A Retrospective Cohort Study of Paediatric Patients Undergoing Percutaneous Vascular Procedures

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BACKGROUND

Thrombotic cardiovascular events are potential serious complications of percutaneous interventions among paediatric patients, particularly among neonates who undergo palliative procedures for congenital heart disease (CHD) [1-5]. However, **paediatric patients who undergo percutaneous vascular procedures are not well-characterised** in terms of their number, demographic and clinical characteristics, clinical diagnoses, and specific procedures received.

OBJECTIVES

This **retrospective population-based cohort study** aimed to quantify and describe:

- **Cohort 1:** paediatric patients (<18 years) undergoing diagnostic or therapeutic percutaneous vascular procedures in England.
- **Sub-cohort 1:** neonates and infants (<1 year) undergoing patent ductus arteriosus (PDA) stent and systemic-to-pulmonary artery shunt procedures in England.

METHODS

This study used data from the **Hospital Episode Statistics (HES) database**, which contains data from all National Health Service hospitals in England and covers approximately 82% of the English population [6-7].

Patients in both study cohorts were identified in HES between **April 2016 and February 2022**, as this was the most recently available data. Patients were included if they had at least one record of receiving a relevant procedure while <18 years old (cohort 1) or <1 year old (sub-cohort 1).

For each study cohort, the following information was reported:

- **Number of patients** identified
- **Demographic and clinical characteristics**
- **Procedures recorded** during the study period
- **Clinical diagnoses recorded** during the study period

RESULTS

58,732 paediatric patients were identified in cohort 1, and 1,354 neonates and infants were identified in sub-cohort 1; selected characteristics are presented in **Figures 1 – 2**. **Mortality in sub-cohort 1 was nearly 4x higher than in cohort 1 during the study period** (**Figure 3**).

Figure 1: Distribution of number of procedures recorded per patient during the study period in each of the study cohorts.

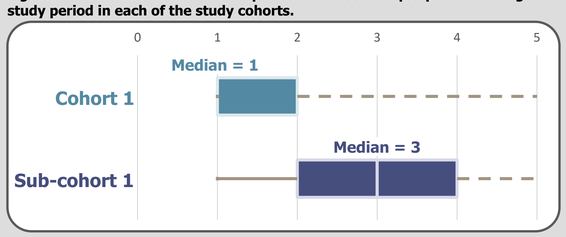


Figure 2: Distribution of average duration of hospital stay (days) for each of the study cohorts.

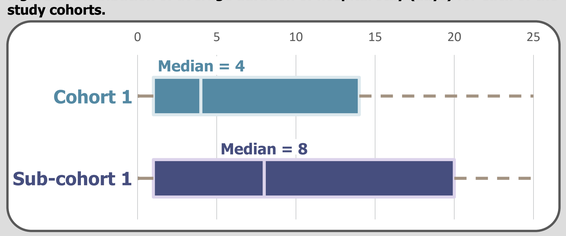
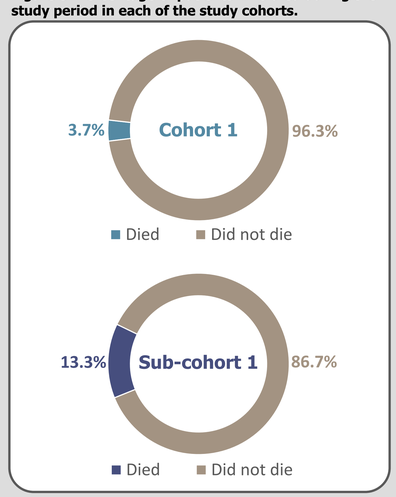


Figure 3: Percentage of patients who died during the study period in each of the study cohorts.



Patients in cohort 1 received 88,987 procedures during the study period (15,040 per year), with diagnostic procedures on the venous side being the most common. **Patients in sub-cohort 1 received 4,133 procedures during the study period (699 per year), with therapeutic procedures on the arterial side being the most common** (**Table 1**).

Table 1: Five most common procedures recorded among patients in each of the study cohorts.

	Procedure	D / T	A / V	N (%)
Cohort 1	**Total number of procedures**			**88,987** (100.0%)
	Insertion of central catheter	**D**	**V**	33,820 (38.0%)
	Monitoring of venous pressure	**D**	**V**	6,632 (7.5%)
	Monitoring of arterial pressure	D	A	5,189 (5.8%)
	Insertion of subcutaneous port	T	V	5,168 (5.8%)
	Cannulation of artery	T	A	3,555 (4.0%)
Sub-cohort 1	**Total number of procedures**			**4,133** (100.0%)
	Vena cava-pulmonary anastomosis	**T**	**A**	681 (16.5%)
	PDA stent	T	V	287 (6.9%)
	Insertion of central catheter	D	V	269 (6.5%)
	Systemic-to-pulmonary artery shunt	**T**	**A**	246 (6.0%)
	Right modified Blalock-Taussig shunt	**T**	**A**	222 (5.4%)

D: diagnostic; T: therapeutic; A: arterial; V: venous.

10,714 patients (18.2%) in cohort 1 and **1,332 patients (98.4%) in sub-cohort 1 received a diagnosis of cyanotic or severe CHD during the study period**.

CONCLUSIONS

Many paediatric patients in England undergo diagnostic and/or therapeutic percutaneous vascular procedures each year.

Neonates and infants who receive PDA stents or systemic-to-pulmonary artery shunts for cyanotic or severe CHD are a small sub-population that require more invasive interventions, spend longer in hospital, and suffer increased mortality.

DISCUSSION & FUTURE WORK

The elevated risks associated with percutaneous arterial procedures among neonates and infants who undergo palliative procedures for CHD may not be adequately mitigated by available therapies. This suggests a potentially **unmet medical need**, for which more research would be beneficial.

REFERENCES

1. Vargas D, et al. Cangrelor PK/PD analysis in post-operative neonatal cardiac patients at risk for thrombosis. Journal of Thrombosis and Haemostasis. 2021;19(1):202-11.

2. Fenton KN, et al. Interim mortality in infants with systemic-to–pulmonary artery shunts. The Annals of Thoracic Surgery. 2003 Jul 1;76(1):152-6.

3. Monagle P. Thrombosis in children with BT shunts, Glenns and Fontans. Progress in Pediatric Cardiology. 2005 Dec 1;21(1):17-21.

4. Agarwal A, et al. Incidence and Management of Thrombotic and Thromboembolic Complications Following the Norwood Procedure: A Systematic Review. Clinical and Applied Thrombosis/Hematosis. 2017 Nov;23(8):911-21.

5. Kaza EA, et al. P2Y12 Receptor Function and Response to Cangrelor in Neonates With Cyanotic Congenital Heart Disease. JACC: Basic to Translational Science. 2017 Aug;2(4):465-76.

6. NHS Digital [Internet]. 2023. Hospital Episode Statistics (HES). Available from: https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/hospital-episode-statistics

7. Boyd A, et al. Understanding Hospital Episode Statistics (HES) [Internet]. London, UK; (CLOSER: The home of longitudinal research). Available from: https://www.closer.ac.uk/wp-content/uploads/CLOSER-resource-understanding-hospital-episode-statistics-2018.pdf

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