

## Original Studies

# Bailout Stenting for Critical Coarctation in Premature/ Critical/Complex/Early Recoarcted Neonates

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**Background:** Surgical repair of critical coarctation can be problematic in premature, critical, complex, or early postoperative neonates. **Objectives:** We aimed to review our experience with stent implantation to defer urgent surgery to an elective time. **Methods:** Fifteen neonates with severe aortic coarctation: five premature-hypotrophic (1,400–2,000 g), six critical and complex cardiac malformation, four early (1 day [0–2 days]; median [range]) after surgical coarctectomy or complex arch reconstruction. Bare coronary stents (diameter 4.0 [3.5–5.0] mm; length 10 [8–16] mm) were used. Stents were removed surgically depending on clinical needs. **Results:** Adequate aortic flow was obtained in 15 patients. The femoral artery was preserved in 13/15 patients. Two deaths occurred before stent removal and were nonprocedure related. In patients with simple stented coarctation, the stent was removed after 2.8 [0.2–5.0] months. In complex cardiac malformation, stents were finally removed 3.0 [0.2–78] months after implantation. **Surgical technique:** simple coarctectomy end-to-end in eight, extensive arch patch reconstruction in four. One patient is awaiting stent removal. The final maximum systolic velocity (cw-Doppler) across the aortic arch was 1.7 [1.2–2.5] m/sec. **Conclusions:** In premature/critical/complex neonates with severe coarctation, bailout stenting followed by early or late surgical coarctectomy appears a promising concept. © 2009 Wiley-Liss, Inc.

**Key words:** congenital heart disease; coarctation; intervention; neonate

## INTRODUCTION

When confronted with significant arch obstruction in a critically ill neonate, the clinician has several options. The final treatment for these small malformed arches is surgical; however, there are different options of how and when to proceed the surgery.

Prostaglandin infusion is the standard treatment to maintain or regain systemic perfusion by opening the arterial duct and relaxing the coarcted isthmus [1]. However, prostin therapy may sometimes only slowly or incompletely reverse ventricular dysfunction and multiorgan failure due to slow and incomplete opening of the duct and residual constriction at the isthmus [2]. In the very small premature infant, aortic arch repair can be performed [3,4], but is frequently complicated by a residual gradient, increased perioperative morbidity due to operative hypoperfusion on top of pre-existing shock, atelectasis of the lung, injury to the phrenic or vagal nerve, and chylothorax. Surgical techniques that require deep hypothermic

circulatory arrest are not easily applicable in this group of patients.

Stenting a coarcted arch can be performed on short notice and acutely improve the patient, and defer

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surgery to a safer period with adequate weight or stabilized hemodynamics. We reviewed our experience with this strategy in the preterm or critically ill neonate, and in neonates with early restenosis after surgical coarctectomy.

## METHODS

### Patient Selection

We screened our database for stent implantation in the aorta in infants (<2 months) between January 1, 1998 and March 30, 2009. We identified two groups: group 1 consisted of patients with a native coarctation where surgery was not considered the best option (very low-birth-weight, critically ill neonates not responding to medical treatment, complex cardiac, and noncardiac disease); a second group consisted of patients with significant early restenosis after primary surgical coarctectomy or arch repair.

The catheterization reports, angiographic data, medical, and surgical records were reviewed in all patients. The studies comply with the Declaration of Helsinki. Approval for review of patient charts was obtained from the Institutional Review Board and informed consent was obtained from the parents (guardians).

### Catheterization

The data obtained from cardiac catheterization reports included sites of access, sheath sizes, catheter selection, balloon or stent size in relation to lesion, haemodynamic data, and complications of the procedures. Medical records were reviewed for complications that occurred during or after the procedure, presence of recoarctation, presence or absence of femoral artery pulse after the procedure, and need for blood transfusion. In addition, the time interval to operation and—on echocardiography—the final morphology as well as cw-Doppler profile of the isthmus were recorded. Criteria for a good final result was systolic peak velocity over the arch of  $\leq 2.5$  m/sec on cw-Doppler [5]. Complications were classified as major or minor as depicted in previous series [6].

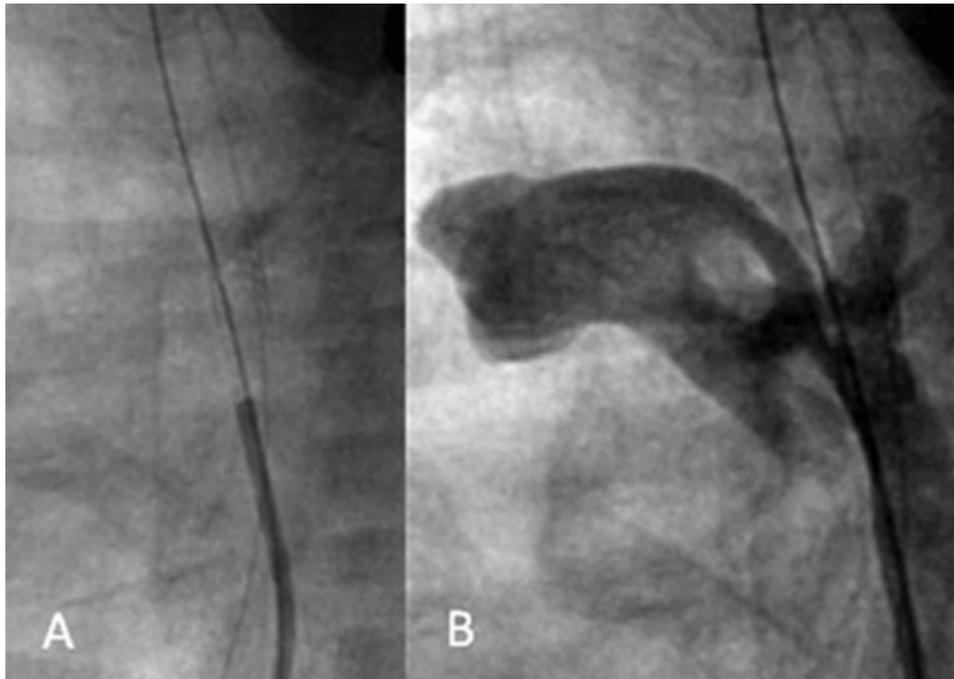
### Catheterization Technique and Materials Used

Before the procedure, all therapeutic options had been discussed with the parents; informed consent had been obtained as requested by institutional regulations. All procedures were performed under general anesthesia. Care was taken to position the patient with moderate hyperextension of the groin; the position of both femoral arteries was identified with a Doppler probe. Puncture of the artery was performed with a butterfly 21 Gauge needle (Surflo<sup>®</sup> SV\*21 BLS, Terumo<sup>®</sup>)



**Fig. 1.** Retrograde aortogram in patient 11, a 1,500 g premature infant under IV prostaglandin. Hand injection of layered contrast-saline through the 4F sheath. A 4/8 mm coronary stent is ready for deployment. Points of reference are as follows: cranial end just beyond take-off of left subclavian artery, caudal end beyond coarctation site within the thoracic aorta.

allowing a 0.014" wire to be introduced into the artery. A 4F short tapered introducer sheath (RCFN-4.0-18-5.5-RA1.5, Cook<sup>®</sup>) was placed in the right or left femoral artery. The sheath was introduced for only about 1–2 cm into the artery with wide tissue support to prevent vascular damage. Typically, two pairs of experienced and coordinated hands were required. Heparin was given at a reduced dosage of 50 U/kg body weight; the sheath and catheter were flushed as required with saline 2 U heparin/ml (half of usual dose). A 4F end hole vertebral catheter was advanced up to the coarctation site where a small (1–2 cc) hand injection was made. The coarctation was crossed using a 0.014" wire ("Ironman," Boston Scientific<sup>®</sup>); if the isthmus could not be entered retrograde, a transvenous antegrade approach was used [7]. A new hand injection was made in the distal arch to delineate the distal arch and origin of the left subclavian artery (Fig. 1). The diameter of the aorta at various levels could thus be assessed. A stent was then implanted (off label use for any coronary stent). As our experience grew, stent length was chosen as the shortest length covering the distal arch from just beyond the left subclavian artery until beyond the coarctation; stent diameter 1 mm



**Fig. 2. A and B: Patient 11: after deployment of the 4/8 mm stent, the narrowing has disappeared. The distal aortic arch is less visualized due to good antegrade flow.**

larger than the proximal isthmus at the origin of the left subclavian artery. In patients early after a failed coarctectomy, a smaller stent size was deployed not to tear the “fresh” anastomosis. If required an additional stent was implanted in hypoplastic segments.

The stent was passed “unprotected” through the valve of the sheath. Stent position was controlled with a retrograde aortogram hand injection through the sheath (sequential gentle aspiration in a vertical 10 cc syringe of 5 cc saline followed by 1 cc contrast keeping contrast and saline layered and separated) (Fig. 1). The stent was deployed using an in-deflator at a pressure as recommended by the stent manufacturer (allows opening the stent within a range of 0.6 mm). In premature and neonates with primary coarctation, the prostaglandin E-1 infusion was stopped immediately after deployment of the stent. If useful and not contraindicated (renal function), stent position was assessed with an aortogram through the 4F catheter below the stent (Fig. 2); no attempt was made to recross the stent, as the “free-hanging” stent in the thoracic aorta can easily be kinked; the wire was carefully withdrawn. After control of clotting time, the sheath was withdrawn applying ample support to the surrounding tissues in the groin. Heparin was not neutralized if ACT was not above 250 sec. Anesthesia was maintained at least until the groin had “dried” up. If no feet pulses were palpable, heparin was restarted after 1 hr for 24–48 hr.

The decision when to surgically remove the stent was taken for every patient individually: criteria were hemodynamic stability after the cardiogenic shock, adequate body weight to safely perform coarctectomy, or when additional surgery was planned (Glenn, VSD closure, etc.). If more time was needed, an additional balloon dilation or additional stent implantation was performed.

### Statistics

Data were recorded using Excel spreadsheets and descriptive statistical analyses were performed using the SigmaStat software (SPSS). Where applicable, results are given as mean with range.

## RESULTS

### Study Population and Catheterization Procedures

Fifteen patients fulfilled the entry criteria. The patients were 36 (30–41) weeks of gestation, 8 out of 15 were premature (<37 weeks of gestation). At cardiac catheterization, the weight of the patients was 2.5 (1.5–3.8) kg and their age was 12 (3–61) days. Demographic data with respect to the two groups are given in Table I.

Group 1 consisted of very small premature–dysmature infants where the neonatologist and the surgeon felt uncomfortable to proceed with surgery at that time.

TABLE I. Clinical Data of Patients

Pt. no	Diagnosis	Age at stent (days)	Weight at stent (kg)	Diameter × length of stent (mm)	Age at surgery (months)	Weight at surgery (kg)	Type of definitive surgical repair
<b>Group I: Patients with primary stent implantation</b>							
1	Shone complex, hypopl. Ao-Arch, CoA, MS, VSD's	12	3.8	5 × 12	1.0	3.5	Ao-Arch patch angioplasty (Norwood-like)
2	TGA, VSD, subAS, hypopl. Ao-Arch, CoA	61	3.2	4 × 10	2.2	3.2	Ao-Arch patch angioplasty (Norwood-like), arterial switch, resection of subAs
3	crit. CoA, musc. VSDs	29	1.8	4 × 9	3.8	2.4	stent removal, ETE
4	crit. CoA, hypopl. Ao-Arch, bic. AoV	17	3.3	4 × 15	3.5	4.8	stent removal, ETE
5	crit. CoA, incomplete AVSD; CHARGE syndrome	8	2.7	5 × 15	–	–	–
6	crit. CoA, hypopl. Ao-Arch, bic. AoV	15	2.2	3.5 × 12	3	4.2	aortic arch patch angioplasty (Norwood-like)
7	crit. CoA, hypopl. Ao-Arch, VSD	9	1.9	4 × 8	3.3	4.9	stent removal, ETE
8	crit. CoA, hypopl. Ao-Arch, bic. AoV, VSD	5	2.5	3.5 × 12	2.2	3.8	stent removal, ETE
9	crit. CoA, hypopl. Ao-Arch, VSD, bic. AoV, PAPVD	3	2.6	4.5 × 16	–	–	–
10	crit. CoA, bic. AoV, VSD, borderline LV	5	1.8	4 × 9	4.2	4.9	stent removal, ETE
11	crit. CoA, bic. AoV, VSD	5	1.5	4 × 8	4.3	5.2	stent removal, ETE
<b>Group II: Patients with primary surgical repair (in brackets type of primary repair)</b>							
12	crit. CoA, hypopl. Ao-Arch, VSD (ETE, reversed Waldhausen plasty)	19	2.7	4 × 10	78	21	stent removal, ETE
13	CoA, hypopl. Ao-Arch, VSD (extended ETE)	15	2.2	4 × 8	69.6	16.2	stent removal, ETE
14	crit. CoA, UVH (dominant RV) (aortic arch patch reconstruction (Norwood-like))	6	3.6	5 × 11	–	–	–
15	crit. CoA, VSD (ETE, reversed Waldhausen plasty)	10	2.1	4 × 8	20.4	6.3	stent removal, ETE

Ao-Arch, aortic arch; AoV, aortic valve; AVSD, atrioventricular septal defect; bic, bicuspid; crit, critical; CoA, coarctation; ETE, end-to-end anastomosis; hypopl., hypoplastic; MS, mitral valve stenosis; musc., muscular; PAPVD, partial anomalous pulmonary venous drainage; Pt-No, patient number; RV, right ventricle; subAS, subaortic stenosis; TGA, transposition of great arteries; UVH, univentricular heart; VSD, ventricular septal defect.

This group further included more mature infants but with poor hemodynamics (poor flow with limited effect of prostin, evolving necrotising enterocolitis, recovery from renal failure-tubulus necrosis), where the clinician felt that coarctectomy with even a short cross clamp at this time would not be well tolerated, or where percutaneous intervention was immediately available for faster relief to buy time for further surgery.

Group 2 consisted of four patients with a surgically failed arch repair in complex coarctation. In 3/4 patients, residual arch dysfunction compromised renal function early (<48 hr) after surgery; one patient was stented in the PICU using a mobile C-arm.

### Catheterization

The arch was probed retrograde in 14/15 patients. In one patient, antegrade catheterization was required: this patient had a critical coarctation and a lusoria right subclavian artery (the preferred route for the wire!). From the femoral vein, a 4F mammary catheter was advanced into the left atrium; from there a Progreat coaxial system was advanced into the left ventricle, out the aorta and around the arch; the inner wire was

snared in the descending aorta allowing retrograde passing of the coarctation [7].

The diameter of the presubclavian aortic arch was measured planimetrically as 3.6 (2.3–5.5) mm, the diameter of the descending aorta at the diaphragm was 5.6 (4.4–7.2) mm. The angiograms in standard profile did not allow to accurately measure the narrowest coarctation diameter.

The fluoroscopy time was 9.4 (3.5–21) min, and the amount of contrast needed was 1–2 ml/angiography.

### Stent Implantation

Bare coronary stents (diameter 4.0 [3.5–5.0] mm; length 10 [8–16] mm) were used in this series. Given the time span of more than 10 years that is covered by our study, stents from various manufacturers were used (e.g., Guidant Multi-Link Ultra<sup>®</sup>, Medtronic Driver Sprint RX<sup>®</sup>, and Abbott Multi-Link Vision<sup>®</sup>). We preferred stents with small cell size, thereby providing good scaffolding and impeding ductal tissue to prolapse through the cells in the days following the procedure (see discussion). In two patients after surgical

repair, an additional stent was put in the distal cross over the extended anastomosis.

Adequate aortic flow was obtained in 14 patients. In the first patient of this series with stenting early after surgery, we implanted a stent which was rather small, because we were afraid to tear the suture line; it was redilated 6 days later uneventfully using a bigger balloon with adequate relief of arch obstruction. As our experience grew, we chose a stent as short as possible covering the isthmus from beyond the subclavian take-off until the descending aorta (Fig. 2). As fetal-neonatal tissue allows for significant stretch, we would slightly oversize the stent in native coarctation (size of distal arch, not beyond 5 mm), and slightly undersize early postop not to tear any recent suture line.

No blood transfusion was required because of the catheterization: all procedures were performed with minimal blood loss.

The arterial duct closed within hours in all patients after discontinuation of prostaglandin E1 infusion.

### Complications of the Percutaneous Intervention

There were no major complications (e.g., procedure related death, cardiac arrest, and arrhythmia) in this series. Arterial hypotension requiring a short term catecholamine treatment was observed in one patient immediately after placement of stent due to reduced systolic left ventricular function. Loss of sheath out of the femoral artery accidentally occurred in one patient during the procedure after stent insertion but before stent positioning; no retrograde angiogram was made before stent deployment.

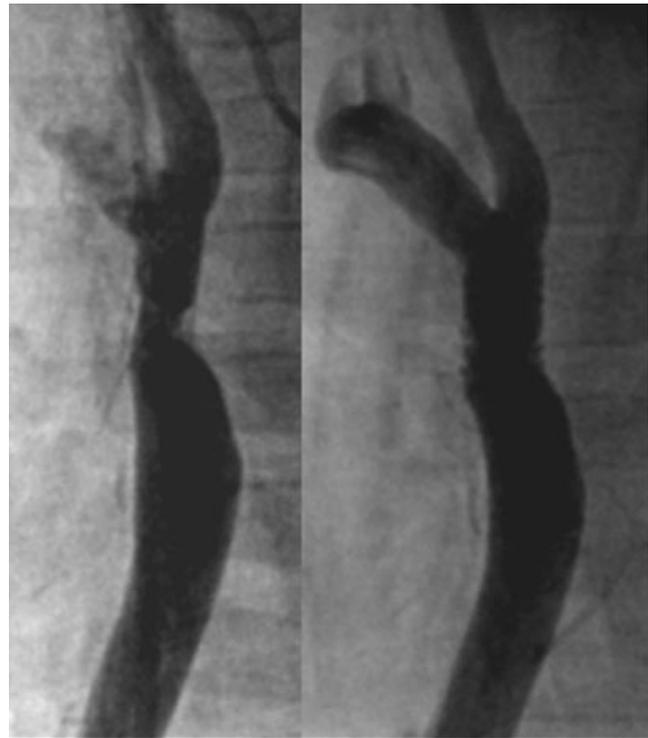
Femoral artery patency was preserved in 13/15 patients. Many patients had transient hypoperfusion of the cannulated leg, but pulsations resumed within hours, frequently under heparin infusion. Femoral pulses had disappeared in two patients with echographic demonstrated thrombosis. The leg was pale with slow capillary refill for several hours; at no point was the viability of the leg at risk. At follow-up at 7 months and 4.3 years, respectively, these two patients did not show abnormal growth of the leg.

### Interval Follow-Up

Most patients with simple coarctation could easily be weaned from supportive therapy as systemic output had adequately resumed.

All patients were given acetylic salicylic acid 1–2 mg/kg BW/d (off label use for this application).

Some patients are described in detail. In patient no. 2 (Table I), a mature 3.2 kg infant with complex dTGA presenting in shock, we first deployed a stent in the coarctation. Intracardiac repair and aortic arch



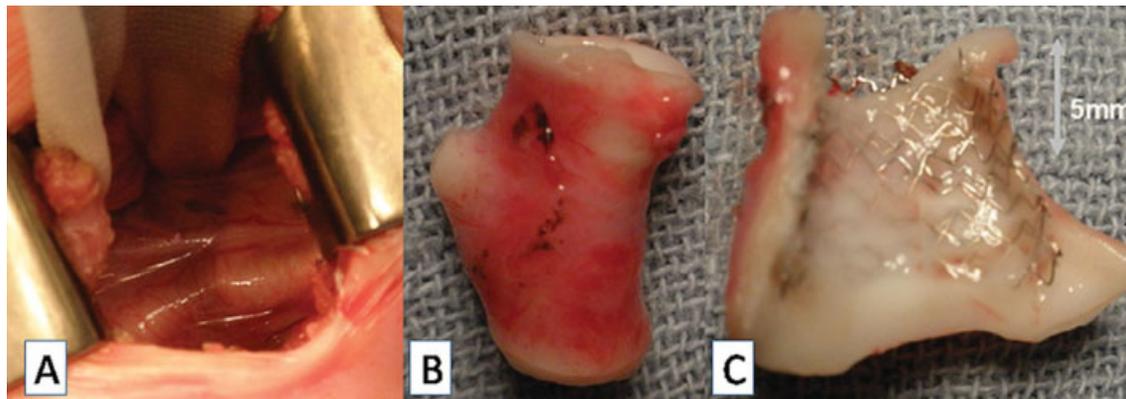
**Fig. 3. A and B: A:** Aortogram in patient 11, 2 months after implantation of the 4/8 mm stent: the isthmus is nice open, but there is prolapse-ingrowth of tissue at the ductal level. **B:** implantation of an additional 5/9 mm stent reopened the aorta adequately. Note that the distal arch has shown some catch-up growth as shown in Figs. 1 and 2.

repair was performed 6 days later with good outcome. In patient no 11 (Table I) presenting with low birth weight (1,500 g) and necrotizing enterocolitis, the lesion was stented primarily to 4 mm (Figs. 1–3) and a second stent (5 mm) was placed 55 days later for restenosis due to ingrowth of intimal tissue (Fig. 3). Aortic surgery could thus be postponed to 5 months of age (Fig. 4).

Management of the stent (dilation, removal) was tuned to the individual needs of the patient. Surgical removal was performed if concomitant surgery was performed (e.g., Glenn, VSD closure), or if a coarctectomy could be performed at an adequate weight in stable conditions with the expectation for optimal outcome.

In two patients with stenting early after coarctectomy, the surgeon preferred a rather “late” reintervention as the dissection planes had healed. A second balloon dilation was performed in patients no. 12 after 13 months, and in patient no. 13 (Table I) after 38 months, allowing to defer redo-surgery until the age of 78 and 69 months (Table I).

**Mortality during interval stent–stent removal.** Two deaths were observed during follow-up: one syndromic



**Fig. 4. Patient 11. A: Surgeons view at thoracotomy: the coarctation site is nicely exposed without trauma of the media or adventitia. B: Resected coarctation site removing the stent in whole. C: Resection piece has longitudinally been opened; the stent-in-stent has completely been covered by endothelium.**

term infant (patient no 5, Table I), with the CHARGE syndrome and perinatal asphyxia presented with incomplete AVSD, small left ventricle and critical coarctation. She was treated with a 5/15 mm stent at postnatal age of 8 days, but died 4 months later from sequelae of perinatal asphyxia. Another term infant with univentricular heart (patient no. 14, Table I) dominant right ventricle with significant tricuspid valve regurgitation) and coarctation was first surgically treated (Norwood variant with Sano shunt) and residual coarctation was stented at day 6; she died 3 weeks later from nonprocedure-related problems.

### Surgical Resection and Arch Repair

Stent removal and arch reconstruction has been performed in 12 patients. One patient (number 9 in Table I) is now 7 months after stenting still awaiting final repair. The peak Doppler gradient across the arch before stent removal was 30 [25–60] mm Hg. In patients with primary surgical approach, the stent was removed after 69 [21–78] months and in patients with primary stent implantation after 2.8 [0.2–5] months. Upon inspection, the surgeon never saw any damage to the adventitia caused by the stent. The arch was carefully dissected taking care not to compress the stent as a balloon expandable stent has no elastic recoil. The stent was completely removed: if surgery occurred within days after implantation the stent was simply “picked” after arteriotomy; if surgery occurred after a few weeks the short stented segment was resected if possible, otherwise an endarterectomy was performed. The arch was reconstructed with end-to-end anastomosis in nine, and extensive arch patch reconstruction in three (Norwood-like repair). The surgeon felt the procedure was not complicated by the presence of the stent; on the contrary, the procedure at this time yielded no risk to leave any resid-

ual active ductal tissue in the anastomosis. The surgery was considered to be easier as all structures had grown, with some catch-up growth of the distal arch (Fig. 3).

After completion of the surgical repair, the final gradient (Doppler) across the arch was 0–20 mm Hg. Control chest roentgenogram showed no residual metal threads in the arch (however, these stents are little radio opaque).

### Late Follow-Up

All patients have regularly been seen at our outpatient clinic for 9 months [0.4 months–5.2 years] after stent removal. On cw-Doppler echocardiography, the peak velocity over the aortic isthmus at last follow up was 1.7 [1.2–2.5] m/sec.

### DISCUSSION

Significant arch obstruction in a critically ill neonate currently does require a surgical intervention; however, there are different options of how and when to proceed the surgery. Any therapeutic strategy in such patients must be judged by efficacy, time to establish adequate perfusion, complications early and late, number of procedures, hospitalization time(s), and last but not least final outcome of the arch and the patient.

This study shows that in critically ill neonates early stenting (of both native coarctation or early recoarctation post surgical coarctectomy) followed by later coarctectomy can be performed safely and with good results.

### Treatment Options

**Prolonged prostin infusion.** Prostaglandin E1 infusion is nowadays the standard treatment to recover or maintain systemic flow in a neonate with critical coarctation, while scheduling him for elective surgical repair. However, this treatment can be associated with

considerable side effects such as pulmonary overflow, haemodynamic instability with low diastolic blood pressure, increased vulnerability for renal failure, sepsis, and necrotizing enterocolitis. Other common side effects include apnea, hyperthermia, diarrhea, skin flushing, edema, and cortical hyperostosis [5,8,9]. Prostaglandin E1 infusion may only result in incomplete ductal reopening and partial isthmus relaxation, leaving insufficient systemic flow for a prolonged time [10].

**Early surgical repair.** In our hands, surgical coarctectomy is the procedure of choice for isolated coarctation in neonates, infants, and young children. Primary surgical coarctectomy has been performed successfully in low birth weight infants, but mortality and morbidity in this age group is increased when compared with mature neonates [11]. Such surgery is associated with an elevated incidence of early recoarctation in up to 30% [3,12]. Early failure after aortic arch repair may be due to inadequate surgical technique (e.g., kinking of a Norwood-patch, excessive tension on the anastomosis), oedema formation of the anastomosis, or constriction of residual ductal tissue.

Mortality rates in the best series have been reported to be as low as 5.5%, but remain clearly higher than in full term neonates and infants [4,12]. If surgery could safely be deferred to a later age or bigger size, it would most likely be reflected in a better final result.

**Percutaneous interventions: Balloon-stent.** Balloon dilatation of coarctation yields varying but usually unsatisfactory results when performed in low-birth-weight infants because of early recoil, or tear and aneurysm formation when overdilated [13–15].

Stent implantation in low-birth-weight infants with coarctation has been reported in isolated cases [16]. Stenting of early recoarctation after primary surgical coarctectomy clearly has the advantage of postponing redo-surgery thus reducing perioperative morbidity.

The series of stented primary coarctation or early recoarctation represents a small subset of the 218 surgical coarctectomies performed in infants <3 months of age within the same time period in our institution. Stenting of the coarctation such as presented here was performed with the aim to provide the surgeon with a bigger and better patient. We feel that this strategy in this highly vulnerable subset of patients has clear advantages compared with alternative concepts such as prolonged prostin infusion followed by surgical coarctectomy or primary surgical coarctectomy.

### Stent Choice

Coronary stents are available in different length and diameters. Nearly all coronary bare stents can be delivered through a 6F guiding sheath or a 4F introducer

sheath. Given the time span of more than 10 years that is covered by our study, stents from various manufacturers were used. The differences in stent design and material determine the cross-sectional area, the strut thickness, and the radial force. Larger metallic cross-sectional areas, thicker struts, and smaller cell-areas result in good scaffolding with limited tissue prolapse [17]. These scaffolding properties reduce the flexibility and conformability of the stent which, however, is no issue for this application (nearly straight course from groin to coarctation). Radial force is also no issue for a stent deployed in this soft fetal–neonatal tissue. Side branch accessibility might be an issue when crossing the (lusoria) subclavian artery, but priority should be given to adequate arch flow; moreover, experience from Waldhausen plasty has learned that even total occlusion of the subclavian artery is nearly always well tolerated. Depending on the design, most stents can be overdilated by 1–3 mm when using bigger balloons.

Clearly, stenting is not a definitive treatment: eventually, all stents need to be excised surgically as the materials used do not allow for redilatation to adult vessel size. In the future, resorbable stents [18] or “breakable” stents [19] may address this issue.

### Vascular Damage

The biggest complication in this series was thrombosis of the femoral artery in 2/15 patients. Occlusion of the femoral artery after vascular access for cardiac catheterization may present in any age group [6]. In neonates and infants, it is usually tolerated without threatening perfusion of the leg, as they have more and develop faster collateral flow. Lee et al. have shown that transfemoral artery balloon dilatation may cause superficial femoral artery compromise, but in their series, there was no significant limb growth retardation at a 3.5-year mean follow-up [20]. The problem may persist as chronic femoral ischemia with claudication and limb-length discrepancy. Limb-length discrepancy exceeding 2 cm is known to be associated with gait disturbance [21]. So, every effort should be taken to avoid this complication.

The lower limit whereby a 4F sheath can be introduced “safely” into and removed from a femoral artery still needs to be determined. For obvious reasons, a trial cannot be performed. Some interventionalists advocate the use of long 4F sheaths in neonatal procedures: such sheaths give very nice support for balloon and stent manipulations, and allow small hand injections to be made during the procedure [22]. Especially in the preterm infants, we preferred to use the short 4F sheaths with minimal entry into the artery, thereby theoretically limiting the damage to the artery. Other

arterial access may be useful such as the brachial artery [22] or carotid arteries via surgical cut-down [23]. Percutaneous interventions through an umbilical artery have been reported [24]. However, in a typical patient, the umbilical artery is thrombosed and no longer available for intervention by the time the coarctation needs attention. In addition, de novo development of critical stenosis of the abdominal aorta has been reported after less invasive procedures such as placement of an umbilical artery catheter [25]. Thus, each method of percutaneous arterial access has its advantages and disadvantages. Our data show that femoral arterial access can be performed with low morbidity.

### LIMITATIONS

This is a retrospective study over a long-time period, trying to determine feasibility, efficacy, and safety. Patients were not randomized to compare treatment strategies, as results of each strategy may differ in each centre over time.

We cannot provide data on long-term growth of the aortic vessel wall after stenting and stent removal. In most patients, the stent and vessel wall were resected in toto with end-to-end anastomosis; in this subgroup, we anticipate long-term results as in patients after primary repair. In some patients, the stent was removed in toto but partially with endarterectomy, whereby the surgeon still used some vessel wall in the final arch reconstruction. It is known that stenting of the aorta may result in morphological changes of vessel wall, with good early growth but with unknown long-term effects [26]. When last seen at echocardiographic evaluation, the arches were free of aneurysm formation; however, aneurysms may form several decades after the initial coarctectomy [27]. The arch of these patients should, therefore, be followed probably lifelong to detect timely late aneurysm formation (as should any patient after coarctation repair).

### CONCLUSIONS

In infants with critical coarctation, bailout stenting and later surgical stent removal and arch repair can be performed safely and effectively with low morbidity. This strategy when applied in selected patients such as in the very premature, critical, or complex neonate, compares competitive with current treatment strategies on overall mortality and morbidity. Long-term studies are needed to define the impact of stenting and stent removal on growth of the aortic vessel wall.

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