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# **Brief Report**

**Cite this article:** Mohammad Nijres B, Carr K, and Aldoss O (2023) A novel approach to place an adult-size stent to treat coarctation of the aorta using small introducers: "Nijres technique". *Cardiology in the Young* **33**: 2395–2401. doi: 10.1017/S1047951123001154

Received: 23 September 2022 Revised: 21 April 2023 Accepted: 25 April 2023 First published online: 26 May 2023

#### **Keywords:**

Coarctation of the aorta; novel technique; arch stent placement

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# A novel approach to place an adult-size stent to treat coarctation of the aorta using small introducers: "Nijres technique"

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## Abstract

Aortic arch stent placement in young children is a medical dilemma. This is attributed to the critical lack of commercially available stents that can be delivered through small sheaths and yet have the potential to be dilated to the adult-size aorta. Here in, we describe an innovative first-in-human technique that allows for overcoming the aforementioned challenges. A Palmaz Genesis XD stent was placed to treat coarctation of the aorta in two young children through small-bore sheaths.

In small children, transcatheter native and recurrent coarctation of the aorta are challenging to treat.<sup>1,2</sup> Contrary to older children and adults in whom stent placement is considered the preferred treatment option, in young children it is only reserved for special scenarios.<sup>3</sup> This is mainly ascribed to the lack of commercially available stents that can be delivered through small introducers and dilated to the adult-size aorta.<sup>1,2</sup> We describe the original method that could provide an additional treatment option in small children with coarctation of the aorta using small sheaths.

# **Case presentation**

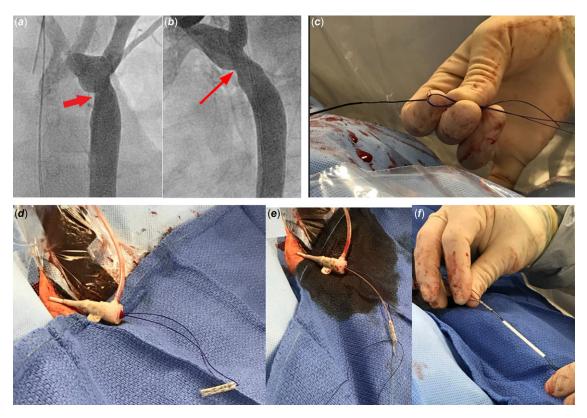
#### Case # 1

A previously healthy 3 years old female weighing 14.5 kg presented with systemic hypertension. A transthoracic echocardiogram revealed the presence of coarctation of the aorta with peak instantaneous and mean pressure gradients of 50 mmHg and 27 mmHg, respectively. Parents refused the surgical repair option and favoured transcatheter stent placement.

# Aortic arch stent placement procedure technique

Under ultrasound guidance, vascular access was obtained in the right femoral artery using a 4-Fr prelude ideal sheath (Merit Medical, South Jordan, UT) and the right axillary artery using a 5-Fr prelude ideal sheath. The peak-to-peak pressure gradient across the aortic arch was only 17 mmHg (under general anaesthesia). We elected to proceed with stent placement due to the presence of systemic hypertension and discrete angiographic narrowing just distal to the take-off of the left subclavian artery (Fig 1a and b). The coarctation segment measured 4.2 mm while the normal descending aorta measured 7 mm. A 0.014" Grand Slam wire (Asahi Intecc Medical, Japan) was advanced through the axillary artery sheath and exteriorised from the femoral artery sheath with the help of a 5 mm Goose Neck Snare (Medtronic, Minneapolis, MN), creating an arterial-arterial rail. A 4-Fr Navicross catheter (Terumo Corporation, Japan) was inserted from the femoral artery sheath over the Grand Slam wire and the tip was exteriorised from the axillary artery sheath. Due to the mismatch between the Grand Slam wire and the catheter, we initially could not advance the catheter inside the 5-Fr sheath. This issue was tackled by inserting the dilator of the 5-Fr sheath over the Grand Slam wire inside the 5-Fr sheath and then the catheter was pushed and exteriorised with ease. The Grand Slam wire was removed. A 0 monofilament (150 cm) string was passed through the distal (inferior) strut of a 19 mm in length 1910B Palmaz Genesis XD stent (Cordis, Dublin, OH). The same 5 mm gooseneck snare was inserted inside the catheter from the femoral artery end and the snare was exteriorised from the catheter tip. The snare was used to pull the two ends of the string inside the axillary artery sheath (Fig 1c). As the string is bulky, it could not fit inside the catheter. Therefore, to exteriorise the ends of the string, we had to remove the catheter (Fig 1d). After exteriorising the string's ends, the same technique was utilised to reestablish the arterial-arterial rail using A Grand Slam wire. A 3-0 Vicryl string was passed through the opposite, proximal end of the stent (superior strut). A  $3 \times 30$  mm NC Emerge (coronary) balloon (Boston Scientific, Marlborough, MA) was inserted inside the femoral artery sheath over the Grand Slam wire and exteriorised from the axillary artery sheath (Fig 1e). The stent was manually crimped on the NC Emerge balloon. To ease advancing the





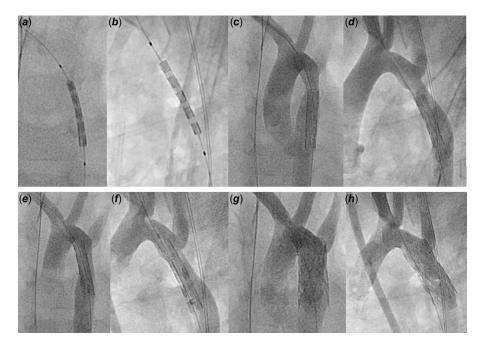
**Figure 1.** *a* and *b*, frontal and lateral aortic angiograms show coarctation of the aorta (red arrow). *c*, the picture shows snaring the 0 string's ends from the right axillary artery sheath to be exteriorised from the right femoral arterial sheath. *d*, the picture shows the string is passed through the inferior strut of the stent with the two ends of the string passing through the right axillary artery sheath. *e*, the picture shows reestablishing arterial-arterial rail, the strings passing through the inferior and superior struts of the stent, and the stent over the coronary balloon). *f*, the picture shows using a cut 5-Fr sheath to aid in further crimping the stent.

stent inside the axillary artery sheath, a cut 5-Fr sheath was placed over the stent and further crimping was performed while the stent is fully covered by the cut 5-Fr sheath (Fig 1f). Under fluoroscopy guidance, the stent/balloon unit was pulled inside the axillary artery sheath by slowly and steadily pulling the balloon and the inferior string together from the femoral artery sheath. It was noticed that the stent slipped toward the distal end of the balloon while it was still inside the axillary artery sheath. The stent was easily re-centered by pulling on the inferior string while fixing the balloon in position (Moving image 1). Then, the balloon and inferior string were pulled together from the femoral artery sheath. After confirming the stent is in the proximal descending aorta (Fig 2a and b), the balloon was inflated to 10 ATMs. The NC Emerge balloon was removed while stabilising the stent by fixing the superior and inferior strings. An angiogram through the axillary artery sheath showed the stent is located distal to the narrowed arch segment (Fig 2c and d). An  $8 \times 20$  mm Sterling balloon (Boston Scientific, Natick, MA) was inserted in the axillary artery sheath over the Grand Slam wire and advanced inside the stent. The stent position was optimised by pulling on the superior and inferior strings as needed (Fig 2e and f; moving image 2). After confirming a good position of the stent across the coarctation and being centred over the balloon, the balloon was slowly inflated to 12 ATMs while maintaining the same amount of tension on the strings to keep the stent in position. The take-off of the left subclavian artery was intentionally jailed due to its proximity to the coarctation. Complete elimination of the waist was noticed during inflation. The balloon was reinflated again (to stabilise the stent) and the inferior string was pulled out of the body. Then, the balloon was deflated and reinflated to pull out the other string. Some degree

of resistance was felt during pulling the strings out. The final angiogram showed the stent seated in the intended position with complete resolution of the coarctation (Fig 2g and h). No pressure gradient was recorded across the stent. No access site complications were encountered. The procedure time was 126 min. Post-procedure echocardiogram showed a stable stent position with a peak instantaneous and a mean gradient of 31 mmHg and 16 mmHg, respectively. She was discharged home the next day on aspirin. At a 14-month post-procedure follow-up, her HTN is well controlled with enalapril. No difference in upper or lower extremities blood pressure was recorded. Her echocardiogram revealed a stable gradient across the stent.

# Case # 2

A 3-month-old female weighing 4 kg was born with a bicuspid aortic valve, hypoplastic aortic arch, ventricle septal defect, and double orifice mitral valve. At 2 weeks of life, she underwent surgical closure of the ventricular septal defect and aortic arch reconstruction. The left subclavian artery was ligated and used to patch the arch. Her hospitalisation was uneventful and discharged home 2 weeks after the surgical repair. The echocardiogram at discharge showed normal left ventricular systolic function with peak instantaneous and mean gradients across the arch of 31 and 18 mmHg, respectively. At 3 months of age follow-up, the echocardiogram showed decreased left ventricle systolic function with an estimated ejection fraction of 39 % and a recurrence of aortic coarctation with peak instantaneous and mean gradients across the arch of 61 and 31 mmHg, respectively. Invasive haemodynamic measurements revealed a peak-to-peak gradient of



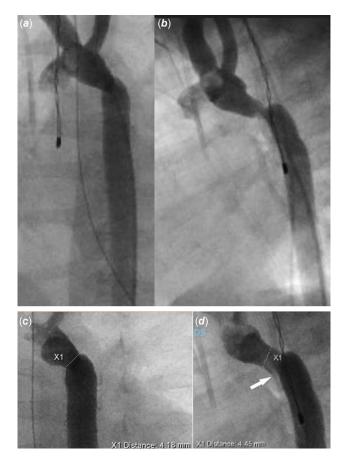
25 mmHg across the aortic arch. A baseline aortic angiogram showed a long hypoplastic arch segment (Fig 3a and b) with the narrowest area measuring 2.1 mm while the normal descending aorta measuring 6.2 mm. Serial balloon angioplasty was performed with the largest balloon diameter being 6 mm resulting in improving the arch gradient to 17 mmHg. An angiogram showed significant improvement in the aortic arch diameter with irregularity at the inferior aspect of the arch (Fig 3c and d). After 1 week of the procedure, no improvement was noticed in the left ventricle systolic function. The decision was made to place a stent across the arch hoping to result in restoring left ventricle systolic function.

# Aortic arch stent placement procedure description

A 4-Fr prelude ideal sheath was placed in the right femoral artery sheath and a 5-Fr sheath was placed in the right axillary artery. At baseline, a gradient of 12 mmHg was recorded across the arch. An angiogram showed a hypoplastic distal arch. The proximal normal arch segment measured 8.1 mm. The distal arch measured 4.6 mm with the narrowest diameter measuring 3.5 mm. The normal descending thoracic aorta measured 6.2 mm. In light of the depressed left ventricle systolic function and the angiographic narrowing, the decision was made to proceed with stent placement.

A 0.014" Grand Slam wire was advanced through the right axillary artery sheath into the descending aorta. A 5 mm Goose Neck snare was used to snare the Grand Slam and exteriorise it through the right femoral artery sheath. A 4-Fr 65 cm straight glide catheter (Terumo Corporation, Japan) was inserted inside the femoral artery sheath. The catheter tip was exteriorised from the axillary artery sheath (Fig 4a) with the aid of the 5-Fr dilator as described in case 1 creating an arterial–arterial rail. The Grand Slam wire was then removed leaving the catheter in place. A 3–0 (135 cm in length) Vicryl string was passed through the most distal (inferior) strut of the 19 mm in length1910 B Palmaz Genesis XD stent (Fig 4b). The same 5 mm Goose Neck snare was inserted inside the catheter and used to exteriorise the two ends of the string from the femoral artery sheath. As opposed to case 1, using a 3-0 string allowed exteriorising the string without the need to remove

Figure 2. a and b, frontal and lateral cine images show the stent centred over the coronary balloon (NC emerge) prior to partial stent expansion. Notice that the balloon was intentionally chosen longer than the stent. c and d, frontal and lateral aortic angiogram through the right axillary artery sheath show the stent was partially expanded and the coronary balloon was removed. The stent is located distal to the coarctation segment. e and f, frontal and lateral aortic angiogram through the right axillary artery sheath show prior to full stent expansion show the stent position was readjusted by pulling on the superior segment. the sterling balloon was positioned inside the partially expanded stent. **q** and **h**, frontal and lateral aortic angiogram through the right axillary artery sheath show the stent has fully expanded with the resolution of the coarctation. the take-off of the left subclavian artery was intentionally jailed.



**Figure 3. a** and **b**, frontal and lateral aortic angiogram show significant narrowing at the distal end of the hypoplastic arch segment. **c** and **d**, frontal and lateral aortic angiogram post balloon angioplasty show improvement in the narrowed aortic segment with irregularity at the inferior aspect of the arch (white arrow).

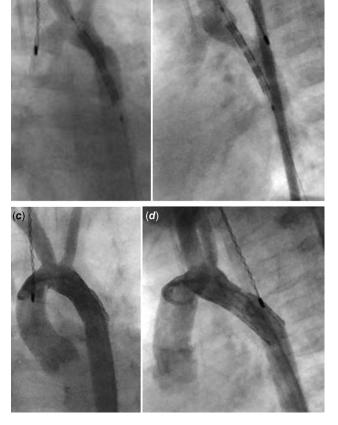
the catheter. The 0.014" Grand Slam wire was advanced through the catheter to re-establish the arterial-arterial rail. The glide catheter was removed. Another 3–0 Vicryl string was passed

**Figure 4.** *a*, the picture shows establishing an arterialarterial rail with the glide catheter inserted from the right femoral artery sheath and exteriorised from the right axillary artery sheath over the grand slam wire. *b*, the picture shows a string is passed through the inferior strut. *c*, the picture shows strings passing through the inferior and superior struts of the stent, stent crimped on the sterling balloon which is inserted from the right femoral arterial sheath and exteriorised over the grand slam wire from the right axillary artery sheath.

through the most proximal (superior) strut of the stent. We selected a  $6 \times 30$  mm Sterling monorail angioplasty catheter. The balloon was advanced from the femoral artery sheath over the Grand Slam wire and was exteriorised through the axillary artery sheath. The Palmaz Genesis XD stent was mounted and crimped on the Sterling balloon (Fig 4c). Similar to case # 1, a cut 5 Fr sheath was used to further crimp the stent on the balloon. Then, the stent/ balloon unit was pulled inside the axillary artery sheath. The stent slipped toward the distal end of the balloon while it was still inside the sheath. The stent was recentered over the balloon by pulling on the inferior string while fixing the balloon in position (Moving image 3). After confirming a good stent position (Fig 5a and b), it was deployed by inflating the balloon to 8 ATMs. An aortic angiogram through the axillary artery sheath revealed a wellpositioned stent with no evidence of injury. The balloon was reinflated to stabilise the stent and the inferior and superior strings were pulled out similar to case # 1. Some resistance was felt during pulling the strings out of the body. Then, the proximal and distal ends of the stent were flared using 8  $\times$  20 mm and 7  $\times$  20 mm Sterling balloons, respectively. An aortic angiogram revealed a well-positioned stent without jailing of the arch branches, no evidence of vascular injury, and resolution of the irregularity in the inferior aspect of the arch (Fig 5c and d). Pressure measurement across the stent revealed only a 4 mmHg peak-to-peak gradient. No access site complications were encountered. The procedure time was 94 min. The echocardiogram after 12 days of the procedure showed improved left ventricle systolic function with an ejection fraction of 57% and the peak instantaneous and mean gradients across the arch of 20 and 10 mmHg, respectively.

# Discussion

The Palmaz Genesis XD is a stainless-steel close cell design stent. It has been widely used in children as it can be serially dilated to accommodate the child's somatic growth with a maximum potential diameter of 20-24 mm.<sup>4,5</sup> It is favourable for stenting



**Figure 5.** *a* and *b*, frontal and lateral aortic angiogram through the right axillary artery sheath prior to stent deployment shows the stent centred over the sterling balloon traversing the entire length of the narrowed aortic segment. the balloon was intentionally chosen to be longer than the stent. *c* and *d*, frontal and lateral final aortic angiogram shows the stent has an excellent expansion with a resolution of the arch stenosis and no evidence of aortic injury.

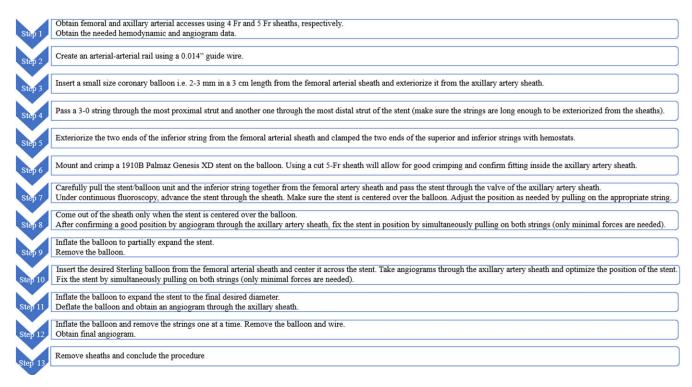


Figure 6. Flowchart summarises the procedure steps when using two balloons (small and final size) is preferred.

narrowed large vessels, such as branch pulmonary arteries, aortic arch, etc.<sup>6</sup> However, similar to other large nonpremounted stents, it requires a large-bore sheath which has been prohibiting its regular use in young children to treat coarctation of the aorta. Placing long and/or large sheaths in a small artery are risk factors for pulse loss and other arterial access complications.<sup>7,8</sup> In 2011, American Heart Association recommended against the routine arch stenting unless the stent can be safely placed and dilated to the adult-size aorta to accompany the natural somatic growth.<sup>3</sup> Unfortunately, no commercially available stent can be placed through a small-bore sheath and has the potential to be dilated to keep up with the child's somatic growth. Therefore, when stent placement is needed in small children, it is a common practice to use a "peripheral type" premounted stent to mitigate the risk of arterial access complications. Although these types of stents can be introduced through a small sheath size, their maximum diameters are far less than the normal adult-size aorta. Placing such stent mandates either future surgical removal or undergoing a risky intentional longitudinal stent fracture which is commonly called "unzipping" the stent.<sup>1-3,9-11</sup>

The novel technique that we are describing (steps are summarised in Fig. 6 and Fig. 7) provides a good treatment option for young children with native or recurrent coarctation of the aorta as it further expands the safe use of Palmaz Genesis XD stent to this age group. There are a few differences worth discussing between the two cases.

In case # 1, the use of a coronary balloon served two purposes. First, it allowed the ease of advancing the stent inside the 5-Fr sheath. Second, the balloon was used to partially dilate the stent and optimise the stent position prior to final dilation with the desired size balloon. This principle provides a similar benefit provided by using a Ballon-in-Ballon (BIB) balloon (NuMed, Hopkinton, NY) for arch stenting. Inflating the inner balloon of the BIB balloon partially expands the stent and allows adjusting position by either advancing or pulling the BIB balloon.<sup>13</sup> Similarly, in our case, after removing the coronary balloon, the stent position was readjusted by pulling on the attached strings as needed. Additionally, at the time of the procedure, we did not have a long enough 3–0 string. Therefore, we used a 0 string which could not be snared inside the catheter. So, the catheter was removed in order to exteriorise the inferior string. This required re-establishing the arterial–arterial rail by snaring the wire again and contributed to increasing the procedure time.

In case # 2, the stent was deployed by using one balloon only. Although this allowed skipping a step (using a coronary balloon), we felt more resistance during advancing the stent inside the 5-Fr sheath. Using a 3–0 string allowed exteriorising the string without losing the catheter position which in turn allowed the fast re-establishing of the arterial–arterial wire rail. Procedure time was shorter in case # 2 which we think is related to the aforementioned differences.

In this technique, using a balloon longer than the stent augments the safety as the stent will continue to be entirely over the balloon when it starts slipping. Nevertheless, care should be taken when the stent is advanced inside the axillary artery sheath and should be continuously observed under fluoroscopy to permit early recognition of stent slipping and to adjust it accordingly. The stent should not be advanced out of the sheath unless it is well centred over the balloon. If needed, the stent position can be adjusted inside the sheath by pulling the strings. We believe having an arterialarterial rail is crucial to provide a stable wire position for such a technically demanding and risky procedure. It was helpful to have an experienced assistant with a full understanding of the procedure's steps to work in harmony with the primary proceduralist. This assistant was assigned to control one string while the primary proceduralist controlled the other string.

There are a few drawbacks to this innovative method. It requires the placement of two sheaths. However, this is counterbalanced by

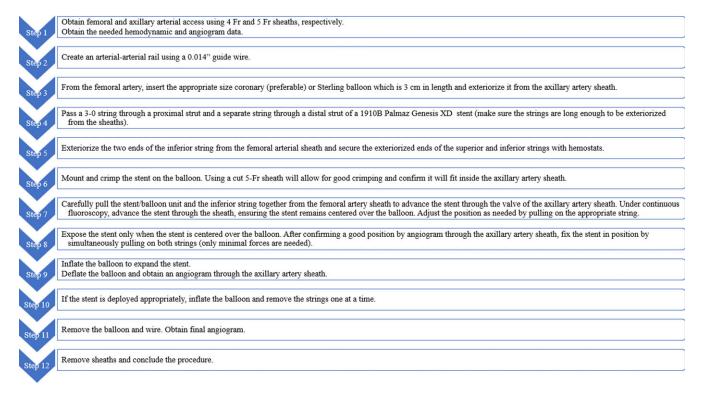


Figure 7. Flowchart summarises the procedure steps when one balloon (final size) is preferred.

the fact that the needed sheaths are small (4-Fr and 5-Fr). Moreover, those sheaths are short. Historically, a long and large sheath is needed for arch stenting (in order to obtain angiograms to guide stent positioning) which has been linked with pulse loss.<sup>2,7,8,12,13</sup> Placing the Palmaz Genesis XD in the traditional method would likely require at least a 7-Fr long sheath in the femoral artery. Additionally, having a short sheath in the axillary artery permits obtaining adequate angiograms to guide stent positioning excluding the need for a long femoral arterial sheath. When compared with the classic arch stent placement through a single femoral arterial sheath, this innovative method requires sophisticated additional steps and the presence of multiple qualified assistants at the table. Therefore, the procedure time is expected to be longer. Nevertheless, taking into account that the placed stent does not need to be surgically removed or undergo intentional fracture, we believe the increase in procedure time is justified.<sup>3,9–11</sup> Moreover, our procedure times for case #1 and case #2 were 126 and 94 minutes, respectively, which are lower than the reported mean procedure time of 158.2 min for arch stent placement in children using the classic femoral access.<sup>6</sup> Additionally, there is a theoretical risk of mispositioning the stent during string removal. The risk can be minimised by inflating the balloon during string removal. Finally, the strings can potentially separate during pulling out. Therefore, the authors advise using absorbable strings, such as Vicryl as an extra safety measure.

# Conclusion

With careful planning and use of the right equipment, a Palmaz Genesis XD stent (which has the potential to be dilated to an adultsize aorta) can be safely placed through small introducers to treat native and recurrent coarctation of the aorta in young children. However, this technique increases the complexity level of the procedure and requires a minimum of two experienced operators. Further studies are needed to investigate the safety of this innovative technique compared with the traditional methods and probably refine it.

Supplementary material. To view supplementary material for this article, please visit https://doi.org/10.1017/S1047951123001154

Conflicts of interest. The authors declare that there is no conflict of interest.

**Research involving human participants.** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

**Informed consent.** As our case report does not meet the definition of research, it is not subject to institutional review board (IRB) oversight as per the University of Iowa IRB. As such informed consent was not obtained from the individual participant included in the case report.

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