Relationship between Caseload and Morbidity and Mortality in Pediatric Cardiac Surgery – A Four Year Experience

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Abstract

Background: The mortality rate associated with congenital heart surgery is apparently related to caseload.

Objective: To determine whether an increase in caseload over the long term at a single center affects management and outcome in children undergoing cardiac surgery.

Methods: Data were collected prospectively over a 4 year period from the computerized registry of the hospital's pediatric intensive care unit. Five parameters were analyzed: age at surgery, type of surgery, preventive measures (open chest), surgery-related and other complications (diaphragm paralysis and acute renal failure, respectively), and mortality. The data of a single-type surgery (arterial switch) were analyzed for bypass time and mechanical ventilation on an annual basis.

Results: The age distribution changed over the years, with more children under 1 year of age (20% newborns) undergoing surgery by the fourth year of the study. The caseload increased from 216 in the first year to 330 in the fourth, with a concomitant decrease in mortality rate from 4.9% to 3.2%. The chest was left open in 3.2% of patients in the first year and in 9.2% in the fourth year. The rate of diaphragm paralysis decreased from 6% to 2.4%. Death due to acute renal failure in patients requiring dialysis decreased from more than 80% in the first 2 years to 36% in the last two. These changes show an improvement but failed to reach statistical significance. Regarding the arterial switch operation, there was a significant improvement in pump time and duration of mechanical ventilation.

Conclusions: The increase in caseload in pediatric cardiac surgery was accompanied by improved management, with a lower complications-related mortality rate. We suggest that for optimal care of children with congenital heart disorders, quality management resources should be concentrated in centers with high caseloads.

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For Editorial see page 521

The last decade has witnessed a change in practice towards early reparative operations for neonates and infants with congenital heart disease [1]. This was made possible by the introduction of modern techniques in cardiac surgery, pediatric cardiology, anesthesia and intensive care, and the establishment of specialized intensive cardiac care units [2].

Studies in adults have shown that patients with cardiac disease have a more favorable outcome when they are treated in hospitals that perform a greater number of heart operations [3–6]. Considering that pediatric cardiac surgery requires a particularly high level of expertise because of the many different types of malformations and the relative rarity of many of them, this finding would be expected in children as well. Indeed, both Jenkins et al. [7] and Hannan et al. [8] reported similar results in comparison studies of hospitals with high and low case volumes of pediatric cardiac operations. However, the specific reasons for the differences in morbidity and mortality were not explored.

In 1995, the Schneider Children's Medical Center of Israel introduced a comprehensive care system for children with cardiac anomalies. A description of the system together with the results after 1 year were reported previously [9]. Since then, the number of heart operations performed at the center has been steadily increasing. The aim of the present study was to determine if an increase in caseload over a relatively long term in a single center is accompanied by changes in patient management, postoperative complications and mortality rates.

Patients and Methods

Data from the computerized database of the Pediatric Cardiac Intensive Care Unit of the Schneider Children's Medical Center were collected prospectively by one of the authors (O.D.). Five parameters were analyzed in the present study: a) age at time of surgery; b) type of surgery – analyzed by complexity, based on the surgical difficulties and the expected postoperative complications [8]; c) preventive measures, i.e., delayed sternum closure (sternum left open at surgery or reopened in the intensive care unit); d) complications, i.e., diaphragm paralysis (on sonography or fluoroscopy), acute renal failure (increase in creatinine level to twice the level before surgery, and need for dialysis (for fluid overload or electrolyte imbalance); and e) in-hospital deaths. The number and ages of the children operated on and the rates for type of surgery, complications and mortality were compared on a yearly basis. One specific type of surgery, arterial switch operation, was analyzed for bypass time and mechanical ventilation.

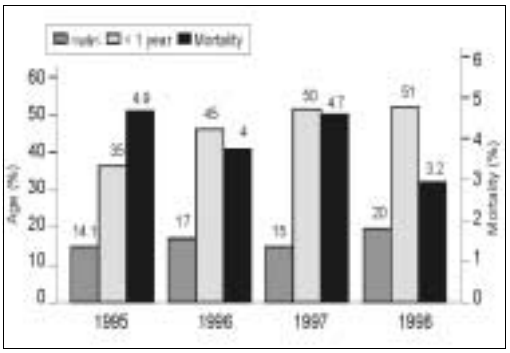

Figure 1. Age distribution and mortality rate by year of children operated for congenital heart disease.

Table 1. Rates and 95% CI of major outcomes in the study population, 1995–1998, and proportion of patients with severe to very severe disease (score 3 to 4) by year

Year	Diaphragm paralysis (%)	Acute renal failure (%)	Dialysis (%)	Mortality from dialysis (%)	Severity score 3 and 4 (%)	95% confidence interval
1995	5.88	3.4	1.96	1.47	34	28–41%
(n=204)	(3.10–10%)	(1.40–6.9%)	(0.5–4.9%)	(0.3–4.2%)		
1996	3.24	5.26	2.02	2.02	27	22–33%
(n=247)	(1.4–6.3%)	(2.8–8.8%)	(0.7–4.7%)	(0.7–4.7%)		
1997	1.46	2.92	2.55	0.73	33	27–39%
(n=274)	(0.4–3.7%)	(1.3–5.7%)	(1–5.2%)	(0.1–2.6%)		
1998	2.4	3.3	1.8	0.6	32	27–37%
(n=330)	(1.23–4.71%)	(1.9–5.87%)	(0.84–3.91%)	(0.17–2.18%)		

Statistical analysis

Distributions of ordinal variables (e.g., severity of disease) were compared using the chi-square test, and 95% confidence interval was calculated according to the formula suggested by Newcombe [10]. Differences in continuous variables by year (e.g., diaphragm paralysis, acute renal failure, dialysis, mortality, pump and ventilation time) were computed by one-way ANOVA. The analyses were conducted with the SPSS for Windows.

Results

During the 4 year period of the study, 1,082 children underwent surgery for congenital heart disease. Figure 1 shows the number of newborns and infants operated on each year and the mortality rates. By the last year, newborns accounted for 20% of the caseload, and infants less than 1 year old for 51%. The mortality rate was 3.2%. The whole caseload increased by 10–15% each successive year, from 216 patients in the first year to 330 in the fourth.

Patient status

No significant differences were found in the proportion of patients with severe and very severe disease (score 3 and 4) over time (P = 0.097), as indicated in Table 1. Nevertheless, the mortality rate decreased, from 4.9% in the first year to 3.2% in the fourth. The overall mortality rate was 4.1%.

The number of sternotomies left open in the operating room increased each year, thereby decreasing the number of emergency sternotomies necessary in the intensive care unit [Figure 2]

The postoperative complications are shown in Table 1. The rate of diaphragm paralysis decreased by more than 50%, from 5.86% to 2.4%, but the difference did not reach statistical significance. The rates of acute renal failure and dialysis remained stable. Mortality rate in the patients who required dialysis decreased from 7 of 8 patients in the first 2 years to 4 of 11 in the last two, but because of the small number of patients the difference did not reach statistical significance. There was also a significant decrease in average pump time (36.39 minutes; confidence interval 3.00–69.78), and ventilation time (31.58 hours, 95%CI 1.77–61.4) from 1996 to 1998. Although both were lower in 1998 than in 1995, the differences were not significant, probably due to the small number of patients in 1995 [Figure 3].

CI = confidence interval

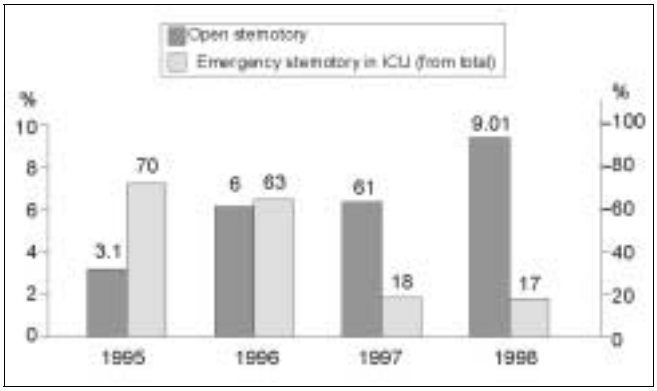

Figure 2. Annual percentage of sternums left open in the operating room and emergency sternotomies in the intensive care unit.

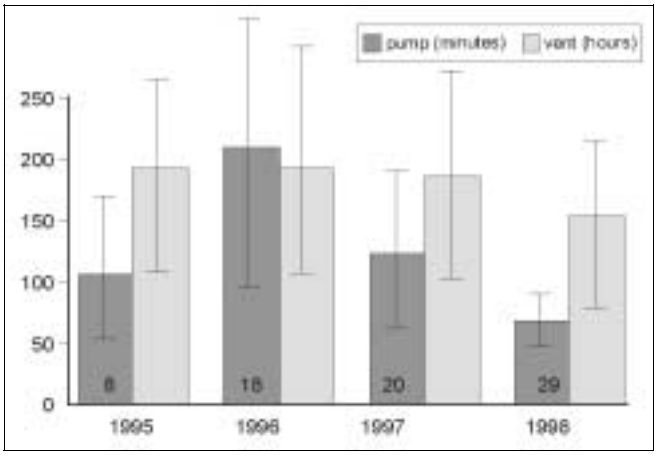

Figure 3. Length of bypass and mechanical ventilation by year for arterial switch operation.

Discussion

In 1995, Jenkins et al. [7] were the first to study the possible relationship between caseload and outcome of congenital heart surgery. They showed that the mortality risk is much lower in

institutions with an annual case volume of more than 300 than in those with a case volume of less than 300. This conclusion was supported by Hannan et al. [8] in a 3 year study involving 7,169 children treated in hospitals with an annual case volume of more or less than 100. These authors noted that after controlling for severity of disease, the respective annual mortality rates of the two groups were 5.95% and 8.26%. Comparison by surgeon caseload yielded similar results: 5.9% vs. 7.56% for more than 75 cases per surgeon per year.

The diverse types of congenital heart malformations warrant a high level of surgical expertise, while the large number of patients affected affords surgeons a wide experience. Both these factors lead to improved patient outcome. Surgical results may also be affected by the level of technology available, type of anesthesia used, and accessibility to specialized pediatric intensive care units and nursing staff. Indeed, we suggest that the findings in the study by Hannan and co-workers [8] may be at least partly explained by the comprehensive infrastructure within which the surgeons with the higher patient volume worked.

Our study is unique in that we followed the change in caseload/postoperative morbidity and mortality over a relatively long period at a single center. A total of 1,082 children underwent cardiac surgery. The caseload increased annually (from 216 the first year to 330 in the fourth), and this increase was accompanied by a change in age distribution. Specifically, by the fourth year, 51% of the children undergoing surgery were less than 1 year old, including 20% neonates. These rates are similar to those reported by major centers in the western world [8]. Mortality decreased by the fourth year to 3.2%, the expected in-hospital rate for centers with more than 300 cases per year [7].

To determine if morbidity played a role in these changes, we examined the rate of diaphragm paralysis. This parameter was selected because it is associated with surgical expertise (causes are cold temperature and surgical trauma) and it also affects the postoperative course (i.e., duration of mechanical ventilation) [11]. We found that the rate of this complication decreased from 6% to 2.4% over the 4 year period (a meaningful albeit not significant change). We suggest that this difference was attributable to the improved skills acquired by the surgeons over the years. The diversity of operations was similar, as shown in Table 1.

All pediatric patients undergoing cardiac surgery receive fluids and inotropic support postoperatively to maintain cardiac output and prevent secondary complications. Cardiac output may also be increased by leaving the sternum open after surgery [12,13]. The approach to open sternotomy is presented in Figure 2. This represents a change in management: the number of sternums left open in the operating room doubled in the second year and tripled in the fourth year. These results are similar to those in the 4 year study of McElhinney et al. [14] where 128 of the 585 affected children were under 1 year old. In the last year of our study, 50% of the patients were less than 1 year old; 9% of the whole sample had open sternotomy, of whom 22% were less than 1 year old. Only 3 of 128 patients required emergency sternotomy [Figure 2].

The proper management of complications is also an important outcome factor. Therefore, we examined the rate of postoperative acute renal failure, which requires a meticulous approach in the intensive care unit for optimal results. We found that the incidence of acute renal failure was similar to that in previous studies [15–18], as was the proportion of dialysis patients. However, although the proportion of patients affected did not change, their mortality rate did, with 7 of 8 patients dying in the first 2 years compared to 4 of 11 in the last two. Even though the difference was not statistically significant, it does represent a major improvement. Since the indications for dialysis (renal failure with fluid overload or change in electrolyte level) were not altered over the years, we attribute the improved outcome to greater experience. The arterial switch operation parameters were collected in order to evaluate a single complicated surgery. More than 50 patients were operated on. The bypass time began to decrease after 3 years, and the duration of ventilation was significantly shorter in the fourth year. Both these parameters are directly influenced by the experience of the operating team.

On the basis of these findings, our conclusions are threefold: a) a higher caseload of pediatric congenital heart disease is associated with a lower rate of complications, b) the management of complications improves with an increase in caseload, and c) the resulting decrease in complications with improved management leads to lower mortality rates. These findings indicate that optimal outcome can be achieved in infants and children with cardiac disease by concentrating state-of-the-art management resources in a few large medical centers.

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