Early morbidities following paediatric cardiac surgery: a mixed-methods study

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Scientific summary

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Scientific summary

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Background

Over 5000 paediatric cardiac surgery procedures are performed in the UK each year and early survival has improved to > 98%. Most stakeholders now believe that although 30-day survival remains an important safety measure, it is not discriminatory enough as an outcome measure for teams seeking to improve care and for families who wish to know what to expect after surgery.

Aims

The research aims as stated in the original study protocol were to identify which surgical morbidities present the greatest burden on patients and health services following paediatric cardiac surgery and to establish how they should be routinely monitored.

Objectives

The objectives that were stated in the original study protocol as required to achieve these aims were to:

- identify the key surgical morbidities following paediatric heart surgery, taking into account views from patients, carers, psychologists, nurses and clinicians, that together capture important aspects of the clinical and health economic burden
- develop objective definitions and measurement protocols for the identified morbidities
- determine which morbidities are suitable for routine monitoring and are amenable to service improvement
- validate a tool suitable for routine screening of neurological disability perioperatively
- measure the incidence of defined morbidities in the UK patient population and in subgroups defined by case complexity
- evaluate the impact of defined morbidities on quality of life and estimate their clinical and health economic burden
- develop and pilot sustainable methods for collection and feedback of surgical morbidity data for use in future quality assurance and for patient and carer information.

Design and setting

Our multidisciplinary mixed-methods study took place over 52 months, across five UK paediatric cardiac surgery centres that care for half of all patients nationally.

Participants

The participants were all children aged < 17 years with congenital heart disease.

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Methods

We reviewed existing literature, ran three family focus groups and undertook a family online discussion forum moderated by the Children's Heart Federation (a user group). These data were subjected to thematic analysis. A multidisciplinary group with patient and carer involvement then ranked and selected a list of nine key morbidities, using the nominal group technique and secret voting. This 'selection panel' was informed by clinical views on definitions and feasibility of routine monitoring provided by an independent 'definition panel'.

We validated a new, nurse-administered early warning tool for assessing preoperative and postoperative child development, called the brief developmental assessment, by testing this among 1200 children.

We measured morbidity incidence in 3090 consecutive surgical admissions over 21 months and explored the relationship between risk factors and morbidities. We measured impact of morbidities for 6 months in 666 children, of whom 340 (51%) had at least one morbidity. Impact was evaluated based on the:

- quality of life and psychological burden on children and parents using age-specific measures
- days at home by 6 months (as an additional measure of disruption to family life)
- NHS costs, including further interventions and hospitalisations, and costs borne by families.

We developed and piloted methods suitable for routine monitoring of morbidity by centres, and co-developed new patient information about morbidities with parents and user groups.

Results

Selection and definition of morbidity

Families and clinicians prioritised overlapping but also different morbidities, leading to a final selected and defined list of acute neurological event, unplanned reoperation, feeding problems, renal replacement therapy, major adverse events, extracorporeal life support, necrotising enterocolitis, post-surgical infection and prolonged pleural effusion or chylothorax.

We considered children with more than one of these events separately as 'multiple morbidity'. Children who needed extracorporeal life support were considered as having the morbidity of extracorporeal life support as standalone morbidity, while recognising that this is a very severe event which nearly always occurs with other morbidities.

Based on the selection and definition meetings and our qualitative analysis of focus groups and online forum data, we found some divergence between the views of clinicians and families about the fundamental issue of what the important morbidities linked to paediatric cardiac surgery are. Health professionals tended to prioritise clearly clinical issues related to the heart (use of extracorporeal life support and reoperation), whereas parents placed greater emphasis on holistic outcomes for their child (feeding, child development and communication).

Incidence morbidity

From prospective assessment of 3090 consecutive paediatric cardiac surgery procedure-related admissions in the five participating centres, we found that 2415 (78.2%) of procedures had no morbidities, 478 (15.4%) procedures had one single morbidity, including extracorporeal life support, and 197 (6.4%) procedures had multiple morbidity excluding extracorporeal life support.

Patients with any of the morbidities had a 6-month survival of 86.5% compared with 99.1% for patients with no morbidity. The 6-month survival was lowest in extracorporeal life support patients (50%), whereas it was 82.9% in those with multiple morbidity and 95.2% in patients with single morbidities other than extracorporeal life support.

Procedures with any morbidity led to a median postoperative hospital stay of 24 (interquartile range 15–42) days compared with 8 (interquartile range 5–13) days with no morbidity. The postoperative hospital stay was longest with extracorporeal life support, at 43 (interquartile range 20–84) days; it was 35 (interquartile range 22–56) days with multiple morbidity and 20 (interquartile range 13–31) days for patients with single morbidities other than extracorporeal life support.

Significant risk factors for morbidity

Multivariable analysis indicated that young age was an important risk factor for the occurrence of any morbidity, with an adjusted odds ratio for neonates of 5.26 (95% confidence interval 3.90 to 7.09), as was the more complex cardiac diagnosis group, with an adjusted odds ratio for the most complex conditions of 2.14 (95% confidence interval 1.41 to 3.24) and prolonged bypass time in excess of 90 minutes, which had an adjusted odds ratio of 2.8 (95% confidence interval 1.67 to 3.12). A palliative or staged procedure increased the chance of a morbidity, as did the related condition of a functionally univentricular heart. There was some contribution from severity of illness factors, such as pre-procedure mechanical ventilation or shock. Factors that were less influential, although significant, were a child being underweight or having acquired comorbidity, congenital comorbidity and additional cardiac risk factors.

Impact of morbidity

Data on 666 children contributed to the impact study; of these children, 19 had died by 6 weeks and 39 had died by 6 months post operation.

Quality-of-life impact

Quality-of-life impact was assessed based on the responses from 478 and 403 children at the two time points of 6 weeks and 6 months, respectively. The greatest impact was seen on physical quality-of-life scores for all patient groups, and total scores were significantly lower at the 6-week time point (e.g. patients with any morbidity scored, on average, 5.2 points lower). At the 6-month mark, patients with most types of morbidity had comparable quality-of-life scores with those of patients without morbidity, except patients with multiple morbidity, who still had significantly lower scores. Extracorporeal life support patients also had a clinically important score reduction at 6 months, which did not reach statistical significance.

Days at home by 6 months

The outcome of days at home by 6 months was based on data from 662 children. All morbidities except renal support had a statistically significant reduction in days at home by 6 months. Again, the most severely affected were extracorporeal life support patients, who had an adjusted median reduction in days at home of 114.7 (interquartile range 76.4–153.1) days and multiple morbidities with minus 21.8 (interquartile range 15.5–28.1) days.

Health economic impact

Health economic data were derived from multiple sources, with differing levels of missing data by source: these are stated in the report. Patients with single and multiple morbidities were significantly associated with higher hospital resource use and costs than patients with no morbidities. Extracorporeal life support and multiple morbidities had a substantial impact: unplanned reintervention, feeding morbidities, renal support, necrotising enterocolitis and prolonged pleural effusion were also associated with significantly higher costs. Extracorporeal life support and multiple morbidities were associated with significantly lower quality-adjusted life-years.

Neurological and developmental surveillance and follow-up

The brief developmental assessment

The brief developmental assessment was valid in children aged between 4 months and 5 years, but not in the youngest babies or 5- to 17-year-olds.

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Neurodevelopmental outcomes

We note that, in the selection work, neurodevelopmental morbidities came up as the most important morbidity, affecting children with congenital heart disease across all stakeholders. Nonetheless, postoperative acute neurological event had a rate of 0.5% as a single event and 2.1% in combination with other morbidities. This low acute neurological event rate may be reviewed in the context of the brief developmental assessment validation study, in which we assessed a representative sample of children with congenital heart disease using validated neurodevelopmental tests against which the brief developmental assessment was compared. In the sample of 400 children between the ages of 15 months and 5 years, which is an age band where developmental tests are more reliable than at a very young age band where they are less reliable, we found that the Mullen Scales of Early Learning result was more than 2 standard deviations below the normative mean in between 17% and 21%.

Feeding back to stakeholders about morbidity

Co-developed parent information

We used study data collected during the course of the morbidity project to co-develop parent and carer information resources. To date, this has been focused predominantly on showing what the morbidities are and how their incidence and the length of stay may vary based on the complexity of the child's condition. Parents told us that it helps to know, first, that they are not alone in facing a complication; second, that clinical teams have seen complications before and know how to deal with them; and, third, that it is better as a parent to 'be prepared'. Furthermore, they indicated that information about impact, such as nearly all children who experience a complication and recover, will have a similar quality of life to children who did not experience a complication by the 6-month mark, was very useful to know.

Quality assurance

In centres

Within the scope of this project a new Excel® tool (Microsoft Corporation, Redmond, WA, USA) has been developed and piloted that enables clinical teams to benchmark and report the local rates of morbidities with a quality assurance goal, such as in a mortality and morbidity conference.

National audit

Over the course of the project, we have kept in close contact with the National Congenital Heart Diseases Audit and the Clinical Reference Group for congenital heart disease services. The National Congenital Heart Diseases Audit has already started to collect postoperative morbidities within the nationally mandated data set, using the definitions that we developed. The first centre-specific results were reported by the national audit in 2019.

Limitations

As with any study, the results and conclusions are reliant on the quality of the data. We used a range of strategies to check and clean our data and the information from hospital-based data sources was of high quality. The greatest amount of missing data were within the family cost questionnaire responses.

Measures that are defined by a treatment rather than a condition, such as 'renal support' or feeding problems based on 'presence of a feeding tube', although pragmatic, are also problematic and may not capture the morbidity perfectly.

Monitoring morbidity is more complex than monitoring mortality, and hence this activity requires resources and clinician buy-in.

Conclusions

At the end of our project we are even more certain than when we started that morbidity is a better measure of paediatric cardiac surgery outcome than early mortality. We are very proud of the prospective data we have collected during this study, which, to our knowledge, is unique worldwide.

We note that the length of stay and mortality outcomes within the population of patients who did not experience any morbidities were excellent: their survival at 6 months post operation was 99.1% and their median length of stay was 8 days, and this leads us to believe that the morbidities we selected do capture most of the complication-related adverse outcomes for this context.

Based on the measures of impact that we studied, extracorporeal life support and multiple morbidities are particularly important adverse outcomes: this should be considered by centres and the national audit going forwards.

Patient families have consistently told us that outcomes affecting the child as a whole over the medium or longer term are very important to them. However, these morbidities, such as feeding problems and developmental difficulties, are the most complicated and problematic outcomes to capture.

Future practice and research

The measurement and monitoring of morbidity is inherently complex and there are logistic difficulties in taking forward some of the morbidity measures. It was noted that, in particular, feeding problems are difficult to capture, although these were considered important by families and hence there is strong motivation to explore these further. Additional research may help determine the best way to alleviate the impact of feeding problems in congenital heart disease.

Our measure of renal failure was the need for renal support, and this may not be the optimal method to capture this morbidity. Further research may help us to understand the best approach to manage postoperative renal injury in congenital heart disease.

Since undertaking the brief developmental assessment validation study, we have completed a Delphi survey in three rounds to establish consensus as to the process for evaluation of suspected neurodevelopmental abnormalities in children with congenital heart disease and a secondary analysis of our study data to explore how many children with low scores on gold-standard testing were under appropriate child development services. We suggest that there is a pressing need to take this topic forwards with changes to the follow-up pathway for neurodevelopment in children who have congenital heart disease. We suggest that further research is needed to explore at what time points in the patient pathway should the brief developmental assessment be used, what actions should be taken when the brief developmental assessment is amber or red and whether or not use of the brief developmental assessment is effective.

It is hoped that the Excel tool we have developed for local morbidity monitoring by centres has the future potential to supplement the previously developed software for monitoring of 30-day mortality rates. Although straightforward to use, resources are required for morbidity monitoring to be implemented.

We believe that the developed parent information resources represent a major step forwards; however, they would be optimally backed up by an evaluation study and a plan for their dissemination.

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