).

All patients had the angiography procedure performed within the first 24 hours after hospital admission due to disrupted general status. After the procedure, all patients with successful balloon use (13/14) had left ventricular functions returned to normal within the first 24 hours (Table 1).

The diameter of the narrowest site increased from 1.71±0.42 to 4.34±0.51 mm ($p<0.001$). The peak-to-peak gradient decreased from 63.5±19 to 20.5±15.1 mmHg ($p=0.002$). The ejection fraction measured 24 hours after angioplasty increased from 42.3±9.1% to 68.3±4.7% ($p<0.001$). There were 2 early complications, 1 periprocedural death, and 3 later, giving 28% mortality. Severe circulatory disorder regressed in 10 patients. Data related to angiography and balloon angioplasty are shown in Table 2 and Table 3.

No patient developed vascular injury at the intervention site, ischemia in extremities, aortic dissection, infection linked to the procedure or complications requiring emergency surgery. Apart from 1 patient, all patients had prophylactic heparin infusion for the first 24 hours. No bleeding or other side effect linked to this was observed. During

the procedure, 1 patient was observed to transition from the contrast agent to the subendothelial area, but this was disappeared spontaneously after the procedure (case 1). tients continue to attend follow-ups without needing surgery or re-ballooning, the remaining two could not be reached.

Table 1. Hemodynamic, Doppler and M-Mode echocardiographic datas of the patients before and after balloon angioplasty

	GA (week)	PA (day)	BW (gram)	HR1 (bpm)	HR2 (bpm)	SBP1 (mm Hg)	SBP2 (mm Hg)	DBP1 (mm Hg)	DBP2 (mm Hg)	CoAGr1 (mm Hg)	CoAGr2 (mm Hg)	RVSP1 (mm Hg)	RVSP2 (mm Hg)	PAPD1 (mm Hg)	PAPD2 (mm Hg)	LVEF1 (%)	LVEF2 (%)
1	39	12	3300	136	124	110	-	80.00	-	70.00	65.00	105	120	45	55	42	40
2	38	28	3050	110	115	90	90	60.00	60	80.00	12.00	30	35	8	8	61	72
3	37	15	2780	127	120	107	80	64.00	50	67.00	15.00	66	35	30	10	40	75
4	39	5	3000	140	130	105	-	68.00	-	68.00	17.00	80	35	36	8	45	68
5	39	15	3250	120	110	140	-	75.00	-	65.00	10.00	115	32	40	8	40	70
6	38	7	3250	150	136	48	80	23.00	45	5.00	35.00	85	45	40	20	36	68
7	40	25	4700	166	148	135	-	77.00	-	72.00	16.00	78	70	36	25	40	58
8	38	14	2860	110	112	114	75	85.00	52	70.00	10.00	60	25	25	8	35	70
9	39	7	3020	125	116	115	105	70.00	90	72.00	15.00	95	-	45	-	28	70
10	38	27	3090	150	125	115	-	70.00	-	70.00	12.00	105	85	60	45	42	63
11	39	14	3400	160	150	120	83	71.00	58	80.00	35.00	85	85	46	36	40	65
12	32	7	1800	170	160	119	60	65.00	29	45.00	15.00	60	28	25	15	60	65
13	38	10	3000	150	140	99	75	62.00	45	55.00	10.00	85	-	36	-	45	75
14	39	8	3000	140	125	88	84	59.00	48	70.00	20.00	90	40	44	12	38	70

BW, Body weight; CoAGr, Coarctation gradient; DBP, Diastolic Blood Pressure; GA, gestational age; HR, heart rate; LVEF, LV ejection fraction; PA, postnatal age; PAPD, pulmonary artery diastolic pressure; RVSP, RV systolic pressure; SBP, Systolic Blood pressure

One patient (case 6) had an increase in coarctation gradient, found to be low before the procedure due to severe ventricular dysfunction (due to amelioration of LV function after the procedure), 1 patient (case 12) had short-duration bradycardia develop (corrected with chest compressions) and 7 patients had erythrocyte transfusion performed after the procedure (Table 2). After a successful procedure, laboratory findings for all patients were observed to improve. Laboratory findings before and after the procedure are shown in Table 3. The mean procedure duration was 82.92±26.92 minutes (60-130) for all patients, while this was 72.86 minutes (60-100) for those not using a catheter and 94.28 minutes (60-130) for those using a catheter. The difference was statistically significant ($p<0.05$). The mean fluoroscopy duration was 14.35 minutes (6-56) for all patients.

Ten of the patients lived and discharged from the hospital after the balloon with or without surgery and they've been called for outpatient clinical follow-ups. After successful balloon angioplasty, surgery was performed in another hospital's good clinical condition in 5 patients (cases 3, 4, 11,13 and 14) due to signs of mild recoarctation in the early period. All of the 5 patients were discharged after successful surgery. One patient (case 5) had balloon angioplasty performed electively twice in the 3rd month and 6th month. While two of the patients Follow-up after surgery revealed that residual coarctation did not develop in patients.

Four patients died within two weeks following the balloon procedure before surgical intervention could be arranged. The first patient (case 1) could not have an effective balloon procedure due to catheter-induced subendothelial injury at the coarctation site. The other cases (cases 6, 10 and 12) had large VSD and PH. Two of these (cases 6 and 12) had balloon inflated in the ductus arteriosus due to inability to pass the coarctation (Figure 2C, D).

At the follow-up, one patient (case 4) developed afebrile convulsions after surgery at age 11 months and EEG and MRI were normal. They were monitored without medication on the recommendation of pediatric neurology. At 14 months, due to increased valvular aorta stenosis (peak gradient 90 mmHg), the patient was referred for valve surgery. One patient (case 11) developed supraventricular tachycardia (SVT) in the postoperative 1st month. Follow-up with ß-blockers (propranolol 1-2 mg/kg/day) has continued for nine months. SVT did not recur with prophylaxis.

DISCUSSION

To the best of our knowledge, this study is the first to use only coronary balloons for emergency palliation of neo-

Table 2. Parameters related to the procedure and follow-up of the patients

	Additional Diagnosis	Area	Shea-th	Cath	CoA type	Diameter Before Balloon (mm)	Diameter After Balloon (mm)	Balloon size (mmx mm)	P atm	Before Balloon Gradient (mm Hg)	After Balloon Gradient (mm Hg)	Proced Time (minute)	Fluoroscopy Time (minute)	NICU Time (day)	MV Time (day)	Blood Transf.	Complication	Success	Follow-up
1	0	RFA	5F	+	T	1.9	-	5x12	3	70	60	130	10	5	4	0	Pass.Diff.	NS	Exitus on 5th d
2	ASD II, LVH	RFA	4F	+	D	1.8	4.5	5x20	8	75	10	75	12	7	0	ES	0	S	Discharged. Alive
3	ASD II, BAV, Asc.Ao.Hyp.	RFA	5F	+	D	2	4.8	5x15	8	55	18	90	12	9	4	ES	0	S	Surgery in good condi-tion. Alive
4	BAV, AS valvular	RFA	5F	+	D	2.4	4.8	5x20	8	50	18	120	15	10	6	0	0	S	Surgery in good condi-tion. Alive
5	BAV, AS Valvular	LFA	4F	+	T	1.7	4.5	5x16	10	60	10	120	20	15	4	0	0	S	Balloon in good condi-tion. Alive
6	VSD, ASD, MI, PDA	RFA	4F	+	T	1.7	5	5x16	20	8	20	60	6	12	12	ES FFP	Pass.Diff.	DA balloon	Exitus on 12 th d
7	0	LFA	5F	+	D	1.8	5	5x12	22	60	14	65	10	1	1	ES	0	S	Discharged. Alive
8	ASD II, BAV, Asc.Ao.Hyp.	RFA	4F	No	T	1.8	5	5x20	20	60	10	60	7	11	0	0	0	S	Discharged. Alive
9	0	LFA	4F	No	D	1.6	5	5x20	20	70	16	60	6	15	2	0	0	S	Discharged. Alive
10	VSD, PDA	RFA	4F	No	D	1.7	5	5x15	22	70	15	65	10	6	6	ES	0	S	Exitus on 6th d
11	BAV	RFA	4F	No	D	1.7	5	5x15	22	75	25	60	7	26	9	ES	0	S	Surgery in good condi-tion. Alive
12	VSD, BAV, Asc. Ao hypoplasia	UV	4F	No	T	1.5	3	3x12	20	42	12	100	56	12	12	ES	Pass. Diff. Brady.	DA balloon	Exitus on 12th d
13	VSD, BAV, Arc.Ao.Hyp.	RFA	4F	No	T	1.7	4.8	5x12	20	50	10	90	14	20	20	0	0	S	Surgery in good condi-tion. Alive
14	VSD, BAV, AS, Arc.Ao.Hyp.	RFA	4F	No	T	1.6	5	5x16	20	66	16	75	20	14	3	0	0	S	Surgery in good condi-tion. Alive

Arc.Ao.Hyp., Arrcus Aorta Hypoplasia; AS, Aortic Stenosis; Asc.Ao.Hyp, Ascending Aorta Hypoplasia; ASD II, Secundum Atrial Septal Defect; BAV, Bicuspid Aortic Valve; Cath, Catheteter; D, Discrete; DA, Ductus Arteriosus; ES, Erytrocyte Suspansion; FFP, Fresh Frozen Plasma; LFA, Left Femoral Artery; LVH, Left Ventricular Hypertrophy; MI, Mitral Insufficiency; MV, Mechanical Ventilation; NICU, Neonatal Intensive Care Unit; NS, Nonsuccessfull; Pass. Diff. Passing Difficulty; PDA, Patent Ductus Arteriosus; RFA, Right Femoral Artery; S, Successfull; T, Tubular; UV, Umbilical Vein; VSD, Ventricular Septal Defect;

nates with critical CoA as a bridge to surgery. There are limited numbers of case reports (12, 13) about similar interventions performed with coronary balloons or a few cases in a case series (3). Critical CoA in the neonatal period is a significant cause of the severe hemodynamic disorder (4,5,11).

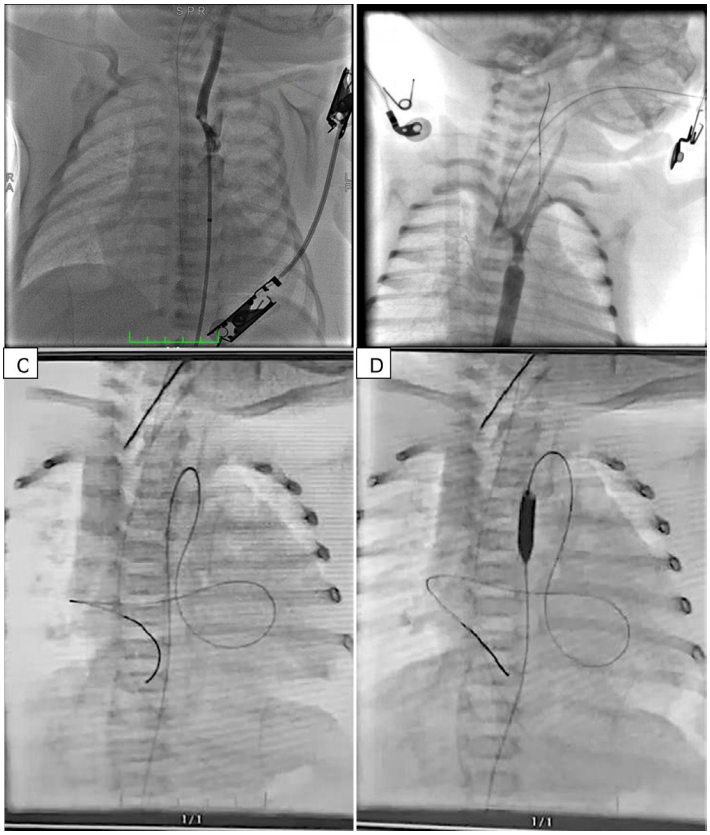


Figure 2. Procedure of angiography with diagnostic catheter (A), procedure of angioplasty without using guiding catheter (B), a coronary 0.014 guidewire that passed through ductus arteriosus (C), ductus arteriosus ballooning over the coronary 0.014 guidewire without using guiding catheter (D)

Though studies report the benefit of balloon angioplasty outside the neonatal period (3,9), the first choice for treating neonates with relatively better clinical status when diagnosed in the early postnatal period is to remove the stricture through surgery (1,4,7). The surgical treatment mortality rates are high for critically ill neonates (11). For these patients, the priority is a medical treatment to resolve circulatory disorder, with publications recommending surgery for those who benefit from medical treatment (7). However, some patients are lost while waiting for the effect of medical treatment. This condition led to the idea of emergency palliative balloon angioplasty to be used as a bridge to surgery for neonates (7). Contrary to this, the small vascular diameter requiring intervention in the neonatal period prepares the ground for vascular complications (vasospasm, thrombosis, aneurysm) (4) and the inability to access appropriate balloons catheters, especially in low-income regions efficiently, affects mortality. The same limitations were encountered due to the absence of neonatal-specific balloons and catheters. Early outcomes are reported herein for coarctation angioplasty performed with coronary balloons.

Table 3. Comparison of hemodynamic, echocardiographic, and laboratory parameters before and after the procedure

	Pre-procedure (mean±SD)	Post-procedure (mean±SD)	p
Systolic BP (mm Hg)	106.5±12.5	81.5±12.9	0.009
Diastolic BP (mm Hg)	67±8.4	54±17.3	0.070
CoA Gradient (mm Hg)	63.5±19	20.5±15.1	0.002
RVSP (mm Hg)	81.3±22.1	52.9±29.9	0.010
PAPD (mm Hg)	36.8±12.3	20.8±16.2	0.006
LVEF (%)	42.3±9.1	68.3±4.7	0.000
AST (U/L)	337.4±647.4	187.9±358.1	0.530
ALT (U/L)	161.2±277.7	161.3±262.8	0.990
BUN (mg/dL)	25.7±29.9	20.1±22.6	0.590
Creatinine (mg/dL)	0.8±0.5	0.7±1.2	0.780
PH	7.26±0.1	7.33±0.1	0.140
Lactate (mmol/L)	6.4±3.3	5.7±5.8	0.530

BPBlood Pressure; CoA, Coarctation of Aorta; RVSP, Right Ventricular Systolic Pressure; PAPD, Pulmonary Artery Diastolic Pressure; LVEF, Left Ventricular Ejection Fraction; AST, Aspartate Transaminase; ALT, Alanine Transaminase; BUN, Blood Urea Nitrogene.

Balloon angioplasty performed using appropriate balloons for neonate, and infantile coarctation is stated to have early period success rates of 76-90% (14). In our series, coronary balloons were successfully used in 13/14 patients (92.85%) (Table 1 and 2). When two patients with ductus balloon inflation are removed from the list, procedure success of 78.57% is consistent with the literature.

Tubular coarctation data appears to be limited in balloon angioplasty publications. The reason for this appears to be that balloon angioplasty is not seen as an appropriate treatment method for tubular type lesions due to aneurysm or dissection. In our series, though 7 patients had tubular aorta coarctation, we did not see any harm in performing palliative balloon angioplasty to reduce mortality in these neonates with severe clinical tableau. Our success rate for the tubular type was 4/7 (57%), which reached 6/7 (85%) when ductus balloon was added. This is compatible with the limited number of publications stating that balloon angioplasty can be used

with this purpose in the literature (15).

Emergency removal of stenosis in critical coarctation causes a rapid amelioration in LV functions. Pawel et al. reported improvement extended until the 4th day in their case (16). In our cases, LV functions returned to normal within the first 24 hours (Table 3).

The major causes of respiratory distress observed in our patients were pulmonary congestion and pulmonary hypertension. Palma et al. (17) reported that the use of sildenafil for one week postoperative in infants with pulmonary hypertension was safe and effective. In our study, 13/14 of our patients had systemic pulmonary hypertension levels and all received sildenafil treatment. Apart from those with comorbid heart diseases, all patients with LVEF and pulmonary pressures returned to normal within the first week, and sildenafil treatment was stopped. Our findings are consistent with the literature.

We think that passing the coarctation region is the most critical stage affecting procedure success. In one of our patients, the procedure was unsuccessful due to the inability to pass the catheter's coarctation region. For two other patients where balloon inflation could not be performed for the same reason, we inflated the balloon in the ductus arteriosus to reduce pulmonary hypertension and support systemic circulation. We observed that the ductus balloon provided stabilization for nearly two weeks in these patients. We can say that a ductus balloon may be alternative palliation in these patients, provided that the patient is given surgery within one week after the balloon.

In limited resources facilities, it may not be possible to access guiding-catheters with appropriate dimensions for use in neonates in angiography laboratories at all times. Additionally, the procedure lengthened due to the catheter and prediction of complication risks led us to search for a solution by performing this procedure without a catheter (Figure A, B). This method provided advantages by shortening the procedure duration, reducing complication risks, and decreasingmaterial dependence while involving the disadvantage of measuring proximal aorta pressure via the indirect route (right arm). We think the catheter-free balloon coarctation angioplasty with the coronary balloon method will be a rapid and effective method in regions with limited facilities.

The study by Lee et al. reported restenosis rates of 20-69% (14). In our study, the recoarctation rate after successful balloon angioplasty was 5/11 (45.5%). Recoarctation rate after surgery has been reported as 3-5% in children (5), but recoarctation has not developed yet in our patients. Our recoarctation rates are compatible with the literature (Table 2).

Despite providing appropriate conditions for a neonate or low birth weight infants, complications may develop in the intervention region (11). None of our patients developed complications in the intervention region. We agree with the authors, who state that using a small sheath, keeping the duration short, and administering prophylactic heparin during and after the procedure will reduce the incidence of vascular complications (11).

The early mortality rate after the balloon angioplasty for coarctation in neonates is 17.5-13.6% (7), while the late mortality rate is 36% (11). There was no patient lost during the procedure or in the early period due to the procedure in our series. Four patients (28.6%) were exitus due to reasons other than the procedure on the mean 9th day, with the earliest on the 5th day. The causes most affecting mortality, apart from low birth weight (7, 18) and late diagnosis (7), are comorbid cardiac pathologies (7) namely VSD, PH, ventricular dysfunction, and hypoplasia of the left ventricle and aorta. The major causes of mortality in our cases were the inability to effectively perform balloon angioplasty in the first patient, ductus balloon dilatation in another two patients (continuation of coarctation) with comorbid VSD + pulmonary hypertension.

Our primary strategy was not to create an alternative treatment to surgery but to reduce the degree of stenosis in such critical newborns with heart failure who could not access surgery due to limited resources and ensure these patients undergo surgery in a good condition with the addition of medical treatment.

Limitations of the Study

This study has several limitations that should be considered when interpreting the results. First, the relatively small sample size may limit the generalizability of the findings. In addition, a proportion of the patients were of foreign nationality and returned to their home countries after treatment, which limited the availability of long-term follow-up data. This was particularly relevant for the assessment of outcomes such as recoarctation and long-term clinical results. Furthermore, as a pediatric cardiovascular surgery department is not available in our center, patients requiring surgical management were referred to external institutions. This may have introduced some variability in management strategies and limited the completeness of follow-up data.

CONCLUSION

It is emphasized that coronary balloons can be safely employed with palliative intent as a bridge to surgery—even in the absence of appropriate balloon and catheter—for neonates with late-diagnosed critical CoA, who cannot be transferred in time for surgical intervention due to various reasons. This approach is not curative;

however, it is a valuable method by which patients' cardiac functions are improved, tissue perfusion is ensured, and time is gained until surgery becomes accessible. The procedure can be readily performed in any center equipped with a coronary angiography laboratory and is expected to substantially reduce mortality in resource-limited regions.

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