

## Short- and midterm results of balloon angioplasty for the treatment of coarctation of the aorta in neonates

*Yenidoğanlarda aort koarktasyonunun tedavisinde balon anjiyoplastinin kısa ve orta dönem sonuçları*

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**Background:** In this study, we reviewed our clinical experience along with the existing data and short- and midterm results of balloon angioplasty for coarctation of aorta in neonates.

**Methods:** The data of 51 neonates (41 boys and 10 girls; mean age 13±9 days; range 1 to 30 days) who underwent balloon angioplasty for aortic coarctation between December 2004 and March 2010 were retrospectively analyzed.

**Results:** Isolated coarctation was found in 13 patients (25%) and complex coarctation in 38 (75%). The left ventricular dysfunction was seen in 18 patients (35.3%), while 17 patients (33.3%) had isthmus hypoplasia. The most common concomitant abnormality was ventricular septal defect (VSD) (49%). Twenty-nine patients (56.9%) had pulmonary hypertension. The mean systolic pressure gradient across the coarctation site fell from 36±20 mmHg before dilatation to 8.6±7.0 mmHg following the intervention. One patient developed femoral artery thrombosis. The mean follow-up was 8.7±9.6 months (range 1-46, median 6 months). Recoarctation developed in 20 patients (39.2%) after an average 3.2±3.1 months. Of these, nine (45%) with recoarctation underwent repeated angioplasty and 11 (55%) surgical repair. During follow-up of 1-7 months, seven (13.7%) patients died.

**Conclusion:** Our short- and midterm results suggest that balloon angioplasty has a higher recoarctation rate than surgery. Therefore, balloon angioplasty should be done to ensure survival until full corrective surgery is performed in patients with complex cardiac disease and poor overall condition.

**Key words:** Aortic coarctation; balloon angioplasty; neonates.

**Amaç:** Bu çalışmada aort koarktasyonlu yenidoğanlarda balon anjiyoplasti ile ilgili klinik deneyimlerimiz, mevcut verilerimiz ve kısa ve orta dönem sonuçlarımız incelendi.

**Çalışma planı:** Aralık 2004 - Mart 2010 tarihleri arasında aort koarktasyonu nedeniyle balon anjiyoplasti uygulanan 51 yenidoğana (41 erkek, 10 kız; ort. yaş 13±9 gün; dağılım 1-30 gün) ait veriler retrospektif olarak incelendi.

**Bulgular:** Olguların 13'ünde (%25) izole koarktasyon, 38'inde (%75) kompleks koarktasyon tespit edildi. On sekiz hastada (%35.3) sol ventrikül disfonksiyonu, 17 hastada (%33.3) isthmus hipoplazisi görüldü. En sık eşlik eden anomali, ventriküler septal defekt (VSD) (%49) idi. Yirmi dokuz hastada (%56.9) pulmoner hipertansiyon vardı. Koarktasyon bölgesinde ortalama sistolik basınç gradiyenti dilatasyon öncesi 36±20 mmHg iken, dilatasyon sonrası 8.6±7.0 mmHg'ye düştü. Bir hastada femoral arter trombozu gelişti. Ortalama izlem süresi 8.7±9.6 ay (dağılım 1-46 ay, ortanca 6 ay) idi. İşlem sonrası ortalama 3.2±3.1 ay sonra 20 hastada (%39.2) rekoarktasyon gelişti. Rekoarktasyon gelişen hastaların dokuzuna (%45) tekrar anjiyoplasti, 11'ine (%55) cerrahi işlem uygulandı. Bir-yedi aylık izlemede yedi hasta (%13.7) kaybedildi.

**Sonuç:** Kısa ve orta izlem sonuçlarına göre balon anjiyoplasti, cerrahi işleme göre yüksek rekoarktasyon oranına sahiptir. Bu nedenle balon anjiyoplasti, kompleks kardiyak hastalığı olan ve genel durumu kötü olan hastalarda tam düzeltme ameliyatı yapılana dek sağkalım için uygulanmalıdır.

**Anahtar sözcükler:** Aort koarktasyonu; balon anjiyoplasti; yenidoğan.



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Coarctation of the aorta consists of a narrowing of the aorta, generally at a point distal to the branching of the left subclavian artery. One possible treatment option is the surgical resection of the stenosis and end-to-end anastomosis. Other possibilities include subclavian flap angioplasty, interventional catheterization with balloon angioplasty, and stent placement. The use of percutaneous balloon angioplasty for the treatment of aortic coarctation was first described in 1982, whereas the open surgical procedure dates from 1945.<sup>[1-4]</sup> Whether surgery or medical treatment is optimal for aortic coarctation is open to debate. Balloon angioplasty for aortic coarctation in neonates and infants is controversial due to the frequency of recoarctation.<sup>[5]</sup> Primary angioplasty performed as a palliative treatment for the coarctation of the aorta in newborns is the first choice of treatment for recurrences following surgery. The advantages of surgical treatment are the less frequent need for repeated intervention, the correction of the increase in the aortic arc, the absence of aortic aneurysm formation, and the reduced need for antihypertensive treatment.<sup>[6]</sup> Balloon angioplasty is applied as a treatment for buying time in babies who cannot undergo emergency surgery because of severe disease, left ventricular dysfunction, or associated complex cardiac abnormalities.<sup>[7]</sup> This report examines our clinical data on balloon angioplasty in neonates with aortic coarctation along with its short- and mid-term results.

## PATIENTS AND METHODS

The data from 51 newborn patients (41 boys and 10 girls; mean age  $13 \pm 9$  days; range 1 to 30 days) who underwent balloon angioplasty for aortic coarctation between December 2004 and March 2010 were retrospectively studied. The patients had either been diagnosed at our center after having consulted for symptoms such as failing to suckle, cyanosis, tachypnea, failure to gain weight, skin discoloration, or direct symptoms of congestive heart failure or their suspected diagnosis of coarctation of the aorta had been confirmed at our center.

All patients had clinical evidence of aortic coarctation, including a weak femoral pulse, systolic hypertension of the upper limbs, and systolic murmur and had been subjected to electrocardiography, telecardiography, and echocardiography. The location, size, and hemodynamic severity of the stenosis was determined by two-dimensional (2D) echocardiography along the suprasternal long axis, color flow Doppler imaging, and continuous-wave Doppler investigations.

Balloon angioplasty of the coarctation was performed on all of our patients at the time of referral to our center

as they all were symptomatic, but it was not performed on patients whose clinical conditions were suitable for elective surgery.

The balloon angioplasty procedure was performed by cardiac catheterization following sedation via midazolam and ketamine. Retrograde catheterization was applied from the femoral artery access. Heparin (100 U/kg) was given after placement of a pediatric 4 French sheath to the femoral artery. A 4 French National Institutes of Health (NIH, Cordis Corporation, Bridgewater, New Jersey, USA) or right coronary artery catheter was advanced into the ascending aorta, and the peak systolic pressure values downstream and upstream from the stenosis were measured. Injections anterior, posterior, and lateral to the aorta were given. The diameter of the balloon chosen for angioplasty was equal to or up to one millimeter smaller than that of the nearest and smallest aortic segment. Once the disappearance or near disappearance of the indentation on the balloon was ascertained, the pressures were measured again following the post-procedure angiographic control for the shape of the stenosis and the possible acute formation of an aneurysm.

If no important concomitant intracardiac lesions were present except for patent ductus arteriosus (PDA), the coarctation was defined as "simple", but it was termed "complex" if these types of lesions were found. Isthmic hypoplasia was defined as the diameter of the isthmic area inferior to 40% of that of the aorta. As for the patients who presented PDA, this was small and porous and therefore not of a size that could have caused pulmonary hypertension. Aneurysms with a larger diameter of up to 0.5 mm were designated as microaneurysms and larger ones as macroaneurysms.

The observed patients were followed up at one and six months from the intervention and yearly thereafter by physical examination, blood pressure measurement in both the upper and lower limbs by a sphygmomanometer, 2D echocardiography, and Doppler echocardiography for a possible recurrence of aortic stenosis. A pressure difference of 20 mmHg or more as measured by transthoracic echocardiography between the ascending and the descending aorta, a flow pattern continuous with the diastole on continuous-wave Doppler echocardiography, or a difference of 20 mmHg or more between the blood pressure in the upper and lower extremities was accepted as showing restenosis (recoarctation). The mean follow-up duration was  $8.7 \pm 9.6$  months (range 1-46, median 6).

**Table 1. Clinical characteristics, procedures and results**

	n	%	Before angioplasty	After angioplasty	p
Total patients	51	100			
Gender					
Male	41	80.4			
Female	10	19.6			
Mean age in days	13±9				
Left ventricle dysfunction	18	35.3			
Isthmic hypoplasia	17	33.3			
Pulmonary hypertension	29	56.9			
Mean systolic gradient, (mmHg)			36±20	8.6±7.0	<0.001
Follow-up duration in months	8.7±9.6				
Recoarctation following balloon angioplasty	20	39.2			
Recoarctation following surgical procedure	0	0			
Time from angioplasty to recoarctation in months	3.2±3.1				
Deaths	7	13.7			

### Statistical analysis

The SPSS 15.0 version for Windows software package (SPSS Inc., Chicago, Illinois, USA) was used for statistical analysis. The analysis of categorical variables was performed by Pearson's chi-squared test and by Fisher's exact test as needed. Odds ratios were calculated within a 95% confidence interval (CI), and the statistical significance limit was placed at  $p < 0.05$ .

### RESULTS

A systolic ejection murmur was found in 44 patients (86.3%). Clinical characteristics, procedures, and follow-up results are summarized in Table 1.

The coarctation was characterized as simple in 13 of the patients (25.5%) and complex in 38 (74.5%). It was in a pre-ductal position in one patient, but in all 50 of the others, it was post-ductal. A patent ductus was found to be present in 29 patients (56.9%) and isthmic hypoplasia in 17 (33.3%). The isthmus diameter was  $3.4 \pm 1.2$  mm. The most frequently associated abnormality was a ventricular septal defect (VSD) in 49% of the patients, and in all cases, the VSD was small in hemodynamic terms (Table 2).

A bicuspid aortic valve (BAV) was present in 10 patients (19.6%). In the end, no correlation was found between recoarctation and the presence of any of the following: BAV, isthmic hypoplasia, PDA, VSD, or left ventricular dysfunction ( $p > 0.05$ ).

Pulmonary hypertension was found in 29 patients (56.9%) while 18 (35.2%) had left ventricular dysfunction. One patient had congenital hypothyroidism, another had renal malfunction, and a third presented with an abnormality of the urinary tract and a cleft palate. In

addition, one developed thrombosis of the femoral artery. Moreover, one of the patients, born with right ventricular hypoplasia and transposition of the great arteries, underwent balloon atrial septostomy at the same time as the coarctation angioplasty. The systolic pressure gradient across the coarctation area fell from  $36 \pm 20$  mmHg (range 0-93) preoperatively to  $8.6 \pm 7.0$  mmHg following the intervention. This reduction satisfied the requirements in all patients. The balloon angioplasty procedure was successful for all who had the anatomical stenosis area widened.

The follow-up duration ranged from one to 46 months, with a median of six months and a mean of  $8.7 \pm 9.6$  months. During this period, 20 patients (39.2%)

**Table 2. Cardiac abnormalities accompanying aortic coarctation (n=38)**

Abnormalities	n	%
Ventricular septal defect	25	49
Patent ductus arteriosus	29	56.9
Atrial septal defect	19	3.3
Bicuspid aortic valve	10	19.6
Mitral valve abnormality	4	7
Pulmonary stenosis	2	3.9
Atrioventricular septal defect	2	3.9
Coronary artery abnormality	2	3.9
Aortic valve stenosis	1	2
Subaortic stenosis	1	2
Transposition of the great arteries	1	2
Double-inlet left ventricle	1	2
Double-outlet right ventricle	1	2
Coronary arteriovenous fistula	1	2
Double-inlet right ventricle	1	2
Hypoplastic left heart syndrome	1	2

**Table 3. Characteristics of the seven deceased patients**

Case	Age in days/gender	Follow-up in (months)	Concomitant cardiac defects (mmHg)	Before angioplasty (mmHg)	After angioplasty	Recoarctation	LVD	Cause of deaths
1	3/M	2	DILV, PDA, PH	43	12	None	Present	MODS
2	3/M	7	VSD, PDA	53	1	None	None	HF
3	11/M	3	ASD, PDA, PH	20	11	None	None	HF
4	12/F	1	DIRV, PH, PDA	40	1	None	None	HF
5	12/F	3	HLHS, VSD, PH, PDA	33	3	None	None	MODS
6	24/F	1	PDA, PH	95	14	None	None	HF
7	7/F	1	PDA, PH	34	11	Yes	None	HF

LVD: Left ventricular dysfunction; DILV: Double-inlet left ventricle; PDA: Patent ductus arteriosus; PH: Pulmonary hypertension; MODS: Multiple organ dysfunction syndrome; VSD: Ventricular septal defect; HF: Heart failure; ASD: Atrial septal defect; DIRV: Double-inlet right ventricle; HLHS: Hypoplastic left heart syndrome.

developed recoarctation  $3.2\pm 3.1$  months after the procedure. Recoarctation also occurred in four of the 17 patients with isthmus hypoplasia and 11 of the 18 with left ventricular dysfunction ( $p>0.05$ ). Repeat angioplasty was performed in nine (45%) of these patients, and 11 (55%) underwent open surgery. The pressure gradient fell satisfactorily following repeat balloon angioplasty in all patients, and repeated recoarctation was not observed after this procedure. Similarly, there was no recurrent recoarctation following open surgery ( $p<0.001$ ). Seven patients (13.7%) died during a period of between one and seven months after the intervention. Of these, three had a complex cardiac abnormality (double-inlet left ventricle, double-inlet right ventricle, and hypoplastic left heart syndrome) and six had pulmonary hypertension (Table 3).

## DISCUSSION

Coarctation of the aorta typically means a stenosis in the proximal thoracic aorta. This is observed in roughly 6-8% of patients with congenital cardiac abnormalities and ranks fourth among the most frequent cardiac abnormalities seen during the first year of life. It is more frequent in boys, with a male/female ratio reported as being between 1:27 and 1:74.<sup>[6-10]</sup> It generally corresponds to the juxtaductal and discrete types, with long-segment and tortuous stenosis seen much less frequently. The transverse aortic arch and isthmus may be hypoplastic in the presence of a left ventricular outflow obstruction or left ventricular septal defect.<sup>[11,12]</sup> Patients who present in the neonatal period generally have complex coarctation. Of the 216 patients under 12 months of age with aortic coarctation seen at the University Hospital at the University of Michigan from 1960 to 1992, 52% had an isolated coarctation, and 48% had the complex type. The most frequently associated cardiac defect was reported as VSDs.<sup>[13]</sup> The male/female ratio of 4:1 in our study is higher than

has been previously reported in the literature. One of our 51 patients had pre-ductal coarctation while the others juxtaductal. Isthmic hypoplasia was present in 17 cases (33.3%). The coarctation was isolated in 13 patients (25.5%) and complex in 38 (74.5%), with the most frequently associated abnormality being VSDs (49%). The relatively high frequency of VSDs in our study as compared to the other reports could be due to the spontaneous closure of a small VSD after the neonatal period.

Untreated aortic coarctation has a poor prognosis and is traditionally corrected by open surgery. Balloon dilatation, either with or without stent implantation, is an established treatment procedure with results comparable to open surgery in older children and adults. In newborns and infants, however, balloon angioplasty is controversial because of recoarctation and the need for multiple procedures, the possible development of limb ischemia, and the high risk of aneurysm formation. Balloon dilatation is proposed in these patients with palliative intent so as to buy time in the presence of a poor general physical condition, concomitant left ventricular dysfunction, and/or complex cardiac lesions when emergency surgical repair cannot be performed.<sup>[7]</sup>

The problems related to balloon angioplasty in neonates and young infants are varied and include the residual pressure gradient in the presence of long-segment coarctation or isthmus hypoplasia and the development of recoarctation or aneurysms. These problems are more frequent after dilatation than surgical repair. The occurrence of early coarctation following angioplasty in newborns is related to the elasticity of the ductal tissue in the coarctation area. Also, in the presence of a hypoplastic isthmus upstream from the coarctation, the blood flow to the dilated portion of the aorta is reduced, causing late elastic

recoil and recoarctation. Several studies have shown the difficulty in differentiating between residual and recurrent stenosis.<sup>[14-16]</sup>

Redington et al.<sup>[17]</sup> reported that restenosis developed in most neonates following balloon angioplasty. Patel et al.<sup>[5]</sup> reported a 41% restenosis rate in 17 hemodynamically stable newborns and infant patients at a mean follow-up of 2.7 years. Rao and Chopra<sup>[18]</sup> reported a recoarctation rate of 83%. On the other hand, restenosis occurred in only 8% of the 167 neonates and infants in a study by Burch et al.<sup>[19]</sup> at a mean follow-up of 4.8 years following surgical repair. These authors proposed that surgical repair was more effective than balloon angioplasty for newborns. The recoarctation rate following the balloon angioplasty of coarctation in our study was 39.2%. We attribute the relatively low frequency rate to the choice of an adequate balloon size for the newborn, the filling of the balloon to the point of losing its indentation, the performance of the procedure by experienced hands, and improvement over time in the instrumentation.

The response to balloon angioplasty for coarctation is insufficient in the presence of isthmic hypoplasia or left ventricular dysfunction.<sup>[7,16]</sup> We observed the development of recoarctation in four of 17 patients with isthmic hypoplasia and 11 of 18 with left ventricular dysfunction, but these findings were not statistically significant ( $p>0.05$ ).

Femoral artery injury and thrombosis can occur during angioplasty, and the frequency of these complications is relatively high in infants under 12 months of age. However, it has been decreasing with the development of smaller angioplasty catheters. Cowley et al.<sup>[4]</sup> reported the long-term development of femoral artery damage or aneurysms in 35% of cases of balloon angioplasty compared with the absence of complications in patients undergoing surgery. Another publication reported a femoral artery complication rate of 21%.<sup>[18]</sup> In this study, there was only one case (2%) of femoral artery complications. We attribute this to the use of adequate sheaths and introduction of appropriate techniques along with the postoperative administration of heparin in prophylactic doses to all patients.

Even though the reported rate of aneurysm formation varies depending on the definition of “aneurysm” that is used, the larger series agree on a rate of 5-10%.<sup>[15,20]</sup> No aneurysms developed in the patients in our study, and no aneurysms were found in the follow-up angiography performed to visualize post-procedure microaneurysms and anatomic stenosis. No advanced imaging techniques for macroaneurysms were used since the findings did

not indicate their presence. We attribute the absence of aneurysm development in our patients to the use of a proper technique for performing balloon angioplasty and adequate balloon size.

Balloon angioplasty for coarctation in newborns carries high mortality and morbidity rates when associated with other cardiac lesions or left ventricular dysfunction.<sup>[21]</sup> After five to nine years of follow-up, a mortality rate of 33% was reported in 67 neonates by Rao and Chopra<sup>[18]</sup> Even though no patient died during the procedure in our study, mortality during the follow-up period was 13.7%. Of the patients who died in our study, three had complex heart disease, six had pulmonary hypertension, and one had left ventricular dysfunction. Even though angioplasty was effective in the later deceased patients, they showed no improvement of pulmonary hypertension or heart failure following the procedure. Elective surgery had been planned for these patients; however, they died before it could be carried out because their heart failure could not be brought under control. In their study of 167 neonates and infants who underwent surgical repair, Burch et al.<sup>[19]</sup> reported less than 1% of patients had early and late mortality. Considering that the balloon angioplasty was performed on patients with a poor general physical condition or complex cardiac abnormalities, a higher mortality might have been expected in this population. Post-procedure mortality past the neonatal age is rare. The Pediatric Angioplasty Association reported a single death (0.7%) in 140 cases.<sup>[16]</sup>

In conclusion, considering both short-term and mid-term results, balloon angioplasty has a higher recoarctation rate than surgical procedures, which is why it should be reserved for cases with complex heart disease and poor general physical condition in order to ensure the patients' survival until full repair surgery can be applied.

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