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# The role of the new Valeo stent in treating pulmonary artery stenoses in children with complex cardiac malformations: A report of two cases

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

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**Case series**
**Patient:** —
**Final Diagnosis:** Pulmonary artery stenosis
**Symptoms:** —
**Medication:** —
**Clinical Procedure:** —
**Specialty:** —

**Objective:** **Congenital defects/diseases • Unusual or unexpected effect of treatment**

**Background:** The decision of which stent can be used for treating a congenital heart lesion can be difficult for a pediatric interventional cardiologist. Features of an ideal stent would be to have a low profile to enable small sheaths to be fitted and allow for advancement. It would need to be flexible to negotiate curves of arteries and have sufficient radial strength to prevent recoil of the lesion and vessel. It should have high trackability and wide struts to enable junctional artery flow and prevention of thrombosis and toxic adverse effects from the stent.

**Case Reports:** Much work is being carried out to design the ideal stent and provide the best treatment for congenital heart lesions. We investigated this matter with the use of the Valeo stent in 2 patients. The Valeo stent is a new premounted stent with several advantages for use in children with complex cardiac conditions. We investigated the Valeo stent's ability to navigate tortuous cardiac anatomy and maintain junctional artery blood flow. In addition, the stents have sufficient radial strength to provide long-term support to the large pulmonary arteries involved.

**Conclusions:** The new open-design, premounted, stainless steel Valeo stent has been shown to be useful in treating pulmonary artery stenosis and in young children when catheterization is a less popular choice in comparison to balloon angioplasty. In addition to previous use of Valeo stents in coarctation of the aorta, we have shown the benefits of the stent for pulmonary artery stenosis.

**MeSH Keywords:** Stents – standards • Stents – supply & distribution • Stents – utilization

**Full-text PDF:** http://www.amjcaserep.com/download/index/idArt/890455

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## Background

The Valeo stent is a premounted stent; there has been limited clinical experience in use of premounted stents in children. We aimed to explore the benefits of the premounted Valeo stent based on our 2 cases. The advantage of premounted stents are that there is a lower risk of losing the stent while negotiating curves, because the stent is strongly embedded in the balloon, compared to unmounted stents that are hand-crimped to the balloon. In addition, the variable anatomy in children increases the risk of losing an unmounted stent. Another benefit is that smaller sheaths can be used, reducing the risk of vascular injury.

One of the most common premounted stents is the Genesis Medium stent (Cordis) [1]. The Valeo stent described in our report is another premounted stent and was used in 2 patients with left pulmonary artery (LPA) stenosis and right pulmonary artery (RPA) stenosis with coexisting complex congenital heart lesions and complex cardiac anatomy after surgery.

The Genesis Medium stent and Valeo stent have some dissimilarities despite both being premounted stents. For example, the Genesis Medium has less maximal expansion of 12–18 mm compared to the Valeo stent, which can be dilated up to 20 mm [1,2]. The Genesis stent is more vulnerable to fractures after inflation. The Genesis Medium is a closed-cell design, which makes it less desirable for junctional vessels that can occur with pulmonary branch arteries. Although there is less radial strength in the Valeo stent compared to the Genesis Medium (which would be expected when comparing an open-cell design with a closed-cell design), the radial strength has been shown to be sufficient to overcome most stenoses encountered. Another feature of an open-cell design in the Valeo stent is that it is more flexible in comparison to the Genesis Medium stent, which is more advantageous in branched and smaller vessels [1,2].

The Valeo stent is a balloon-expandable stent, which enables redilation of the stent if necessary. It is made of stainless steel, which is the most common material used for stents because it provides good radial strength. The stent comes in 6–10 mm diameters with 18–56 mm lengths. The stent is mounted on a nylon balloon catheter with a burst pressure of 14 atm. A 6F sheath is used for stents mounted on 6–8 mm balloons and a 7F sheath for balloons mounted on 9–10 mm balloons.[2]

## Case Reports

### Case report 1

A 10-year-old Fontan surgery patient with a history of mitral atresia, pulmonary stenosis, double outlet right ventricle, and RPA hypoplasia presenting with a narrowed RPA had a 7×18 mm Valeo stent placed at the junction of the RPA with the superior vena cava (SVC) to open the narrowed RPA. The patient had a Fontan operation and soon after required stent placement due to a narrowed RPA. There was a branched vessel coming off the right pulmonary artery, which needed to be preserved to maintain the low pulmonary vascular resistance necessary in Fontan surgery patients. The Valeo stent was suitable for this application because it is an open stent design. In addition, it was not desirable to use balloon angioplasty due to the long tubular stenosis, for which balloon angioplasty (BA) is not reliable.

Angiography with a NIH catheter showed a well developed LPA. A 6F sheath was used to introduce the Valeo stent. A 5F Cobra catheter was positioned at the RPA and an Amplatzer exchange wire was positioned in the distal RPA. The stent was positioned at the junction of the RPA and SVC and inflated to 8 atm. The balloon was pulled proximally to half the length of the stent and re-inflated to 8 atm to flare the proximal end of the stent. It was important to prevent the stent from protruding, for which the Valeo stent is useful. The use of the short sheath and the premounted stent reduces risk of vascular injury and stent dislodgement. The mean pressure gradient increased from 16 mmHg to 19 mmHg after stent insertion. In addition, the proximal LPA diameter increased from 3.6 mm to 7.6 mm and the distal LPA diameter increased from 7.4 mm to 8.1 mm (Figures 1–5).

### Case report 2

A 2-year-old, 11-kg patient with a history of pulmonary atresia and VSD, 22q11 microdeletion, and an aberrant-origin right subclavian artery with significant left pulmonary artery stenosis, had a 10×17 mm Valeo stent implanted into the LPA. An MRI showed proximal left pulmonary artery stenosis. The catheterization procedure involved the LPA stenosis initially being crossed with a 0.035” guidewire followed by a Terumo guidewire to achieve a distal position of the catheter in the pulmonary branches. The guidewire was then replaced with an Amplatz wire and a 7F sheath was then introduced into the right femoral vein (RFV) followed by a 7F multi-track catheter placed in the main pulmonary artery. An 8F flexor sheath was introduced across the proximal stenosis into the distal LPA and then the 10×17 mm Valeo stent was advanced. Multiple hand injections were performed to confirm the location of the stent. The stent was implanted with 8 atm. After confirmation of good positioning of the stent, it was dilated with 12 atm at the proximal end. The stent was inflated distally and then pulled back to prevent the stent lodging in the main pulmonary artery (MPA) and to limit protrusion of the stent at the junction between the MPA and LPA.

The mean pressure in the LPA prior to the stent insertion was 11 mmHg and after stent insertion it was 16 mmHg. The

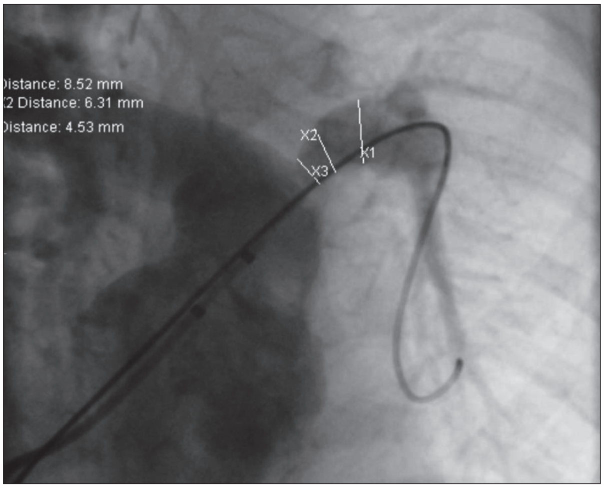


**Figure 1.** Diagram showing narrowed LPA with proximal diameter of 4.53 mm (×3), distal diameter of 8.52 mm (×1).

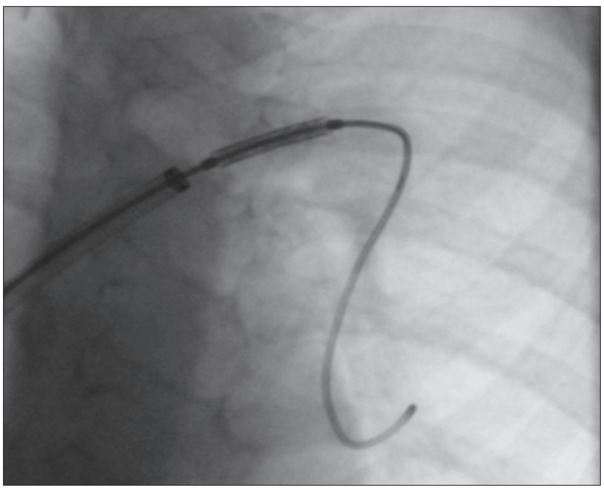

**Figure 2.** Diagram showing stent placement over LPA stenosis via catheter.

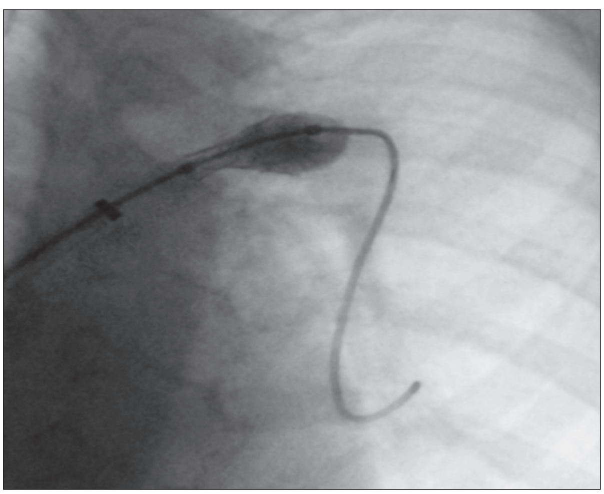

**Figure 3.** Diagram showing stent inflation.

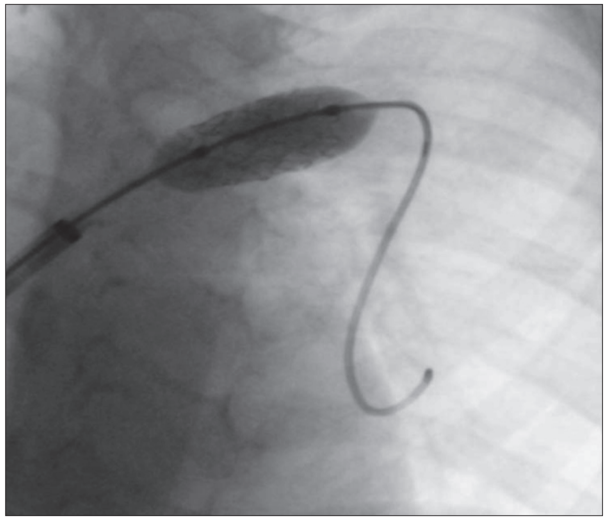

**Figure 4.** Diagram showing stent after full inflation.

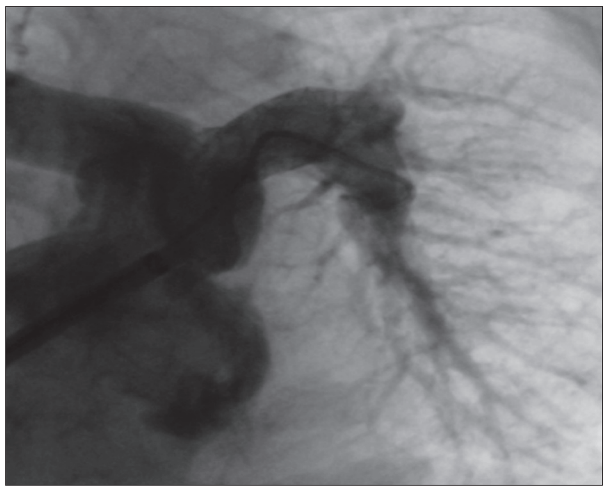

**Figure 5.** Diagram showing LPA stenosis resolved after stent insertion via contrast.

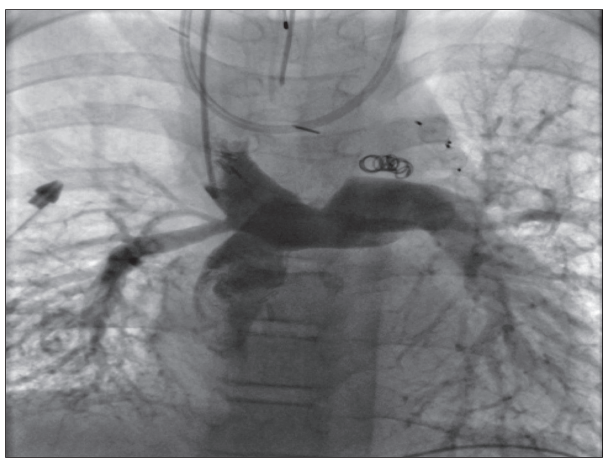

**Figure 6.** Diagram showing RPA long tubular stenosis with proximal narrowing and distal narrowing.

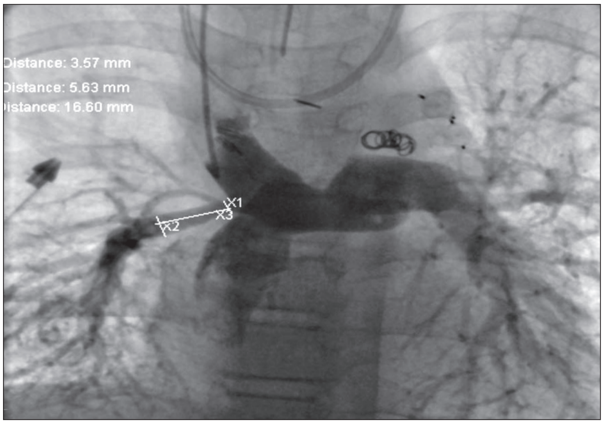


**Figure 7.** Diagram showing RPA proximal narrowing of 3.57 mm (×1) and distal narrowing of 5.63 mm (×2).

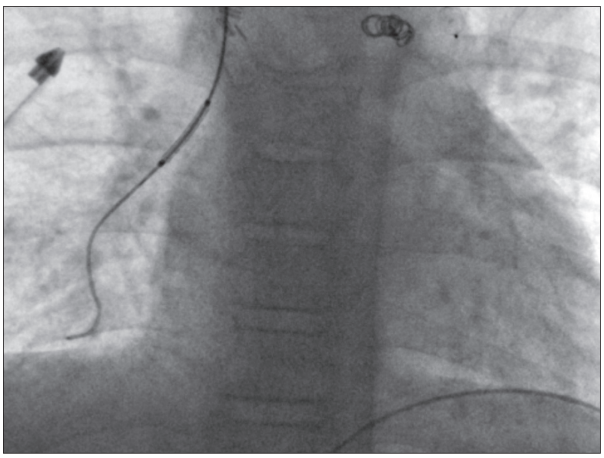

**Figure 8.** Diagram showing stent placement over narrowing.

systolic pressure gradient across the MPA and left pulmonary artery (LPA) improved considerably after the stent insertion. The systolic pressure in the LPA was 12 mmHg and in the MPA was 32 mmHg prior to the stent insertion. After stent insertion, the systolic pressure in the LPA was 25 mmHg and in the MPA it was 24 mmHg. The angiogram after the stent insertion showed a well-positioned stent in the proximal LPA with mild discrete waist proximally and with full expansion of the middle and distal areas of the stent (Figures 6–10).

## Discussion

The new premounted Valeo stent was used with success in these patients 2 patients with complex cardiac anatomy and after having cardiac operations performed on them. The advantages shown with the use of this stent are that it is a premounted stent, enabling safer use in small children via intravascular stenting as opposed to balloon angioplasty [2]. In addition, the fact that the stent is an open stent enables more flexibility at the branch arteries and for the possibility

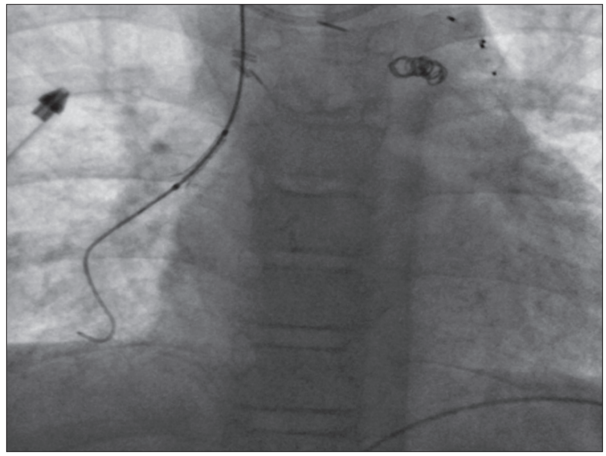

**Figure 9.** Diagram showing stent inflation process.

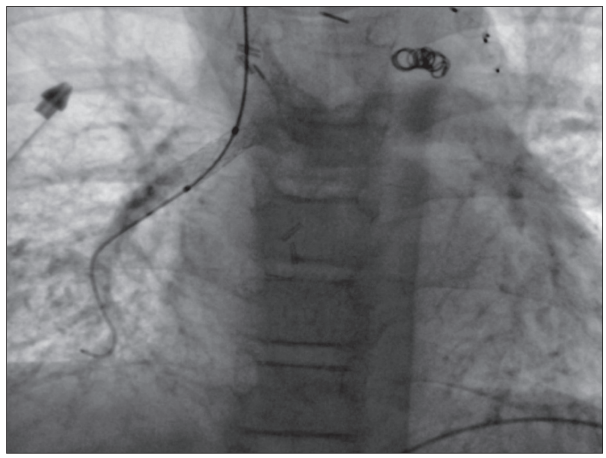

**Figure 10.** Diagram showing full stent inflation with preservation of the proximal branch artery near the RPA in the fontan patient.

of further stent insertion if necessary. It is a stent that can be re-dilated if required [3].

The use of interventional cardiology for treating congenital heart disease has expanded dramatically in the last 30 years, with much future promise for treating many lesions with new and interesting techniques such as hybrid procedures. The first interventional procedure in children was performed by Rashkind in 1966 and interventional pediatric cardiology has been growing in popularity ever since [4]. There are multiple indications for performing percutaneous interventional cardiology in children, which can be acquired soon after surgical repair, other obstructive lesions such as stenoses in arteries or major veins, obstruction of artificial shunts, coarctation and recoarctation of the aorta in children, maintaining patency of the RVOT, and other conduits involved in complex congenital heart defects [2].

A very recent case report by Morgan et al. demonstrated the efficacy of Valeo stents in treating coarctation lesions in children, with similar positive results to what we have shown here. The case report also highlighted the benefit of using the Valeo stent technology as an alternative to surgery. That case report highlights the expanding use of stent technology in treating congenital heart lesions, which is equally supported in our cases described here [5]. We have demonstrated the use of the Valeo stent for alternative congenital cardiac malformations and highlighted their benefits in preserving junctional artery blood flow, as well providing sufficient radial strength for use in the pulmonary arteries. In addition, we have presented evidence supporting the use of the Valeo stent in navigating tortuous vessels due to the fact that the stent is premounted.

There are various characteristics to a stent that can be best suited for treating different congenital stenotic heart lesions. Key features of stents that the interventionalist looks at include whether the stent is an open or closed design, the material the stent is made of, whether the stent is premounted or mounted, if the stent is a balloon-expandable stent (BES) or a self-expandable stent, the size of the stent, and the sheath required to introduce the stent and catheter. In addition, the choice of stent will depend on the child's age and the condition being treated [3,6–8].

Although intravascular stenting (IS) is a common interventional procedure in pediatric cardiology, it is less commonly performed in smaller children [2]. This is because of the large sheaths required for introducing the stent into the vessels, which can lead to vascular damage at the point of insertion, particularly the femoral artery or veins. This can lead to thrombosis of arteries, losing the patency of vessels, and precipitating damage to the veins. In addition, there is a need to account for growth in children and hence a change in diameter of the blood vessels, which would require further re-dilation of stents to accommodate these changes. This would in turn require re-entry of sheaths, which can further contribute to vascular damage [9,10]. Therefore, in place of IS, balloon angioplasty (BA) can be performed. The drawback of BA compared to IS is a less than optimum outcome. These include re-stenosis associated with elastic recoil in many cases, as well as an increased risk of aneurysms and vessel disruption [1,11]. There is also a problem of external compression from adjacent structures, and BA is not a useful treatment for long tubular stenosis, as described in our case report 2. However, it has been shown that the use of premounted stents can provide an alternative approach for stent insertion in smaller children [3].

Interventional cardiology can be performed for children with heart disease that is congenital or acquired. They are routinely performed after cardiac operations to correct any acute complications or alterations in the heart, such as stenoses that can occur. Children with complex cardiac anatomy usually have coexisting cardiac lesions that may commonly require an interventional approach. This was exhibited in both patients described in this report. Considering the growing importance of interventional cardiology to treat congenital heart disease, it is important to provide evidence-based reports on the usefulness of the most appropriate stents in accordance with the congenital heart lesion being treated and the age of the patient. We described a new stent that shows much promise in treating stenotic arteries in children with complex cardiac malformations, due to various aspects of the design of the stent.

## Conclusions

The new open-design, premounted, stainless steel Valeo stent has been shown to be useful in treating pulmonary artery stenosis and in young children, in whom catheterization is a less popular choice in comparison to balloon angioplasty. In addition to previous use of Valeo stents in coarctation of the aorta, we have shown the benefits of the stent for use in pulmonary artery stenosis. Despite much research into stents for treating congenital heart lesions, the ideal stent remains to be developed. The Valeo stent is another positive step in this direction.

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