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Original Article

The application of a simplified system of criterions for audit to improve paediatric cardiologic and paediatric cardiac surgical care: evidence from a regional approach in Hungary

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Abstract *Aims:* To evaluate the quality of cardiac and surgical care provided for children with congenital cardiac malformations in the eastern county of Hungary. *Methods:* We used the method of clinical audit based in selection of criterions, developing five such criterions concerning timely diagnosis, access to treatment, and outcome. To examine compliance with these criterions, we analysed retrospectively the routine data relating to children living in Hajdu-Bihar County. The period of observation lasted from January, 1994, until December, 2001, and was divided into two epochs in order to evaluate any changes over time. *Results:* In the first epoch, 28 infants, representing 0.1% of all newborns, died of congenital cardiac disease, with one of the malformations being recognised post mortem. In the second epoch, 21 infants died, representing 0.09% of newborns. In this group, each malformation was diagnosed before death. In each period, 6 infants died without having undergone cardiac surgery, and having no other non-cardiac disease. The overall postoperative mortality was 9.2% for the first period, and 4.6% for the second. The number of patients waiting for non-urgent repair had reduced significantly by the end of the second epoch. *Conclusions:* The results show that the timely diagnosis of congenital cardiac malformations is in line with accepted international standards. Conversely, the access to invasive treatment was limited over the period of observation, albeit that the waiting list was reduced significantly by the end of the second epoch. The postoperative mortality for those suffering congenital cardiac malformations is also comparable with international standards, except for mortality during infancy for treatment of complex anomalies. Our audit highlights the need for surgical repair of the more complex malformations during infancy.

Keywords: Clinical audit; infant mortality; waiting lists; congenital heart disease; Hungary

Although the prognosis of children with congenital cardiac malformations has never been so favourable, significant deficiencies still occur during their treatment.[1–3] Up to now, to the best of our knowledge, there is no published data in the English language about the quality of care provided to such children born in Hungary. The aim of our study, therefore, was critically to evaluate the care provided with children born with cardiac malformations in Hajdu-Bihar County, this being one of the 19 counties of Hungary, and having half a million inhabitants. We used the method of clinical audit based on selected criterions to answer the following questions:

- Are congenital cardiac malformations diagnosed in timely fashion?
- Are the access and quality of invasive procedures, including surgery and interventional catheterisation, appropriate?

Methods

Audit is the process of critically and systematically assessing our own professional activities with a commitment to improving personal performance and, ultimately, the quality and/or cost-effectiveness of care

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provided for our patients.[4] Creating proper criterions and standards is the most critical step in this process. Criterions have been defined as "systematically developed statements that can be used to assess the appropriateness of health care decisions, services and outcomes".[5] On the other hand, a standard is "the percentage of events that should comply with the criterion".[6]

Selecting criterions for audit

In order to identify measurable and scientifically sound criterions of acceptable practice, we reviewed the process of care according to the methodology used by the British Review Group,[7] and developed five measurable criterions concerning diagnosis, treatment and outcome:

- Infants must not die of unrecognised heart diseases.
- The number of patients on the waiting list should not be more than the capacity for surgical or catheter intervention over one year.
- Non-urgent cases should not wait for the procedure longer than one year.
- Postoperative and post-interventional catheter mortality must be acceptably low.
- Unoperated "isolated" congenital cardiac disease in infants without associated serious non-cardiac illness must not be the cause of death in infancy.

A measurable criterion of timely diagnosis can be that no infant should die of unrecognised cardiac disease, because in Hungary each infant who died must have an autopsy. The term "infant" was used to describe children under the age of one year. There is a well established network of district nurses who routinely collect the data for infants dying under the age of one year. As a result, data on infant mortality caused by cardiac disease could be collected reliably. The first phase of the process of care fails if the disease remains unrecognised.

The measurable criterion for the second phase of the process of care, which lasts from the diagnosis to the eventual outcome, was the waiting list for the surgical procedure or the interventional catheterisation in case of non-urgent conditions. Long waiting lists indicate limited access to invasive care. The number of patients on a waiting list at the end of each epoch should not be more than one fourth of the repairs carried out over a period of 4 years, otherwise capacity does not meet the demand. Waiting lists are very difficult to define, partly because the optimal age for a procedure varies. Moreover, surgical policy has changed over time, making the definition of criterions for inclusion more difficult. Parental decisions might have influenced the waiting time considerably, especially in the case of transcatheter closure of interatrial communications. In spite of these limitations, we considered it important to investigate the waiting periods. An infant or a child was considered to be on a waiting list when his or her age and general condition was eligible for the procedure required.

The effectiveness of invasive treatment was measured by the postoperative and postcatheter mortality, and by the mortality of unoperated "isolated" congenital cardiac disease. The death was considered to be "postoperative" or "post-catheter" if it occurred within 30 days after the surgical or interventional catheter procedure.

Concerning outcome, the perioperative mortality should not be higher than the unavoidable risk. On the other hand, there was insufficient evidence about a sensible threshold in Hungary. Because of this, we used data from the international literature, taking a postoperative mortality of 8.1% as a benchmark. Moller et al.[8] reported an overall postoperative mortality of 8.1%, and a postoperative infant mortality of 8.7%, for a consortium reported in the United States of America in 1994. It is difficult to determine a "true" mortality rate for the 1990s for paediatric cardiac catheterisation because of the various criterions used for collecting population data. We accepted 0.9% as a benchmark for mortality for paediatric cardiac catheterisation, based on the study by Gibbs et al.,[9] who reported 0.9% mortality within 30 days after therapeutic catheterisation in 2000.

Except for very rare cases, a surgical solution is available nowadays for nearly all congenital cardiac malformations. Because of this, no infant should die of unoperated "isolated" congenital heart disease. We selected this as our fifth criterion for the study. A congenital cardiac malformation was considered "isolated" if the patient had no other non-cardiac malformation that could alter the survival. The calculation of standards for the criterions, and their expected value, are shown in Table 1.

Population studied

We included all children who were residents of Hajdu-Bihar County, Hungary. The county has approximately 541,000 inhabitants, in whom "significant" congenital cardiac disease could be verified during the eight years of our period of study. The age of children varied between newborn and 18 years. We considered a cardiac lesion to be significant if surgery or interventional catheterisation was indicated, or if death occurred because of cardiac disease in the absence of any intervention. Premature babies with symptomatic persistent patency of the arterial duct were excluded. There was minimal migration from our chosen region, so we assumed that the loss to follow-up was negligible.

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The service for paediatric cardiology

The care for children with cardiac disease was provided by several participants in the region. Obstetricians and echo technicians provided ultrasonic screening for each fetus. If congenital cardiac disease was suspected, the pregnant woman was referred to a specialist in fetal echocardiography who was available outside the region, based in Budapest. Neonates, infants, and children with suspected cardiac disease were referred to one of the four full-time paediatric cardiologists working in the region.

Paediatric cardiologists, working as the part of the paediatric cardiological network have the skill of diagnosing congenital cardiac lesions using non-invasive methods, apart from fetal echocardiography, and they follow-up patients after surgical repair. Diagnostic catheterisation and surgical repair were available for children over the age of three in the local tertiary hospital. During the period of study, patients requiring intervention under the age of three were sent to the national cardiac centre in Budapest, apart from 4 children, of whom 2 underwent surgery in the third Hungarian cardiac centre at Szeged, and two were referred for surgical treatment in the United States of America. As a result, our study does not reflect the performance of a single centre, but rather the quality of care provided to a region.

Collection of data

The period of study was 8 years, lasting from 1st January, 1994, until 31st December, 2001. The period was divided into two epochs, from 1994 through 1997, and 1998 through 2001, in order to evaluate any changes over time. Data was collected retrospectively.

Since no single reliable database was available, multiple databases were used to collect all the necessary data. We collected data from the Hungarian Central Statistical Office, the three paediatric cardiac services working in the region, the two surgical centres where patients were referred, the reports of the district nurses on infant mortality, and the departments of pathologies where any of the patients underwent an autopsy. In Hungary, each infant who dies must have an autopsy. We matched the data collected from different databases, using the national insurance number as the common and unique identifier. Any differences were examined individually by one of the members of the audit team. In addition, we were able to check medical and autopsy records in the case of any discrepancy between the various databases. These records were considered as the final arbiter of accuracy.

Statistical analysis

Two-Tailed Fisher's Exact Test was used to prove any statistically significant changes over time.

Results

The basic demographic and cardiac data of the population studied are shown in Table 2. The infant mortality reduced remarkably, from 0.98% to 0.64% in the second period. On the other hand, deaths of infants due to congenital cardiac diseases showed only a slight, and insignificant, decrease, from 0.10% to 0.09%.

The summary of compliance with criterions for treatment is shown in Table 3.

In the first epoch, we identified only one case where congenital cardiac disease was recognised after death, this being a patient with discordant ventriculo-arterial but concordant atrioventricular connections, in other words, transposition. In the second epoch, no infant died of unrecognised cardiac disease.

In the first epoch 11, and in the second epoch 10, significant "isolated" cardiac lesions were diagnosed by pre-natal screening. In the first epoch 4, while in the second 3, of the pregnancies were terminated because of the cardiac disease. In spite of the pre-natal diagnosis, only three of the 21 fetuses survived beyond the period of infancy.

Table 4 shows the patients waiting for correction at the end of each epoch. The total number of patients

Table 1. Standards for criterions and their expected value.

Criterion	Calculation of standard	Expected value of standard %
Deaths due to unrecognized cardiac disease under the age of one	Unrecognized cardiac deaths/all cardiac infant deaths	0
Patients on a waiting list at the end of the epoch	Patients on a waiting list/repairs during a four year period	<25
Patients on a waiting list longer than one year	Waiting longer than one year/repairs during a four year period	0
Overall postoperative mortality	Deaths within 30 days/all surgical interventions	<8.1
Postoperative infant mortality	Infant deaths within 30 days/infant surgical interventions	<8.7
Therapeutic catheterisation mortality	Deaths within 30 days/all therapeutic catheter interventions	<0.9
Deaths due to unoperated "isolated" heart disease in infancy	Unoperated fatal "isolated" cardiac disease/all cardiac infant deaths	0

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Table 2. Demographic and cardiac data of Hajdu-Bihar County, Hungary.

Time period	1994–1997	1998–2001
Number of births	26932	23768
Deaths under age of one	264	152
Infant mortality (%)	0.98	0.64
Infant deaths during infancy due to congenital cardiac disease	28	21
Infant mortality due to congenital cardiac disease (%)	0.10	0.09
Deaths due to unoperated "isolated" cardiac disease in infancy	6	6
Patients on a waiting list at the end of the epoch		
All ages	29	12
Under the age of one	2	1
Over the age of one	27	11
Patients on a waiting list longer than one year	11	6*
Cardiac surgery (bypass and non-bypass)		
All ages (0–18 years)	109	108
Neonate (0–30 days)	6	6
Infant (30–365 days)	26	19
Child (1–18 years)	77	83
Postoperative deaths within 30 days		
All ages	10	5
Neonate	0	2
Infant	5	1
Child	5	2
Catheter intervention		
All ages	12	25
Neonate	2	4
Infant	7	5
Child	3	16
Post catheter deaths within 30 days of cardiac catheterisation		
All ages	0	1
Neonate	0	1

*Five out of six patients were waiting for the advent of transcatheter closure of atrial septal defect

waiting for elective surgery or therapeutic catheterisation was 29 at the end of the first epoch, and had reduced to 12 by the end of the second epoch. The change proved to be statistically significant, with p equal to 0.01. The number of patients waiting for more than one year reduced from 11 to 6. At the end of the second epoch, five out of six patients waiting for more than one year had interatrial communications across the oval fossa. The reason for this was that the transcatheter closure of such defects became a procedure routinely available at the end of the second epoch, and many parents or patients decided to wait for the advent of this new procedure. Besides the 5 patients awaiting such interventional closure, a 6-year-old child was waiting for more than one year for construction of a total cavopulmonary connection. If only the latter patient is classified as waiting for more than

Table 4. The number of patients on waiting lists at the end of the epochs.

Diagnosis	Epoch 1 (1994–97)	Epoch 2 (1998–2001)
Atrial septal defect	12	5 (each patient waiting for transcatheter closure for more than one year)
Ventricular septal defect	8	4
Tetralogy of Fallot	3	1
Functionally univentricular heart	2	1 (waiting for total cavopulmonary connection for more than one year)
Atrioventricular septal defect	2	0
Patency of the arterial duct	1	1
Fixed subaortic stenosis	1	0
Total	29	12

Table 3. Actual performance of the care of children with congenital cardiac disease.

Standard	Expected value of standard %	Performance in epoch 1 (1994–97) %	Performance in epoch 2 (1998–2001) %	p
Unrecognised cardiac deaths/all cardiac infant deaths	0	3	0	
Patients on a waiting list/repairs during a four years period	<25	24	9.2	0.01
Patients waiting longer than one year/repairs during a four year period	0	9.1	4.6	0.2
Deaths within 30 days/all surgical procedures	<8.1	9.2	4.6	0.31
Postoperative infant deaths within 30 days/all surgical procedures under the age of one	<8.7	19.2	5.3	0.38
Deaths within 30 days/all therapeutic catheter interventions	<0.9	0	0.04	
Unoperated fatal isolated heart disease/all cardiac infant deaths	0	21.4	28.6	

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one year, then the reduction in the number of patients waiting for more than one year is statistically significant, with p equal to 0.005.

Tables 5 and 6 show the numbers of surgical and therapeutic catheter interventions over the period of study. In the first epoch, 109 surgical operations, and 12 catheter interventions, were performed. Of these, 78 surgical procedures were carried out in Budapest, 31 in the University Hospital of Debrecen, while two patients underwent surgery in the third Hungarian cardiac centre at Szeged, and two in New York. Of the catheter interventions, 10 occurred in Budapest, and 2 in Debrecen.

In the second epoch, only 2 centres were involved, with 74 surgical procedures performed in Budapest, and 34 in Debrecen. All of the 25 catheter interventions were performed in Budapest.

The overall mortality was lower in the second period compared to the first. In the first epoch, among 121 invasive procedures 10 had a fatal outcome, while in the second epoch there were 133 procedures, 6 patients died within 30 days of their procedure. The postoperative mortality, including interventional catheterisation, reduced from 9.2% to 4.6%, but the reduction did not prove statistically significant (p equal to 0.31). Although the postoperative mortality for procedures performed during the first year of life also reduced considerably, from 19.2% in the first to 5.3% in the second epoch, owing to the small numbers, the reduction was not statistically significant. Only one death, of a neonate, occurred after therapeutic catheterisation during the whole period of study.

During the period of the first epoch, 9 died of isolated heart disease, with this figure being 10 in the

Table 5. Surgical and catheter interventional procedures under the age of one year.

Type of procedure	Epoch 1 (1994–97)	Epoch 2 (1998–2001)
Pulmonary banding of pulmonary trunk	6	0
Blalock–Taussig shunt	5	3
Closure of ventricular septal defect	5	6
Surgical repair of the coarctation of the aorta	4	4
Ligation of patent arterial duct	4	1
Coil closure of patent arterial duct	1	3
Rashkind septostomy	3	2
Surgical repair of valvar aortic stenosis	3	0
Balloon dilatation of valvar aortic stenosis	2	2
Arterial switch operation	1	2
Repair of atrioventricular septal defect	1	3
Other	6	10
Total	41	34

Table 6. Surgical and catheter interventional procedures over the age of one year.

Type of procedure	Epoch 1 (1994–97)	Epoch 2 (1998–2001)
Surgical closure of atrial septal defect	25	18
Transcatheter closure of atrial septal defect	0	1
Surgical closure of ventricular septal defect	20	17
Correction of tetralogy of Fallot	11	12
Reoperation of tetralogy of Fallot	0	3
Ligation of patent arterial duct	4	2
Coil closure of patent arterial duct	2	4
Balloon dilatation of the coarctation of the aorta	4	4
Atrioventricular septal defect repair	1	6
Senning operation	3	0
Total cavopulmonary connection	3	0
Bidirectional Glenn	1	2
Ross procedure	0	3
Fixed subaortic stenosis	0	3
Balloon dilatation of valvar aortic stenosis	1	3
Balloon dilatation of valvar pulmonary stenosis	1	3
Blalock-Taussig or central shunt	0	3
Other	5	13
Total	80	97

Table 7. Infant deaths owing to "isolated" cardiac diseases with or without intervention.

Diagnosis	Epoch 1 (1994–97)	Epoch 2 (1998–2001)
Hypoplastic left heart syndrome	2	3
Valvar aortic stenosis	1 (after surgery)	1 (after balloon dilatation)
Pulmonary atresia with intact ventricular septum	1 (after surgery)	
Pulmonary atresia with functionally univentricular heart		1
Common arterial trunk	1	1
Discordant ventriculo-arterial connections	1	1 (after surgery)
Pulmonary valvar agenesis	1	
Atrioventricular septal defect	1 (after surgery)	
Functionally univentricular heart with coarctation of the aorta		1 (after surgery)
Aortic arch hypoplasia	1	
Pulmonary branch agenesis of pulmonary arteries with pulmonary hypertension		1
Ventricular septal defect		1 (after surgery)
Total	9	10

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second epoch (Table 7). Of these, 6 had neither surgery nor therapeutic catheterisation, partly because during the period in question there was no surgical therapeutic option for such complex malformations as hypoplasia of the left heart and certain other similar lesions (Table 4). We can conclude, therefore, that the fifth audit criterion was not met during the period of our study.

Discussion

Our study represents a criterion-based clinical audit of paediatric cardiac care provided to children living in Hajdu-Bihar County of Hungary, 5 criterions being used concerning diagnosis, access, and outcome of care. We consider our data reliable because of the thorough nature of the collection of data, and the cross-match of several databases. The audit generated new information that can be used as benchmark for further evaluations.

The waiting list for surgical repair decreased significantly, partly due to the increased capacity, the technological change, and the declining demand. While a new paediatric cardiac centre was opened in 1999, increasing the capacity of surgical and interventional cardiac procedures, the birth rate declined significantly. Among the patients waiting for more than one year for repair, almost all had an interatrial communication within the oval fossa, a so-called "secundum" type of defect, these patients waiting for transcatheter closure of the defect, a procedure which has become routine in Hungary since 2001. At present, no such patient with an atrial septal defect is on a waiting list for more than one year.

No remarkable change could be observed in the mortality of patients with complex cardiac malformations. The same number of patients having complex lesions, but not undergoing any intervention, in both epochs indicates that therapeutic strategy did not change during the period of study. It was an elective decision of surgeons and/or the parents not to intervene for certain complex congenital cardiac lesions. In the last 5 years, nonetheless, there has been a trend to offer correction for such more complex cases.

International comparison

We found remarkable differences between our report and reports from other countries in terms of the number of patients who died of unrecognised heart disease. Only one patient died of unrecognised heart disease during the entire period of our investigation in the Hungarian region, whereas other investigators in other countries reported much higher rates of deaths due to unrecognised cardiac disease.[10–12] We assume that errors in measurement cannot explain all the differences. Although the lack of skill in the autopsy diagnosis of congenital cardiac malformations may confound the results, the prevalence at birth of "critical" cardiac diseases is comparable with other epidemiological studies. We assume, therefore, that variance in the systems provided for healthcare between Hungary and the United Kingdom, or the United States of America, should be responsible for most of the differences observed, such as the network of paediatric cardiologists, fetal screening, and policies for discharge.

Fetal screening, which became routine in Hungary, played a role in timely diagnosis, although the majority of cardiac lesions were identified after birth. In addition, the longer stay in hospital in Hungary, offering more time for observation, could have had a positive impact, because early discharge, within the first 2 days, is considered one of the risk factors for cardiac malformations remaining unrecognised.[12] In Hungary, newborns are usually discharged on their fourth day of life. The delayed discharge alone, however, without easy access to outpatient paediatric cardiac examination, would not ensure the timely diagnosis of heart diseases, because, according to Wren et al.,[11] routine neonatal examination fails to detect more than half of babies with cardiac disease. In contrast to other Western European countries, the Hungarian system of healthcare offers easy access to paediatric cardiac services. One of the factors contributing to the favourable results in our region, therefore, could have been that four, full-time, paediatric cardiologists were available during the period of study, providing good access to cardiac evaluations. These cardiologists do not cover the full range of paediatric cardiac procedures, especially invasive techniques, but can provide better care than general paediatricians in case of the assessment of congenital or acquired cardiac diseases.

The perioperative mortality in Hungary was in line with results reported from the United Kingdom and the United States of America. In our region, after having surgical correction or palliation, 9.2% and 4.6% of the patients died within 30 days of the operative procedures during the first and second periods respectively. The severity of the cases selected for correction will obviously alter significantly the outcome, so we performed a sensitivity analysis. Theoretically, if all the infants who died without surgery had undergone correction, the overall mortality after repair would have been between 8.7% and 13.9%, taking the best and worst possibilities, in the first epoch, while in the second epoch, the range would have been 4.4% and 9.6% respectively. On the other hand, in results reported in 1994 from the United States of America, the overall postoperative mortality was 8.1%, and the postoperative mortality for infants was 8.7%.[8] For the United Kingdom, over

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the period 2000 through 2001, Gibbs et al.[9] reported mortalities of 5.1% overall, and 5.5% for infants. Our results, therefore, seem to be similar to those reported from other countries, but it is inevitable that applying different criterions for selection of the most complex cases confounds the comparisons.

Limitation of the study

The methodology we chose has its limitations. None of the current databases concerning the care of children with congenital cardiac malformations proved to be either complete or comprehensive. Likewise, the national vital statistics can be insufficient to measure the quality and performance of paediatric cardiac care in Hungary. Cronk et al.[13] found similar limitations in the United States of America. Moreover, Gibbs et al.[9] found substantial differences in volunteered and centrally tracked mortality in the United Kingdom. Use of the National Insurance Number in Hungary makes it possible to cross-match various databases in a reliable way. Without this unique identifier, this study might not have been feasible. Moreover, the methodology used may not be adaptable in countries without such a unique common identifier.

The results should be interpreted with care, because some of the criterions are based on the international literature, rather than local benchmarks. The generalisability and adaptability of these benchmarks is limited due to the considerable differences in socioeconomic circumstances, financing of healthcare, mechanisms for payment, and demographic composition of the population studied.

Implications for policy-making

We found the criterions used in our study to be simple and measurable, and that the international literature could be used as source of initial benchmarks. Although the chosen criterions do not cover all key aspects of care, they can be used successfully to monitor the quality of paediatric cardiac care at both local and regional levels. Moreover, the methodology can be adopted to design and deliver clinical audits in other fields of medicine in Hungary, and other middle-income countries. The new information generated can be used to inform planning of healthcare, and setting priorities at either district or regional level.

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