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One center experience in pulmonary artery stenting without long vascular sheath

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Abstract

Background: *Pulmonary artery stenting without a long vascular sheath has a special significance, particularly for children with low body weight. Using only a short sheath often permits the implantion of a stent of the correct size; moreover, it improves access to peripherally located stenoses. The aim of this paper is to present the results of a balloon expandable stent implantation into pulmonary arteries without using a long vascular sheath.*

Methods: *The subjects were divided into two groups. The first group (28 patients, mean age 3.2 years) comprised patients with a single-ventricle heart after bi-directional Glenn procedure (Fontan procedure). The second group (22 patients, mean age 8.3 years) consisted of patients with a two-ventricle heart. Patients were retrospectively analyzed with regard to stenosis size widening and change in trans-stenotic pressure gradient after stenting.*

Results: *In our data, no statistically significant differences between the two groups in terms of the number of complications and incorrect stent position following implantation were noted (3% and 4%). Good treatment results, with a decrease in trans-stenotic pressure gradient in the first group of 3.2 mm and in the second group of 13.4 mm of mercury, and a widening of the stenosis, were obtained in most cases in both groups (97% and 96%). The average change of the vessel's diameter was in the first group 4.2 mm and in the second 5.4 mm.*

Conclusions: *The obtained results suggest that pulmonary artery stenting with a short vascular sheath has numerous advantages and can be successfully performed in children. In the case of single-ventricle hearts after a Glenn procedure, it may indeed be the method of choice.* (Cardiol J 2010; 17, 2: 149–156)

Key words: catheterization, interventional treatment, balloon angioplasty

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Introduction

Implanting a balloon expandable stent into the pulmonary artery without using a long vascular sheath constitutes an interesting alternative to the traditional method of stenting, in which a long vascular sheath is introduced into a stenosis. This method permits the use of a smaller-sized introducer sheath, which is of crucial importance in children, because the sheath's size can be an obstacle to using a stent with adequate parameters [1, 2].

On the other hand, veins cannulated by a smaller introducer sheath have more chance of being patent after procedure and this would be a valuable approach during the next catheterization. The vast majority of the method's reported disadvantages concern the lack of control over the stent's position directly before expansion and absence of protection of the stent on the balloon during passage to the pulmonary arteries. This means pre-procedure angiography must be carried out. During the procedure, the patient's position relative to the X-ray tube must remain unchanged. Unfortunately, these methods (aimed at ensuring optimal stent localization) are difficult to reproduce and to a large extent rely on the experience of the operator and the team conducting the procedure. The alternative to this procedure is to cannulate the opposite vein and then, through a catheter, control angiography before stent implantation is possible.

In some clinical situations, stenting without the use of a long vascular sheath may be selected by choice. In the case of single-ventricle hearts after bi-directional Glenn, it is often possible to perform angiography through a short vascular sheath next to the balloon catheter [2].

The aim of this paper is to present a one-center experience of pulmonary artery stenting in children using a short introducer sheath.

Methods

This study is based on a retrospective analysis of 50 consecutive patients with pulmonary artery stenosis qualified for angioplasty and balloon expandable stent implantation at our center between 2003 and 2008. The patients were divided into two groups depending on co-existing heart defects, which affected the nature of the procedure and its course. The first group comprised 28 children (girls accounted for 35% of the group, boys 65%) aged three months to seven years (average age: 3.2 years), with a single-ventricle heart after a bi-directional Glenn procedure. In this group, a short vascular sheath was introduced through the right internal jugular vein. The second group consisted of 22 patients (girls 36%, boys 64%), aged one month to 20 years (average age: 8.3 years) with other heart defects (two-ventricle hearts). In this group, a short vascular sheath was introduced through a femoral vein and the defects included tetralogy of Fallot and multilevel peripheral stenoses in William's syndrome.

As for the first group, stenting with a short sheath is in our department the procedure of choice, so the group consisted of consecutive patients following bidirectional Glenn (BDG) operation. Most of this group are children with hypoplastic left heart syndrome (HLHS). We do not perform primary angioplasty because, in our experience, primary angioplasties in these patients are ineffective and widened stenoses quickly return. In this group, angiographic control of the stent position was performed directly before expansion (the short sheath is quite near to the site of the stenosis).

In the second group, short introducer sheaths were used in specific cases: in small children with recurrent, multifocal stenoses of the pulmonary arteries such as William's or Allagile syndrome (three patients in the second group), a short sheath was preferable because it meant less trauma for vessels and easy stent delivery into peripherial parts of the pulmonary atresia. In patients with a single ventricle with pulmonary valve atresia, a short sheath was also used to reach the site of the stenosis in pulmonary arteries though the femoral vein, tricuspid and aortic valves and Blalock-Taussing shunt as well as through the femoral artery, aorta and Blalock-Taussing shunt. In all these patients, pre-dilatation was performed and when angioplasty was ineffective, a decision about stenting was made. In this group, we did not perform control angiography before stenting expansion, as it would require secondary femoral vein cannulation. To set it in the proper position, we used the method described by Pass et al. [1].

All the interventions were performed under general anesthesia with endotracheal intubation in the catheter laboratory. Heparin 50–100 U/kg of body weight was given after vascular access was obtained. A single-plane Philips Integris CV angiograph was employed in the procedures. Average fluoroscopy time was for Group 1: 18 min (8–42) and for Group 2: 28 min (15–36). Four hours after completion of the procedure, 1–2 mg/kg of body weight low-molecular weight heparin (enoxaparin sodium--clexane) was administered subcutaneously and the patients were then maintained on oral acetyl-

Table 1. Characteristics of group 1.

No.	Age (months)	Weigh [kg]	Pre-dilatation stenosis diameter	Post-dilatation stenosis diameter	Pre- and post-dilatation difference in pressure gradient [mm Hg]	Type of stent (size of sheath)	Complications
1	72	15	3	7.5	3	Genesis 7 × 24 (6 F)	
2	20	18.5	3.9	7.5	2	Genesis 7 × 24 (6 F)	
3	34	8	3.6	7.4	5	Genesis 7 × 25 (6 F)	Severe complication (CNR)
4	20	10.5	5.2	8.5	5	Genesis 8 × 30 (7 F)	
5	41	13	4.2	8.5	2	Genesis 8 × 24 (7 F)	
6	60	15	3	10*	1	Genesis 8 × 29 (7 F)	
7	32	13	4.1	8.1	0	Genesis 7 × 13 (6 F)	
8	10	5.6	4	7.3	4	Genesis 8 × 25 (7 F)	
9	6	5.5	3.5	6	6	Genesis 6 × 18; 7 × 24 (6 F)	Mild complication (CNR)
10	72	17	3.5	7.5	1	Genesis 7 × 24 (6 F)	
11	3	4.5	1.5	4.2	2	Coroflex 3.5 × 16 (4 F)	
12	7	6	2	7	12	Genesis 7 × 24; CP (9 F) 8 × 22	Unexpected course (CNR)
13	81	19	7.8	14	3	P-308 J & J 14 × 40 (10 F)	Severe complication (CR)
14	39	15	4	6	5	Genesis 6 × 25 (6 F)	Critical complication (CNR)
15	34	13	3.5	7	2	Genesis 7 × 24 (6 F)	
16	34	14	3.5	7	2	Genesis 7 × 24 (6 F)	
18	5	5.4	3.5	9.3*	3	Genesis 6 × 15 (6 F)	
19	46	15	3.5	7.5	0	Genesis 7 × 24 (6 F)	
20	36	11.5	6	10*	2	Genesis 8 × 25 (7 F)	
21	66	17	4.5	11	6	Genesis 8 × 29 (7 F)	
22	48	19	6	10	2	Cordis 10 × 35 (9 F)	
23	35	13	3.5	10*	5	Genesis 8 × 36 (7 F)	
24	29	12	4.2	8.5*	4	Genesis 6 × 16 (6 F)	
25	48	12	4.75	7	2	Genesis 7 × 24 (6 F)	
26	52	14	5.5	8	3	Genesis 8 × 18 (7 F)	
27	45	13	2	8.4	4	Genesis 8 × 18 (7 F)	
28	64	15	4.1	8*	1	Genesis 7 × 24 (6 F)	

*patients with second angioplasty and additional stent dilatation; CNR — complications not related to performed procedures with short vascular sheath; CR — complications related to performed procedures with short vascular sheath

salicylic acid 2–3 mg/kg of body weight once daily. The technique of stenting and all procedures remained unchanged during the period of study. A short vascular sheath was used in both groups: 6 French for 7 mm stent and 7 French for 8 mm stent diameter (Tables 1, 2).

Patients in both groups were retrospectively analyzed with regard to stenosis size, widening obtained after stenting, change in the mean pressure in the stented artery after implantation, arterial blood saturation,their clinical condition, and the presence of complications stemming from the treatment method used. The balloon expandable stents were delivered uncovered to the distal pulmonary circulation using a short vascular sheath. The position of the stent prior to deployment was confirmed via comparison with a digital freeze frame of initial angiograms (method described by Pass et al. [1]). In the first group, additional angiography was performed by a short sheath. For the second group, we did not repeat angiogram with a second angiographic catheter. In all control cases, angiography was performed after stent implantation to confirm its proper position.

Table 2. Characteristics of group 2.

No.	Age (months)	Weigh [kg]	Pre-dilatation stenosis diameter	Post-dilatation stenosis diameter	Pre- and post-dilatation difference in pressure gradient [mm Hg]	Type of stent (size of sheath)	Complications
1	44	14.5	2.5	7.2	28	Cordis 6 × 30 (6 F)	
2	72	28	3	11*	16	Genesis 8 × 29 (7 F)	Severe complication (CNR)
3	192	55	5.6	15.5	12	Genesis 8 × 39 (7 F)	
4	2	4.5	2.3	10	2	Coroflex 3.5 × 16 (4 F)	
5	1	3.3	1	4.2	11	Coroflex 3.5 × 16 (4 F)	
6	45	14	4.2	6.5	49	Genesis 7 × 25 (6 F)	Mild complication (CNR)
7	15	8.8	2.7	8	18	Genesis 6 × 23 (6 F)	Critical complication (CNR)
8	72	19	2.5	8	7	Genesis 6 × 24 (6 F)	
9	240	64	6.3	12*	4	Genesis 7 × 24 (6 F)	
10	204	57	6	14	10	Genesis 14 × 40 (9 F)	
11	156	44	4.5	10	18	J & J 8–12/30 mm (9 F)	
12	79	21	3	7	3	Genesis 7 × 22 (6 F)	
13	72	19	1.5	8	5	Genesis 6 × 22; 7 × 24 (6 F)	Mild complication (CR)
14	42	12	6	7	14	Genesis 7 × 24 (6 F)	
15	240	52	6	15.2**	34	Genesis 8 × 29 (7 F)	
16	120	34	5.2	12	2	Palmaz P-308 (7 F)	
18	156	49	2.1	7.4	11	Genesis 7 × 23 (6 F)	
19	120	32	3.5	9.3	16	Genesis 8 × 26 (7 F)	
20	144	43	5	9.2	13	Genesis 9 × 35 (8 F)	
21	60	18	0	4	8	2 × Cordis 4 × 23 (4 F)	
22	11	6.8	4	5.6	2	Genesis 8 × 29 (7 F)	

*patients with second angioplasty and additional stent dilatation; **stent was manually crimped on OPTA high pressure balloon 16 × 40; CNR — complications not related to performed procedures with short vascular sheath; CR — complications related to performed procedures with short vascular sheath

The observed complications were classified into three main groups with regard to their severity: critical complications (procedures ending in the patient's death or in the need for resuscitation), severe complications (necessitating simultaneous additional emergency or surgical procedures), and mild complications (resulting in the postponement of the procedure or in a non-optimal result of the stent implantation). In each case, efforts were made to establish and account for the mechanism of origin and the cause of the complications. Statistical analyses of the results were performed using Statistica 8.0 software.

Results

In the first group (single-ventricle hearts), 80% of the stenoses were located in the left pulmonary artery: anatomically, at the primary bifurcation of the pulmonary arteries. The disparity results from the quantitative dominance of patients with HLHS, in whose case stenoses may stem, among others, from changes to the geometry of the pulmonary arteries following the first stage of the Norwood procedure, which constitutes a predisposition to their kinking or stenosis and results (in most cases) in angioplasty proving ineffective [3].

Stenoses subject to intervention (average stenosis size: 4 mm; 1.5–5.5 mm) were dilated with the use of a short introducer sheath inserted through the right internal jugular vein. Successful widening was obtained in 27 patients (97%), with an average change of 4.2 mm ($p < 0.01$; Shapiro-Wilk test, dependent t-test); the average decrease obtained in the trans-stenotic pressure gradient in the pulmonary artery was 3.2 mm of mercury ($p < 0.01$).

Within this group, complications occurred in four procedures (14%); only two were however related to the short sheath stent implantation procedure (7%).

In one case, the patient with HLHS developed bradycardia and cardiac arrest during a 6 × 25 mm

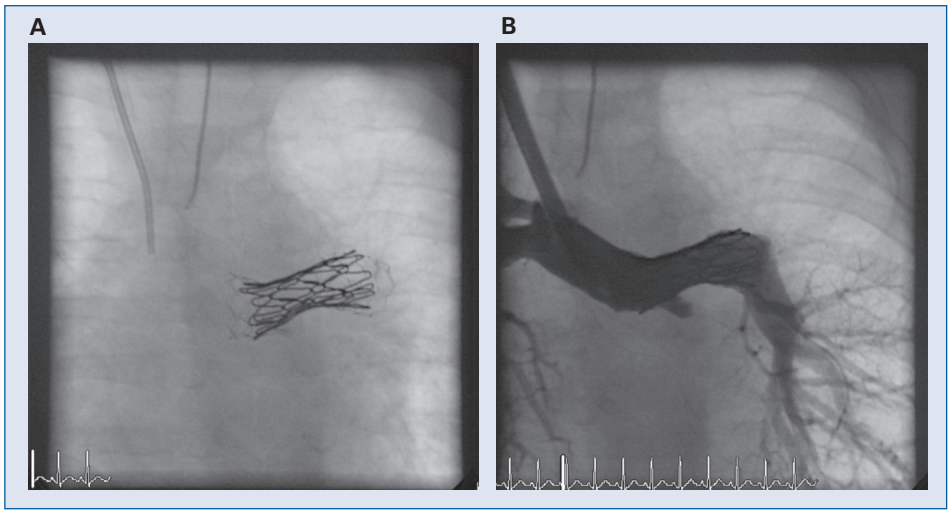

Figure 1. A. Fluoroscopic view: CP-stent implanted into the broken Genesis stent. Treatment of complication not related to performed procedures with short vascular sheath; **B.** Angiography: contrast medium flow.

Genesis stent implantation into a tight stenosis located at the left pulmonary artery bifurcation. Following 30-minute full resuscitation, hemodynamically efficient heart function was restored. On day two after the procedure, aortography and coronarography were performed. Theserevealed reshaping of the primary ascending aorta's border because of the stent's proximal end. Further post-dilatation of the stent's proximal section, planned earlier, was considered inadvisable and thus was not performed, despite the existing disproportion between the stent and the right pulmonary artery (Table 1, No. 14).

Regarding severe complications, there was one case when during introduction of a manually crimped Palmaz P-308 stent on a 12 mm balloon through a narrowed left pulmonary artery, the stent slipped off the balloon and migrated into the left lower lobe pulmonary artery. The unexpanded stent was removed over a smaller 6 mm balloon up to the right internal jugular vein, from where it was removed after surgical exposure. Three months later, the intervention was repeated with successful implantation of a P-308 stent into the left pulmonary artery (Table 1, No. 13).

In one child, an over-lengthened stent was implanted in the long-segment hypoplasia of the left pulmonary artery. Its proximal end protruded into the Glenn anastomosis. One week later, at the time of completion of the Fontan operation, the stent was trimmed surgically (Table 1, No. 3).

One stent was implanted too proximally and as a result, did not cover the whole stenosis of the left pulmonary artery; angiography repeated three months later revealed further development of the stenosis directly behind the stent. A second stent was implanted in an overlapping fashion, with the proximal segment of the second stent over the first one. The stent covered the stenosis completely with a good result (Table 1, No. 9).

In this group, we had also one unexpected course which involved a child catheterized because of a severe condition after a bi-directional Glenn procedure: high systemic venous pressure and low oxygen saturation. During this procedure, we implanted a Palmaz-Genesis stent 7 × 24 mm into the critical stenosis of the left pulmonary artery. After the heart catheterization, the patient was in good condition; one week later, however, during preparation for extubation, the infant suddenly developed bradycardia and subsequent asystole. A resuscitation procedure with heart massage was successful. But afterwards, an X-ray examination revealed that the stent was broken into two parts and dislocated. Another cardiac catheterization was performed and the distal end of the broken stent was gently translocated using a low-pressure TYSHAK balloon, which was pulled back, together with the distal part of the stent. Afterwards, we implanted a CP-stent 8 × × 22 mm (something typically used in the treatment of aortic coarctation) into the two separated parts of the broken stent (Fig. 1). The CP-stent was manually crimped onto an 8 mm high-pressure balloon. We stabilized and connected the proximal and distal parts of the broken Genesis stent (Table 1, No. 12) [4, 5].

In the second group (two-ventricle hearts), the stenoses were not observed more frequently in any

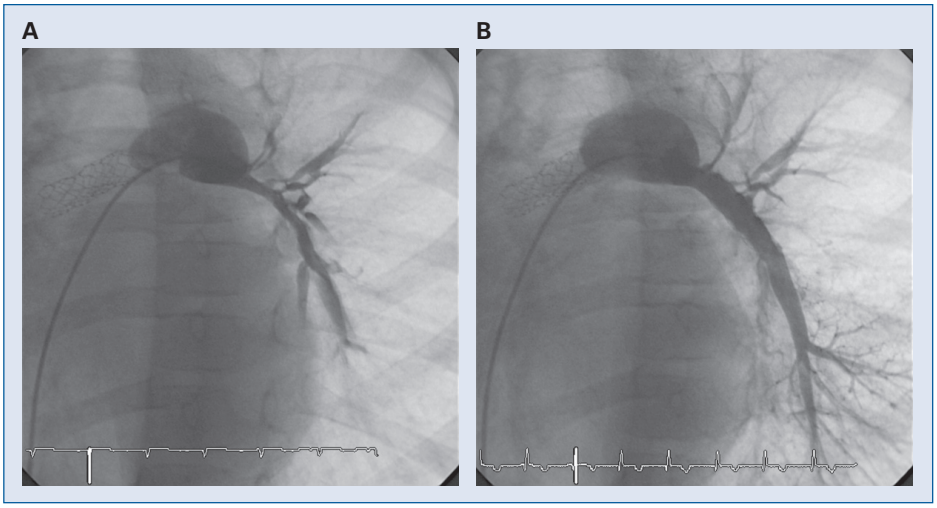

Figure 2. Angiographic view. Patient with William's syndrome and pulmonary artery hypoplasia with stent in the right pulmonary artery before (**A**) and after (**B**) stent implantation to the left pulmonary artery.

of the pulmonary vessels (LPA 40%; RPA 44%). The stenoses (on average 3.66 mm) were dilated with very good results: in 21 patients (96%), a statistically significant widening of the vessel's diameter was obtained, on average by 5.4 mm ($p < 0.01$; Shapiro-Wilk test, dependent t-test), with a decrease in mean gradient at the stenosis by 13.4 mm of mercury ($p < 0.01$). Within the group discussed, one critical, one severe, and two mild complications were observed. In total, complications amounted to 18% of cases. Only one was directly connected to our method of stent implantation, and no complications related to tricuspid or pulmonary valve damages were observed.

There was a critical complication in the case of a child with William's syndrome and extreme hypoplasia of the pulmonary arteries. The patient's condition deteriorated rapidly after stent implantation into the right pulmonary artery, and a significant increase in blood flow through the right lung was observed. The patient developed pulmonary oedema; mechanical ventilation was needed, followed by the patient's one-week stay in the intensive care unit (ICU). After this period, the patient's condition improved and no further complications were observed (Fig. 2; Table 2, No. 7).

Another child with tetralogy of Fallot (a severe cardiac complication) after palliative surgical treatment underwent catheterization due to a tight left pulmonary artery stenosis. A stent covering the proximal stenosis was then implanted. The stent broke during post-dilatation. A high-pressure balloon was used in order to adjust the stent's edges to the diameter of the pulmonary artery behind the stenosis. It was removed surgically while complete repair of the defect was conducted (Table 2, No. 2).

In one patient with multi-level stenosis of the pulmonary arteries, after an implantation on a high-pressure balloon, a mild complication was observed in the form of minor bleeding into the bronchial lumen and the presence of blood in the intubation tube. Mechanical ventilation was continued and the patient was monitored in the ICU. Heparin was not administered. On day two after the procedure, the patient was awakened from the anaesthesia and extubated without any further complications (Table 2, No. 6).

In one case, the implanted stent did not cover a multilevel stenosis (Fig. 3A). It was necessary to implant another stent in an overlapping fashion (Fig. 3B; Table 2, No. 13).

No statistically significant differences were observed between the two groups as to the number of complications or the frequency of improper stent placement, with the stenosis outside the expanded stent (3% and 4% respectively, Fisher's exact test).

Discussion

Nowadays, the use of metallic stents for the treatment of pulmonary arterial stenosis (first described in 1989) is a well-known treatment. Apart from discrete stenoses, in which balloon angioplasty may have some success, stents can also be used for treating hypoplastic pulmonary arteries in which balloon angioplasty has been shown to be ineffective. Stents can be used to treat these lesions when

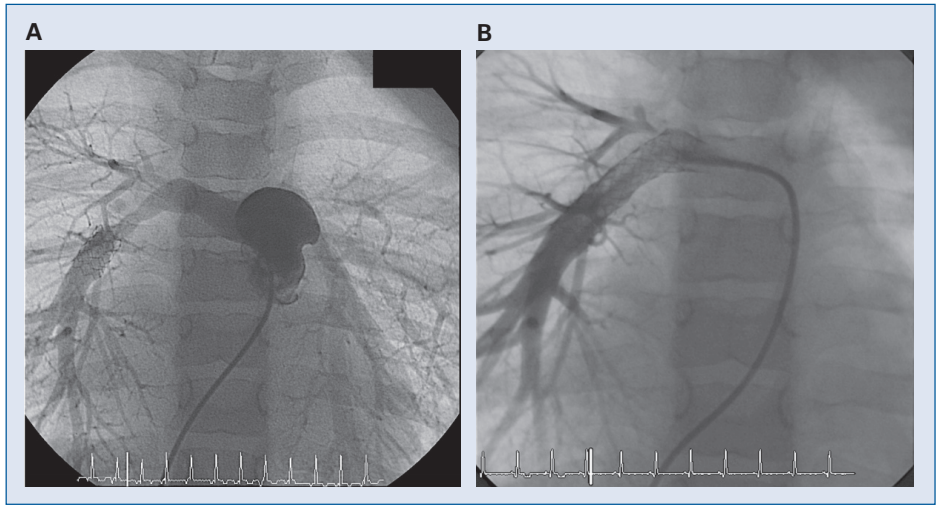

Figure 3. A. Angiographic view. Stent implanted into right pulmonary artery did not cover the whole stenotic fragment; **B.** The same patient after second stent implantation.

they are noted before or after the staged surgical treatment [6–8].

Stenting of branch pulmonary arteries produces good long-term results. But if used on infants, stents need to be redilated to keep pace with the patient's growth. It has been shown that implanted stents are covered by endothelium within about six months and can be redilated several times during growth, thus enabling the adaptation of diameter of the pulmonary arteries during the growth of the patient to adulthood. Fogelman has shown that the Palmaz stents can be redilated safely up to a diameter of 18 mm, which is usually an acceptable diameter in adults [6, 9–11].

Due to its advantages, stent implantation using a short vascular sheath is used at our centre in the treatment of children to bring positive results. The use of a short vascular sheath increases the possibility of implanting stents of suitable size parameters: for introducing a long sheath, cannulation with two-size larger short sheath is required. Alternative for this procedure is direct vessel canulation with a long sheath. Both methods are more traumatic for vessels, especially in infants. Sometimes, when a stent has to be implanted through the femoral artery (pulmonary atresia, patent Blalock--Taussig shunt) in a young patient, using a long sheath is simply impossible because of its required size. Intracardiac manipulation of a long introducer sheath, especially passing through tricuspid and pulmonary valves and right ventricle, may cause cardiac arrhythmia, because of the low agility of a long sheath reaching pulmonary stenosis in some cases, especially with multilevel stenosis and high right ventricular pressure. Moreover, a short sheath does not reduce agility, and thus facilitates access to areas anatomically difficult to reach [1, 2].

The method's drawbacks concern the lack of control over the stent's position before implantation. This, to a large extent, depends on the experience of the center and the operator. The probability of a stent being in the wrong position may be reduced by employing proper procedures facilitating control over the stent's position in the vessel (such as pre-implantation angiography) and also by ensuring that the patient's position relative to the X-ray tube after angiography remains unchanged. It is possibile to control stent position before expansion via a second venous approach and angiography. However, children with a stent in pulmonary arteries require several catheterizations to control patency of pulmonary vessels and to widen the stent to follow the child's growth. For this reason, we try to avoid unnecessary cannulation to keep second vein patent for future, when the cannulated one becomes unpatent. In the authors' opinion, two veins cannulation for stenting significantly reduces the advantages of a short sheath and should be reserved for difficult cases when other methods are impossible to apply.

Our data showed no substantial differences in the frequency of improper stent placement between the two groups, although in one of them (single--ventricle hearts after bi-directional Glenn procedure) the stent's position before implantation was controlled, while in the two-ventricle hearts group it was not. Understandably, control over the stent's position through a short vascular sheath in the case

of children after bi-directional Glenn procedure is attainable only if there is no additional pulmonary supply through a Blalock-Taussig shunt. Similarly in both groups, the degree of widening obtained was satisfactory in all cases with properly placed stents.

Using a short sheath may also induce complications, as the stent may slip off the balloon while it is moved in the vessel without a cover. In our study, we encountered one case of this type in which the stent was manually crimped onto the balloon. Today, as most implanted Palmaz-Genesis stents are crimped onto the balloon in the production process, such complications are rare.

Conclusions

Using only a short vascular sheath for balloon expandable stent implantation into pulmonary arteries is a method which brings with it numerous advantages and can be safely used in children so long as the proper procedures are followed. The operator's and the team's own experience are relevant factors in its success.

In the case of single-ventricle hearts after bi-directional Glenn procedure, and if stenting is performed using the jugular approach, a short sheath may be preferred, as it permits the performance of angiography directly from the sheath and allows control over the stent's position directly before expansion, provided that there is no additional pulmonary blood supply.

In two-ventricle hearts, using a short sheath to implant a stentmay be an option in small children, with systemic pressure in right ventricle or pulmonary valve atresia. Another group of patients who can benefit from this procedure are those with multilevel or recurrent pulmonary stenoses, which require several catheterizations to provide pulmonary blood flow and control patency of pulmonary arteries. In complicated cases, when it is impossible to reach, or confirm the correct position of, the stent, control angiography should be performed via a second catheterization, set up through the opposite femoral vein cannulation.

Our data shows that pulmonary artery stenting without a long introducer sheath can be performed safely with good results and low levels of complications. Most of the described complications occurred due to pulmonary stenosis anatomy and were not related to the technical method of stent implantation.

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