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ORIGINAL ARTICLE

Percutaneous Angioplasty Used to Manage Native and Recurrent Coarctation of the Aorta in Infants Younger than 1 Year: Immediate and Midterm Results

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Abstract Balloon angioplasty (BAP) used to manage native coarctation of the aorta (CoAo) in infants remains controversial. This study aimed to compare short- and mid-term results of BAP between native CoAo (NaCo) and postsurgical recoarctations (ReCo) in infants younger than 1 year. This retrospective study compared the clinical, echocardiographic, hemodynamic, and angiographic data for infants who underwent BAP between July 2003 and September 2012. The 12 NaCo and 13 ReCo patients in this study underwent BAP at 4.61 ± 3.69 and 4.88 ± 3.07 months ($p = 0.84$) and weighed 5.49 ± 2.57 and 6.10 ± 2.11 kg ($p = 0.52$), respectively. Their respective heights were 60.58 ± 10.58 and 61.15 ± 6.74 cm ($p = 0.87$). All the ReCo patients had their initial surgery before the age of 3 months. The minimal CoAo diameter was 2.81 ± 0.96 mm in the NaCo group and 2.86 ± 1.0 mm in the ReCo group ($p = 0.90$). The relative gradient reduction was 62.79 ± 32.43 % in the NaCo group and 73.37 ± 20.78 % in the ReCo group ($p = 0.33$). The in situ complication rate (pseudoaneurysm) was 8.33 % in the NaCo group and 7.69 % in the ReCo group ($p = 0.74$). During the early follow-up evaluation, five NaCo patients (41.66 %) presented with recoarctation requiring BAP re-intervention within 1.75 ± 1.41 months (all had their initial BAP before 3 months of age) compared with 1 ReCo patient (7.69 %) ($p = 0.165$). The mean follow-up period was 3.09 ± 2.69 years for the NaCo patients and 3.6 ± 3.18 years for the ReCo patients ($p = 0.69$), during which the blood pressure gradient was 12.33 ± 9.67 for the NaCo patients and 7.80 ± 8.78 for the ReCo patients ($p = 0.17$), with corresponding Doppler peak instantaneous gradients of 21.29 ± 11.19 and 16.20 ± 10.23 ($p = 0.24$). The resultant diameter ratio between the minimal isthmus diameter and the aortic diameter at the diaphragmatic level was 0.81 ± 0.15 in the NaCo group and 0.85 ± 0.12 in the ReCo group ($p = 0.53$). The immediate and midterm results of BAP for the NaCo and ReCo infants were comparable. Accordingly, BAP seems to be an acceptable alternative to surgery for infants older than 3 months.

Keywords Percutaneous angioplasty · Coarctation of the aorta · Balloon angioplasty · Postsurgical recoarctations · Native recoarctations

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Introduction

Balloon angioplasty (BAP) used to manage native isthmic coarctation of the aorta remains controversial [5, 20]. This controversy mainly arises due to the risks of local vascular complications, including dissection and rupture of the aorta and subsequent development of aneurysmal lesions.

In 1990, a multicenter study of 140 patients ages 3 days to 29 years from the Valvuloplasty and Angioplasty of Congenital Anomalies database who underwent percutaneous BAP of recoarctation of the aorta was first published [7]. Since then, data from several patient series addressing the safety of this technique have been published [2, 4, 8, 13, 15, 16, 18, 21]. Nevertheless, the lack of comparative long-term data on the surgeries entertains the controversy. This is particularly true for children younger than 1 year with discrete coarctation.

This study aimed to test the effectiveness and safety of BAP used to treat native coarctation of the aortic isthmus in infants younger than 1 year. For this purpose, the results for infants who underwent native coarctation balloon dilation were compared with those for infants who benefited from the same procedure used to treat recurrent coarctation after surgical repair. Institutional approval was granted before this study was conducted.

Methods

Study Population

The medical charts of infants 12 months of age or younger referred between 2002 and 2012 for cardiac catheterization to manage coarctation of the aorta were reviewed. The subjects were divided into two groups: the patients with native coarctation (NaCo) and the patients with postsurgical recoarctation (ReCo). We excluded patients who had received complex cardiac surgery for palliation of a single-ventricle physiology before coarctation BAP, patients with coarctation of the abdominal aorta, and patients treated with a hybrid approach.

Data Analysis

In this retrospective, descriptive, and analytical study, the records of eligible patients were studied for demographic, clinical, echocardiographic, and hemodynamic data. Angiographic and imaging studies (magnetic resonance and computed tomography scans) also were examined. Data analysis was performed using Epi Info 3.5.4 (CDC, Atlanta, GA, USA) and SigmaStat 3.5 software (Systat, Software Inc., Atlanta, GA, Germany). Quantitative variables are expressed as mean ± standard deviation, and qualitative variables are presented as proportion and percentage. Student's t test was used for normally distributed data, and the Mann–Whitney test was used for series with abnormal distribution. The χ^2 test and Fisher's exact test were used to compare proportions. A p value lower than 0.05 was considered statistically significant.

Results

Baseline Characteristics

During the study period, 29 patients underwent a percutaneous BAP for coarctation of the aorta during the first year of life. One of these patients was eliminated due to a coarctation of the abdominal aorta, and one patient underwent a hybrid procedure. Two patients were born with hypoplastic left heart syndrome, for which they received a stage 1 palliative procedure.

Of the 25 patients who fulfilled the selection criteria, 12 had NaCo and 13 had ReCo. The mean age at the time of intervention was 4.61 ± 3.69 months for the NaCo patients and 4.88 ± 3.07 months for the ReCo patients ($p = 0.84$), with no significant difference in weight or height between the two groups (Table 1). The age at the initial surgery for the ReCo patients was 8.42 ± 3.82 days (median, 9 days; range, 2–30 days), and the interval between surgery and BAP was 4.49 ± 3.08 months. The type of surgery was an end-to-end anastomosis for six patients (46.1 %), an aortic arch patch reconstruction for five patients (38.5 %), and a subclavian artery flap for two

Table 1 Study population, basic characteristics, and preintervention clinical data

	NaCo (range)	ReCo (range)	p Value
Age (months)	4.61 ± 3.69 (1.37–11.80)	4.88 ± 3.07 (1.90–11.63)	0.84
Height (cm)	60.58 ± 10.58 (46–78)	61.15 ± 6.74 (48–76)	0.87
Weight (kg)	5.49 ± 2.57 (1.60–9.80)	6.10 ± 2.11 (2.80–11.20)	0.52
RA-BP (mmHg)	120.33 ± 25.23 (75–150)	104.5 ± 19.95 (80–140)	0.09
LL-BP (mmHg)	81.5 ± 16.93 (51–104)	66.25 ± 16.25 (40–86)	0.03
BP gradient (mmHg)	38.83 ± 18.24 (10–70)	38.25 ± 15.59 (19–71)	0.93
Peak Doppler gradient	54.94 ± 26.52 (18–105)	60.61 ± 19.22 (8–81)	0.85

NaCo native coarctation, *ReCo* postsurgical recoarctation, *BP* blood pressure, *RA-BP* right arm blood pressure, *LL-BP* left leg blood pressure

patients (15.4 %). The male-to-female ratio was 2:1 for the NaCo patients and 2.25:1 for the ReCo patients ($p = 0.61$).

Clinical Characteristics

In the NaCo group, the sphygmomanometer blood pressure gradient before the intervention showed a trend for a higher left arm blood pressure and a significantly higher femoral blood pressure (Table 1). The cuff pressure gradient was 38.83 ± 18.24 mmHg in the NaCo group and 38.25 ± 15.59 mmHg in the ReCo group ($p = 0.93$). Before BAP, the peak instantaneous Doppler gradient across the coarctation site was similar in the two groups.

In the NaCo group, other clinical signs such as upper limb hypertension, heart failure, and nonpalpable femoral pulses were present (Table 2). In the ReCo group, the majority of the patients (11/13, 84.6 %) were referred for an abnormal pressure gradient between the right arm and the left leg. In one ReCo patient (4 %), the diagnosis was made on the basis of a scheduled follow-up echocardiography. Coarctation was an isolated finding in 2 of the 12 NaCo patients, whereas in the ReCo group, it was always associated with an intracardiac defect. The most frequent association was with a bicuspid aortic valve. Hypoplastic aortic arch and transposition of the great arteries were present in both groups (Table 3).

Percutaneous Intervention

The procedure was performed with all the patients under general anesthesia. The retrograde arterial route was the preferred choice for 22 patients (88 %), whereas a prograde venous approach across the foramen ovale was used for 2 patients (1 in each group). A transhepatic access with needle atrial septostomy was required for one patient in the ReCo group. The introducer size was 4 Fr for 21 patients (87.5 %), 3 Fr for 2 patients, and 5 Fr for 1 patient. All the patients received a bolus of intravenous heparin (50 U/kg) after vascular access.

Table 2 Summary of clinical presentation and indication for percutaneous intervention

	NaCo *n* (%)	ReCo *n* (%)
Blood pressure gradient	3 (25)	11 (84.62)
Blood pressure gradient + HTN ± absent femoral pulses	4 (33.33)	0 (0)
Blood pressure gradient + HTN + HF	2 (16.67)	2 (15.38)
Blood pressure gradient + HF	2 (16.67)	0 (0)
Doppler pressure gradient and small persistent ductus arteriosus	1 (8.33)	0 (0)

NaCo native coarctation, *ReCo* postsurgical recoarctation, *HTN* arterial hypertension, *HF* heart failure

Table 3 List of associated cardiac lesions

	NaCo	ReCo
None	2	0
Bicuspid aortic valve ± small shunt	5[a]	6
Hypoplasia of the transverse arch or the aortic isthmus	3	6
D-TGA ± VSD	2[b]	1[c]

NaCo native coarctation, *ReCo* postsurgical recoarctation, *D-TGA* dextro-transposition of great arteries, *VSD* vascular septal defectjdm

[a] One case of mild mitral stenosis

[b] One case of perimembranous ventricular septal defect

[c] One case of double-outlet right ventricle and arterial malposition

Angiography was performed using Isovue 300 (Bracco, Newark, NJ, USA), with an average of 4.35 ± 1.7 ml/kg (range, 0.81–6.39 ml/kg) administered in the NaCo group and an average of 5.91 ± 3.22 ml/kg (range, 2.09–12.14 ml/kg) administered in the ReCo group ($p = 0.23$). Angiography injections and measurements were obtained in the lateral and 30° left anterior oblique projections. The minimal diameter of the aortic isthmus was measured and compared with the diameter of the descending aorta at the level of the diaphragm. Angiography was repeated after BAP to evaluate the anatomic outcome and the integrity of the aortic wall.

The BAP procedure was performed using either a Tyshak or a mini Tyshak balloon catheter (NuMED, Hopkinton, NY, USA) for 23 patients (92 %), Powerflex (Cordis, Johnson & Johnson, Bridgewater, NJ, USA) for 1 patient, and a coronary Quantum XL Maverick balloon (Boston Scientific, Maple Grove, MN, USA) for 1 patient. The balloon size ranged from 5 to 10 mm depending on the anatomy as defined angiographically. The maximal balloon diameter did not exceed the diameter of the diaphragmatic aorta.

A single inflation was sufficient for 18.6 % of the patients, whereas 61.1 % received two inflations and 22.2 % required three inflations during the procedure. The balloons were inflated to the nominal limit set by the manufacturer (average of 4 atm for the Tyshak and mini Tyshak balloons, and 10–17 atm for the coronary balloon).The ratio of the final balloon diameter to the coarctation diameter was 2.70 ± 0.80 for the NaCo group and 2.85 ± 0.97 for the ReCo group ($p = 0.68$). The ratio of the final balloon diameter to the aortic diameter at the diaphragm was 1.11 ± 0.14 in the NaCo group and 1.12 ± 0.13 in the ReCo group ($p = 0.79$).

Finally, the average fluoroscopy time was 20.19 ± 6.94 min per procedure (range, 6.5–28.5 min) in

the NaCo group versus 18.8 ± 8.49 min (range, 9.1–40.20) in the ReCo group ($p = 0.69$). The duration of the procedure, calculated from the time of vascular access until catheter withdrawal, was 1.26 ± 0.17 h (range, 1–1.47 h) in the NaCo group versus 1.69 ± 0.82 h (range, 1.04–3.19 h) in the ReCo group ($p = 0.19$).

Hemodynamic and Angiographic Outcome

The peak-to-peak pressure gradients were significantly reduced in the two groups after balloon dilation. In the NaCo group, the peak-to-peak pressure gradient decreased from 28.73 ± 12.02 to 9.27 ± 7.87 mmHg ($p < 0.001$) compared with a reduction from 30.69 ± 14.53 to 9.23 ± 7.81 mmHg in the ReCo group ($p < 0.001$).These changes represent pressure gradient reductions of 28.73 ± 12.02 and 9.27 ± 7.87 mmHg, respectively ($p < 0.001$). The reduction in peak-to-peak gradient was comparable in the two groups ($p = 0.98$) (Fig. 1).

Similarly, the relative gradient reduction was 62.79 ± 32.43 % in the NaCo group versus 73.37 ± 20.78 % in the ReCo group. The difference between the two groups was not statistically significant ($p = 0.33$). From an angiographic perspective, the minimal coarctation diameter increased from 2.81 ± 0.96 to 4.33 ± 0.98 mm in the NaCo group (<0.001) and from 2.86 ± 1.01 to 4.55 ± 1.27 mm in the ReCo group ($p < 0.001$). These changes also were comparable between the study groups (Fig. 2). Similarly, the ratio of the minimal isthmic diameter to the diaphragmatic aorta improved from 0.44 ± 0.15 to 0.67 ± 0.11 in the NaCo group ($p < 0.001$), and from 0.42 ± 0.10 to 0.68 ± 0.12 in the ReCo group ($p < 0.001$). These changes were comparable between the two groups (Fig. 3). Clinically, the overall results (Table 4) were considered excellent (<10 mmHg) or satisfactory (10–20 mmHg) in 3 and 7 of the NaCo patients (83.4 %) and in 7 and 5 of the ReCo patients (92.3 %), respectively ($p = 0.99$).

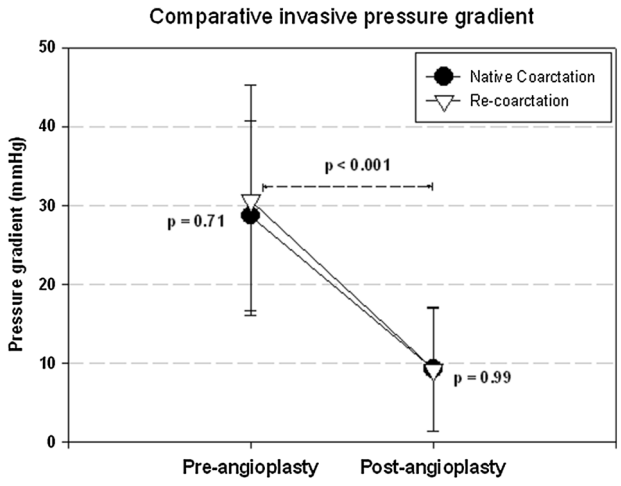

Fig. 1 Comparative invasive pressure gradient before and after balloon angioplasty

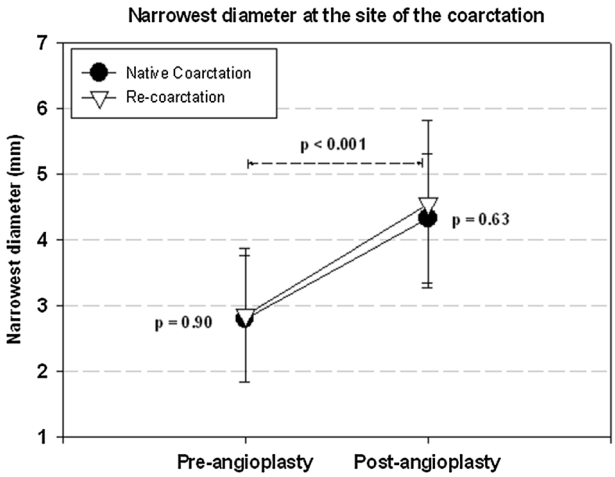

Fig. 2 Comparative angiographic measurements of the narrowest diameter of the coarctation before and after balloon angioplasty

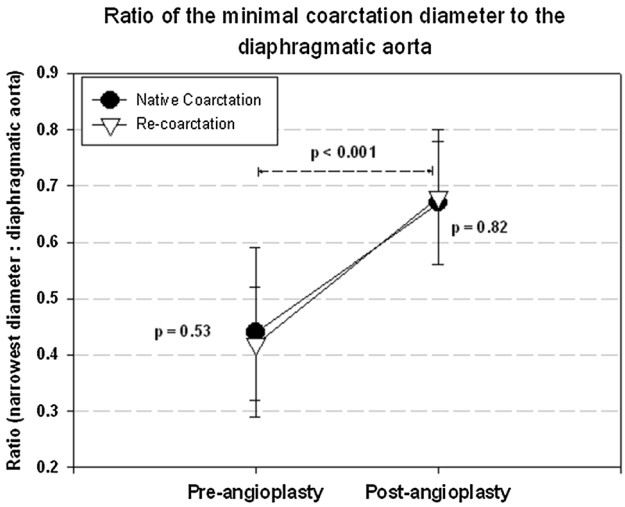

Fig. 3 Ratio of the minimal diameter at the coarctation site to the aorta at the diaphragmatic level. Angiographic comparison before and after angioplasty

Table 4 Graded hemodynamic peak pressure gradient at the end of the first percutaneous procedure similarly distributed between study groups ($p = 0.67$)

Pressure gradient (mmHg)	NaCo *n* (%)	ReCo *n* (%)
≤10	7 (58.4)	7 (53.8)
11–20	3 (25.0)	5 (38.5)
>20	2 (16.6)	1 (7.7)

NaCo native coarctation, *ReCo* postsurgical recoarctation

Given the persistence of the suboptimal residual gradients, five patients in the NaCo group (41.66 %) underwent a reintervention after a period of 1.75 ± 1.41 months (range, 0.27–4 months). Four of these patients benefited from a successful percutaneous redilation, and one patient required surgical correction. Among the four patients who were redilated, one had to undergo reoperation later for a residual gradient. All four patients had undergone their first percutaneous approach before the age of 3 months.

Comparatively, one ReCo patient (7.69 %; $p = 0.167$) experienced recoarctation 8 months after percutaneous intervention and benefited from a second BAP. This patient also had his first BAP before the age of 3 months. The mean follow-up interval after the second percutaneous intervention was 3.09 ± 2.69 years in the NaCo group and 3.6 ± 3.18 in the ReCo group ($p = 0.67$). The final pressure gradient by noninvasive (cuff) measurement was 12.33 ± 9.67 in the NaCO group and 7.80 ± 8.78 in the ReCo group ($p = 0.17$) (Fig. 4), similar to the Doppler peak instantaneous gradients (21.29 ± 11.19 vs 16.20 ± 10.23, respectively, $p = 0.24$) (Fig. 5).

Complications

No threatening events or deaths occurred relative to the procedures or during the follow-up period of 3.09 ± 2.69 years in the NaCo group and 3.6 ± 3.18 years in the ReCo group ($p = 0.69$). Acute complications occurred for three ReCo patients (20.1 %). One patient (7.7 %) experienced a localized aneurysm without hemodynamic consequence, and two patients (15.4 %) experienced peripheral vascular complications.

In a 3.5-month-old infant, a balloon catheter remained temporarily trapped in the left femoral artery after balloon rupture during inflation. A surgical arteriotomy of the superficial femoral artery was performed, with extraction of the entire catheter and balloon. The child was discharged the next day and showed no significant morbidity during the follow-up evaluation.

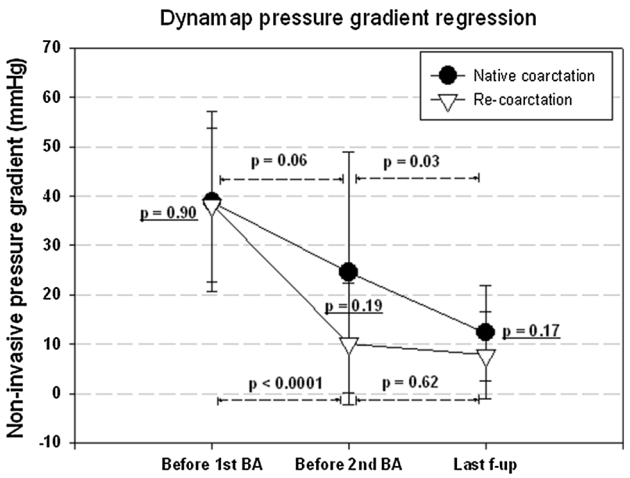

Fig. 4 Clinical blood pressure gradients at the last clinical assessment before the initial cardiac catheterization, between the initial and second catheterizations, and at the final follow-up evaluation

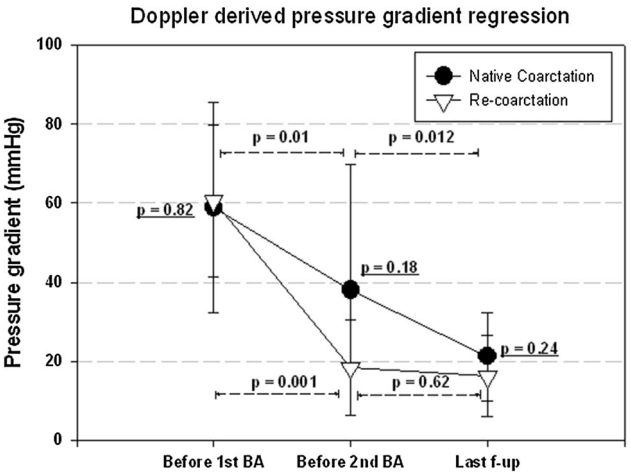

Fig. 5 Doppler-derived transisthmic pressure gradients at the last clinical assessment before the initial cardiac catheterization, between the initial and second catheterizations, and at final follow-up assessment

In another 3-month-old baby, thrombosis of the common iliac and the ipsilateral femoral artery was noticed immediately after intervention. Resolution of the thrombosis was achieved after 1 week of low-molecular-weight heparin.

To assess the anatomic results or possible in situ complications, computed tomography angiography or cardiac magnetic resonance were obtained for all the subjects at an interval of 2.21 ± 2.97 years in the NaCo group and 3.21 ± 2.12 years in the ReCo group ($p = 0.15$). The diameter ratio between the minimal isthmus diameter and the aortic diameter at the diaphragmatic level was 0.81 ± 0.15 in the NaCo group and 0.85 ± 0.12 in the ReCo group ($p = 0.53$). A small pseudoaneurysm was observed in one NaCo patient (8.33 %) without hemodynamic consequence versus one ReCo patient (7.69 %) ($p = 0.74$).

Discussion

This report describes our experience with consecutive infants who underwent a percutaneous dilation of the aortic isthmus. We sought to compare the results between patients with native coarctation and those with a recurrent or residual coarctation after surgical repair. This was based on the historic trend advocating primary surgical intervention for infants with coarctation of the aorta. Because the baseline characteristics of the study were equivalent, it may

be concluded that the final results and the success rates are comparable. This highlights the noninferiority of primary balloon dilation for coarctation of the aorta in infants.

Although a relatively larger number of patients in the native group had to undergo a secondary intervention, it should be considered that in practical terms, the postsurgical subjects in this cohort required a second intervention. In addition, the limited success and the need for an intervention typically occurred only in those for whom the intervention was performed before the age of 3 months. Arguably, the ductal tissue in this neonatal period did not achieve its complete anatomic retraction.

Our immediate results are in disagreement with those of previous reports on native coarctation for infants younger than 3 months [18] but comparable with the results for infants younger than 1 year, both for native and postsurgical recurrent coarctation [4, 11], whereas another study reported more favorable results for native coarctation [13]. In a native coarctation series, for instance, BAP resulted in a 44 % rate of recoarctation in the presence of two risk factors: a minimal stenotic diameter smaller than 3 mm and a residual pressure gradient greater than 10 mmHg [11]. Other series have reported a recoarctation rate of 50 % for native lesions before the age of 3 months [18] and 25 % after 5–9 years of follow-up evaluation in a diverse series of patients ranging from birth to adolescence, with a higher rate of recoarctation (83 %) when the procedure was performed within the first month of life [17]. Comparatively, the need for reintervention in surgical series comprising patients of all ages ranges between 3 and 26 % [9] irrespective of the type of repair. At our institution during a 3 years period, the rate of residual or recurrent coarctation after surgical repair in neonates and infants was approximately 17 % (unpublished).

In our series, the clinical success rate for achieving a residual gradient lower than 20 mmHg was 83.4 % for native coarctation and 92.3 % for postsurgical recoarctation, which is similar to the rates in other pediatric series of infants and older children (respectively, 70–90 % [3, 10, 15] and 90 %) [12]). In pediatric series of mixed age groups, the success rate for native coarctation remains in the same range of 91.2 % [6] and 100 % [2]. In our experience, we were able to achieve similar final results, which are comparable with those of percutaneous series (residual gradient of 16 ± 21 mmHg in native and 15 ± 15 mmHg in postsurgical coarctation) [8] and surgical series of native coarctation (residual gradient of 15 ± 9.8 mmHg for the surgical vs 12 ± 9.1 mmHg for the percutaneous approach) [21].

The in situ complications (i.e., dissection and pseudoaneurysm of the isthmus) are the most dreaded outcomes. In our series, they represented 7–8 %, which is in concert with those of another series reporting a stable pseudoaneurysm in 1 % and isolated ectasis of the site of BAP in 7 % of patients [14]. In the same series, an intimal flap was documented in 5 % of patients at early magnetic resonance without dissection, aneurysm, or ectasis, which disappeared thereafter [14].

In another series comparing balloon BAP between native and postsurgical coarctation [8], the rate for all complications was 12.5 % in NaCo and 19 % in ReCo cases. This included aortic aneurysms in 1.8 % of NaCo and 5.2 % of ReCo cases. The difference did not reach statistical significance. Interestingly, this multicenter survey from Japan clearly indentified a higher risk of recoarctation among infants younger than 4 months in both groups. In comparison, surgical series report in situ complication rates of 0–24 % [1, 7, 19].

In a series of 181 infants younger than 1 year with native coarctation, the complication rate for all cases was 2.7 %, including diaphragmatic nerve palsy requiring plication [22], and between 2 % for chylothorax and 3 % for other complications such as bleeding, vocal chord palsy, and seizure [23]. The major decision process typically is based on clinical and hemodynamic success as well as on the risk of mortality. From this perspective, the absence of mortality in our series is favorable compared with a surgical mortality rate of 0.5 % [22] to 4 % [23] and an interventional mortality rate of 1 % for children in general [14].

Study Limitations

The retrospective nature of this study and the limited number of subjects were the main limitations of this work. The cohort presented in this report was a consecutive nonselective percutaneous series. Nevertheless, the approach may not be regarded as exclusive considering that three patients ages 4–12 months old were directed to surgery for a first approach during this period and did not require reintervention. Finally, the design of this work was not aimed at comparing BAP and a primary surgical approach for infants with native coarctation. Our results, however, pave the way for a future randomized trial comparing the two approaches.

Conclusion

In this series, the outcomes of BAP in the treatment of native coarctation and postsurgical recoarctation were similar for infants younger than 12 months. Because BAP during the first 3 months of life is associated with a high risk for recoarctation, this approach should be avoided in this age group but can be offered to older infants.

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