Initial experience introducing an enhanced recovery program in congenital cardiac surgery

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ABSTRACT

Objective: We hypothesized that a new enhanced recovery after surgery (ERAS) program would accelerate functional recovery after congenital heart surgery and reduce length of stay and complications.

Methods: Evidence-based interventions in perioperative care were evaluated for relevance, and components of the ERAS cardiac program were determined. The target patient population included infants to adults with low comorbidities. Major outcomes were compared to a pre-ERAS era cohort using propensity matching.

Results: From October 1, 2018, to February 28, 2019, 155 of 448 patients were eligible for the ERAS program. The median age was 3.6 years (interquartile range, 0.5-12.3). Key metrics included early extubation (<8 hours), achieved in 84 patients (54%; median 7.6 hours; interquartile range, 3.8-12.3), and multimodal pain regimen used in all patients (100%) postoperatively, but in only 88 of 155 patients (57%) intraoperatively. Opioid analgesia was highest the night of surgery (oral morphine equivalent: 0.36 mg/kg/12 hours; interquartile range, 0.21-0.57). In matched analysis, raw median mechanical ventilation time was 7.6 hours (interquartile range, 3.8-12.2) in ERAS versus 8.2 (interquartile range, 4.0-17.0) in pre–ERAS era ($P = .001$ log-hours). Raw median intensive care unit length of stay was shorter with ERAS: 1.12 days (interquartile range, 0.93-2.01) versus 1.28 days (interquartile range, 0.96-2.09) pre-ERAS ($P = .046$ log-days), but there was no difference in hospital length of stay. There was no increase in Society of Thoracic Surgeons–reported complications, readmissions, and reinterventions.

Conclusions: This represents the initial implementation experience of an enhanced recovery after surgery program after congenital surgery at a large pediatric hospital. Adherence to the program component metrics is not yet optimized, but monthly sharing of quality metrics allows multidisciplinary collaboration, provider engagement, and opportunities for research and process improvement. (J Thorac Cardiovasc Surg 2020;160:1313-21)

Congenital ERAS cardiac program graphic summary.

Central Message

This study represents the initial experience and early results of developing and adopting an ERAS program in congenital heart surgery at a large pediatric hospital.

Perspective

We developed and implemented an ERAS program in congenital cardiac surgery at a large pediatric hospital. Preliminary data suggest that through multidisciplinary collaboration and monthly review, an ERAS cardiac program reduces mechanical ventilation and ICU LOS, without increasing complications. We believe it will also improve family experience.

See Commentaries on pages 1322, 1323, and 1324.

Enhanced recovery after surgery (ERAS) programs are comprehensive multidisciplinary interventions spanning the entire perioperative period targeting the reduction of surgical stress and catabolic states. The goals are to optimize fluid balance, nutrition, use multimodal pain management, improve lung function, and accelerate the return of normal gastrointestinal function. These interventions have led to shortened and improved recovery, reduced morbidity and length of stay (LOS), improved patient experience, and optimization of resource use around surgical care.[1] ERAS programs have been developed for the care of adults after abdominal surgical procedures,[1,2] but ERAS principles are applicable to different surgical specialties, and programs have recently emerged in the fields of

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CONG

Abbreviations and Acronyms

CPB = cardiopulmonary bypass
ERAS = enhanced recovery after surgery
ICU = intensive care unit
IQR = interquartile range
LOS = length of stay
OME = oral morphine equivalent
PONV = postoperative nausea and vomiting
STS = Society of Thoracic Surgeons

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cardiothoracic[3-8] and the pediatric surgical populations.[9-13] The feasibility and effectiveness of an enhanced recovery program are unknown in the context of congenital heart surgery for which the complexity of congenital heart disease, the magnitude and diversity of operations, and the populations from neonate to adult have been arguments against to the widespread adoption of early extubation, lower doses of opioids, and other ERAS program components. We hypothesized that a new ERAS cardiac program would accelerate functional recovery after congenital heart surgery, reduce LOS and adverse outcomes, and improve patient and family satisfaction.

MATERIALS AND METHODS

Enhanced Recovery After Surgery Cardiac Surgery Program Development

Evidence-based interventions in perioperative care[13-20] were evaluated for relevance in a congenital cardiac population, and existing institutional experience[21-25] was reviewed. Through discussions and consensus building, components of the congenital ERAS cardiac program were developed (Figure 1). Guidelines (Appendix E1) and quality metrics were determined by a multidisciplinary group of stakeholders, including cardiac surgeons, anesthesiologists (cardiac, pain, and regional anesthesia), cardiac intensivists, cardiologists, perfusionists, nurses and mid-level providers across the heart center, dieticians, rehabilitation medicine, and child-life and respiratory care specialists. In addition to guideline development, process improvement opportunities were identified at all phases of care.

Target Population

The program targets infants (>30 days of age) to adults undergoing elective surgical procedures for lower-complexity congenital heart defects (The Society of Thoracic Surgeons [STS]–European Association for Cardio-Thoracic Surgery 1-3 risk category, in general). This includes optimized patients undergoing staged palliation for single ventricle physiology (stages 2 and 3). The selected patients have few comorbid conditions that could significantly affect their recovery. They are identified as ERAS cardiac preoperatively, and this is displayed in the electronic surgical schedule.

Program Implementation

Education of bedside, mid-level, and medical providers was performed and is ongoing. An ERAS cardiac order set was created in the electronic medical record for postoperative care. Patient education aids were created, and an electronic patient reported outcomes tool was developed. Monthly multidisciplinary review of program outcomes is performed.

Study Design

This study was approved by the institutional review board at Boston Children's Hospital (BCH IRB-P00029161). The program was launched in October 2018, and the results of the first 5 months were included. All patients meeting eligibility criteria were included in the ERAS cardiac surgery program. The decision to follow the program was determined by the surgeon depending on the intraoperative course and the results of the surgical repair in consultation with the anesthesiologist or critical care physician.

Data Collection and Analysis

An electronic database was created to capture demographic data and adherence to metrics related to program component guidelines (Table 1). Common surgical outcomes obtained from Boston Children's Hospital STS congenital database were recorded: postoperative mechanical ventilation time, LOS in the intensive care unit (ICU), postoperative LOS, all complications (as defined by the STS congenital database), readmissions at 30 days from discharge, reinterventions, and mortality. In addition, opioid use was collected intraoperatively and every 12 hours for the first 96 hours after surgery, and reported as oral morphine equivalents (OME). Median pain scores (range, 1-10) per 12 hours were reported using age-appropriate scales. Finally, clinical data from postoperative virtual and clinic visits were collected.

Statistical Analysis

ERAS patient data are displayed as mean ± standard deviation for normal distribution and as median with interquartile range (IQR) (25th-75th) for asymmetric distributions. The effect of opioid use over time was compared using Friedman test, and Wilcoxon signed-rank test was used for paired comparisons.

To compare patients with a pre-ERAS era cohort from 2016 to 2017, a period when our institution had already instituted a fast-track extubation program, a propensity score for being selected in the ERAS cardiac program was developed using logistic regression analysis. Demographic and clinical preoperative and perioperative measures were candidate predictors; age, sex, weight for age z-score, prematurity, syndrome, associated conditions, previous cardiac operations, STS–European Association for Cardio-Thoracic Surgery risk category, diagnosis, primary procedure (STS), associated surgery, use of cardiopulmonary bypass (CPB), total CPB time, and crossclamp time. Nine predictors with a multivariable P value .25 or less were retained in the model (c-static = 0.77), and the estimated propensity score was used in an optimal matching algorithm to match 2 pre-ERAS era controls to each ERAS cardiac case, except in 1 case for whom a single match was found. A caliper of 0.25 was used for matching, that is, each control was required to have a propensity score no more than 0.25 units smaller or larger than the matched case. A total of 151 ERAS patients were matched to 301 controls.

Characteristics of the matched ERAS and historical (pre-ERAS) cohorts were compared using the Wilcoxon rank-sum test for asymmetric distributions, expressed as median with 25th and 75th IQR. Normally distributed continuous variables were expressed as mean with standard deviation and compared using the Student t test. Categorical variables were

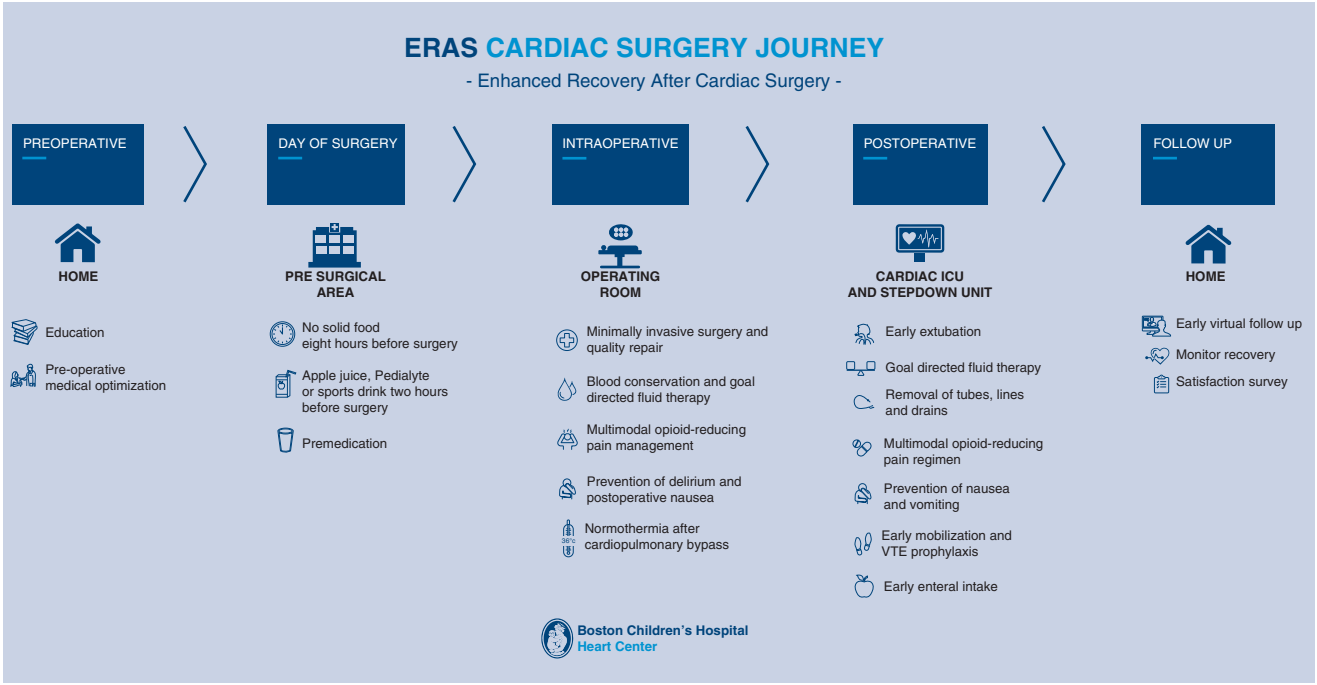

FIGURE 1. Major components of the ERAS cardiac program at Boston Children's Hospital throughout the patient's surgical journey. Evidence-based guidelines were developed for the program components, and targets were set by multidisciplinary stakeholders. *ICU*, Intensive care unit; *VTE*, venous thromboembolism.

compared using a Fisher exact test, except when a large number of categories with sparse cell counts were present, such as STS diagnosis, diagnosis category, STS surgical procedure, and surgical procedure category, which were compared with the chi-square test.

Exact conditional logistic regression was used to compare binary clinical outcomes between the ERAS cardiac and pre-ERAS era cohorts within cluster (1 case, 2 controls). Linear fixed-effects regression modeling accounting for cluster was used to compare continuous clinical outcomes between both cohorts within cluster. Poisson regression modeling conditional on cluster was used to compare the number of complications between the ERAS cardiac and historical cohorts, with an unstructured covariance matrix and log (30 days) as the offset. The time-based continuous outcomes were log-transformed to better meet the assumptions of the regression model; thus, the units are in log-days (LOS) or log-hours (mechanical ventilation). For all mechanical ventilation times, 0.1 hour was added to perform a log transform. OME data were right-skewed and square-root transformed to better meet assumptions of the regression model. A linear model with fixed effects for cohort and cluster was used to estimate the differences in square-root transformed OME measures for each intraoperative and postoperative 12-hour period. The Wilcoxon rank-sum test was also used to compare OME of the 2 matched cohorts without accounting for cluster. Statistical analyses were performed using SAS version 9.4 (SAS Institute Inc, Cary, NC).

RESULTS

From October 1, 2018, to February 28, 2019, 155 of 448 patients (34.6%) who underwent cardiac surgery at our institution were eligible for the enhanced recovery program (ERAS cardiac). The median age was 3.6 years (IQR, 0.5-12.2), and 82 (52.9%) were male. Program components and key metrics, results, and adherence to these metrics are shown in Table 1. Important preoperative interventions in the program include education, family engagement, and setting expectations for recovery, and these remain areas of development. Limitation of fasting by encouraging the ingestion of a glucose-containing clear beverage 2 to 4 hours before surgery was observed in only 18 of 104 patients (17%), with a median time to last ingested fluids of 5.5 hours (IQR, 3.4-10.5). In addition, we found hypoglycemia (first blood glucose <80 mg/dL) in 25 of 151 patients (17%). Intraoperatively, the following ERAS components were reviewed: multimodal anesthesia (intravenous acetaminophen, 88/155), local anesthesia (119/155), and postoperative nausea and vomiting (PONV) prevention (51/155) were used in 57%, 77%, and 33% of patients, respectively. The use of sedation agents at the conclusion of the case, continued in the in the ICU such as dexmedetomidine and propofol, enabling rapid emergence, and prevention of delirium and of postoperative nausea,[19] was adopted in 125 of 155 patients (81%).

Key postoperative metrics included early extubation (<8 hours), achieved in 84 patients (54%; median, 7.6 hours; IQR, 3.8-12.3), and 24 patients were extubated in the operating room (15% of all patients). No patient required reintubation. Normothermia (T $\geq$ 36°C) was achieved in 60 minutes in 68 of 155 patients (44%).

TABLE 1. Enhanced recovery after surgery cardiac program components, metrics, and adherence to guidelines

Program component	Guideline and metrics	Metric component adherence (%)
Preoperative		
Education	Preoperative education, expectations for recovery	N/A
Preoperative nutrition optimization	Nutrition consultation	Program in development
Limitation of fasting	Clear glucose-containing beverage: 2-4 h from surgery	18/104 (17%)
	Hypoglycemia (<80 mg/dL) during surgery	25/151 (17%)
Intraoperative		
CPB and blood conservation	Hematocrit during CPB ≥25%	121/142 (85%)
	Patients receiving TXA	140/142 (97%)
	Cell saver use	136/142 (96%)
Multimodal pain regimen	Multimodal pain regimen in operating room	88/155 (57%)
	Local anesthetic to incision	119/155 (77%)
PONV prevention	Intraoperative PONV Prevention	51/155 (33%)
Goal-directed fluid therapy	Intraoperative fluid balance/kg	8.7 mL/kg (IQR, 4.4-19.1)*
Normothermia	Temperature coming off bypass	35.4 ± 1.0†
Prevention of delirium and sedation	Dexmedetomidine or propofol for sedation	126/155 (81%)
Postoperative		
Early extubation	Mechanical ventilation <8 h	84/155 (54%)
	Extubation in operating room	24/155 (15%)
Normothermia	Temperature 36°C within 60 min	68/155 (44%)
	Rewarming time to 36°C in ICU	106 min (IQR, 8-256 min)*
Multimodal pain regimen	Multimodal pain regimen	155/155 (100%)
	Acetaminophen	155/155 (100%)
	NSAID	138/155 (89%)
	Opioid medications	152/155 (98%)
PONV prevention	PONV prophylaxis	102/155 (66%)
	Any postoperative emesis	83/155 (54%)
	Postoperative emesis >2	38/155 (25%)
Early mobilization	Mobilization 4 h from extubation and time to ambulation	N/A
Limitation of fasting	Time to first enteral intake and full diet	N/A
Goal-directed fluid therapy	Discontinue IV fluids when taking 80% orally	N/A
Blood conservation	Postoperative transfusions	19/155 (12%)
Early removal of lines and drains	Chest tube guideline observed	N/A
	Duration of chest tubes	2.0 d (IQR, 1.8-3.1)*
Residual Lesion Score	RLS 1-2	138/144 (96%)
Follow up		
Virtual survey	Virtual visit after discharge (data from January 1, 2019)	45/56 (80%)
Patient-reported outcomes	Enrollment in patient-reported outcomes	N/A
Satisfaction survey	Child HCAHPS survey	N/A

N/A, Not available; *CPB*, Cardiopulmonary bypass; *TXA*, tranexamic acid; *PONV*, postoperative nausea and vomiting; *IQR*, interquartile range; *ICU*, intensive care unit; *NSAID*, nonsteroidal anti-inflammatory drug; *IV*, intravenous; *RLS*, residual lesions score; *HCAHPS*, Hospital Consumer Assessment of Healthcare Providers and Systems. *Reported as median (IQR, 1-3). †Reported as mean ± standard deviation.

Nineteen patients received blood products postoperatively (12%), and no patient required reintervention for bleeding. Fifty-four percent (54%) of patients (83/155) experienced postoperative emesis, with 38 (25%) experiencing severe emesis (>2), delaying postoperative oral intake and extending the duration of intravenous fluid infusions. All 155 patients (100%) received a multimodal pain regimen with acetaminophen and at least 1 nonsteroidal anti-inflammatory agent in 138 patients (89%). However, opioids remain the principal postoperative analgesic medication used. Opioid analgesia was calculated as OME per kilogram and reported every 12 hours. Although median pain scores (range, 1-10) were 2 or less throughout the postoperative period, opioid use was highest the night of surgery: Median OME was 0.36 mg/kg/12 hours (IQR, 0.21-0.57). Opioid requirement decreased consistently; however, 92 patients (59%) continued to receive opioid on postoperative day 3. This parallels chest tube duration, which remained for a median of 2.0 days (IQR, 1.8-3.1).

TABLE 2. Demographic, preoperative, and postoperative characteristics of patients in the enhanced recovery after surgery cohort and propensity score matched pre–enhanced recovery after surgery cohort

Characteristics	ERAS cardiac (N = 151)	Pre-ERAS (N = 301)	*P* value
Age (y)	3.8 (0.5-12.3)	3.3 (0.5-9.4)	.55*
Male (%)	79 (52.3)	168 (55.8)	.49
Weight for age Z-score	−0.67 (−1.63 to −0.06)	−0.65 (−1.57 to −0.14)	.88*
Preterm (%)	19 (14.1)	40 (14.3)	1.00
Associated conditions (%)	40 (26.5)	71 (23.6)	.56
Genetic syndrome (%)	24 (15.9)	59 (19.7)	.37
Prior cardiac surgery (%)	47 (32.0)	76 (26.2)	.22
Physiology related to primary diagnosis			.21†
Left ventricle volume overload	16 (10.6)	31 (10.3)	
Right ventricle volume overload	60 (39.7)	140 (46.7)	
Left ventricle obstructive lesion	21 (13.9)	24 (8.0)	
Right ventricle obstructive lesion	15 (9.9)	22 (7.3)	
Tetralogy of Fallot	10 (6.6)	34 (11.3)	
Ischemic/coronary anomaly	5 (3.3)	14 (4.7)	
Single ventricle	16 (10.6)	25 (8.3)	
Arch anomalies	8 (5.3)	10 (3.3)	
Associated cardiac diagnosis (%)	49 (32.5)	83 (27.7)	.32
CPB use (%)	138 (91.4)	276 (91.7)	1.00
STAT category (%)			.24
1	46 (30.5)	100 (33.2)	
2	71 (47.0)	153 (50.8)	
3	21 (13.9)	35 (11.6)	
4	12 (8.0)	13 (4.3)	
Procedure description			.44†
Atrial-level shunt repair	31 (20.53)	63 (21.0)	
Ventricular-level shunt repair	10 (6.6)	32 (10.7)	
CAVC repair	5 (3.3)	15 (5.0)	
Atrioventricular valve repair or replacement	16 (10.6)	31 (10.3)	
RVOT surgery, including TOF	30 (19.9)	64 (21.3)	
Aortic valve repair or replacement, LVOT surgery	21 (13.9)	23 (7.7)	
Single ventricle palliation	13 (8.6)	28 (9.3)	
Other surgery	25 (6.6)	44 (14.7)	
Combined procedure (%)	53 (35.1)	84 (27.9)	.13
CPB time (min)	94.5 ± 56.1	88.5 ± 52.4	.27‡
Aortic crossclamp time (min)	59.7 ± 50.3	57.2 ± 45.7	.66‡

Summary statistics are median (IQR), mean ± standard deviation, or frequency (percentage). *P* value by Fisher exact test unless *Wilcoxon, †chi-square, ‡*t* test. *ERAS*, Enhanced recovery after surgery; *CPB*, cardiopulmonary bypass; *STAT*, The Society of Thoracic Surgeons–European Association for Cardio-Thoracic Surgery; *CAVC*, common atrioventricular canal; *RVOT*, right ventricular outflow tract; *TOF*, tetralogy of Fallot; *LVOT*, left ventricular outflow tract.

The median ICU LOS was 1.1 day (IQR, 0.9-2.0) for the ERAS cardiac program, and median postoperative hospital LOS was 5.1 days (IQR, 4.0-6.9). STS-reportable complications (Table E1) were noted in 25 patients (17%). Two patients required cardiac reintervention, and the residual lesions score[23,24] was 2 or less (none or mild) in 138 of 144 patients scored (96%). Seven patients were readmitted (5%), and there was no mortality.

Follow-up was available in all patients at 30 days from discharge. In addition to clinic appointments, we have instituted follow-up with patient-reported outcomes surveys and video conferencing. Since January 1, 2019, 80% of patients were followed with video conferencing (45/56) at a median of 8 days after surgery (IQR, 6-11). Of these, 18 patients (40%) continued to require medications for pain, but only 2 (4%) were taking opioids.

TABLE 3. Exact conditional logistic regression results for binary and Poisson (number of complications) clinical outcomes (matched analysis)

Outcome	ERAS (N = 151)	Pre-ERAS (N = 301)	Odds ratio (95% CI)	Exact regression *P* value
Mechanical ventilation ≥8 h	69 (45.7%)	151 (50.2%)	0.82 (0.54-1.25)	.39
ICU LOS ≥1.25 d	65 (43.1%)	152 (50.5%)	0.72 (0.46-1.10)	.14
Patients with complications	25 (16.6%)	52 (17.3%)	0.96 (0.55-1.63)	.97
No. of complications	0.62 per 100 patient-d	0.68 per 100 patient-d	**Relative risk** 0.91 (0.57-1.46)	.82
0	126 (83.4%)	249 (82.7%)		
1	22 (14.6%)	44 (14.6%)		
2	3 (2.0%)	7 (2.3%)		
3	0 (0%)	1 (0.3%)		
Reoperation	2 (1.3%)	3 (1.0%)	1.33 (0.11-11.64)	1.00
Readmission 30 d from discharge	7 (4.6%)	20 (7.7%)	0.64 (0.23-1.59)	.42
Mortality	0	0	-	-

ERAS, Enhanced recovery after surgery; *CI*, confidence interval; *ICU*, intensive care unit; *LOS*, length of stay.

Results From Matched Analysis With Pre–Enhanced Recovery After Surgery Historical Cohort

The patient characteristics shown in Table 2 compare 151 propensity score–matched ERAS patients with 301 patients from 2016 to 2017, and there is no difference in demographic and perioperative characteristics between the 2 cohorts.

Table 3 reflects exact conditional logistic regression results for binary clinical outcomes. The set point for cutoff for continuous outcomes such as extubation and ICU LOS was determined relative to the program metric targets (Appendix E1) and by relevance for value-based care (ie, if a patient is in an ICU bed at midnight), respectively. By regression analysis, binary outcomes relative to program metrics for mechanical ventilation time (<8 hours), ICU LOS (<1.25 days), and adverse outcomes (complications, readmissions, reinterventions) did not significantly differ between the 2 cohorts.

Continuous variables for mechanical ventilation times, LOS in the ICU, and postoperative LOS were compared. In matched analysis, there was shorter mechanical ventilation time in the ERAS cohort (mean ± standard error 1.45 ± 0.11 vs 1.93 ± 0.08 log-hours, $P = .001$). The raw median mechanical ventilation times in the ERAS cardiac and pre-ERAS cohorts were 7.6 hours (IQR, 3.8-12.2) versus 8.2 hours (IQR, 4.0-17.0), respectively. ICU LOS was also shorter in the ERAS cardiac cohort (0.30 ± 0.05 vs 0.42 ± 0.03 log-days, $P = .046$), with raw median times of 1.12 days (IQR, 0.93-2.01) and 1.28 days (IQR, 0.96-2.09) in the pre-ERAS cohort. There was no difference in postoperative hospital LOS between the ERAS cardiac era and pre-ERAS era (1.65 ± 0.03 vs 1.68 ± 0.02 log-days, $P = .29$), and raw median times were 5.10 days (IQR, 4.00-6.90) and 5.24 days (IQR, 4.22-7.15), respectively.

We compared opioid use and found significantly less intraoperative opioid use in the ERAS cardiac cohort compared with the pre-ERAS era cohort in matched analysis, using square-root transformed OME dose in milligram per kilogram (ERAS cardiac: 2.59 ± 0.08 vs 2.89 ± 0.05 pre-ERAS era, $P = .001$). The raw median intraoperative dose for the ERAS cohort is 6.05 mg/kg (IQR, 3.75-9.78) and 7.27 mg/kg (IQR, 4.65-11.84) for the pre-ERAS era cohort ($P = .003$). There was no significant difference in the postoperative period between the 2 cohorts.

DISCUSSION

This represents the development and initial implementation of an enhanced recovery program after congenital surgery at a large pediatric institution (Video 1). We were able to demonstrate a reduction in mechanical ventilation time and ICU LOS relative to the pre-ERAS era. This occurred

VIDEO 1. Dr Roy discusses the development process and major components of the enhanced recovery after cardiac surgery program, as well as the implementation challenges, early results, and conclusions. Video available at: https://www.jtcvs.org/article/S0022-5223(19)32279-2/fulltext.

despite a suboptimal adherence to program guidelines, and many elements of the program are under development. It is plausible that the reduction in intraoperative opioid use seen with ERAS and the use of short-acting titratable sedatives immediately postoperatively affected the total ventilation time. We observed a high incidence of PONV. A previous study from our institution[25] did not show factors other than age and CPB time, and we wonder about the possible effects on gastrointestinal function from opioids and the long fasting periods observed in our patients. These are areas for which optimization of guideline observance (PONV prophylaxis) coupled with opioid-reducing pain management strategies could lead to improvement in functional recovery.

Overall, we noted suboptimal adherence to program guidelines; this can be partly explained by the recent implementation of the program, the challenges of educating large number and multiple groups of providers with guidelines departing from long-standing practices, and the lag in developing electronic aids such as specific ERAS cardiac order sets. In a pediatric abdominal surgery patient population, Short and colleagues[26] demonstrated that an increase in program component compliance led to a reduction in LOS. The other challenges of a pediatric population are patient engagement, family dynamic, and motivation.[27]

A recent publication refers to less than rigorous expansion of ERAS without evidence.[28] Recently, adult thoracic and cardiac surgery institutions have implemented ERAS programs based on comprehensive literature review of perioperative components[3-8] and published promising results. A common thread has been multimodal pain management and preoperative preparation. In the pediatric population, the challenge of pain management is significant,[27] with the parent as surrogate of the child's perception of pain. In the past few years, publications[9-13] regarding the adoption of ERAS concepts in pediatric surgical specialties have shown encouraging results and have emphasized the specific difficulties.[27]

We agree with Memtsoudis and colleagues[28] that a critical hypothesis-generating approach and equipoise are essential to the development of ERAS programs. The original ERAS components had the objective of reducing perioperative stress. With that in mind, a large body of research in pediatric cardiac surgery in the past 3 decades has focused on reducing intraoperative stress and inflammation in congenital surgery, from anesthetic agents[21] to CPB equipment and perfusion strategies.[22] Simultaneously, the development of surgical techniques to allow the repair of complex defects in neonates and children has continued to push the boundaries and the field forward.

Study Limitations

The limitations of this study are the recent launch of this program and suboptimal adherence to guidelines. In addition, critical elements such as education, patient-reported outcomes, and preoperative nutrition evaluation have not been fully implemented. Finally, the observational nature of this study prevents causal inferences to be made, although our carefully matched analysis minimizes bias in the comparison of the ERAS cardiac and pre-ERAS era cohorts.

These results identified significant opportunities: investigation of novel regional approaches for pain management[29] and strategies to reduce perioperative stress, and PONV; to pilot a program for preoperative evaluation and optimization of nutrition[30]; and improvement of processes such as selective placement of intracardiac lines, validation of chest tube removal algorithms and limitation of fasting to reduce discomfort, immobility, and affect LOS. Finally, little is known about functional recovery once the patients are discharged, and the expansion of a program with patient-reported outcomes monitoring will help to improve follow-up and assess patient and family satisfaction.

CONCLUSIONS

This study represents the initial experience from an ERAS program after congenital cardiac surgery at a large pediatric quaternary-care hospital. Adherence to our congenital ERAS cardiac guidelines is suboptimal at this early stage, but our results identified major areas for improvement and investigation. Momentum is building around monthly sharing of quality metrics and outcomes, which offer opportunities for multidisciplinary collaboration and provider engagement.

Webcast

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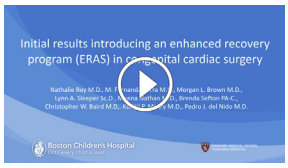

Conflict of Interest Statement

Authors have nothing to disclose with regard to commercial support.

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Key Words: ERAS, enhanced recovery after surgery, congenital, perioperative care, postoperative outcomes

Discussion

Dr Jennifer C. Romano *(Ann Arbor, Mich)*. Congratulations on an excellent presentation and your progress on a challenging endeavor. The buzzword of care is clearly minimizing practice pattern variation and improving patient throughput and experience. However, this is challenging, especially in a large, highly complex health system such as Boston Children's. I congratulate you on getting all the key stakeholders at the same table with a common vision. I have found that if you can get all the key stakeholders involved in the patient care experience together in the same room, it can be immensely powerful in terms of understanding everyone's roles as well as a platform for change. Your study is really evaluating the infantile phase of implementation of this complex care model. It is notable that you were able to identify subtle but real improvements, but, most important, areas for future focus. I have several questions.

First, I was impressed by the level of compliance of multimodal pain regimen, PONV prophylaxis, and early extubation in the operating room. To me, it would seem that the operating room is the best place to achieve compliance because it's a controlled environment, and early capture of pain and nausea in the operating room can have a huge impact in those first postoperative hours.

Dr Nathalie Roy *(Boston, Mass).* As you stated, it took a while to get everybody in the same room, get started with the process, and develop guidelines. I think looking at early data was key in identifying where we had issues and discussing it with our cardiac anesthesia colleagues. We found great collaborators in the anesthesia pain team, and the cardiac anesthesia group. Showing stakeholders data from month to month makes a big difference in achieving compliance, and there has been a lot more interest in extubating patients in the operating room now. As you stated, it's a lot easier to move on with the process when things are started in the operating room.

Dr Romano. Next, over the study period, only 35% of patients were eligible for this program. It seems that it is easier to implement something that is applied to the majority rather than the minority. Is this primarily driven by the comorbidity burden of your remaining patient population or the neonatal age of your remaining patient population?

Dr Roy. It is both. We have a high number of neonates, also a high number of patients who are referred for complex care after multiple operations. We wanted to start the process and achieve compliance in the order of 65% to 70% for major components and get buy-in from the providers by showing that we can do ERAS in this group of patients first. The plan, in the next year or 2, is to expand the program to different populations.

Dr Romano. Although your intubation ICU LOS was statistically shorter, when you look at the time difference, it is clinically insignificant. What do you think is ultimately going to be the primary end point to monitor success for your initiative? You already have excellent hospital length and ICU LOS.

Dr Roy. Patient-reported outcomes and satisfaction surveys are going to be important. We have little insight on how well patients are recovering after surgery. We implemented virtual visits a couple of years ago, and as part of this program we have added questions about pain medications and activity level and sleep. I have no data related to the last two, yet. We are in the infantile stage at this point, but that's going to be really important to understand recovery.

I also think there are real opportunities for improvement in a subset of patients who come in with failure to thrive at surgery, and implementing a nutrition program with visits before surgery to optimize their status going into surgery will hopefully make a difference in this population.

Dr Romano. How do you track in real-time compliance with this program? Are there repeated alerts or reminders for patients who are on this protocol or how do you make sure that all the care providers are aware of what they should be doing for this program?

Dr Roy. Real-time alerts is a research interest of one of my ICU colleagues. It would be great to let clinicians and bedside providers know it is time to extubate patients or to draw another lab sample. His research group is working on this challenge, but we don't have alerts at this point.

Currently, we have education aids such as guidelines and ERAS journey posters. I am present in the ICU, and we are considering hiring a nurse navigator/coordinator to educate and get feedback from the ICU and floor nurses. We also hold monthly multidisciplinary meetings where data are presented: It is powerful and engaging to show outcomes and differences, especially for bedside providers. We have a large cardiac program, as you mentioned. However, we have dedicated providers who want to improve the outcomes of our patients. They can be very engaged once they see how it affects results.

Dr Kevin Lobdell *(Charlotte, NC).* Please allow me to reinforce the importance of the question about real-time compliance and what's called an ERAS coordinator or a quality improvement coordinator. In my 15 years of experience doing this work, the 2 components are central to a program's success.

Dr Daniel T. Engelman *(Springfield, Mass).* Dr Roy, I noticed you have an Amazon skill now being rolled out. How is that going to allow you to collect patient-reported outcome measures through an Alexa app? Can you give us some broad picture of what this could possibly bring to future iterations of your ERAS program?

Dr Roy. This is just being rolled out now. We are currently receiving patient-reported outcomes via an electronic platform that the hospital has created; it's sent to families via text messaging or E-mail. To that we will be adding a voice component through voluntary registration with the hospital Health Insurance Portability and Accountability Act–compliant skill. The registered families will get reminders and can engage while on their phone application or through a voice speaker in their home. We are hoping that it will improve compliance by being interactive, rather than just filling in questionnaires related to outcomes. We will have to follow up once it's deployed for many months. We are in the process of launching it in the postoperative period, but we are hoping to develop interactive education preoperatively and have reminders about surgery and appointments soon.

APPENDIX E1. BOSTON CHILDREN'S HOSPITAL ENHANCED RECOVERY AFTER CARDIAC SURGERY PROGRAM GUIDELINES

1. Sedation and emergence guideline

Rationale

- Emergence from anesthesia should be optimized to minimize peri-extubation stress by allowing progressive awareness and minimizing agitation. It should happen in concert with multimodal pain medication regimen.
- Delirium[E3,E4] increase cardiovascular strain and perioperative complications. A screening tool[E3,E4] should be used in the ICU. Environmental changes to respect sleep-wake cycle should be implemented.

Guidelines

- If operating room (OR) extubation, patient can be maintained on intravenous (IV) dexmedetomidine, to be weaned over a period of 1 to 2 hours.
  - IV dexmedetomidine: Consider IV bolus 0.5 to 1.0 μg/kg, and infusion to start at dose 0.2 to 0.5 μg/kg/h, titrate to maximum of 2 μg/kg/h pro re nata (PRN) agitation.
- If patient is not extubated in OR, sedation will be started in OR with:
  - IV propofol: Start at 25 to 50 μg/kg/min, titrate up to 100 μg/kg/min PRN agitation; or
  - IV dexmedetomidine per above.
- For emergence delirium in the cardiac ICU:
  - Consider IV dexmedetomidine per above.
  - An age-appropriate delirium screening tool should be used at emergence from anesthesia in all patients.[E1] In addition, delirium screening should be performed every 12 hours in the cardiac ICU.[E3,E4]
  - Avoid using benzodiazepines.[E5]
  - Appropriate use of pain medications (using age-appropriate pain scales).

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2. Extubation guideline

Rationale

- Patients with low to moderate complexity lesions and minimal comorbidities can be safely extubated within 8 hours from surgery, pending they have minimal residual lesions and exhibit signs of good cardiac output.[E1-E5]
- At the discretion of the operating surgeon and anesthesiologist, certain patients can be extubated in the OR or upon early emergence in the ICU by the cardiac ICU team.

Conditions for early extubation (checklist)

- Surgical repair with minimal residual lesions.
- Patients with stable hemodynamics and blood pressure on no or low-dose inotropes or vasoactive medication at stable levels.
- Clinical evidence of good cardiac output: mixed venous oxygen saturation, acid-base, urine output
- No evidence of surgical bleeding
- Patient normothermic ($T \geq 36^{\circ}C$ and $\leq 38^{\circ}C$)
- Labs, chest x-ray reviewed by medical team

Guideline

- Selected cases can be extubated in the OR at the discretion of the attending anesthesiologist and attending surgeon: ERAS_A
- Target extubation within 8 hours from surgery:
  - Elective patients with minimal comorbidities, most patients with STAT 1-3 complexity score: ERAS_B

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3. Multimodal pain regimen guideline

Rationale

- The use of IV acetaminophen and IV ketorolac provides fast onset of pain and can be helpful in reducing the dose of opioid medication used in the postoperative period.[E1-E4]

- An opioid-reducing strategy reduces the incidence of ileus and postoperative nausea.

Guideline

- Infiltration of the surgical areas with ropivacaine 0.2% 0.5-1.0 mL/kg at the completion of the case.
- Regional anesthesia[E3,E5,E6] can be used as an alternative to local infiltration. Paravertebral or Erector spinae regional block(s) with catheter(s) placed by the regional pain service with ropivacaine infusion.
- Multimodal pain regimen should be initiated by anesthesia at the end of the procedure.[E3,E4,E7,E8]
    - IV acetaminophen15 mg/kg (max 975 mg) given in the OR, unless contraindicated.
    - A longer-acting opioid (eg, IV morphine or IV hydromorphone) should be considered once the patient is off CPB.
- Postoperative multimodal pain guideline:
    - Acetaminophen
        - IV acetaminophen 15 mg/kg (max 975 mg) every 6 hours for 4 doses, then acetaminophen per os/per rectum 15 mg/kg (max 975 mg) every 6 hours for 4 additional doses (next 24 hours), unless contraindicated.
            - Alternate acetaminophen (dosed every 6 hours) doses with ketorolac doses (dosed every 6 hours) so that pain medication is given every 3 hours.
            - Can transition to PRN earlier if chest tubes are discontinued, and if pain is well controlled without opioid medication.
        - Once scheduled acetaminophen doses (up to 8 doses) are completed, acetaminophen per os/per rectum 12.5 mg/kg every 4 hours PRN pain.
        - Acetaminophen should be discontinued if evidence of hepatic insufficiency and scheduled administration should be avoided in patients at risk for hepatic dysfunction.
    - Ketorolac
        - IV ketorolac 0.5 mg/kg (max 30 mg) every 6 hours for 8 doses (48 hours).
            - Can transition to PRN or discontinue earlier if the patient is no longer requiring opioid medications.
            - This medication should be stopped after 48 hours and transition to ibuprofen per os 10 mg/kg (max 800 mg) every 6 hours PRN pain.
            - Serum creatinine should be monitored daily when using scheduled ketorolac.
            - Routine administration of ketorolac should be discontinued if evidence of acute kidney injury and scheduled administration should be avoided in patients at risk for renal dysfunction.
    - Oxycodone:
        - Oral oxycodone should be used for moderate to severe pain not controlled by above medications
        - Per os 0.1 mg/kg (max 10 mg) every 4 hours PRN pain.
        - Patients should not be discharged home on opioid medications.
    - IV opioids
        - Rescue dose of IV opioids can be given PRN, for severe pain when patients have received acetaminophen and ketorolac, unless contraindicated.
        - IV morphine 0.05 mg/kg (max 2 mg) every 1 hour PRN severe pain
        - IV hydromorphone 0.008 mg/kg (max 0.4 mg) every 1 hour PRN severe pain

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4. Postoperative nausea prophylaxis guideline

Rationale

- General anesthesia is known to have side effects such as nausea and vomiting.[E1]
- PONV can lead delayed enteral nutrition, prolonged IV fluids, inability to take oral medications including pain medication, and delayed mobilization.

Nausea prevention medication guideline

- In the OR
  - IV dexamethasone 0.15 mg/kg (max 4 mg). Can be continued postoperatively every 8 hours PRN
- Postoperatively
  - IV ondansetron 0.1 mg/kg (max 4 mg) every 8 hours for 3 doses, then PRN PONV
    - Schedule first dose before extubation
    - Contraindicated if QTC prolongation (>460 ms)
  - Scopolamine patch: can be considered in patients aged ≥12 years. If placed in OR, remove when no longer needed; max 72 hours postoperatively. Discontinue if delirium or hallucinations or other complication.
  - Alternative: IV metoclopramide 0.2 mg/kg (max 10 mg) every 6 hours PRN PONV
    - Contraindicated if QTC prolongation (>460 ms)

E-Reference

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5. Nutrition and fasting guideline

Rationale

- Nutrition should be optimized before surgery to reduce perioperative complications.[E1,E2](nutrition references)
- Avoiding prolonged periods of fasting, reduces metabolic stress.
- Early enteral intake and bowel regimen improve return of bowel functions after surgery and accelerate functional recovery.

Preoperative protocol: Curtailing the fasting period

- No solid foods 8 hours before surgery, no formula 6 hours before surgery (<12 months), no breast milk 4 hours before surgery, no clear fluids 2 hours before surgery
- To limit fasting, the patient is advised to intake a carbohydrate-containing clear oral solution during the period from 2 to 4 hours before surgery[E1-E4](fasting references)
- Recommendations are as follows:
  - <12 mo: Pedialyte (Abbott Laboratories, Chicago, Ill), up to 4 oz
  - >12 mo and <15 kg: apple juice 4 oz
  - 15-<30 kg: apple juice 6 oz
  - 30-<50 kg: apple juice 8 oz
  - ≥50 kg: apple juice 10 oz

*Apple juice can be substituted by same quantity of Pedialyte or clear sports drink for intolerance/allergy or per parental choice. The carbohydrate content is approximately 50% of apple juice for clear sports drink and approximately 25% of apple juice for Pedialyte.

Postoperative guideline

- Allow clear fluids within 2 hours postoperatively as long as State Behavioral Score = 0 and stable respiratory status (low-flow nasal cannula or no supplemental oxygen).
- Advance diet as tolerated once tolerating clear fluids: Goal is a normal diet for age.
- Stop IV fluids once oral intake meets 50% of fluid goals for body weight in the first 24 hours after surgery. For subsequent days postoperatively, oral intake should meet 80% fluid goals for body weight goals.
- Start bowel regimen on postoperative day (POD) 1 in all patients. Bowel regimen can consist of nutritional intervention, if appropriate (eg, prune juice).
- Chewing gum can accelerate postoperative bowel function and should be allowed when age appropriate. However, please note that it is considered ''solid food'' when it comes to anesthesia.
- For sedated postoperative studies, the same guidelines as preoperative guidelines should be used to curtail the fasting period.

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Fasting

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Nutrition

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6. Early mobilization guideline

Rationale

- Early mobilization leads to improved pulmonary mechanics and reduces the risk of postoperative DVT.
- Early mobilization helps with fluid mobilization.

Guideline

POD 0

1. Patients should be mobilized to chair within 4 hours of extubation.

2. Patients should be walking on the unit within 8 hours of extubation.

**Age-appropriate pain score are recorded during activities.*

POD 1 to discharge

1. Extubated patients should be mobilized a minimum of 3 times per day to chair, with the goal of ambulating a minimum of 3 times per day.

**Age-appropriate pain score is recorded during activities.*

2. Venous thromboembolism (VTE) prophylaxis should be ordered (pneumoboots or enoxaparin) for patients aged ≥12 years, with moderate to severe risk of VTE per standard hospital VTE assessment tool. The prophylaxis should be maintained until full ambulation is demonstrated.

Safety: Prerequisites for Mobilization

- Sedation-state behavioral scale score = 0
- Monitoring for orthostatic hypotension: blood pressure lying, sitting, and upright, as indicated, for first time doing the activity and if clinically symptomatic.
- Observation for patient's balance should be performed before ambulation.
- At minimum, bedside nurse plus an additional caregiver or parent should accompany the patient on initial walk. Additional personnel may be required to help with equipment, when appropriate.
- "Rest and reassess" PICU Up[E1] guidelines should be followed:
  - 20% change in heart rate, blood pressure, and respiratory rate
  - 15% decrease in oxygen saturation, increase in oxygen requirements by 20%
  - Respiratory distress, new arrhythmia, change in mental status
  - Concern for vascular access or drain integrity

Full ambulation

- Defined as unrestricted ability to perform daily activities
- Demonstrated ambulation 3 times per day at minimum

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Lines, tubes, and drains guideline

Arterial line, central line, and Foley catheter should be removed when deemed unnecessary by the clinical team. This should happen ideally before 7 AM if the patient is scheduled to transfer to the step-down unit in the morning.

If the patient is planned to transfer on POD 0 (same day transfer), the central line can remain in place if access is inadequate.

Two working peripheral or central IVs should be in situ for transfer to the step-down unit for a patient within 24 hours of surgery. One of the IV accesses has to be of appropriate caliber for fluid resuscitation in function of patient's weight/body surface area.

Chest tube removal

A chest tube cannot be removed if the drainage is sanguinous, chylous, or presence of an air leak, without consulting with the attending surgeon.

The chest tube(s) can be removed on POD 1 only after the chest x-ray showed no effusions, and the patient has been mobilized out of bed (age appropriate) at least once.

Drainage criteria: After patient mobilization, a chest tube can be removed* if

- <20 kg: 1 mL/kg/tube in a total period of 4 consecutive hours
- >20 kg: 0.5 mL/kg/tube in a total period of 4 consecutive hours
- Adult size patient: 10 mL/h × 3 consecutive hours for each tube

**In patients with 2 ventricles, barring the above 3 contraindications: sanguinous, chylous, air leak*

If drainage is in excess of these criteria, consult surgical team for directions.

TABLE E1. Exact conditional logistic regression results for binary individual complications (matched analysis)

Complications	ERAS (N = 151) n (%)	Pre-ERAS era (N = 301) n (%)	ERAS vs pre-ERAS era relative risk (95% CI)	Exact *P* value
Incidence of STS complications (per 100 patient-d)	0.70	0.90	0.79 (0.48-1.28)	.33
			OR (95% CI)	
Arrhythmia requiring temporary pacemaker (%)	9 (6.0)	14 (4.7)	1.29 (0.49-3.19)	.70
Arrhythmia requiring drug therapy (%)	6 (4.0)	9 (3.0)	1.33 (0.39-4.19)	.76
Arrhythmia requiring permanent pacemaker (%)	1 (0.7)	3 (1.0)	0.67 (0.01-8.30)	1.00
Pericardial effusion requiring drainage (%)	0 (0.0)	2 (0.7)		.44
Pneumothorax requiring drainage (%)	1 (0.7)	3 (1.0)	0.67 (0.01-8.30)	1.00
Pleural effusion requiring drainage (%)	0 (0.0)	4 (1.3)		.20
Chylothorax (%)	2 (1.3)	3 (1.0)	1.33 (0.11-11.64)	1.00
Wound infection (%)	0 (0.0)	1 (0.3)		.67
Mediastinitis (%)	0 (0.0)	1 (0.3)		.67
Vocal cord dysfunction, possible recurrent laryngeal nerve injury (%)	2 (1.3)	2 (0.7)	2.00 (0.15-27.59)	.81
Seizure (%)	0 (0.0)	1 (0.3)		.67
Transient neurologic deficit (%)	0 (0.0)	2 (0.7)		.44
Unplanned interventional cardiovascular catheterization (%)	1 (0.7)	1 (0.3)	2.00 (0.03-156.99)	1.000
Unplanned noncardiac reoperation (%)	2 (1.3)	0 (0.0)		.11
Unplanned cardiac reoperation (%)	2 (1.3)	3 (1.0)	1.33 (0.11-11.64)	1.00
Unplanned readmission within 30 d of surgery (%)	6 (4.0)	18 (6.0)	0.64 (0.23-1.59)	.53
Other complication (%)	1 (0.7)	14 (4.7)	0.14 (0.003-0.94)	.039

ERAS, Enhanced recovery after surgery; *CI*, confidence interval; *STS*, Society of Thoracic Surgeons; *OR*, odds ratio.