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# Transcatheter interventions post Norwood/ Sano procedures: single-centre experience

Huzeifa Elhedai[1], Charalampos Kotidis[1], Ahmed Afifi[1,2], Atul Kalantre[1], Ikenna Omeje[1] and Marinos Kantzis[1]

[1]East Midlands Congenital Heart Centre, University hospitals of Leicester NHS trust, Leicester, UK and [2]Pediatric Department, Benha University, Egypt

**Original Article**

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**Corresponding author:**
Huzeifa Elhedai;
Email: huzeifa.elhedai@nhs.net

## Abstract

*Introduction:* Transcatheter interventions are becoming increasingly used to address postoperative residual lesions after Norwood procedure with Sano shunt. *Methods:* This is a single-centre retrospective review of the outcome of all cases with Sano shunt at our institution over a 6-years period (2017–2023) who underwent transcatheter interventions. *Results:* Thirteen out of the total 34 patients (38%) needed transcatheter interventions. The most common interventions were left pulmonary artery balloon angioplasty ($n = 6$), balloon angioplasty of aortic recoarctation ($n = 6$), and Sano shunt stenting ($n = 5$). Left pulmonary artery size improved from 3 [IQR; 2–5] mm to 4.9 [IQR; 2.7–7.3] mm post-intervention ($p$-value = 0.068), and gradient from 28 [IQR; 25–33] mmHg to 11 [IQR; 10–13] mmHg ($p$-value = 0.109). Balloon angioplasty of aortic recoarctation improved vessel size from 6.7 [IQR; 4–9] mm to 9.5 [IQR; 7–13] mm ($p$-value = 0.066), and reduced peak-to-peak gradient from 22.3 [IQR; 10–39] mmHg to 7.6 [IQR; 4–14] mmHg ($p$-value = 0.109). Finally, Stenting of Sano shunt resulted in increased shunt size from 3.4 [IQR; 3.1–3.6] mm to 5.5 [IQR; 4.2–6] mm ($p$-value = 0.066), and improvement of the oxygen saturation from 71.3 [IQR; 69–74] % to 85.3 [IQR; 83–89] % ($p$-value = 0.066). There was one procedure-related death. *Conclusion:* Transcatheter intervention for patients post Sano shunt is feasible with good results, improving haemodynamics and oxygenation of the patients and thereby allowing them to come on the proper time for the second stage palliation.

## Introduction

The Norwood procedure is the standard of care first-stage palliation for neonates with single-ventricle physiology and systemic outflow obstruction.[1] Improved survival for patients after first-stage palliation became more reproducible for many centres by the application of the modified Norwood procedure with the right ventricle–to–pulmonary artery conduit (Sano shunt)).[2]

Despite the relatively large worldwide experience and the important technical modifications of the Norwood procedure, operative mortality and postoperative morbidity remain high.[3] Thus, patients who survive neonatal surgery may develop obstruction in the aortic arch, distortion of the pulmonary arteries, as well as Sano shunt obstruction. Traditionally, these complications have been treated surgically, but transcatheter interventions have become increasingly used in this population to relieve symptoms.[4]

The aim of this study is: (a) to determine which interventions were performed at most after the implantation of Sano shunt, in order to find out any association between the size of the branch pulmonary arteries at birth and need for catheter intervention, (b) to determine whether the position of the Sano shunt and surgical techniques were associated with the need for catheter-based interventions and (c) to study the outcomes of those interventions.

## Materials and methods

This is a single-centre retrospective review of the outcome of all cases with Sano shunt at our institution over a 6-year period (2017–2023) who underwent catheter interventions. The hospital records, including case notes and other electronic data, were reviewed. Patient characteristics, primary cardiac lesions, and non-cardiac diagnosis, as well as the types of interventions, were reviewed. The project was registered as service evaluation project with the audit department under registration number (12,963).

Data were collected and analysed using SPSS (version 27). Demographics were described using median, interquartile range, frequencies, and percentages as appropriate. Analysis was performed on the full cohort as well as two subgroups (intervention versus non-intervention) based including age and weight at Sano shunt procedure, cardiac diagnosis, comorbidities, and

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the pulmonary artery Z scores using the Lopez et al Z scoring system.[5] Comparison between groups was performed with Student *t* test or Mann–Whitney *U* test, depending on distribution. Pearson correlation analysis was used to compare outcomes before and after the three common interventions (left pulmonary artery balloon angioplasty, stenting of Sano shunt and aortic recoarctation balloon angioplasty). Power calculation was performed using standard methods.[6] Statistical significance was set at $P < 0.05$.

The standard surgical technique for creation of Sano shunt in our centre is by using 5 mm reinforced Goretex tube inserted into the right ventricle outflow tract (dunking technique) and secured with 6-0 or 7-0 Prolene sutures. The position of the tube in the right ventricle is inspected via the pulmonary valve. The distal end of the tube is then trimmed to length and anastomosed to the pulmonary artery, usually at the bifurcation or to the right pulmonary artery.

Indications for interventions were based on early detection of symptoms such as systemic oxygen desaturation, along with significant vessel narrowing (35% or less than the largest vessel diameter) on imaging techniques (ultrasound, MRI, multislice CT), along with catheterisation data such as pressure gradients and vessel size. MRI was used in selected patients such as those with severe left pulmonary artery stenosis to determine differential blood flow to pulmonary artery before intervening. Post-intervention assessment relied mainly on catheter angiographic and haemodynamic data, as well as clinical assessment and non-invasive ultrasound and CT scans. We did not use MRI for post-intervention as MRI scans need sedation and heart rate control to maximise image quality.

## Results

Between December 2017 and September 2023, a total of 34 patients underwent Norwood procedure with Sano shunt for various indications. Thirteen of those patients needed transcatheter intervention for indications related to the Norwood/Sano shunt. A comparison between baseline characteristics of the intervention and non-intervention groups is outlined in Table 1. Of note, our case number was only 34 in 6 years, but we take into account that there was 2-year lockdown during the COVID-19 pandemic, when our centre was turned into an extracorporeal membrane oxygenation specialist centre.

Thirteen out of the total 34 patients (38%) needed transcatheter interventions. A total of 29 interventions (21 procedures) were performed on those 13 patients. All but eight of the procedures were performed before the Glenn shunt. The eight procedures that were performed after the Glenn shunt were to address branch pulmonary artery narrowing ($n = 6$); these included two balloon angioplasty and two stents to left pulmonary artery, one balloon angioplasty and one stent to right pulmonary artery, and aortic recoarctation ($n = 2$). Six out of the 13 patients with interventions had single catheter procedure (which included one or more interventions per procedure). The remaining seven patients needed more than one catheter procedure (each of which included one or more interventions per procedure).

The most common intervention was left pulmonary artery balloon angioplasty ($n = 6$) and aortic recoarctation balloon angioplasty ($n = 6$), followed by stenting of Sano shunt ($n = 5$), then stenting of left pulmonary artery ($n = 3$) and occlusion of collateral vessel ($n = 3$), right pulmonary artery balloon angioplasty ($n = 2$) and stenting of right pulmonary artery ($n = 2$), and finally reduction of aorto-pulmonary shunt ($n = 1$) and stenting of aortic recoarctation ($n = 1$). To relieve aortic recoarctation, all patients but one underwent balloon angioplasty of the recoarctation. This patient was critically ill with multiple co-morbidities, including single kidney, and was on peritoneal dialysis. The attempt at balloon angioplasty was done; however, there was still significant peak-to-peak gradient (from 36 to 26 mmHg). The decision was made for stenting of recoarctation as salvage procedure as the patient was not stable for cardiopulmonary bypass. The patient, unfortunately, died of catastrophic bleeding following right ventricular perforation.

There were other seven interstage mortalities that were not related to catheters procedures; four between first and second stage (two died because of respiratory failure on back ground of severe tracheobronchomalacia, one due to severe intracerebral haemorrhage and one due to severe right ventricular dysfunction and tricuspid regurgitation, (which were mild at the stage of Sano shunt and then progressively worsened then after), the remaining three deaths happened after second stage and they were due to right ventricular dysfunction and tricuspid regurgitation in two (the two patient had normal baseline right ventricular function and tricuspid valve), and severe necrotising enterocolitis in one. This gives overall interstage mortality of 24%, splitting into 14% between stages 1 and 2 and 10% after stage 2.

The balloons used for left pulmonary artery angioplasty included Powerflex, Coronary and Tyshak II balloons. Left pulmonary artery size improved from 3 [IQR; 2–5] mm to 4.9 [IQR; 2.7–7.3] mm post-intervention ($p$-value = 0.068), and gradient from 28 [IQR; 25–33] mmHg to 11 [IQR; 10–13] mmHg ($p$-value = 0.109) – (Figure 1). On the other hand, the balloons used for angioplasty of aortic recoarctation included mainly Tyshak balloons (except one patient needing Sterling balloon). This improved vessel size from 6.7 [IQR; 4–9] mm to 9.5 [IQR; 7–13] mm ($p$-value = 0.066), and reduced peak-to-peak gradient from 22.3 [IQR; 10–39] mmHg to 7.6 [IQR; 4–14] mmHg ($p$-value = 0.109). Finally, the stents used for Sano shunt were Cook Formula 414 & 418 stents, resulting in increasing shunt size from 3.4 [IQR; 3.1–3.6] mm to 5.5 [IQR; 4.2–6] mm ($p$-value = 0.066), and improvement of the oxygen saturation from 71.3 [IQR; 69–74] % to 85.3 [IQR; 83–89] % ($p$-value = 0.066) (Figure 3).

## Discussion

The outcomes for neonates with hypoplastic left heart syndrome and its variants have significantly improved since the introduction of the staged Norwood procedure in the early 1980s. Over the years, various modifications to the Norwood procedure have been developed. The introduction of a right ventricle-to-pulmonary artery valveless conduit, as recommended by Sano, in place of the traditional modified Blalock-Taussig-Thomas shunt has enhanced the haemodynamics of the Norwood circulation, leading to improved postoperative survival rates.

The Sano modification involves placing a valveless Gore-Tex conduit (4–5 mm) between the right ventricle and pulmonary artery, typically running to the left of the neo-aorta. In some centres, further refinement is made by routing the conduit from the right ventricle outflow tract to the right pulmonary artery, along the right side of the neo-aorta for better control of pulmonary blood flow and to facilitate easier access to the central pulmonary artery at the time of cavo-pulmonary shunt stage.[7] However, interstage mortality and morbidity rates remain significant, with some cases directly attributable to shunt complications.

Post stage 1 Norwood surgery has the highest rate of interstage mortality compared to stages 2 and 3 of total cavo-pulmonary

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**Table 1.** Baseline characteristics of patients in the intervention and non-intervention groups

| Variable | Overall | Intervention group | Non-intervention group | *p*-value |
|---|---|---|---|---|
| *n* | 34 | 13 | 21 | |
| Age at Sano, days (median, IQR) | 5.5, [4, 10] | 5, [3, 10] | 6, [4, 10] | 0.79 |
| Weight at Sano, kg (median [IQR]) | 3.0, [2.6, 3.3] | 2.9, [2.5, 3.4] | 3.1, [2.8, 3.3] | 0.40 |
| Sex = Male (%) | 18 (59.2) | 6 (46.2) | 12 (57.1) | 0.79 |
| LPA *Z* score (median [IQR]) | −0.3 [−1.4, 0.4] | 1.0, [−0.3, 1.4] | −1.0, [−1.8, 0.1] | 0.004 |
| RPA *Z* score (median [IQR]) | −0.3 [−1.3, 0.6] | 0.7, [−0.3, 1.3] | −0.5, [−1.3, 0.0] | 0.02 |
| **Cardiac diagnosis (%)** | | | | |
| Aortic atresia | 3 ( 8.8) | 3 (23.1) | 0 ( 0.0) | |
| Complex | 1 ( 2.9) | 0 ( 0.0) | 1 ( 4.8) | |
| HLHS/ Shones | 25 (73.5) | 8 (61.5) | 17 (81.0) | |
| PAVSD | 1 ( 2.9) | 0 ( 0.0) | 1 ( 4.8) | |
| Truncus Arteriosus | 1 ( 2.9) | 1 ( 7.7) | 0 ( 0.0) | |
| uAVSD | 3 ( 8.8) | 1 ( 7.7) | 2 ( 9.5) | |

HLHS = hypoplastic left heart syndrome; LPA = left pulmonary artery; PAVSV = pulmonary atresia with ventricular septal defect; RPA = right pulmonary artery; uAVSD = unbalanced atrioventricular septal defect.

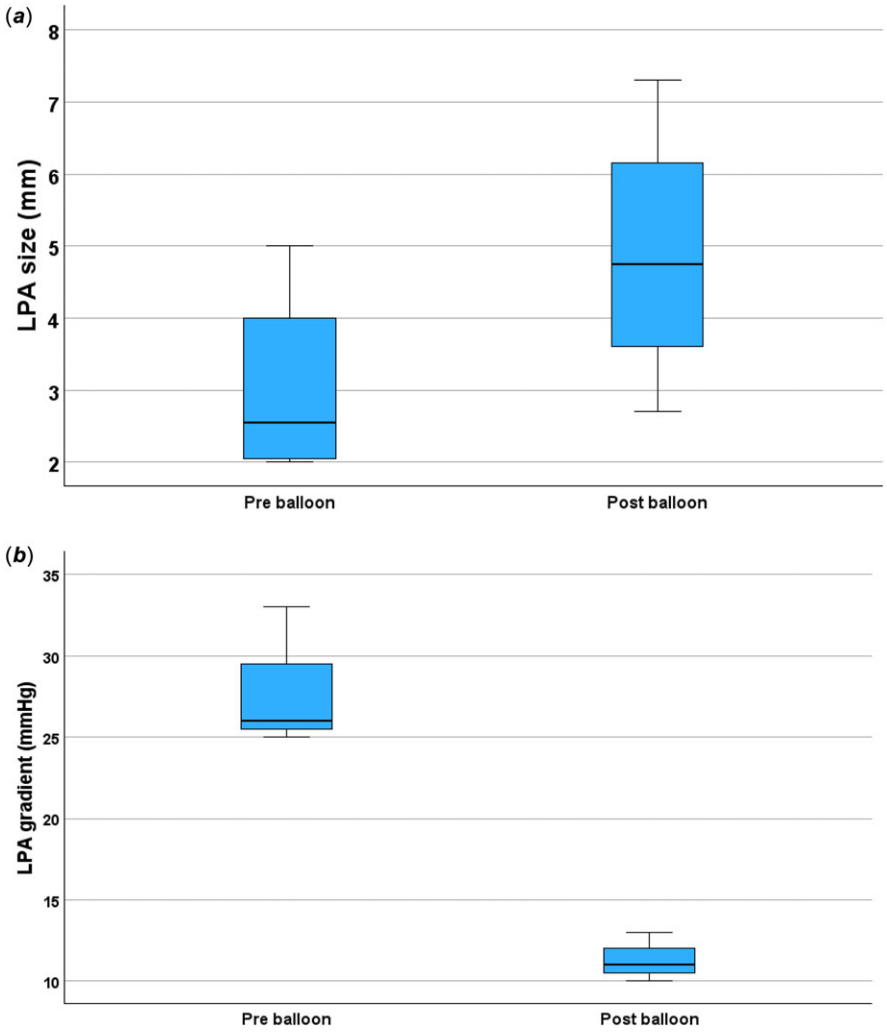



**Figure 1.** (***a***) Change in size of LPA in mm pre and post balloon angioplasty, and (***b***) change in pressure gradient in mmHg pre and post balloon angioplasty of LPA. LPA = left pulmonary artery.

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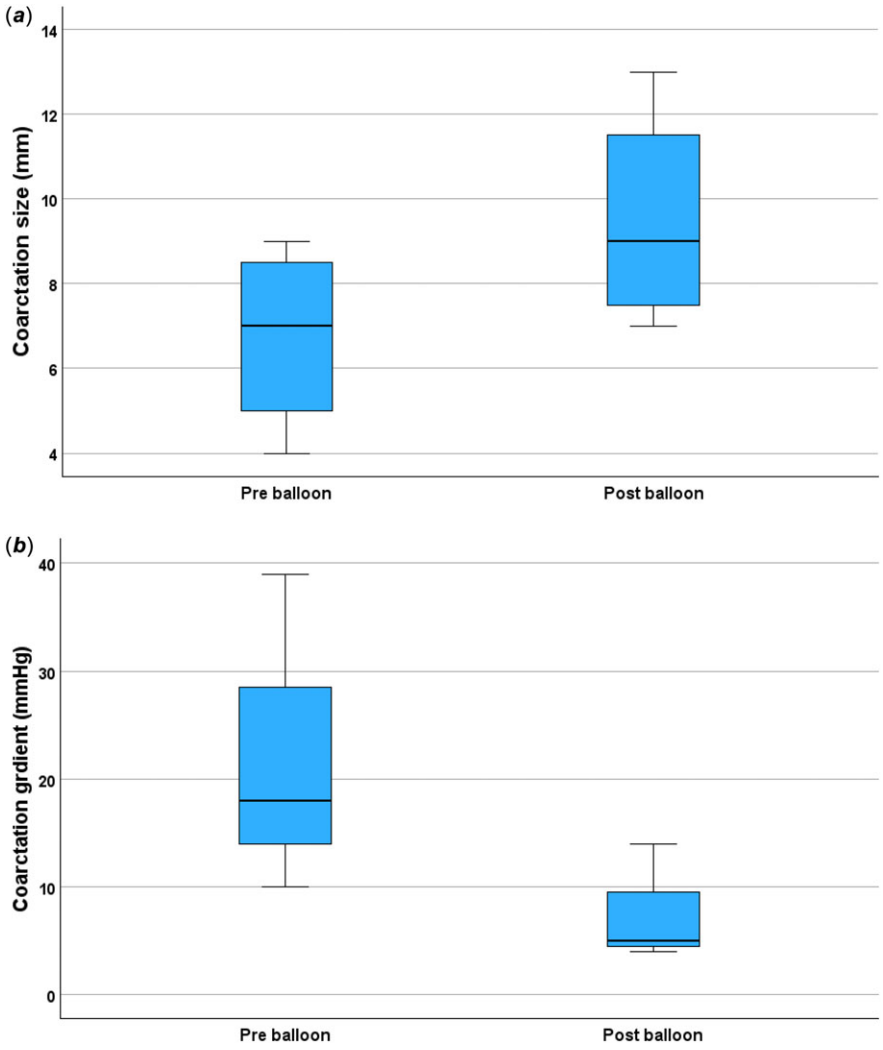



**Figure 2.** (***a***) Change in size of coarctation segment in mm pre and post balloon angioplasty, and (***b***) change in peak-to-peak pressure gradient (mmHg) pre and post balloon angioplasty of aortic recoarctation.

connection completion journey. We had total interstage mortality of 24% which is comparable to the reported literature.[8–10] A significant proportion of patients in this stage have significant residual lesions and need interstage interventions or redo surgeries. Due to advances in cardiac catheterisation and availability of sheaths, balloons and stents, which can be used in low-weight infants, an increased rate of cardiac interventions has been witnessed in this stage.

In our study, total of 34 patients had stage I Norwood surgery with Sano shunt. Thirteen (38%) of them were diagnosed to have significant residual lesions and therefore had interventions done via cardiac catheterisation. We typically perform the second stage (Glenn shunt) 4–6 months after the Norwood, and follow up duration was up to 48 months. All patients deemed to benefit from catheter interventions related to Norwood/Sano shunt (i.e Sano shunt, pulmonary artery or aortic arch) were accepted for intervention, whether that was between first and second stage or after second stage. Our results show a rate of need for catheter interventions which is slightly less than the reported 46% in the literature.[11] Recent reports by Bouyaala and colleagues[1] documented even higher percentage (66%) of the need for catheter-based interstage interventions following the Norwood procedure, indicating that the interstage management of this delicate group of patients is tricky, and that low threshold for reintervention is essential to the success of staged surgical palliation for this patient cohort. Comparing our results to the published reports, we can infer that our reintervention rates are slightly lower than the others.

Residual obstruction of the aortic arch, branch pulmonary arteries, or the Sano shunt is the usual reason for intervention need. In our study, balloon angioplasty of the left pulmonary artery was the most common intervention performed. Historically, late left pulmonary artery stenosis occurs commonly after the Norwood procedure, and complicates subsequent stages. Compression by the neo-aorta and ductal stump may favour flow into the right pulmonary artery, resulting in left pulmonary artery hypoplasia.[12] The size of the pulmonary arteries at birth in our cohort did not seem to have a statistically significant effect on the need for pulmonary arteries intervention. In our centre, the placement of the Sano shunt to the right pulmonary artery or at the bifurcation is a standard procedure, and as Gist et al have reported,[13] we have seen increased number of interventions to left pulmonary artery, presumably because of the preferential flow to the right pulmonary artery. However, the pressure on the left pulmonary artery by the newly created neo-aorta remains the main reason for lesser growth of the left pulmonary artery. Surgical alternatives to balloon angioplasty/stenting of pulmonary arteries were considered in all patients in our series. All patients were discussed in our multi-disciplinary meetings. We consider the less invasive method for

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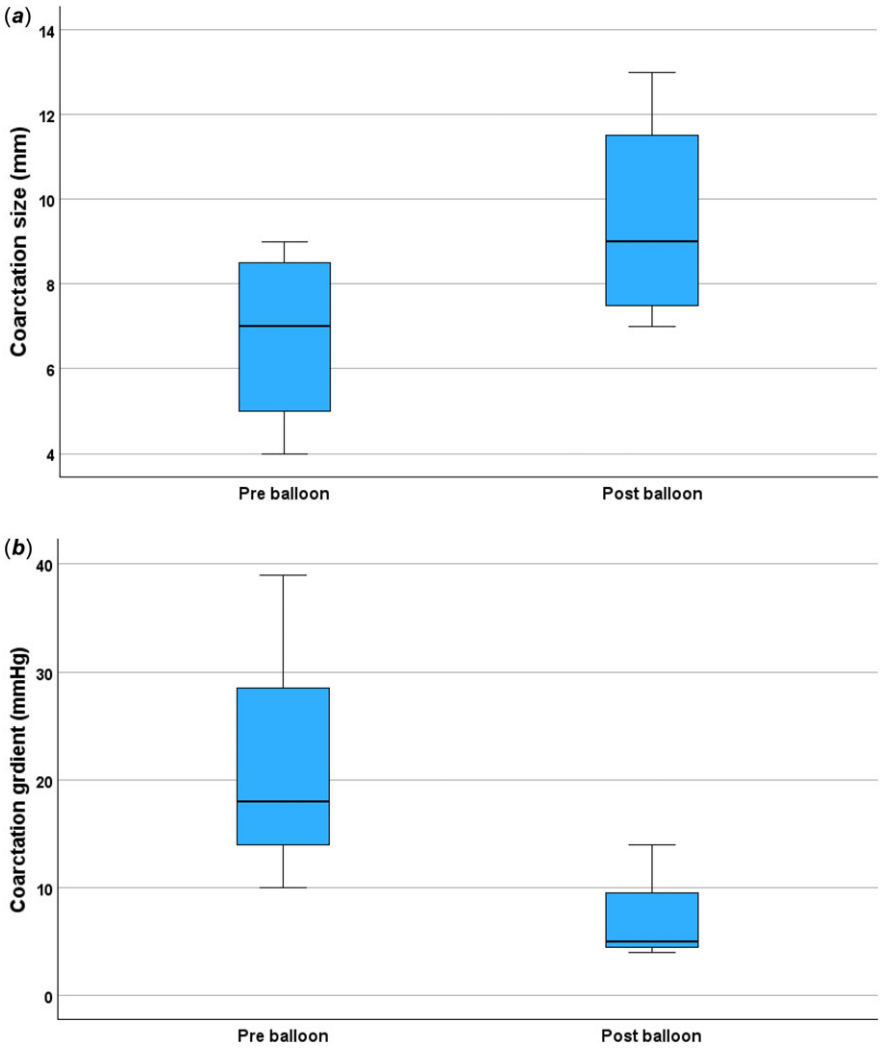



**Figure 3.** (***a***) Change in size of coarctation segment in mm, and **(*b*)** change in peak-to-peak pressure gradient after balloon dilatation of coarctation.

those critically ill patients as the most indicated. Stenting of pulmonary arteries is the last resort for lesions not amenable to balloon angioplasty. In general, we prefer an early second-stage procedure with augmentation of the PAs rather than a revision of the SS.

One of the surgical challenges of the Norwood procedure is the reconstruction of the hypoplastic aortic arch, which bears the risk of recurrent obstruction. The rate of recoarctation of the aorta is reported to be between 13.4 and 29% on recent data set by Cleuziou et al and Porras et al.[14,15] Our series had similar incidence of aortic recoarctation around 14%. Balloon angioplasty is accepted as an effective method for relief of aortic arch recoarctation. Chessa and associates reported the feasibility of use of venous approach in the settings of Norwood procedure in order to reduce the vascular complications of balloon aortic angioplasty to arterial access.[16] In our cohort, all procedures were done through an arterial access, and we have not documented any vascular complications. Furthermore, the reduction of the peak-to-peak gradient across the coarctation segment was comparable to the reported results in literature, although it did not show statistical significance.

Another common complication is the need for reintervention for aortic recoarctation post-balloon angioplasty, which we observed in 2/6 (33%) of the patients in our group. Despite a high acute success rate, a significant proportion of patients treated with balloon angioplasty for recoarctation may need reintervention during follow-up.[15] One of our patients did not respond to balloon angioplasty of recoarctation, needing to go for salvage stent placement interstage. This approach could have helped the child beyond that critical moment and allowed further management of recoarctation either by surgery but also by hybrid approach during the cavopulmonary or Fontan stage. This approach has been described by Hass and colleagues,[17] and found to be an easy and safe concept to manage recurrent aortic arch hypoplasia and stenosis. There is, however, need to use large stents allows redilatation to adult size diameters later on.

Stenosis of Sano shunt may develop later on after shunt placement, leading to life-threatening complications.[18,19] Several mechanisms may lead to shunt obstruction: proximal stenosis may be caused by right ventricular hypertrophy (intramural stenosis), kinking of the conduit, or fibrointimal hyperplasia.[19] Distal shunt stenosis mainly results from pseudointimal peel or tension on the distal anastomosis. Obstruction of the Sano shunt necessitating reintervention can take place in up to 24% of patients.[20,21] In our series, only 5/34 (14%) of patients treated with Sano shunt developed obstruction leading to intervention by placing an endovascular stent within the Sano shunt. This is perhaps due to improvement in surgical techniques recently adopted for the classic Sano shunt by placing the proximal end of the Sano shunt

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using "dunking technique" and directing the distal end towards the right pulmonary artery, avoiding potential obstruction by the neo-aorta.[22]

We achieved excellent results with stenting the Sano shunt in our patient, with instant improvement in oxygen saturation and shunt size. There has not been any adverse event or need for further stenting post-initial stent. This gave our patient the opportunity to grow until second stage surgical palliation, thereby avoiding early second stage, which, although described in some centres with similar survivals probability, may come at increased cost,[23] and also avoiding surgical shunt revision, which could be associated with increase in infection rates, extracorporeal membrane oxygenation use, hospital mortality, and resource utilisation with this strategy.[24]

## Conclusion

This is small volume, single-centre experience of transcatheter intervention post Norwood-type procedures with Sano shunt. Our results demonstrated lower incidence of interventions compared to the published data. The most common interventions were for left pulmonary artery stenosis, aortic arch recoarctation, and Sano shunt obstruction. Transcatheter intervention is feasible, allowing patients to grow the PAs and to reduce the burden of the coarctation stenosis on the systemic ventricle. Thereby, patients come smoothly to the second-stage operation.

## Limitations

Our study has some limitations. It is a retrospective study, which may increase risk of bias. Additionally, the study is a single centre with small cohort size. Despite reaching comparable outcomes to the multicentre trials, we acknowledge that results should be interpreted with caution, given our small sample size. Future prospective multicentre trials will be useful to support existing data.

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**Competing interests.** None.

**Ethical Standard.** The study was classified and registered as service evaluation following assessment using the United Kingdom NHS research governance assessment tool (https://www.hra-decisiontools.org.uk/research/). The study was then reviewed by the Research Governance department at our institution and deemed not to require ethical approval. Due to the long-time span of the study and the retrospective nature, patients' consents have been waived.

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