Hospital Costs Related to Early Extubation after Infant Cardiac Surgery

Running Head: Early Extubation and Hospital Costs

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ABSTRACT

Background: The Pediatric Heart Network Collaborative Learning Study (PHN CLS) increased early extubation rates after infant Tetralogy of Fallot (TOF) and coarctation (CoA) repair across participating sites by implementing a clinical practice guideline (CPG). The impact of the CPG on hospital costs has not been studied.

Methods: PHN CLS clinical data were linked to cost data from Children's Hospital Association by matching on indirect identifiers. Hospital costs were evaluated across active and control sites in the pre- and post-CPG periods using generalized linear mixed effects models. A difference-in-difference approach was used to assess whether changes in cost observed in active sites were beyond secular trends in control sites.

Results: Data were successfully linked on 410/428 (96%) of eligible patients from 4 active and 4 control sites. Mean adjusted cost/case for TOF repair was significantly reduced in the post-CPG period at active sites ($42,833 vs. $56,304, p<0.01) and unchanged at control sites ($47,007 vs. $46,476, p=0.91), with an overall cost reduction of 27% in active vs. control sites (p=0.03). Specific categories of cost reduced in the TOF cohort included clinical (-66%, p<0.01), pharmacy (-46%, p=0.04), lab (-44%, p<0.01), and imaging (-32%, p<0.01). There was no change in costs for CoA repair at active or control sites.

Conclusions: The early extubation CPG was associated with a reduction in hospital costs for infants undergoing repair of TOF, but not CoA repair. This CPG represents an opportunity to both optimize clinical outcome and reduce costs for certain infant cardiac surgeries.

In the current healthcare environment, there is increasing emphasis on both improving quality of care and reducing costs, or providing high "value" care. Congenital heart disease accounts for the highest hospital costs among all children with birth defects, and is among the most frequent high-cost conditions treated at children's hospitals across all pediatric diseases[1,2].

Few studies have evaluated specific interventions that may hold the potential to both improve clinical outcomes and lower costs in this population. The Pediatric Heart Network Collaborative Learning Study (PHN CLS)[3] demonstrated that a collaborative learning strategy involving development and implementation of a clinical practice guideline (CPG) was successful in significantly increasing the rate of early extubation (extubation within 6 hours of admission to the intensive care unit) in infants undergoing repair of Tetralogy of Fallot (TOF) and coarctation of the aorta (CoA) at active sites compared to controls. At active sites, the rate of early extubation increased from 11.7% to 66.9% (p<0.001). Other key findings included a significant decline in postoperative critical care length of stay (LOS) in the TOF group (44.2 vs. 51.8 hours, p=0.04), although there was no change in total hospital LOS in either the TOF or CoA patients. In addition, time to discontinuation of continuous intravenous analgesics and time to introduction of oral feeds were reduced following introduction of the CPG with more prominent changes in the TOF group. It is not known whether these changes translated into reductions in hospital costs, as there may be other practices and factors influencing cost of care for these patients across hospitals beyond the timing of extubation and associated factors[4,5].

This study merges PHN CLS clinical data with cost data from the Children's Hospital Association Inpatient Essentials database to study the impact of the CPG on hospital costs. In addition to an assessment of total hospital costs in the pre- and post-CPG periods, we also evaluated specific cost categories in order to assess which of these may be the most impacted.

PATIENTS AND METHODS

Data Sources

The PHN CLS was performed over a two-year period from 2013 to 2015. The methods and main study results have been previously published[3,6]. Briefly, the investigative team observed clinically important variation in postoperative mechanical ventilation practices and clinical outcomes after infant surgery at five congenital heart programs[6]. One hospital was identified as a positive outlier with much lower median ventilation times and shorter length of stay. Participants engaged in a series of round-robin site visits and then created a CPG to mimic the extubation strategy and associated key practices at the "model" hospital after infant repair of TOF and CoA. In the main study, clinical outcomes at the four active hospitals who implemented the CPG were measured during the 12 months before (pre-CPG) and the 12 months after (post-CPG) implementation, and were compared with 5 other PHN sites during the same time period (controls) who continued with usual practice[3].

The Inpatient Essentials database (formally known as the Case Mix database) is a large administrative database maintained by Children's Hospital Association (CHA; Lenexa, KS). The database contains total hospital resource utilization and other inpatient data from 90 US children's hospitals[7].

Linkage

PHN CLS clinical data and hospital cost data from the Inpatient Essentials database were linked at the patient level using the method of probabilistic matching of indirect identifiers as previously described[7,8]. The following identifiers were utilized for record linkage: center, gender, date of admission (+/- 1 day), date of discharge (+/- 1 day), and date of birth (+/- 1 day).

The analysis performed for this project was a pre-specified secondary aim of the primary PHN CLS, which was reviewed and approved by the PHN's Data and Safety Monitoring Board as well the individual centers' Institutional Review Boards (IRB) with waiver of informed consent.

Study Population

All patients enrolled in the PHN CLS were eligible for inclusion[3]. Similar to the main analysis, the "model center" was excluded as it served as the prototype for CPG development. Additionally, one non-US center was excluded from the control sites as it did not contribute data to the CHA Inpatient Essentials Database.

Data Collection

Data collected as a part of the PHN CLS have been previously reported[3]. All clinical data for this study was obtained from variables in the PHN CLS. Data contained in CHA Inpatient Essentials Database were used to estimate hospital costs as described below. These data consist of daily total hospital charges, hospital and department specific cost-to-charge ratios, and daily line item charges for every service grouped into standard categories including: clinical, pharmacy, imaging, laboratory, supplies, and "other". Of note, the "other" category is primarily comprised of room and board costs, and the clinical service category includes costs related to testing, procedures, and other aspects of clinical care delivery such as mechanical ventilation and other respiratory care. Professional fees are not captured by CHA or other frequently used administrative datasets and therefore could not be included in the analysis. CHA does not separate out facility fees from other charges.

Analysis

Total hospital costs were estimated from charges using hospital and year specific cost-to-charge ratios for the time periods before and after CPG implementation with a three-month

wash-out phase for each period. Hospital costs were adjusted for geographic region using the Centers for Medicare and Medicaid Services price wage index, and values were indexed to 2015 US dollars to account for inflation.

Total hospital costs were modeled as continuous variables in mixed effects models. Separate models were constructed for the TOF and CoA patients. The skewed distribution of cost was accounted for by using a gamma distribution and a random intercept was used for each hospital to account for patient clustering within center. Models were adjusted for any clinical variables which approached significance in bivariate analyses (p<0.2), which included diagnosis type for the CoA cohort (see Table 1).

These models were utilized in a difference-in-difference (DID) analysis. This approach, which employs econometric techniques, isolates changes in outcomes associated with an event of interest above and beyond any changes in a control group not exposed to the event or change[9-11]. This methodology allowed us to evaluate the impact of the CPG on hospital costs at active sites, taking into account cost trends during the study period at the control sites. This approach has been employed across several fields to examine a number of outcomes before and after the implementation of various policies or initiatives[9,12,13].

Finally, in addition to total hospital costs, categories of cost described in the preceding sections were also assessed, followed by specific line items for which we anticipated there might be reductions given the clinical context and findings of the main CLS study. All analyses were performed using SAS version 9.4 (SAS Institute Incorporated, Cary, North Carolina). A p-value <0.05 was considered statistically significant.

RESULTS

Study Population

All 4 active PHN CLS sites and 4 control sites were included. As described in the preceding section, one model site and one non-US control site was excluded. From these sites, data were successfully linked between the CLS PHN and CHA datasets on 410/428 (96%) eligible patients. The remaining 23 unmatched patients were distributed among 6 sites, with a range of 0-5 unmatched patients per site.

Study population characteristics are displayed in Table 1. Median age at surgery was 20 days for CoA patients and 153 days for TOF. On average, CoA patients underwent surgery on hospital day 4 with 74.3% of hospital costs occurring on or after the day of surgery. TOF patients underwent surgery on average on hospital day 2 with 85.9% of hospital costs occurring on or after the day of surgery.

TOF Costs Pre- and Post-CPG

The mean adjusted cost per case in the TOF cohort across the pre- and post-CPG periods are shown in Table 2. There was no significant difference in the pre-CPG hospital costs in the active versus control sites (p=0.35). Assessing change over time at the active sites, there was a significant reduction in mean adjusted cost per case following CPG implementation ($56,304 in pre-CPG period vs. $42,833 in post-CPG period, p<0.001). At the control sites, there was no significant change from the pre- to post-CPG periods (Table 2). Overall, our difference-in-difference analysis showed that there was a 27% reduction in hospital costs in the active vs. control sites (95% CI -42% to -13%, p=0.03) in the TOF cohort.

Specific categories of cost are displayed in Figure 1. We found the greatest reduction in hospital costs from the pre- to post-CPG period for the "clinical" category (-66%, p<0.01). Notably for the purpose of this study, the clinical category also includes costs related to

mechanical ventilation and other respiratory care. Significant reductions were also seen for pharmacy (-46%, p=0.04), laboratory (-44%, p<0.01), and imaging (-32%, p<0.01) costs. There was no significant change in supplies or other costs; of note the "other" category is primarily comprised of room and board costs.

In addition to these overall categories, we further examined specific line items of interest. Within the clinical category, we found significant reductions in costs related to mechanical ventilation (-161%, p=0.03) and nebulized mist treatments (-110%, p=0.04). In the pharmacy domain, there were significant reductions for ketamine (-139%, p=0.005) and fentanyl (-125%, p<0.001). In the lab category, blood gas costs were reduced (-39%, p=0.01), and there was a trend toward reduction of chest x-ray costs within the imaging domain (-22%, p=0.07).

CoA Costs Pre- and Post-CPG

The mean adjusted costs per case in the CoA cohort across the pre- and post-CPG periods are shown in Table 2. There was no significant change in costs over time from the pre- to post-CPG periods in either the active or control sites for CoA repair.

COMMENT

In this study, we merged PHN CLS clinical data with cost data from a large CHA dataset to study the impact of an early extubation CPG on hospital costs after infant cardiac surgery. We found a significant reduction in hospital costs associated with the CPG for infants undergoing TOF repair, while there was no change in hospital costs for those undergoing CoA repair.

Although both cohorts in the study had increased rates of early extubation following CPG implementation in the primary study, the cost reduction we found in the present analysis was limited to the TOF group. These observations mirror those from the primary study[3] where

improvements in some of the secondary endpoints examined were more prominent in the TOF group than the CoA group. These included reduced intensive care unit length of stay in the TOF group but not the CoA group, a more prominent decrease in time to discontinuation of all continuous sedation/analgesia in the TOF compared to CoA group, and significant declines in cumulative doses of specific sedation/analgesia medications in TOF patients compared to no change in CoA patients[3].

These findings were further highlighted by our examination of specific cost categories and line items that were reduced in the TOF cohort. With earlier extubation, clinical costs, specifically those related to mechanical ventilation and respiratory care, were reduced. Consistent with the primary study findings regarding analgesia and sedation[3], pharmacy costs and related specific line items were also reduced. Despite the reduced intensive care unit length of stay[3], room and board costs (which comprised the majority of the "other" category) were not significantly reduced. This may be because the main CLS study demonstrated no change in total hospital LOS. Laboratory and imaging costs were lower, which could be related to the de-escalation of care that is typically associated with transition from the intensive care unit and/or associated with the shorter duration of mechanical ventilation, as declines in costs related to blood gasses and chest x-rays were seen.

Within the CoA group, we hypothesized that the hospital costs associated with non-cardiac care of newborns with critical CoA may mask changes from a CPG focused on post-operative care, while in contrast most TOF patients are older infants likely admitted from home within 24 hours of surgery to undergo elective repair. We found that CoA patients did indeed have a longer pre-operative hospital stay in our analysis, with a lower proportion of overall hospital costs related to the post-operative period compared to the TOF group.

The potential implications for cost savings related to implementation of this CPG are considerable. For example, recent data from the Society of Thoracic Surgeons Congenital Heart Surgery Database suggest approximately 1,250 TOF repairs occur annually in the United States[14]. Based on the cost estimates for TOF repair in our study and the magnitude of reduction associated with the CPG, this could translate into total cost savings of ~ $10-15 million each year for repair of TOF alone.

Through employing data linkage techniques, our study was able to provide unique insights that supplement the primary PHN CLS findings. Specifically, by merging clinical PHN CLS data with administrative data from CHA through linking on indirect identifiers, we were able to understand the impact of the quality improvement initiative not only on clinical outcomes, but costs of care as well. Similar techniques have been used to merge cost data with trial datasets and registry data[8,15-18] and highlight how this methodology can foster investigations not otherwise possible with isolated datasets alone. The methods used in the present analysis can be applied to other quality initiatives to support more comprehensive understanding of healthcare value, and the impact of various initiatives geared toward optimizing both clinical outcomes and costs of care.

Limitations

There are several limitations to consider. Our results relate to the two forms of infant heart surgery examined as a part of the PHN CLS (TOF and CoA repair, both resulting in biventricular circulations and normal oxygen saturations), and may not be generalizable to all forms of congenital heart disease or outside of the context of the 8 centers included in this analysis. Regarding the changes in hospital costs observed in our study, it is possible that these could be related to other general improvements in care over time rather than the early extubation CPG. However, the inclusion of control sites and use of a difference-in-difference design to account for secular trends makes this unlikely. The observation of cost reductions in the categories that

we would expect to be most impacted by the CPG based on the clinical findings also supports the validity of our findings. It is possible that our analysis was underpowered to detect small changes in hospital costs over time. In addition, although standard methods were employed across hospitals to derive estimated hospital costs, it is possible that some cost differences were related more to hospital accounting practices and/or regional differences rather than actual resources utilized. However, the design of this study, in which a center's data from the post-CPG era were compared to their data from the pre-CPG period, mitigates some of these concerns related to center effects. Finally, given the findings of the accompanying study in this issue of the *Annals* by Gaies et al.[19] regarding limited sustainability of the early extubation CPG practices and outcomes at most centers, it is possible that some of the gains described here may not persist over time. Further efforts are necessary to investigate strategies to support sustainability, whether related to clinical outcomes or hospital costs.

Conclusions

This study demonstrates that implementation of an early extubation CPG through a collaborative learning approach was associated with reduced hospital costs for certain infant cardiac surgeries, in addition to the improvement in certain clinical outcomes observed during the study period. With the ability to both reduce hospital costs and improve outcomes, the early extubation CPG has potential to improve value in infant heart surgery. These results and the unique methodology employed in this study can inform future initiatives aimed at improving healthcare value across other patient populations. Further investigation into strategies to promote sustainability is also necessary.

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TABLE 1: Study Population Characteristics

	CoA				TOF			
	Total N=163	Active N=85	Controls N=78	p	Total N=247	Active N=141	Controls N=106	p
Male	103 (63%)	53 (62%)	50 (64%)	0.82	141 (57%)	78 (55%)	63 (59%)	0.52
Birth weight (kg)	3.3 [2.8-3.6]	3.3 [2.8-3.6]	3.2 [2.9-3.6]	0.84	3.1 [2.7-3.4]	3.1 [2.8-3.5]	3.1 [2.8-3.5]	0.56
Gestational age <37wks	16 (10.7%)	8 (10.3%)	8 (11.1%)	0.87	33 (15.9%)	20 (16.1%)	13 (15.5%)	0.90
Age at surgery (days)	20 [7-59]	19 [7-63]	20.5 [8-52]	0.99	153 [112-208]	153 [125-198]	152 [92-219]	0.49
Chromosomal anomaly	1 (0.6%)	1 (1.2%)	0	0.34	8 (3.2%)	6 (4.3%)	2 (1.9%)	0.30
Diagnosis								
Isolated Coarctation	64 (39.3%)	35 (41.2%)	29 (37.2%)					
Isolated Coarctation + VSD (not requiring intervention)	21 (12.9%)	7 (8.2%)	14 (17.9%)	0.18	NA			
Coarctation + other lesion	78 (47.9%)	43 (50.6%)	35 (44.9%)					
TOF + PS	NA				236 (95.5%)	135 (95.7%)	101 (95.3%)	
TOF + AVSD					9 (3.6%)	5 (3.5%)	4 (3.8%)	0.98
TOF + Absent pulmonary valve					2 (0.8%)	1 (0.7%)	1 (0.9%)	

VSD – ventricular septal defect
TOF – Tetralogy of Fallot
PS – pulmonary stenosis
AVSD – atrioventricular septal defect

Continuous variables are reported as medians and interquartile range.

TABLE 2: Change in Hospital Costs Pre- vs. Post-CPG

CoA repair

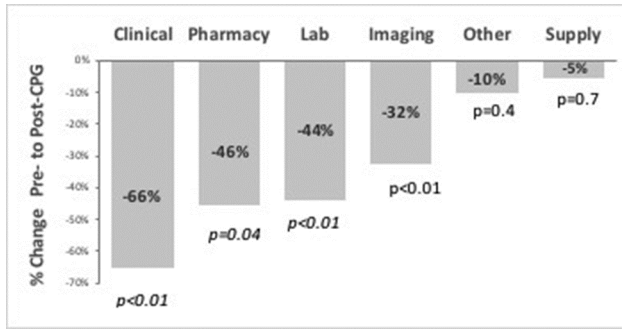| Group	Pre-CPG	Post-CPG	Change
Control	$35,912 ($23,754-$54,291)	$39,053 ($26,459-$57,643)	8.4% (-25%, 41.7%) p = 0.6
Active	$44,535 ($32,105-$61,777)	$39,196 ($27,552-$55,764)	-12.8% (-41.1%, 15.6%) p = 0.4
			Difference-in-Difference -21.2% (-65.2%, 22.9%) p = 0.3

TOF repair

Group	Pre-CPG	Post-CPG	Change
Control	$47,007 ($32,080-$68,882)	$46,476 ($31,847-$67,823)	-1.1% (-20.1%, 17.9%) p = 0.9
Active	$56,304 ($40,794-$77,711)	$42,833 ($31,061-$59,067)	-27.3% (-41.5%, -13.2%) p < 0.001
			Difference-in-Difference -26.2% (-49.9, -2.5) p = 0.03

CoA = coarctation of the aorta, TOF = Tetralogy of Fallot

Change denotes the percent change from pre- to post-CPG eras

FIGURE LEGENDS

Figure 1. Categories of Cost for TOF repair

Specific categories of cost in the Tetralogy of Fallot (TOF) cohort are displayed, with percent change from pre- to post-clinical practice guideline (CPG) on the y-axis. Standard cost categories included: clinical, pharmacy, imaging, laboratory, supplies, and "other". The "other" category is primarily comprised of room and board costs. Notable for the present study, the clinical category contains costs related to mechanical ventilation and other respiratory care. There was a significant reduction in clinical, pharmacy, laboratory, and imaging costs, while supply and other costs remained unchanged.