

The use of small stents to delay surgical intervention in very young children with critical congenital heart disease

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INTRODUCTION

Critical obstructive congenital heart disease in very young children is often lethal and may require immediate life-saving interventions. Primary corrective surgery remains the treatment of choice for these lesions (e.g. coarctation of the aorta [COA], right ventricular outflow tract [RVOT] obstruction). Overall surgical mortality in this group of seriously ill patients varies between 10% and 40% and pre-operative cardiorespiratory status and associated lesions influence outcomes with regards to predictability and consistency.⁽¹⁻⁴⁾

In cases where it is not possible to proceed to immediate corrective surgery, alternative treatment options may be considered. These situations include: low or very low birth weight newborns, severe infectious risk, haemodynamic instability, technical and system factors.⁽²⁾ Alternative treatment options include palliative surgery, prolonged prostaglandin administration, balloon angioplasty and stent implantation.

In units where primary repair is not possible or an option, placement of a systemic-to-pulmonary artery shunt (e.g. Blalock Taussig and Sano shunt) are frequently used in the management of lesions with compromised pulmonary blood flow (e.g. severe tetralogy of Fallot and critical RVOT obstruction). However, this procedure has been associated with numerous complications such as differential pulmonary artery flow and distortion, pulmonary over circulation, kinking, stenosis, thrombosis, chylothorax and phrenic nerve palsy.^(1,2,5-7)

ABSTRACT

Introduction: Surgery in very young children with critical obstructive congenital heart disease has a high morbidity and mortality. The aim of this study was to determine whether the use of small stents is feasible and if it could delay surgery.

Materials and methods: Nineteen children were included in a retrospective review spanning 7 years. Patients were included in circumstances where surgery needed to be delayed and the use of a small stent could alleviate the underlying obstruction.

Results: All attempts at stenting were successful (100%). Indications were diverse and included: aortic obstruction (n=9), right ventricular outflow tract obstruction (n=3), systemic-to-pulmonary artery shunt occlusion (n=5), infradiaphragmatic pulmonary vein obstruction (n=1) and salvage of a discontinuous left pulmonary artery (n=1). Reasons patients were not fit for surgical intervention included: low weight (n=4), poor general clinical condition (n=12), surgical technical difficulty (n=2) and unavailability of a critical care bed (n=1). Median age and weight at procedure was 4.6 months (range: 0.1 - 18.3) and 4.5kg (range: 1.7 - 9.5), respectively. Pressure gradients and saturations showed significant improvement post stenting. Periprocedural complications were few (n=3) and there were no fatalities. Last follow-up was at a median of 7.8 months (range: 0.1 - 69.0) post initial procedure. Nine cases proceeded to corrective surgery. Surgery was delayed by a median 13.5 months (range: 0.3 - 69.0 months) and weight increased to a median of 10.3kg (p<0.001). Five cases demised at a median of 73 days (range: 1 - 422) post initial stent placement, most at home secondary to unknown causes. Four patients remain in follow-up. One patient was lost to follow-up.

Conclusion: The placement of stents in small, ill children is feasible. It immediately relieves the obstruction and improves the general clinical condition. Surgery can be delayed for weeks or months, thus giving the opportunity for somatic growth. SAHeart 2014;11:128-134

These are major causes of early morbidity and mortality. Poor clinical condition at the time of surgery also plays a role in exacerbating the outcome as this may increase the risk of shunt occlusion.^(7,8) Prostaglandin E1, as a continuous intravenous infusion to maintain ductus arteriosus patency, is often used in resource limited settings where waiting lists for surgery are lengthy. This may be at the expense of well known reported side effects such as apnea requiring prolonged ventilation, convulsions, necrotising enterocolitis and fever.^(2,9)

Congenital aortic arch obstruction is common. Primary surgical repair is the treatment of choice in newborns with COA.⁽¹⁰⁾ Primary surgical repair and redo surgeries in critically ill patients are risky and there is a higher rate of recoarctation (10% - 29%) in very small and premature infants. Also, COA associated with other lesions and complicated by left ventricular dysfunction and cardiorespiratory decompensation, may adversely affect surgical outcomes.^(3,11) Percutaneous balloon angioplasty of native COA in infants is associated with suboptimal and unpredictable results and has a risk of restenosis and aneurysm formation, especially in patients with long segment or complex COA.⁽¹²⁻¹⁴⁾

The use of stents is an accepted and well-established method of treating children with congenital heart disease. The reported periprocedural complications and mortality rates have been low.⁽¹⁴⁾ Experience in stenting very young and small patients with critical obstructive congenital heart disease is limited and consists mostly of case reports and a few review articles.^(5,6,10-12,15-31) The majority reported good immediate results, but limited data on follow-up and final outcomes is available.

The aim of this study was to determine whether the use of small stents is feasible and if surgery could be delayed as well as to analyse the short and medium-term outcomes.

MATERIALS AND METHODS

This was a retrospective analysis done from August 2006 - December 2013 of patients presenting at our centre. The local Paediatric cardiology database as well as the hospital records were used to acquire the required data.

Inclusion criteria

Patients were included in circumstances where surgery needed to be delayed and the implantation of a small stent could alleviate the underlying obstruction. During this period 19 patients were identified.

Technical aspects

All procedures were performed under general anesthesia. Vascular access was obtained via the femoral artery and/or vein depending on the procedure and the smallest possible sheath size was used (4-6 French). Routine intravenous antibiotics (2nd generation Cephalosporin) were given at commencement of the procedure and continued 8 hourly thereafter for a total of 3 doses. Intravenous heparin was administered at commencement (50U/kg) as well as post-procedure for 24 hours. All patients were started on low dose (2 - 3mg/kg/day) oral acetylsalicylic acid post-procedure. As most patients were critically ill, limited diagnostic cardiac catheterisation and angiography was performed. Premounted, low profile, bare metal stents were preferred.

Ethics and statistics

Approval by the local medical ethics committee was obtained. All cases involved a multidisciplinary team approach and the

nature of the intervention was discussed prior to the procedure with the cardiothoracic surgeons. Written informed consent was obtained from parents or legal guardians, specifically for the use of the coronary stents off-label. The data was captured using Microsoft Excel spreadsheets and analysed using standard statistical software (PRISM v 4; GraphPad, San Diego, CA, US). The data is presented as medians with a range of minimum to maximum values where appropriate. Paired data was analysed using a student's t-test. A p-value <0.05 was considered statistically significant.

RESULTS

Demographic and procedural data can be viewed in Tables 1 and 2. Median age at first stent placement was 4.6 months (range: 0.1 - 18.3 months) of which 35% required intervention within the first 2 months of life. Median weight was 4.5kg (range: 1.7 - 9.5kg) with a quarter of patients weighing less than 2.5kg. There was a female preponderance with a ratio of almost 2:1 (females n=12, males n=7).

Patients had quite a diverse group of primary lesions, including both right and left sided obstructive lesions. The majority of patients had aortic arch obstruction (n=9). Almost half of the patients had undergone previous surgery. Obstructive lesions requiring stenting included native COA (n=5), post-operative recoarctation (n=4), native RVOT obstruction (n=3), systemic-to-pulmonary artery shunt occlusion (n=5), native infradiaphragmatic pulmonary vein obstruction (n=1) and also a markedly stenosed native patent ductus arteriosus (PDA) to a discontinuous left pulmonary artery (LPA) (n=1). Reasons patients were not fit for surgical intervention at that time, included very low weight <2.5kg (n=4), poor general clinical condition with associated anesthetic risk (n=12), potential technical difficulty of the procedure due to the nature of the lesion (n=2) and unavailability of a critical care bed (n=1).

Procedure

Balloon angioplasty preceding stenting was required in 2 cases. In the majority (68%) of cases only one stent was necessary to treat the obstruction. Eighty percent of stents were 5mm or smaller in diameter.

Immediate outcome

All attempts at stenting were successful (100%). Angiographic examples of obstructive lesions can be viewed in Figures 1 to 4. The gradient over the COAs was significantly reduced: from a median 43.5mmHg - 12.7mmHg (n=6, p<0.001) and the narrowest diameter increased from a median 1.8mm (range: 1.3 to 2.4mm) to 4.0mm (range: 3.3 - 5.8mm) (n=7, p<0.001). Saturations improved in all patients with obstructive pulmonary blood flow to more than 85%.

Complications

There were no periprocedural deaths. Complications were few and easily managed. These included a temporary bradycardia that needed cardiac massage and atrial fibrillation requiring

TABLE 1: Demographic data.
Age and weight at time of first stent procedure.

	Age (months)	Weight (kg)	Primary lesion	Associated lesions	Stent procedure	Indication for stent
1	1.5	3.9	COA	PDA, VSD	Native COA	Critically ill - post PDA ligation and cardiac failure
2	2.67	3.17	COA	PDA, VSD, ASD	Recoarctation	Surgical technical difficulty
3	10.07	5.1	COA	PDA	Recoarctation	Critically ill
4	4.63	4.7	COA	PDA, VSD	Recoarctation	No intensive care bed available
5	4.87	5.4	COA	PDA, VSD	Native COA	Critically ill - very large VSD and cardiac failure
6	5.27	6.0	COA	PDA	Native COA	Critically ill
7	1.13	1.8	COA	PDA, VSD	Native COA	Extremely low weight
8	7.57	4.5	COA	Bicuspid aortic valve	Native COA	Critically ill
9	5.93	4.7	IAA	Bicuspid aortic valve, VSD, ASD	IAA arch repair stenosis	Surgical technical difficulty
10	1.93	2.4	DORV & PS	PDA	RVOT obstruction	Very low weight
11	0.07	2.3	Tet		RVOT obstruction	Very low weight
12	1.47	2.2	Tet	PDA, MAPCAs	RVOT obstruction	Anaesthetic risk - airway problem and very low weight
13	11.27	8.3	PA	VSD, ASD, PDA, Ebstein	Occluded shunt	Critically ill
14	9.87	5.7	DORV & PS	ASD	Occluded shunt	Critically ill
15	8.3	5.5	Tet		Occluded shunt	Critically ill
16	1.1	3.8	d-TGA	Aortic coarctation, ASD	Occluded shunt	Critically ill
17	17.67	9.5	TA	PDA, MAPCAs	Occluded shunt	Critically ill
18	3.33	4.1	Subdiaphragmatic TAPVD	ASD	Subdiaphragmatic pulmonary vein obstruction	Critically ill - cardiac failure
19	0.43	1.67	Discontinuous LPA from PDA		To maintain discontinuous LPA flow via PDA	Extremely low weight

COA: coarctation of the aorta, IAA: interrupted aortic arch, DORV & PS: double outlet right ventricle and pulmonary stenosis, Tet: tetralogy of Fallot, PA: pulmonary atresia, d-TGA: dextro transposition of the great arteries, TA: tricuspid atresia, TAPVD: total anomalous pulmonary venous drainage, LPA: left pulmonary artery, PDA: patent ductus arteriosus, VSD: ventricular septal defect, ASD: atrial septal defect, MAPCAs: major aortopulmonary collateral arteries, BTS: Blalock-Taussig shunt, DKS: Damus-Kaye-Stansel.

electrical cardioversion. Technical difficulty in stent placement in one case led to stent dislodgement, which was successfully managed by fixation with additional stents.

Follow up

A summary of medium term outcomes can be viewed in Figure 5. Patients have been followed up for a median 7.8 months (range: 0.1 - 69.0 months). Six patients required a second procedure (balloon angioplasty n=4, restent n=2) at a median 4.7 months (range: 1.6 - 17.8 months) post initial procedure to accommodate for growth, 5 having had a previous aortic arch stent. Nine patients were scheduled for elective corrective surgery at a median 7.8 months (range: 0.3 - 69.0 months) after first stent implantation. During the follow-up period, two cases with coarctation were able to undergo repair of associated lesions (VSD closure). There were 5 deaths at a median of 73 days (range: 1 - 422 days) since the first stenting procedure was performed. Patient 5 was sent home for palliative care. He had an inoperable VSD due to accelerated development of severe pulmonary hypertension. Patient 16 was a critically ill patient with severe hypoxia and acidosis after

occlusion of a Blalock-Taussig shunt performed 8 days before at 25 days of age. Patients 2, 10 and 19 died at home of undetermined causes. Four patients currently remain in follow-up and are doing well. Surgery has so far been postponed by a median 13.5 months (n=13, range: 0.3 - 69.0 months; patients that died and were lost to follow-up were excluded). In 10 of these patients, weight had also increased from a median 4.6kg to 10.3kg (p<0.001). One patient has been lost to follow up and was last seen at 1.4 months post first procedure doing well and was scheduled to follow up in 6 months.

DISCUSSION

Results of our study show that the use of small stents to treat obstruction in young, critically ill children is feasible. Immediate success is good and periprocedural complications few. Surgery can be delayed short term until condition improves or longer (may need redilation) if required.

Most of our patients were small and 2 weighed less than 2kg. The procedure was technically relatively easy in most cases and

TABLE 2: Procedural data.

	Sheath size (F)	FIRST STENT			SECOND STENT		
		Type	Diameter (mm)	Length (mm)	Type	Diameter (mm)	Length (mm)
1	4	Liberte™	5	12			
2	4	Liberte™	4	8			
3	4	Genesis®	6	12			
4	4	Genesis®	5.5	15			
5	4	Liberte™	5	16	Liberte™	5	12
6	4	Racer RX	6	12			
7	4	Omega™	3.5	12	Liberte™	3.5	16
8	5	Formula™	6	16			
9	4	Liberte™	5	12			
10	4	Liberte™	5	12			
11	5	Integrity®	4	15	Liberte™	5	16*
12	5	Liberte™	5	12			
13	5	Liberte™	4	12			
14	4	Liberte™	4.5	16			
15	4	Liberte™	4.5	20	Liberte™	4.5	12
16	4	Omega™	4	8	Omega™	4	8
17	5	Omega™	4	20			
18	6	Genesis®	8	12			
19	4	Liberte™	2.5	12	Liberte™	2.5	12

Manufacturers: Liberte™, Boston Scientific, Natick, MA; Genesis®, Cordis, Warren, NJ; Racer RX, Medtronic Inc., Minneapolis, MN; Omega™, Boston Scientific, Natick, MA; Formula™, Cook Inc., Bloomington, IN; Integrity®, Medtronic Inc., Minneapolis, MN.
*patient 11: additional stents placed - Liberte™ 5mmx12mm (3rd) and 5mmx24mm (4th).

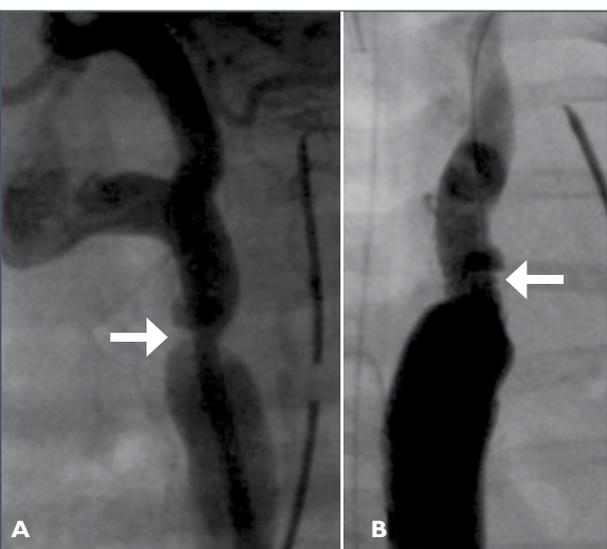


FIGURE 1: Stenting of native COA (patient 1).
Lateral angiographic view. Arrow indicates area of COA in descending aorta (A).
Antero-posterior (AP) angiographic view. Arrow indicates successful COA stent with much improved flow to descending aorta (B).

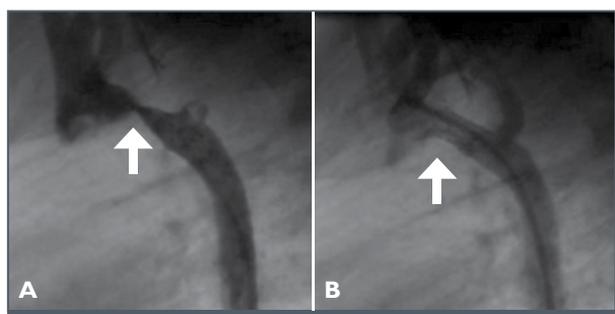


FIGURE 2: Stenting of post surgical recoarctation of the aorta (patient 3).
AP angiographic view. Arrow indicates area of severe narrowing in aortic arch proximal to left subclavian artery in a patient post COA repair (A).
AP angiographic view. Arrow indicates area of stent placement in a technically challenging position (B).

we were able to implant stents successfully in all patients, with immediate relief of all forms of obstruction. In 2 cases (patients 15 and 18), balloon angioplasty prior to stent placement was required because of the severity of the stenosis, making it possible to safely advance the stent beyond the obstruction.

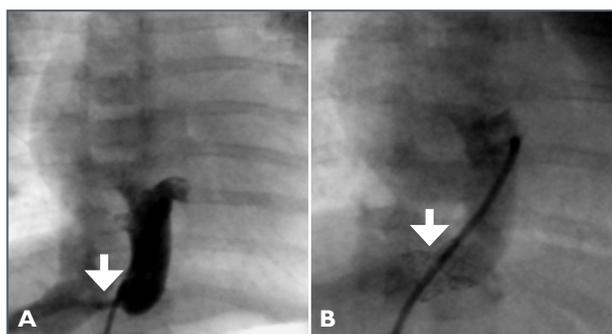


FIGURE 3: Stenting of subdiaphragmatic pulmonary venous obstruction (patient 18).
 AP angiographic view. Arrow indicates area of severe obstruction below the diaphragm at the junction of the pulmonary vein to the IVC, crossed by a guide wire pre-stent placement (A).
 AP angiographic view. Arrow indicates area of stent placement showing improvement of flow in pulmonary venous chamber (B).

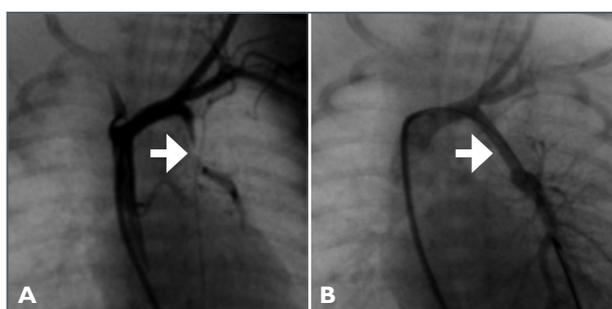


FIGURE 4: Stenting of PDA to discontinuous LPA (patient 19).
 AP angiographic view. Arrow indicates PDA with severe stenosis at junction with discontinuous LPA (A).
 AP angiographic view. Arrow indicates PDA stent with much improved blood flow to LPA (B).

Almost half the patients had undergone prior surgery. Four patients had undergone aortic arch repair and 5 patients a systemic-to-pulmonary artery shunt procedure that subsequently required emergency management. Redo surgeries in these small, critically ill children would have been extremely challenging due to localisation of the obstruction or clinical condition at the time of presentation. Small stents under these circumstances may be a useful option to supplement future surgery. In our experience, stents should be used in a post surgical lesion where marked elastic recoil is observed after balloon angioplasty.

Stenting is considered safe and has been extended for use in the management of complex obstructive congenital heart disease in small newborns and infants over the last few years. Reported success rate ranges between 80% - 100%.^(5, 6, 10-12, 15-31) Our findings compare favourably with this. Overall, low per-procedural complication rates have been reported in stents used in older children (up to 16%). These include stent migra-

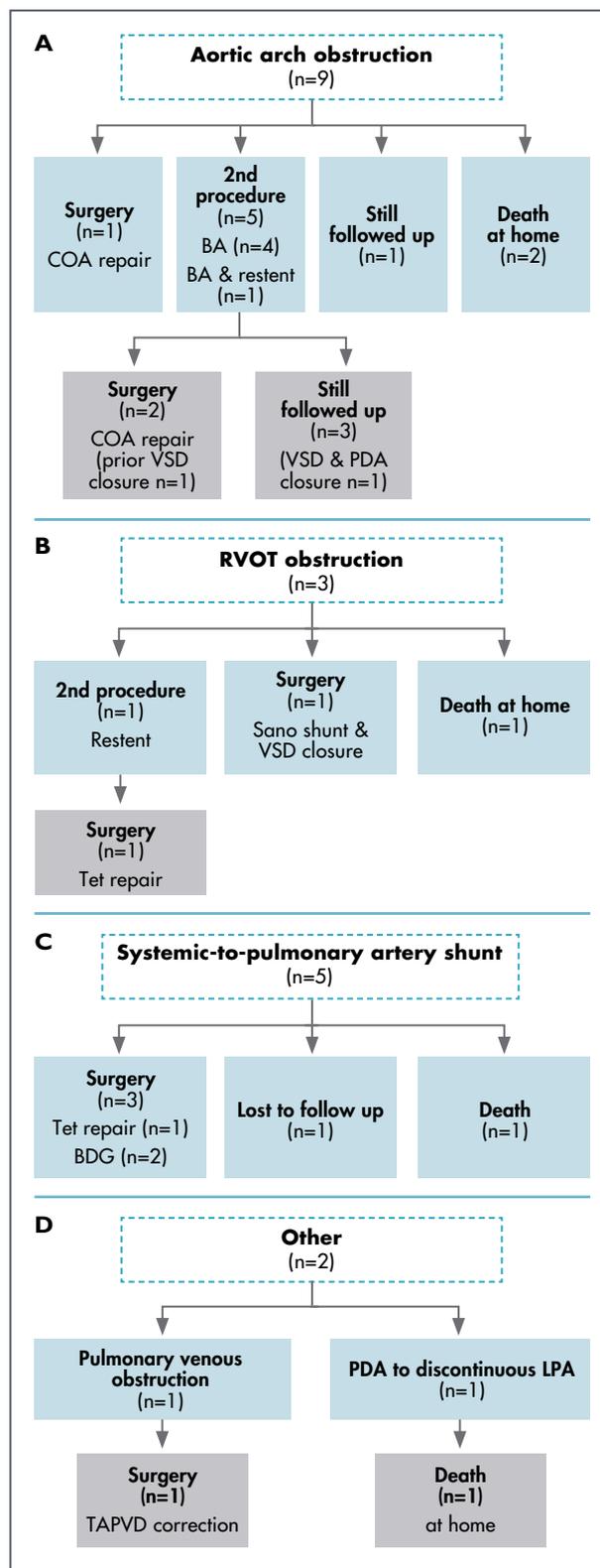


FIGURE 5: Summary of medium term outcomes at follow up after initial stent placement.
 Aortic arch obstruction group (A).
 BA, balloon angioplasty.
 RVOT obstruction group (B).
 Systemic-to-pulmonary artery shunt group (C).
 Other group (D).

tion (5%), stent malposition (3-16%) and vascular compromise.^(21,32,33) In younger and smaller patients, complications mostly consist of vascular compromise, haemorrhage and dysrhythmias. Later complications include intrastent proliferation, restenosis and occlusion (3-36%).^(5,10,12,25,31)

There were no periprocedural deaths in the study group and complications were mild and few: dysrhythmias (n=2) and stent migration (n=1). The latter occurred in patient 11. The first stent did not adequately cover the entire narrow portion of the RVOT. A second stent was placed, however this stent did not hook firmly onto the first stent. A third stent was then required to bridge this gap and during placement the second stent dislodged back into the right ventricle. A much longer fourth stent was then required to successfully stabilise the entire RVOT. We did not experience any vascular problems in any of the patients.

A second procedure can be performed if required to extend the lifespan of the stent. Five patients that had previous aortic arch stents underwent second percutaneous procedures. Four of the 5 required only balloon angioplasty to accommodate for somatic growth and further postpone surgery. These patients will be followed up closely for development of stent narrowing and referred for surgery once it is no longer possible to manage the patient percutaneously. One stent fractured on redilation. Implanting a larger covered stent successfully treated this. Almost 5 years later this patient still remains in follow-up and is doing well. We observed minimal stent peeling at this second procedure and we can only speculate that it may be related to the administration of aspirin or that peeling is less frequent if stent diameter exceeds a certain minimum (the majority of our stents were expanded to 5mm).

Surgery could be delayed and clinical condition improved in all patients. Two patients were also able to undergo elective surgical VSD closure after COA stenting at a time when they were clinically stable, out of cardiac failure and had gained significant weight. Elective repair of native COA was carried out in patient one, 2 weeks after stent implantation after cardiac failure abated. In patient 3, redo COA repair was delayed by more than 5 years and in patient 7 (that was 1.8kg at stent procedure), COA repair was delayed by 18 months. There was also a statistically significant increase in weight in patients that proceeded to corrective surgery and in those that remain in follow-up. The 4 patients that currently remain in follow-up all had COA stents. They are doing well without medication and have minimal COA gradients. Future surgery may be necessary once somatic growth overcomes the ability to further balloon dilate the stent.

The overall mortality rate in our study was 26%, which is similar to other reports in these small, critically ill children and compares favourably to overall surgical mortality. However, as the group of patients is quite diverse, it is difficult to compare the overall mortality to a similar surgical series.^(3-6,10-12,15-31)

Mortality in surgical COA repairs in infants for example, is known to be much lower (<2%), but higher in small, complex patients (5 - 25%).^(3,12) It should be mentioned that one patient was sent home for palliative care and one patient had severe post-operative hypoxia and acidosis. The deaths at home raise concern, as it is unknown whether they were attributed to the stents or not. In our setting, follow-up can be problematic. Patients face challenges such as transport, financial problems and migrant labour, which make it difficult to attend regular scheduled follow-up visits. Patients become lost in the system and only reappear once critically ill. One patient defaulted follow-up for 4 years post RVOT stent and presented with near total stent occlusion. She subsequently proceeded to surgical repair.

Advantages of placing stents at a young age include the abolishment of severe obstruction, avoidance of major cardiac surgery during a time of critical illness and potentially shorter hospital stays. Disadvantages of early stenting in small patients consist of: vascular compromise and an increased rate of developing in-stent stenosis due to the use of smaller diameter stents (the incidence of abrupt stent thrombosis is uncertain).^(25,32) However, the purpose of implanting stents in this subgroup of patients is not to avoid, but only to delay surgery until either clinical condition improves (days) or somatic growth allows lower risk surgery (weeks to months). We consider the team approach and joint decision-making process with our surgeons not only extremely helpful and beneficial, but essential.

STUDY LIMITATIONS

The small number of patients and its retrospective nature limits this study, but emphasises that this procedure only applies to a select subgroup of patients. Certain procedural information such as paired pre and post procedure pressure gradients, diameters and saturation values could not be obtained in all patients, as most were critically ill and time was of the essence. We were also not able to ascertain the cause of death in 4 of the children who died at home.

CONCLUSION

The placement of small stents for these obstructive lesions (either native or post surgical) in small, ill children is feasible and associated with minimal complications. It immediately relieves the obstruction and improves the general clinical condition. It allows surgery to be delayed from days to months, giving opportunity for somatic growth. Mortality remains high in this group of high-risk critically ill patients. There are unique challenges in our setting and therefore short interval follow-up is crucial to monitor these patients closely and prevent defaulting.

ACKNOWLEDGEMENTS

National research fund IFR1203130601.

Conflict of interest: none declared.

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