Impact of the International Quality Improvement Collaborative on outcomes after congenital heart surgery: A single center experience in a developing economy

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ABSTRACT

Background: The International Quality Improvement Collaborative (IQIC) for Congenital Heart Surgery in Developing Countries was initiated to decrease mortality and major complications after congenital heart surgery in the developing world. **Objective:** We sought to assess the impact of IQIC on postoperative outcomes after congenital heart surgery at our institution. **Methods:** The key components of the IQIC program included creation of a robust worldwide database on key outcome measures and nurse education on quality driven best practices using telemedicine platforms. We evaluated 1702 consecutive patients ≤18 years undergoing congenital heart surgery in our institute from January 2010-December 2012 using the IQIC database. Preoperative variables included age, gender, weight at surgery and surgical complexity as per the RACHS-1 model. The outcome variables included, in- hospital mortality, duration of ventilation, intensive care unit (ICU) stay, bacterial sepsis and surgical site infection. **Results:** The 1702 patients included 771(45.3%) females. The median age was 8 months (0.03-216) and the median weight was 6.1Kg (1-100). The overall in-hospital mortality was 3.1%, Over the three years there was a significant decline in bacterial sepsis (from 15.1%, to 9.6%, $P < 0.001$), surgical site infection (11.1% to 2.4%, $P < 0.001$) and duration of ICU stay from 114(8-999) hours to 72 (18-999) hours ($P < 0.001$) The decline in mortality from (4.3% to 2.2%) did not reach statistical significance. **Conclusions:** The inclusion of our institution in the IQIC program was associated with improvement in key outcome measures following congenital heart surgery over a three year period.

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INTRODUCTION

Congenital heart surgery is rapidly evolving in developing nations with increasing surgical volumes and better outcomes. Developing economies face the issues of a huge burden of congenital heart disease, limited infrastructure, lack of dedicated pediatric cardiac programs, limited numbers of trained personnel, suboptimal funding and lack of health insurance policies.[1] In addition to these several preoperative and postoperative factors contribute to morbidity and mortality in children with congenital heart disease. There is a paucity of data on outcomes from the developing world due to lack of robust databases. In an attempt to address the challenges that emerging congenital heart programs in developing nations are facing, a group of physicians attending the Global Forum on Humanitarian Medicine in cardiology and cardiac surgery in Geneva initiated the concept of a quality improvement project for the developing nations.[2] The collaborative began its pilot year in 2008 with 5 participating centers. They formed a comprehensive congenital heart surgery database with the goal of bench-marking data from various

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centers in developing countries that would facilitate introspection and scope for improvement in outcomes at each center.

The pediatric heart program at our institute has been addressing high surgical volumes as well as increasing complexity of congenital heart disease over the past decade. The members of the pediatric heart program felt the need of an efficient system for collection and analysis of surgical outcomes that could be benchmarked with international standards. An important additional goal was to identify areas requiring potential improvement for providing quality care to children with congenital heart disease. We joined the International Quality Improvement Collaborative (IQIC) in January 2010 agreeing to the collaborative protocol. In this paper, we aim to assess the impact of IQIC on the postoperative outcomes after congenital heart operations at our institute.

METHODS

General information about International Quality Improvement Collaborative

The IQIC functions with an objective to create tailored quality improvement strategies to reduce mortality and major complications for developing world programs. They also aim to employ a telemedicine platform to facilitate distance-learning, dialogue and to disseminate knowledge and skills. The collaborative strives to achieve these goals by targeting the key drivers of mortality by improving team based practice through nurse empowerment, reducing surgical site infections (SSIs) and bacterial sepsis and promoting safe perioperative practices.

The quality improvement strategies for each of the key drivers that impacted mortality were disseminated among participating centers through a series of educational sessions that advanced from beginning, intermediate and advance-level of learning and acquisition of skills [Figure 1]. The educational sessions were telecast as live webinars in fixed timelines every year. The recorded webinars and learning modules were also made available to all centers for in-house training of nursing personnel and pediatric critical care team.

Data collection

A team-based approach was used to collect data. Physicians in the operating room and Intensive Care Unit (ICU) used preprinted data sets to capture patient data at respective locations. Senior member of the key contact team verified and completed the data before final electronic entry by nonmedical personnel into IQIC central database in accordance with the collaborative data protocol. Data were source verified during a series of data auditing trips from 2010 to 2012.

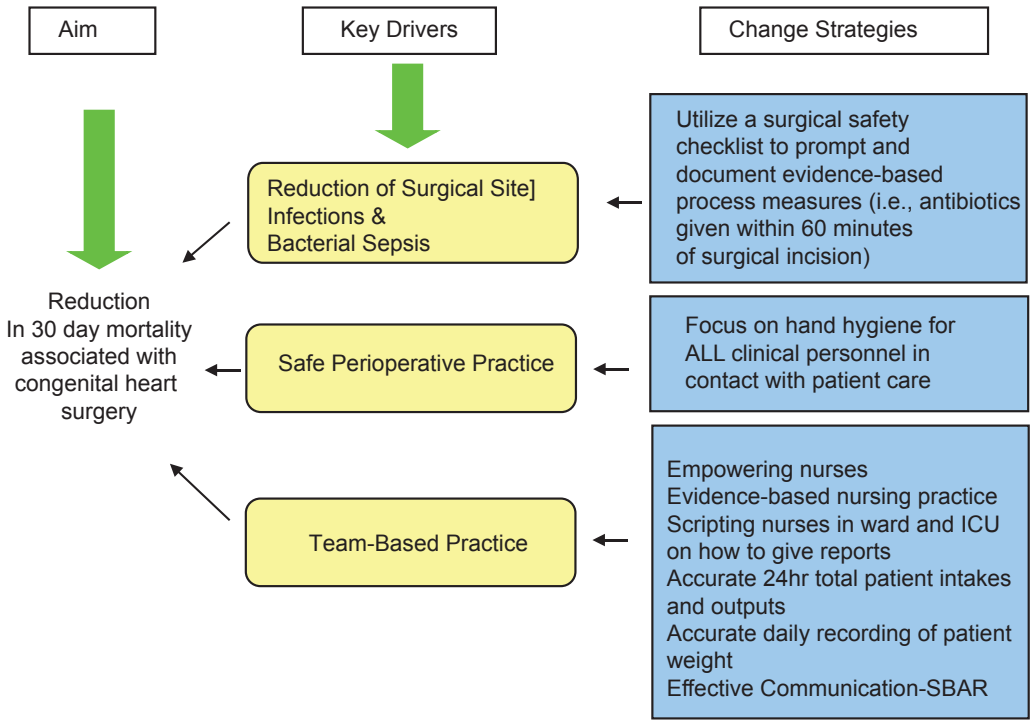

Figure 1: Key driver diagram

Institutional database

Demographic data and clinical data of patients undergoing congenital heart surgery were prospectively entered into the database including information on the preoperative status, clinical diagnosis, surgical risk category (Risk Adjustment for Congenital Heart Surgery [RACHS-13])[3], surgical procedure, and surgical outcomes namely, in-hospital mortality, ICU stay, duration of mechanical ventilation, bacterial sepsis, SSI and 30 day survival. The data of 1,702 consecutive patients ≤18 years of age undergoing congenital heart surgery during the period January 2010 to December 2012 were included. The preoperative variables included age, gender, weight at surgery and surgical complexity as per the RACHS-1 model. The postoperative outcomes included in- hospital mortality, duration of ventilation, duration of intensive care unit stay, bacterial sepsis and SSI. Bacterial sepsis was defined as any two clinical signs of sepsis (fever or hypothermia, tachycardia, hypotension, tachypnea, leukocytosis or leucopenia) with a positive blood culture. SSI was defined as an infection that could be sub classified as superficial incisional SSI, deep incisional SSI or mediastinitis. Formal Centers for Disease Control and Prevention[4] definitions of all the three sub classifications were used, and positive cultures were not required if all other clinical indicators suggested significant infection. In-hospital mortality was defined as any death occurring during a patient's hospital stay prior to postoperative discharge. The entire cohort was divided into three groups according to the year of the surgical procedure (2010, 2011, 2012) for analysis of trends in outcomes over the period of 3-year after joining the collaborative.

Statistical methods

The data were expressed as mean ± standard deviation or median and range as appropriate. The data were analyzed using SPSS statistics, version 17.0 (SPSS Inc. Chicago, IL, USA). For comparing the categorical variables between the cohorts of each year, Pearson Chi-square test was used. Continuous variables between the groups were tested using ANOVA. The mean values of variables namely duration of ventilation and ICU stay did not follow a normal distribution to permit comparison between groups. Hence, analysis of mean log values of ICU stay and duration of ventilation was done, and statistical significance was tested using ANOVA. A $P < 0.05$ was considered to be significant.

RESULTS

Of the 1,702 consecutive patients ≤18 years, 771 (45.3%) were females, and 931 (54.7%) were males. The median age was 8 months (0.03–216). The median weight at surgery was 6.1 kg (1–100). The distribution of surgical procedures as per RACHS-1 classification included category 1, 13.5% ($n = 230$), category 2 47.9% ($n = 815$), category 3, 29.9% ($n = 509$), category 4, 7.6% ($n = 129$), category 5 $n = 2$ (0.1%), category 6, 0.6% ($n = 11$). Six patients could not be assigned RACHS category. Analysis of postoperative outcome for the entire cohort showed in-hospital mortality 3.1%, median ICU stay 100 h (1–1960) and a median ventilation duration of 23 h (1–999). 11.9% had bacterial sepsis, and 6.4% had SSI. The year-wise comparison between cohorts operated in each year was performed to analyze the trends in outcomes over three years [Figure 2].

When analyzing the homogeneity between the cohorts of 3 years, the number of patients, age and gender distribution was comparable between the

Table 1: Gender distribution in the yearly cohorts

Year	Number (%)		Total	*P*
	Female	Male		
2010	209 (43.1)	276 (56.9)	485	0.248
2011	262 (44.4)	328 (55.6)	580	
2012	300 (47.8)	327 (52.2)	627	
Total	771 (45.3)	931 (54.7)	1702	

Table 2: Surgical case distribution by RACHS-1 model

Year	RACHS-1 *n* (%)						*P*
	1	2	3	4	5	6	
2010	61 (12.6)	238 (49.1)	155 (32)	30 (6.2)	0 (0.0)	1 (0.2)	0.370
2011	75 (12.7)	287 (48.7)	176 (29.9)	47 (8.0)	0 (0.0)	4 (0.7)	
2012	94 (15.1)	290 (46.5)	179 (28.7)	52 (8.3)	2 (0.3)	6 (1.0)	
Total	230 (13.6)	815 (48.0)	510 (30.1)	129 (7.6)	2 (0.1)	11 (0.6)	1697

RACHS-1: Risk adjustment for congenital heart surgery-1

Table 3: Mortality data

Year	Mortality (%)		Total	*P*
	Yes	No		
2010	21 (4.3)	464 (95.7)	485	0.125
2011	17 (2.9)	573 (97.1)	590	
2012	14 (2.2)	613 (97.8)	627	

Table 4: Bacterial sepsis and SSI

Year	Bacterial sepsis *n* (%)		*P*	SSI *n* (%)		*P*
	Yes	No		Yes	No	
2010	73 (15.1)	411 (84.9)	<0.05	54 (11.1)	431 (88.9)	<0.001
2011	70 (11.9)	518 (88.1)		40 (6.8)	550 (93.2)	
2012	60 (9.6)	567 (90.4)		15 (2.4)	612 (97.6)	
Total	203 (11.9)	1496 (88.1)		109 (6.4)	1593 (93.6)	1702

SSI: Surgical site infection

Table 5: Age, weight, ICU stay and ventilation hours

Variable	Median, range			*P*	Total
	2010	2011	2012		
Age (months)	7.0 (0.03-216)	8.0 (0.07-216)	8 (0.03-216)	0.324	8.0 (0.03-216)
Weight (kg)	5.7 (1-70)	6.2 (1.7-100)	6.3 (1.4-55.6)	0.421	6.1 (1-100)
ICU stay (h)	114 (8-999)	120 (1-1960)	72 (18-999)	<0.001	100 (1-1960)
Ventilation (h)	22 (1-999)	25 (1-840)	22 (1-794)	0.235	23 (1-999)

Yearly trends. ICU: Intensive care unit

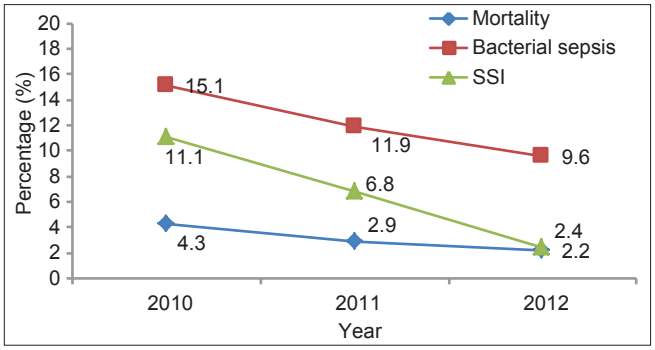

Figure 2: Outcome trends over three years: Mortality and infection data

groups [Tables 1 and 5]. The surgical case mix and complexity as per the RACHS-1 model were also comparable between the groups [Table 2].

On analysis of outcomes over the 3 years it was found that the decline in mortality from 4.3% in 2010 to 2.9% in 2011 and to 2.2% in 2012 was not statistically significant ($P = 0.125$) [Table 3]. There was a significant decline in bacterial sepsis from 2010 through 2012 (15.1% in 2010, 11.9% in 2011 and 9.6% in 2012, $P < 0.05$) SSIs decreased from 11.1% in 2010, to 6.8% in 2011 and to 2.4% in 2012, $P < 0.001$ [Table 4]. To permit comparison of non normal data of ICU stay and ventilator duration, the mean log values were taken. The mean log ICU stay was 4.72 ± 0.74 in 2010, 4.790 ± 70 in 2011, 4.39 ± 0.79 in 2012 ($P < 0.001$) There was a statistically significant decrease in ICU stay in 2012 compared to the previous 2 years. The mean log values of ventilator duration did not differ significantly between the 3 years (3.38 ± 1.07, 3.4 0 ± 99, 3.3 ± 1.04, $P = 0.235$).

Standardized mortality ratio taking IQIC database as reference population decreased from 0.65 (confidence interval [CI]; 0.52-0.78) in 2010 to 0.35 (CI; 0.22-0.47) in 2012.

DISCUSSION

There is increasing awareness for the need for evaluation of data and qualitative assessment of program performance while treating congenital heart disease. Some of the various quality improvement measures suggested for pediatric cardiac care include establishment of multi-institutional databases, data verification and validation processes, and the development of complexity stratification and risk assessment for congenital heart disease.[5] The IQIC for Congenital Heart surgery in developing countries originated to facilitate a collaborative of health care teams from around the world creating a culture of patient safety and quality for children undergoing congenital heart surgery in developing countries.[4] As a part of the collaborative in addition to sharing our patient data, we participated in the distance-learning processes through the monthly webinars coordinated by Boston Children's Hospital through the IQIC platform. The learning modules were also used for in-house training of nurse and physician staff. We also successfully piloted and implemented a safe surgical checklist[6] for congenital heart surgery at our institute.

The most striking outcome improvement, which we identified, was a substantial reduction of bacterial sepsis and SSIs. Bacterial sepsis occurred in 11.9% of the entire cohort. But the analysis of yearly trends showed a significant reduction in bacterial sepsis from 15.1% in year 2010 to 11.9% in 2011 and to 9.6% in 2012. Similarly, SSI decreased significantly from 11.1% in 2010 to 2.4% in 2013. An analysis of the annual reports of 2010, which was the 1st year after joining the collaborative, provided insight into the fact that our infection rates were above average for other contemporary sites in the collaborative. This prompted specific intervention measures to decrease bacterial sepsis namely enhancement of hand hygiene techniques, nurse education about preventing blood stream infection and SSIs, increasing compliance with the safe surgical checklist and the bundle checklist for prevention of catheter related blood stream infection. Though we could not exactly determine the specific intervention, which brought about the reduction in infection rates, a multimodal approach along with increased awareness of the care team toward this potential complication might have brought about the difference over the time period.

Though it could be argued that this outcome benefit may reflect just a general improvement of the unit, there is a strong possibility that IQIC could have directly influenced these outcomes, since the specific areas that showed improvement were given key emphasis through IQIC educational initiatives.

Mortality is one of the most frequently quoted measures of quality improvement. But the validity of mortality rate as a quality indicator is questionable when the event rates are too low, or surgical volumes are less.[7] We have found that our mortality rates declined from 2010 through 2012. This did not reach statistical significance probably due to the fact the our unit had already matured with lower mortality rates in par with acceptable standards by 2010 and further reduction would not have been possible unless there was a huge reduction in the number of deaths. Additionally, standardized mortality ratio taking IQIC database as a reference population showed a significant reduction in the mortality rates of our institution. A study done by Larrazabal *et al*.[8] demonstrates substantial improvement in outcomes after congenital heart surgery in Guatemala in which they showed the feasibility of measurement of risk-adjusted mortality in pediatric cardiac programs in the developing world.

The analysis of ICU stay showed a decline from 2011 to 2012. Though ICU stay is a known quality measure it may be influenced by many confounding factors like availability of beds in the step down unit, difference in discharge practices and team consensus.[9] Hence, the validity of this variable in our context is questionable. The ventilation hours also did not decrease significantly between the cohorts in the consecutive years. We did not implement any major change in our ventilation and extubation practices in the intensive care unit over the past 3 years, and this probably was the reason for the observed similar values over the 3 years.

Morbidity and complications like infections are also useful as quality measures and can be used as targets for improvement initiatives.[10] These events are more common than mortality and can be directly influenced by the standard of care. Health care associated infections are a major cause of morbidity and mortality in any population. In addition to this, infections can potentially escalate health care associated costs and consume resources, which can be detrimental in a limited resource environment. The fact that IQIC database captures the infectious complications and that the event rates are higher makes it a useful quality indicator in a developing world program. The fact that outcome analysis have been suggested as part of cost benefit analysis of pediatric cardiac intensive care programs carries particular relevance in developing economies where cost efficiency is vital for appropriate resource utilization.[11]

Large multicenter quality improvement initiative can go a long way toward implementing changes in individual centers.[12] The sharing of outcomes about quality improvement successes at one center can positively influence other centers to improve their standards as well. The availability of bench-marking data through the IQIC project facilitates comparison of our data between other centers and enhances program performance at a comprehensive level.

Limitations of the study

This paper is a prospective observational study aimed to track outcomes and trends. Though the infection emerged as a major morbidity, we have not specifically looked into the risk factors involved with increased bacterial sepsis. This is being planned and executed as a separate research project. Though we were able to demonstrate improved outcomes over the 3-year period after joining the collaborative, we have not compared the outcomes to an era where IQIC collaboration was nonexistent. This would have added more credibility to associating the improvement in outcomes with a quality improvement project. We have also not specifically looked at the standardized infection rates, and only the raw rates are computed.

CONCLUSIONS

The enrolment into a multicenter congenital heart surgery database is likely to have facilitated improved outcomes in terms of reduction in bacterial sepsis and SSIs, reduction in length of ICU stay and a trend toward decreasing mortality in a pediatric heart program in a limited resource setting. In developing nations with inherent limitations of lack of proper data capturing systems for analysis and improvement, the utilization of internationally accepted congenital heart surgery databases is a worthwhile investment.

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