Innominate artery patency after direct cannulation in neonates

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ABSTRACT

Objective: The study objective was to determine the short-term incidence of innominate artery stenosis for neonates who underwent direct innominate artery cannulation during the Norwood procedure.

Methods: This is a retrospective, single-institution review of 92 patients who underwent the Norwood procedure with direct innominate artery cannulation from 2006 to 2017. The primary outcome was angiographic evidence of patency at pre-Glenn cardiac catheterization. Patient characteristics, intraoperative surgical and hemodynamic measurements, and postoperative neurologic findings were recorded.

Results: At a median age of 5.0 days, 92 neonates underwent the Norwood procedure with direct innominate artery cannulation. These patients underwent cardiac catheterization at a median of 3.0 months after the index operation. In 5 of 92 patients with catheterization images available for review, there was angiographic evidence of mild innominate artery stenosis, and none had moderate or severe stenosis. Review of follow-up records did not reveal evidence of clinically significant stenosis or innominate artery reintervention.

Conclusions: In neonates undergoing the Norwood procedure with direct innominate cannulation, innominate artery stenosis was uncommon and clinically significant stenosis did not occur. (JTCVS Techniques 2022;14:171-6)

CENTRAL MESSAGE

In neonates undergoing Norwood procedure with direct innominate cannulation, innominate artery stenosis was uncommon and clinically significant stenosis did not occur.

PERSPECTIVE

Ideal arterial cannulation strategy in complex arch reconstruction for neonates remains debated. This retrospective study was performed to radiographically assess short-term patency in neonates who underwent direct innominate artery cannulation and suggests high patency rates.

Video clip is available online.
end of the shunt. However, this technique often takes the longest and is prone to bleeding along the suture lines of the graft.\textsuperscript{2,3} Cannulating the aorta and repositioning the cannula into the innominate artery during ACP are limited to amenable anatomy (requires a sufficiently large ascending aorta), and manipulation of the aortic cannula may result in displacement or worse—periods of circulatory arrest or air embolization. For these reasons, our institution has favored direct innominate artery cannulation.

As described in previous studies,\textsuperscript{4,5} our institution has used direct innominate artery cannulation in both neonates and children with low operative mortality and complication rates (Video 1). However, a question often raised with this technique that has not been thoroughly assessed is the potential risk of postoperative stenosis of the innominate artery. In the present study, we used pre-Glenn cardiac catheterizations to radiographically assess short-term patency rates after direct innominate artery cannulation in patients who previously underwent the Norwood procedure.

**MATERIALS AND METHODS**

**Study Design**

A retrospective, single institution review was performed for all neonates who underwent a Norwood procedure with direct cannulation of innominate artery between January 2007 and December 2017. Angiograms from the pre-Glenn cardiac catheterization were independently reviewed by 2 experienced pediatric interventional cardiologists to evaluate for stenosis, occlusion, or other abnormalities of the innominate artery. Patient characteristics at the time of surgery (age, sex, body surface area) were collected from hospital records, and intraoperative measurements (circuit pressure during ACP, ACP flow, upper-extremity pressures before and during ACP, continuous near-infrared spectroscopy (NIRS) before, during, and after ACP) were collected from perfusion records. Postoperative clinical outcomes (30-day mortality, 30-day neurologic status, innominate artery reinterventions, upper-extremity blood pressure differential) were collected from hospital records. Neurologic status was determined by documented physical examinations by the primary team attending physician. Upper-extremity blood pressure differential was documented for patients with angiographic signs of innominate artery stenosis, and a value of less than 5 mm Hg was considered insignificant. The study was approved by our Institutional Review Board. Statistical analysis was performed using R (version 4.0.4 GUI 1.74 Catalina Build 7936). Data were presented as number (%), mean ± standard deviation, or median (25th, 75th percentiles).

The Institutional Review Board of Stanford University approved the study protocol and publication of data (Institutional Review Board 61, registration 4947, e-protocol 52170; approval period 7/26/21, does not expire). The patients provided informed written consent for the publication of the study data.

**Inclusion/Exclusion Criteria**

A global search of “Norwood operation” from the internal database returned 126 potential patients. Of these, 7 patients underwent a Norwood variation not requiring Glenn palliation (ie, Norwood hybrid, Yasui/...
In the 92 patients, cardiac catheterization was performed at a median of 3.0 (2.7-3.4) months after the Norwood operation (Figure 1). Five of 92 (5.4%) catheterizations were identified as having radiographic evidence of mild stenosis and no, moderate, or severe stenosis (Figure 2). Notably, there was no significant difference in the bi-extremity blood pressure differential for these 5 patients, there were no documented symptoms or signs suggestive of clinically significant stenosis, and there were no reinterventions documented. Retrospective chart review revealed there were no issues documented regarding cannulation, and intraoperative line pressures (mean 103 ± 16 mm Hg) were not significantly than those from the overall population (97 ± 29 mm Hg). Five additional patients were noted to have mild innominate artery irregularities without significant stenosis (Figure 2).

**Clinical Outcomes**

For the 5 patients with an angiographic suggestion of mild stenosis, upper-extremity pulses and range of motion were symmetric, there were no signs of claudication or skin changes, and blood pressures on the right upper extremity were not significantly lower (>5 mm Hg) than those on the left.

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**TABLE 1. Patient and intraoperative characteristics (N = 92 patients)**

| Characteristic                  | No. of surgeries | ACP time, min |
|---------------------------------|------------------|---------------|
|                                 | 100              | Mean ± SD     |
|                                 |                  | Median (25th, 75th) |
|                                 |                  | Max, Min      |
| Age at surgery, d               |                  | Mean ± SD     |
| Mean ± SD                       | 7.1 ± 7.4        | Median (25th, 75th) |
| Median (25th, 75th)             | 5.0 (3.6, 8.0)   | Max, Min      |
| Max, Min                        | 1, 49            |               |
| Body surface area, m²           |                  | Mean ± SD     |
| Mean ± SD                       | 0.21 ± 0.03      | Median (25th, 75th) |
| Median (25th, 75th)             | 0.21 (0.20, 0.22)| Max, Min      |
| Max, Min                        | 0.12, 0.33       |               |
| Weight, kg                      |                  | Mean ± SD     |
| Mean ± SD                       | 3.23 ± 0.52      | Median (25th, 75th) |
| Median (25th, 75th)             | 3.27 (2.88, 3.50)| Max, Min      |
| Max, Min                        | 1.37, 4.60       |               |
| Bypass time, min                |                  | Mean ± SD     |
| Mean ± SD                       | 148 ± 36         | Median (25th, 75th) |
| Median (25th, 75th)             | 144 (127, 165)   | Max, Min      |
| Max, Min                        | 60, 315          |               |
| Cross-clamp time, min           |                  | Mean ± SD     |
| Mean ± SD                       | 72 ± 26          | Median (25th, 75th) |
| Median (25th, 75th)             | 67 (55, 84)      | Max, Min      |
| Max, Min                        | 21, 162          |               |
| ACP flow, mL/kg/min             |                  | Mean ± SD     |
| Mean ± SD                       | 38 ± 6           | Median (25th, 75th) |
| Median (25th, 75th)             | 40 (30, 40)      | Max, Min      |
| Max, Min                        | 30, 50           |               |
| Line pressure on ACP, mm Hg     |                  | Mean ± SD     |
| Change in NIRS on ACP, %        |                  | Median (25th, 75th) |
| Mean ± SD                       | 1.3 ± 7.5        | Max, Min      |
| Median (25th, 75th)             | 0 (~0.5, 0.5)    |               |
| Max, Min                        | –23, 33          |               |
| Change in NIRS post-ACP, %      |                  | Mean ± SD     |
| Upper-extremity MAP on ACP, mm Hg|                  | Median (25th, 75th) |
| Mean ± SD                       | –0.8 ± 6.5       | Max, Min      |
| Median (25th, 75th)             | 0 (~0.5, 1)      |               |
| Max, Min                        | –18, 20          |               |

The 25th and 75th denote percentiles. ACP, Antegrade cerebral perfusion; SD, standard deviation; NIRS, near-infrared spectroscopy; MAP, mean arterial pressure.

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**Pre-Glenn Catheterizations**

In the 92 patients, cardiac catheterization was performed at a median of 3.0 (2.7-3.4) months after the Norwood operation (Figure 1). Five of 92 (5.4%) catheterizations were identified as having radiographic evidence of mild stenosis and no, moderate, or severe stenosis (Figure 2). Notably, there was no significant difference in the bi-extremity blood pressure differential for these 5 patients, there were no documented symptoms or signs suggestive of clinically significant stenosis, and there were no reinterventions documented. Retrospective chart review revealed there were no issues documented regarding cannulation, and intraoperative line pressures (mean 103 ± 16 mm Hg) were not significantly than those from the overall population (97 ± 29 mm Hg). Five additional patients were noted to have mild innominate artery irregularities without significant stenosis (Figure 2).

**Clinical Outcomes**

For the 5 patients with an angiographic suggestion of mild stenosis, upper-extremity pulses and range of motion were symmetric, there were no signs of claudication or skin changes, and blood pressures on the right upper extremity were not significantly lower (>5 mm Hg) than those on the left.
of the left upper extremity at an average of 2.1 ± 1.3 years after the Norwood procedure. Moreover, none underwent transcatheter or surgical reintervention on the innominate artery.

Among the entire cohort, there were 3 deaths and no intraoperative deaths within 30 days of surgery. The 3 deaths occurred in the setting of myocardial dysfunction of unknown etiology requiring inotropic support postoperatively and ultimately venoarterial extracorporeal membrane oxygenation. All 3 patients were unable to be weaned off extracorporeal membrane oxygenation because of persistent bradycardia and hypotension, and were transitioned to compassionate care. There were no strokes and no clinically evident neurologic deficits within 30 days of operation.

FIGURE 2. Composite image of innominate artery abnormalities. Aortic angiograms for pre-Glenn evaluation are shown in 9 patients with mild stenosis (first 4 panels) or mild distortion/irregularity without stenosis (arrows) of the innominate artery or common brachiocephalic trunk after innominate artery cannulation for ascending aortic and arch reconstruction.
based on clinical evaluation by the primary team per discharge documentation.

**DISCUSSION**

Since its description by Asou and colleagues, continuous cerebral perfusion via direct innominate cannulation has become a mainstay technique for cerebral protection during arch reconstruction in neonates. Although studies have yet to demonstrate a convincing superiority to traditional deep hypothermic circulatory arrest due to insufficient power, continuous cerebral perfusion has emerged as the predominant technique, and our institution has had success in particular with direct innominate artery cannulation. In our experience, there are no obvious contraindications, and for anatomic variants such as anomalous right subclavian artery, we will still cannulate the right carotid directly. As mentioned previously, there were zero intraoperative conversions to alternative cannulation strategies for this cohort. High line pressures were also rare, as shown in Table 1. Although we use 8F cannulas in the majority of patients, for very small patients we opt for a 6F cannula and if necessary, can usually troubleshoot simply by placing slight tension on the cannula to take it off the back wall. Relatedly, there is no observed weight limitation for this cannulation technique, with the smallest patient in this cohort weighing 1.37 kg.

Despite the technical advantages in minimizing circulatory arrest, bleeding, and operative time, concerns about postoperative stenosis are often raised. To address this question, the present study examined our institution’s Norwood experience and demonstrated through expert review of pre-Glenn cardiac catheterizations high short-term patency rates of the cannulated innominate artery. Intraoperative perfusion and anesthesia records confirmed immediate postoperative patency, as well as stable cerebral perfusion and adequate line pressures throughout the operation. The stability of short-term neurologic status, lack of significant upper-extremity blood pressure differences, and absence of clinical suggestions of stenosis or reintervention further support the safety and efficacy of this technique.

**Study Limitations**

As with all retrospective, observational studies, key limitations include potential selection bias and incomplete data from missing records or incomplete follow-up. Although the present study failed to find any evidence of clinically significant stenosis of the cannulated innominate artery, these results are relevant only to the perioperative and short-term period. Medium- and long-term patency rates cannot be extrapolated from these results and warrant further investigation. Excluding patients who experienced early deaths that were primarily due to heart failure and intractable hypoxia (unlikely related to innominate artery stenosis), this study had an exclusion fraction of 14 of 106 patients (13.2%) in the final analysis due to lost follow-up and catheterizations that did not adequately capture the innominate artery. Although this is not an insignificant percentage, in the context of 0% clinically significant stenosis, these results remain relevant. It is also important to note that the present study does not compare direct innominate artery cannulation with alternative strategies, but rather focuses only on the safety and efficacy of direct innominate cannulation. This is intentional because of our institutional bias toward direct innominate cannulation and therefore poor comparator groups.

**CONCLUSIONS**

Direct innominate artery cannulation is a common method of providing cerebral protection during complex arch reconstruction in neonates. The present study confirms that this technique can be used with appropriately low line pressures and stable NIRS intraoperatively, in addition to no clinically significant innominate artery stenosis or neurologic complications in the perioperative and short-term period. Although patients with radiographic evidence of mild stenosis remained symptom free at 2 years from surgery, it will be important in future studies to investigate medium- and long-term patency rates of the cannulated innominate artery.

**Conflict of Interest Statement**

The authors reported no conflicts of interest.

The Journal policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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**Key Words:** aortic reconstruction, congenital, innominate cannulation, neonate, Norwood