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Featured Articles

Prognostic profiling of children with serious post-operative complications: A novel probability model for failure to rescue☆,☆☆

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ABSTRACT

Background: Failure to rescue (FTR), mortality after a major postoperative complication, is a superior surgical quality metric compared to surgical mortality or complications rates alone. Our objective was to develop and validate a novel pediatric profiling to identify high-risk subjects among the subset of children who develop serious post-operative complications.
Methods: We performed a retrospective study of children who developed one or more serious postoperative complications following inpatient surgery across NSQIP-Pediatric hospitals (2012–2017). We evaluated the rate of FTR according to pre-operative comorbidity burden.
Results: We identified 45,504 surgical cases with major post-operative complications (FTR rates: 2.4%). Surgical cases with greater than six pre-operative comorbidities (n = 12,148;28%) accounted for 80% of FTR events. The expected probability of FTR was 0.1%(95%CI:0.1%–0.2%) among low-risk cases, 3.3%(95%CI:3.0%–3.5%) among intermediate-risk cases, and 22.6%(95%CI:20.9%–24.3%) among high-risk cases. About half of surgical cases in the high-risk profile group died within 48 h of surgery. Comparatively, cases in the intermediate-risk group had a much longer time to mortality (10 days).
Conclusion: We propose a prognostic index to accurately identify children at risk for FTR. The use of such an index may provide surgeons with a window of opportunity to implement aggressive monitoring and therapeutic strategies to reduce mortality.
Level of evidence: IV

Thirty-day postoperative mortality has been used in a variety of risk stratification indices to guide perioperative care for decades [1–8]. However, most risk-scoring systems were primarily intended for preoperative profiling and thus do not measure the ability of clinicians to rescue the subset of patients who develop complications [9–11]. A metric that evaluates the rescue process of patients who develop post-surgical complications could provide an avenue to benchmark institutions and identify tailored quality improvement interventions [12]. Such a metric could also be valuable for identifying subjects with a high risk of mortality following major complications. Furthermore, with the heightened emphasis on patient safety and minimization of preventable decompensation, both mortality rates and complication rates have progressively lost their discriminatory properties as metrics of surgical quality [13–15].

To overcome these limitations, we are proposing a novel risk profiling for pediatric surgical patients that is based on failure to rescue (FTR). FTR, which is defined as death following a major complication, is a reliable metric that quantifies the ability of clinicians to initiate timely monitoring protocols, diagnoses, and remedial procedures when a complication develops [16]. Compared to traditional indicators such as mortality rate alone, FTR is superior because it maintains a discriminatory power where traditional indicators of the quality of surgical care fail to distinguish between high performing institutions [13]. Additionally, FTR correlates better with hospital performance than mortality rate alone [14,17]. Given the preceding properties, FTR has been endorsed as an indicator of hospital performance by the National Quality Forum [18].

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Predicting FTR has been mostly attempted among adults [12,19–21]. The few studies evaluating pediatric cases have mainly focused on the association between FTR and organizational-level factors, including hospital volume, hospital teaching status, nurse experience and education [13,22–25]. However, to utilize FTR in quality improvement initiatives, it is essential to produce risk-adjusted data by accounting for patients-level perioperative risks. Therefore, the purpose of this study was to develop and validate a pediatric profiling system to identify subjects at high-risk for FTR among children who develop major complications following surgery.

1. Methods

1.1. Study population

We queried data on a multi-institutional cohort of children who underwent inpatient surgical procedures, between 2012 and 2017, from the National Surgical Quality Improvement Program for Pediatrics (NSQIP-P) Participant Use Data File. Briefly, the NSQIP-P Participant Use Data File is a validated, nationally representative, and case-mix-adjusted perioperative database of children < 18 years who underwent surgical procedures at hospitals across the United States. Trained data abstracters collect and maintain data on demographic, surgical profile, clinical preoperative, laboratory, intraoperative, and postoperative characteristics [26]. Additional details about the NSQIP-P including sampling design, data management procedures, and variables collected are described elsewhere [26–30]. This study was approved by the institutional review board of the Nationwide Children's Hospital, Columbus, Ohio.

1.2. Inclusion criteria and outcome measures

We included in our analytical cohort all children who developed one or more major postoperative complications. As defined by the NSQIP-P [31], and adopted in previous studies [12,32,33], major postoperative complication indicates the occurrence of one of seven postoperative events: (1) wound complications (deep organ space surgical site infection, deep surgical site infection, and surgical wound dehiscence); (2) pulmonary complications (pneumonia, unplanned reintubation, pulmonary embolism, deep venous thrombosis, and mechanical ventilation longer than 48 h); (3) renal complications (acute renal failure, progressive renal insufficiency, and urinary tract infection); (4) neurologic complications (coma for more than 24 h, and stroke); (5) cardiac complications including cardiac-arrest; (6) sepsis (sepsis, and septic shock); and (7) bleeding or unplanned reoperation. Our primary outcome was FTR, considered as the occurrence of mortality within 30 days of surgical procedure, among children who developed one or more major postoperative complications (coded as a binary variable: not rescued vs. survived).

1.3. Explanatory variables

As previously described [34], we accounted for the intrinsic risk of each surgical procedure by categorizing Current Procedural Terminology (CPT) codes into risk tertiles: low, intermediate, and high. These risk tertiles were built based on the empirical rates of FTR for each CPT code. Our variable selection approach relied on existing literature and our hypothesis on the association of FTR with factors that were available in the NSQIP-P database. We selected a variable if it met either of the following criteria: (1) the variable has been shown to be a predictor of postoperative mortality, or (2) there is a clinical plausibility of a relationship between the variable and postoperative mortality. Using this approach, we selected the following demographic characteristics: age at the time of surgery (Older children (>12 months), infants (>1 month-12 months), neonates (≤1 month)), and sex (male vs. female). We also selected the following baseline risk factors that were coded as binary (yes vs. no) variables: emergent/urgent surgery, preoperative oxygen support, ventilation dependency, inotropic support, central nervous system abnormality, congenital malformation, cardiac risk factor, gastro-intestinal disease, hematologic disorder, chronic lung disease, childhood malignancy, preoperative sepsis, seizure disorder, structural airway abnormality, prematurity, Do-Not-Resuscitate (DNR) status, nutritional support. We also included ASA physical classification (>3 vs. ≤3), and wound classification (clean, clean/contaminated, contaminated, dirty/infected).

1.4. Statistical analyses

We used logistic regression to build a prognostic model and derive the prognostic index for FTR. Using a purposeful framework [35], a variable was included into the multivariable model if its crude association with FTR was significant at the alpha level of 0.20 [36]. Because of the potential dependence within pre-operative factors, we assessed

Table 1
Characteristics of infants who developed major post-operative complications, NSQIP-P 2012–2017*.

	Overall	Survived	Failure to rescue
	No. (%)†	No. (%)†	No. (%)†
Study population	45,504 (100.0)	44,415 (97.6)	1089 (2.4)
Baseline risk factors			
Female sex	22,429 (49.3)	21,923 (49.4)	506 (46.5)
Age			
Older children (>12 months)	29,968 (65.9)	29,705 (66.9)	263 (24.2)
Infants (>1 month-12 months)	10,384 (22.8)	10,054 (22.6)	330 (30.3)
Neonates (≤1 month)	5152 (11.3)	4656 (10.5)	496 (45.5)
CPT risk category‡			
Low	16,822 (37.0)	16,818 (37.9)	4 (0.4)
Intermediate	13,548 (29.8)	13,472 (30.3)	76 (7.0)
High	15,134 (33.3)	14,125 (31.8)	1009 (92.7)
Emergent/urgent surgery	11,758 (25.8)	11,032 (24.8)	726 (66.7)
Oxygen support	7344 (16.1)	6645 (15.0)	699 (64.2)
Ventilation dependency	7619 (16.7)	6845 (15.4)	774 (71.1)
Inotropic support	1866 (4.1)	1490 (3.4)	376 (34.5)
Central nervous system abnormality	11,349 (24.9)	11,086 (25.0)	263 (24.2)
Congenital Malformation	19,780 (43.5)	19,331 (43.5)	449 (41.2)
Cardiac risk factor	10,960 (24.1)	10,374 (23.4)	586 (53.8)
Gastro-intestinal disease	14,297 (31.4)	13,635 (30.7)	662 (60.8)
Hematologic disorder	5230 (11.5)	4857 (10.9)	373 (34.3)
Chronic lung disease	5536 (12.2)	5294 (11.9)	242 (22.2)
Childhood malignancy	3294 (7.2)	3197 (7.2)	97 (8.9)
Pre-operative sepsis	4922 (10.8)	4554 (10.3)	368 (33.8)
Seizure disorder	5329 (11.7)	5203 (11.7)	126 (11.6)
Structural airway abnormality	5887 (12.9)	5629 (12.7)	258 (23.7)
Prematurity	11,693 (25.7)	11,103 (25)	590 (54.2)
ASA classification >3	7051 (15.6)	6289 (14.2)	762 (72.9)
Do-not-resuscitate status	96 (0.2)	73 (0.2)	23 (2.1)
Nutritional support	12,368 (27.2)	11,684 (26.3)	684 (62.8)
Wound classification			
Clean	27,485 (60.4)	27,181 (61.2)	304 (27.9)
Clean/contaminated	11,616 (25.5)	11,263 (25.4)	353 (32.4)
Contaminated	2091 (4.6)	1973 (4.4)	118 (10.8)
Dirty/infected	4312 (9.5)	3998 (9)	314 (28.8)
Post-operative complications§			
Wound complications	5224 (11.5)	5185 (11.7)	39 (3.6)
Pulmonary complications	7455 (16.4)	7209 (16.2)	246 (22.6)
Renal complications	329 (0.7)	266 (0.6)	63 (5.8)
Neurologic complications	1046 (2.3)	951 (2.1)	95 (8.7)
Cardiac complications	811 (1.8)	504 (1.1)	307 (28.2)
Sepsis	2647 (5.8)	2510 (5.7)	137 (12.6)
Bleeding or unplanned reoperation	37,490 (82.4)	36,626 (82.5)	864 (79.3)

* We retained in our sample children (age < 18-year-old), who underwent inpatient surgery and developed one of more post-operative complications. †Percentages are for column. ‡CPT risk category was generated based on the empirical rates of FTR for each CPT code. §Assessed during the 30 days following surgery. **Abbreviations**: CPT, Common Procedural Technology; NSQIP-P, National Surgical Quality Improvement Program-Pediatric; FTR, Failure to rescue.

multicollinearity by computing the correlation matrix of fitted coefficients from the multivariable model. A multicollinearity was considered present if the magnitude of the correlation of a fitted coefficient was greater than 0.50. We created a prognostic index by multiplying each regression coefficient of the final prognostic model by 10 and rounding it to the nearest integer [37]. The total index for each surgical case was represented by the sum of the values for each predictor in the final prognostic model. We sought to classify the prediction score and estimate stratified risk of FTR. We specifically avoided assigning arbitrary cut-off points, but instead explored data driven categorizations that would account for potential non-linearity of the risk score. We identified appropriate cut-points by plotting the probability of FTR with prediction score using restricted spline with five knots. We then plotted the predicted probability of FTR against the prognostic index using restricted spline with five knots and identified points of inflection at which the predictive probability of FTR changed (Supplemental Materials-Fig. S1). Based on this assessment, we categorized the prognostic index into three mutually exclusive groups with increasing risk of FTR: low-risk (index between 0 to 40), intermediate-risk (index between 41 to 70), and high-risk (index > 70). To assess model discrimination and calibration, we estimated the C-statistic and Somer'D coefficient, respectively. It is not useful to interpret a measure of predictive performance that is derived from the original sample because such measure will likely be overestimated (optimism) [38]. To adjust for this optimism, we used bootstrap by which we generated 1000 random samples with replacement from the original sample. For each replication dataset, we fit the final prognostic model that was developed from the original sample and estimated the C-statistic (called C_{boot}). We then calculated the statistical optimism by subtracting C_{boot} with the C-statistic estimated from the original sample (called $C_{original}$). The bootstrap corrected C-statistic (called $C_{corrected}$), that penalizes for model overfitting, was obtained by subtracting $C_{original}$ to the mean statistical optimism [38]. We used the same approach to correct the Somer'D coefficient for potential optimism. In addition to the bootstrapping, we randomly divided the sample into a derivation cohort (70%) and a validation cohort (30%) and used the validation cohort to assess the predictive accuracy of a model derived from the derivation cohort (Supplemental materials).

We performed all analyses using Stata, version 15 (StataCorp), for which a *P*-value less than 0.05 was considered as statistically significant.

2. Results

2.1. Study population

A total of 276,427 inpatient surgical cases were identified between 2012 and 2017, of whom 45,504 (16.5%) developed one or more major postoperative complications and were retained in our analytical cohort. (Table 1) Of these 45,504 surgical cases, 1089 (2.4%) did not survive. The median age was 83 months (interquartile range, 6--167 months); 11.3% (n = 5152) of cases were neonates (<1 months), 22.8% (n = 10,384) were infants (1–12 months), and 65.9% (n = 29,968) were older children (>12 months). Just below half of patients were female (49.3%, n = 22,429).

2.2. Preoperative comorbidities and failure to rescue

Fig. 1 summarizes the distribution of FTR according to the number of preoperative risk factors. There was a monotonic relationship between preoperative risk factors and FTR (Fig. 1). Specifically, cases with six or more preoperative comorbidities (n = 12,148; 28%) accounted for most of the FTR events (80%). Conversely, cases with fewer than three preoperative risk factors accounted for only 5.5% of FTR events.

2.3. Prognostic index for failure to rescue

The strongest predictor of FTR was preoperative inotropic support (OR: 2.98; 95%CI:2.53–3.50; $P < 0.001$ – Fig. 2). Other factors associated with FTR include, preoperative ventilator dependency, emergent/urgent case status, malignancy, preoperative sepsis, oxygen support, younger age, seizure disorder, hematologic disorder, female sex, wound classification, and cardiovascular risk factors (Fig. 2). The bootstrap corrected C-statistic, penalizing for overfitting was 0.91, indicating excellent predictive discrimination of the prognostic model (95% CI: 0.90–0.92). The bootstrap corrected Somers' D rank correlation was 0.82(95% CI:

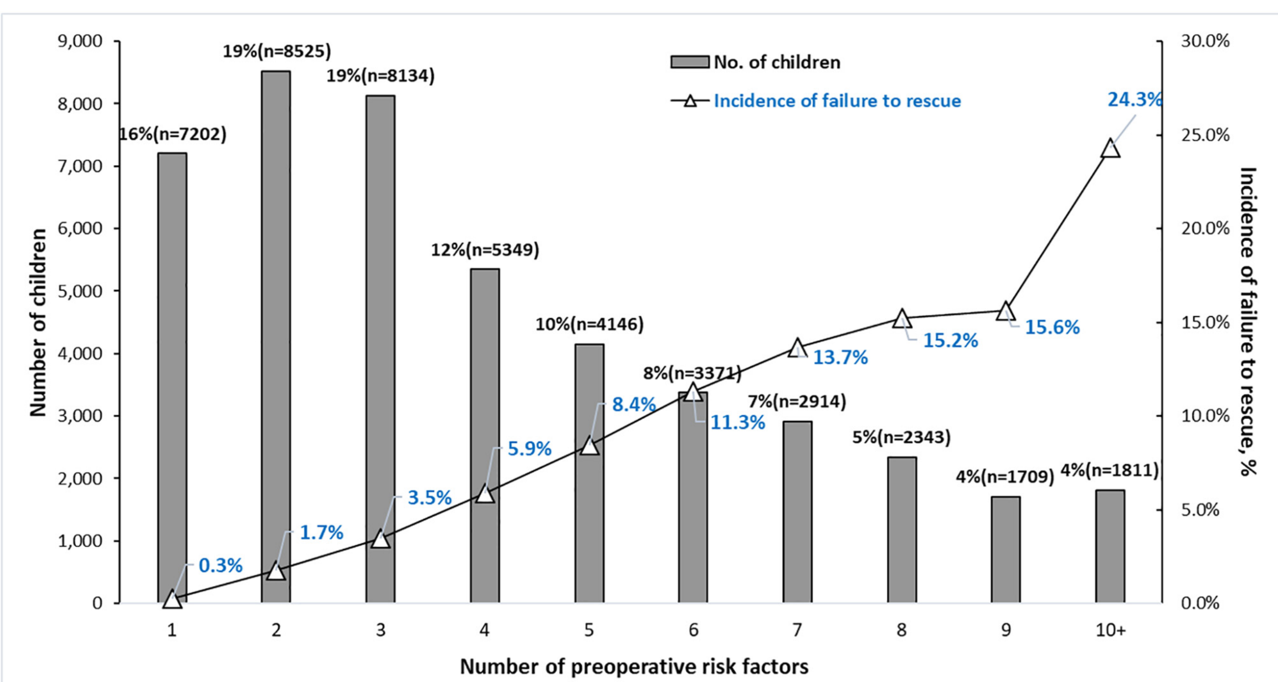

Fig. 1. Number of pre-operative comorbidities and failure to rescue, National Surgical Quality Improvement Program-Pediatric, 2012–2017.

Characteristics	β(95% CI)	Score	OR(95% CI)	P-value
Age				
Older children (>12 months)	Reference	0	1.00 (1.00, 1.00)	
Infants (>1 month-12 months)	0.19(-0.02,0.39)	2	1.21 (0.98, 1.48)	0.075
Neonates (≤1 month)	0.39(0.18,0.60)	4	1.48 (1.20, 1.83)	<0.001
CPT risk category				
Low	Reference	0	1.00 (1.00, 1.00)	
Intermediate	3.18(2.17,4.18)	32	23.96 (8.75, 65.62)	<0.001
High	4.44(3.45,5.43)	44	85.01 (31.54, 229.14)	<0.001
Wound classification				
Clean	Reference	0	1.00 (1.00, 1.00)	
Clean/contaminated	0.10(-0.07,0.27)	1	1.10 (0.93, 1.31)	0.265
Contaminated	0.34(0.09,0.58)	3	1.40 (1.09, 1.79)	0.008
Dirty/Infected	0.30(0.09,0.51)	3	1.35 (1.10, 1.66)	0.005
Pre-operative risk-factors				
Female sex	0.18(0.05,0.31)	2	1.20 (1.05, 1.36)	0.007
Emergent/urgent surgery	0.60(0.44,0.76)	6	1.82 (1.56, 2.13)	<0.001
Oxygen support	0.47(0.31,0.63)	5	1.60 (1.36, 1.88)	<0.001
Ventilation dependent	0.78(0.60,0.96)	8	2.18 (1.82, 2.62)	<0.001
Inotropic support	1.09(0.93,1.25)	11	2.98 (2.53, 3.50)	<0.001
Cardiac risk factor	0.17(0.03,0.32)	2	1.19 (1.03, 1.38)	0.021
Hematologic disorder	0.23(0.08,0.38)	2	1.26 (1.09, 1.46)	0.002
Childhood malignancy	0.64(0.38,0.90)	6	1.90 (1.47, 2.45)	0.002
Pre-operative sepsis	0.49(0.32,0.66)	5	1.63 (1.38, 1.93)	<0.001
Seizure disorder	0.37(0.16,0.58)	4	1.45 (1.17, 1.79)	0.001

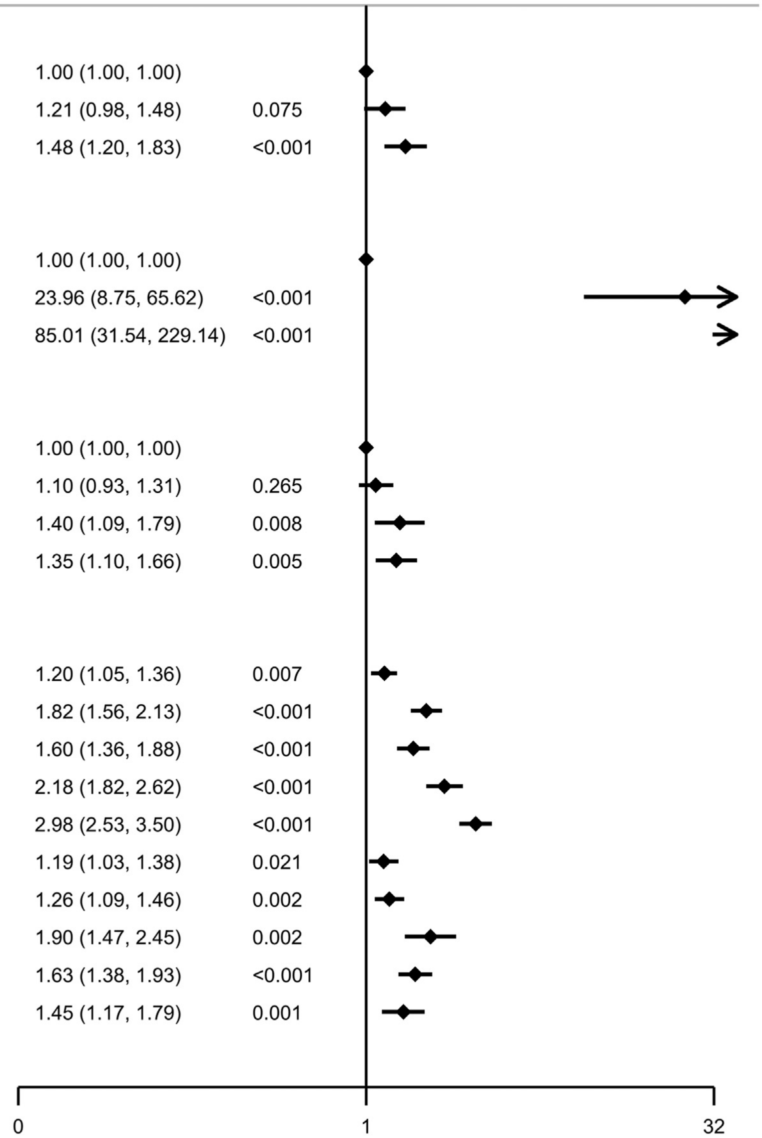

Fig. 2. Multivariable logistic regression for the prediction of failure to rescue and creation of a prognostic index by incorporating socio-demographic characteristics *and* pre-operative co-morbidities, NSQIP-P 2012–2017. The bootstrap corrected C-statistic and Somers' D rank correlation were **0.906 (95% CI: 0.901–0.916)** and **0.815 (95% CI: 0.786–0.820)** respectively. The derived prognostic index ranged from **0** to **98**, with a median (interquartile range) of **34 (6–52). Abbreviations**: CPT, Common Procedural Technology; NSQIP-P, National Surgical Quality Improvement Program-Pediatric; OR, odds ratio; CI, confidence intervals.

0.79–0.82) indicating excellent predictive calibration between survivors and non-survivors. After randomly splitting the sample into a derivation (70%) and a validation cohort (30%), we found a C-statistic of 0.91 for the validation cohort (supplemental materials-Fig. S3).

The prognostic index ranged from 0 to 98, with a median (interquartile range) of 33 (6–52). (Fig. 2) Cases were grouped into three risk categories with increasing risk of FTR: low-risk (index between 0 to 40), intermediate-risk (index between 41 to 70), and high-risk (index >70). The high-risk group comprised 5.2% (n = 2354) of the sample; the intermediate and low-risk groups comprised 35.0% (n = 15,882) and 60.0% (n = 27,267) of the sample, respectively. (Supplemental Materials-Table S1). The expected probability of FTR was 0.1% (95%CI: 0.1%–0.2%) among low-risk cases, 3.3% (95%CI: 3.0%–3.5%) among intermediate-risk cases, and 22.6% (95%CI: 20.9%–24.3%) among high-risk cases. Among high-risk cases, half of mortality events occurred within the first 48 h following surgery. (Fig. 3) Among intermediate risk cases, half of mortality events were observed about 10 days after surgery.

3. Discussion

In this study, we developed and validated a prognostic profiling of FTR among pediatric surgical cases with one or more major post-surgical complications. We found that among high-risk surgical cases, half of mortality events occurred within the first 48 h following surgery, suggesting that timely and aggressive treatment is needed to improve FTR. Comparatively, surgical cases in the intermediate-risk group had a much longer time to mortality (10 days), suggesting that clinicians have a larger window of opportunity to implement appropriate rescue process. A small proportion of surgical cases (28%) with the largest pre-operative comorbidity burden accounted for the highest proportion (80%) of deaths. Our prognostic index would reliably identify high-risk children because of its excellent predictive calibration and discrimination. In addition to guiding the postoperative rescue of patients through early identification of high-risk subjects, our prognostic profiling would undoubtedly be helpful during discussions with parents of children with major postoperative complications.

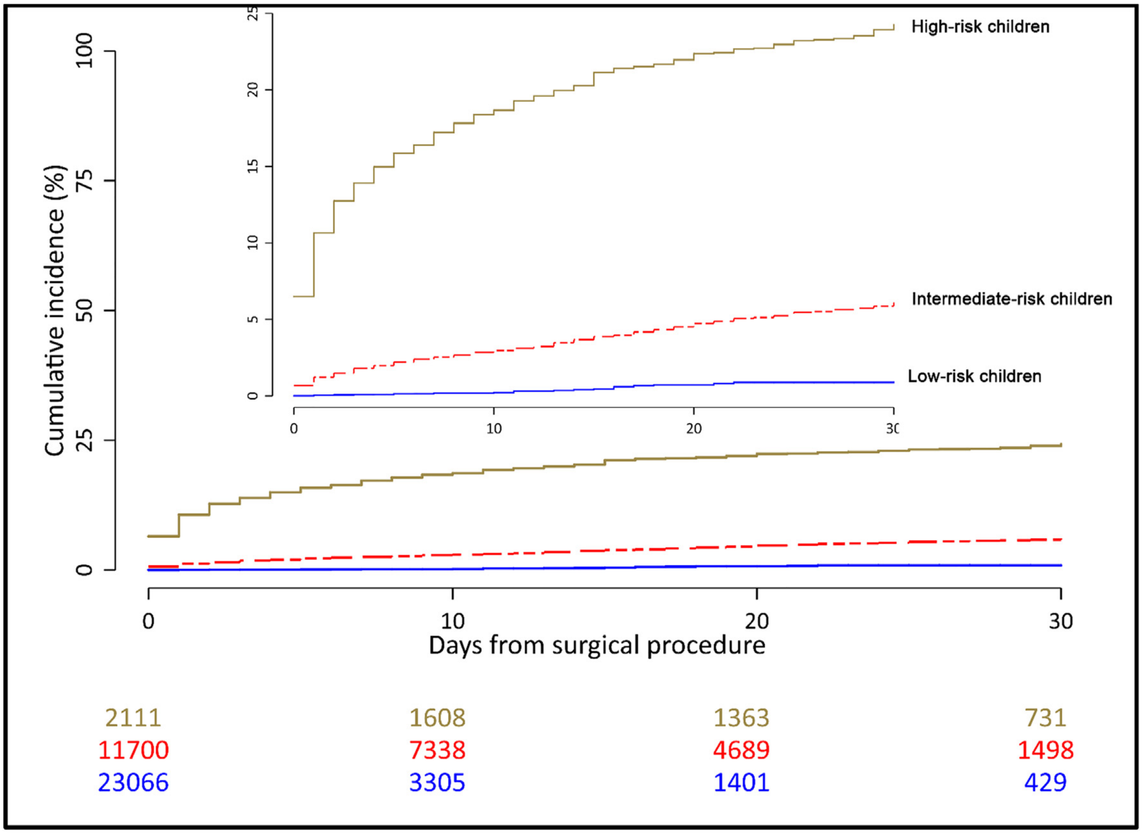

Fig. 3. Time from occurrence of serious post-operative complications to mortality comparing children across the three risk categories for FTR (low, intermediate, high). National Surgical Quality Improvement Program-Pediatric 2012–2017. *The inset graph represents the same data, but with enhanced y axis.*

The main value added from utilizing our prognostic index is the opportunity to optimize the management of major postoperative complications by improving the recognition of high-risk children. Early identification of patients with a high risk of mortality is crucial in triggering appropriate actions to prevent the expected mortality before it unfolds [9]. The benefit of early identification of high-risk patients is attributed to the process of "situation awareness," which is defined as "the perception of elements in the environment within a volume of time and space, the comprehension of their meaning, and the projection of their status in the near future." [9,39] In addition, our analyses provide an empirical evaluation of the potential window of opportunity that would be available to a clinician to implement a rescue process following surgery, according to patients' risk for failure-to-rescue. This knowledge is crucial not only for resource planning and monitoring, but also for risk mitigation. An additional value added from utilizing our prognostic index is the opportunity for institutions to better track their performance against expected performance. For example, by estimating the ratio of observed failure-to-rescue/expected failure-to-rescue, one would be able to better capture the ability to terminate the potential transition from a sentinel complication to mortality—in a way that the ratio observed overall mortality/expected overall mortality cannot. Of note, it was not our intent to supplant the existing models to predict pediatric surgical mortality, most of which relate to pre-operative profiling of all patients admitted for surgery [1–8]. Instead, we are providing a complementary tool using a different indicator (failure-to-rescue) which provides better benchmarking, compared to assessing overall mortality rate alone.

Given the importance of our prognostic index for not only improving care, but also benchmarking institutions, we recommend its integration into an electronic medical system, to allow for real-time prognostic profiling of patients. The index includes fewer patient's characteristics than an existing risk calculator [7], and these characteristics are easy to ascertain in hospital settings. Furthermore, because the index only includes preoperative risk factors, a prognostic profiling can be established before the occurrence of a complication, thus giving surgeons a window for intervention to prevent FTR. This advantage suggests that our index could be utilized on an empirical basis for setting-up tailored monitoring system, and appropriate level of vigilance or communication. Another corollary is that our prognostic model does not need to be updated with each new complication while maintaining excellent discriminatory and calibration properties to accurately identify high-risk children.

Some limitations must be accounted for when interpreting our findings. First, our analysis was based on a retrospective design, indicating that we had no control over variable definitions, coding, and granularity of patient characteristics. Relatedly, the study database did not have information pertaining to socio-economic factors such as urban–rural, zip code, mean income, and parents' education. Furthermore, the use of a large database may include pitfalls from data errors and thus introduce information bias. Despite these limitations, the NSQIP-P is one of the largest and most reliable surgical databases in the United States [40]. Study nurses who collect data at individual hospitals routinely undergo audit by the ACS-NSQIP oversight committee. Third, our prognostic index has not been validated using an external population. However, several risk profiling systems have not been externally validated but have been valuable in perioperative medicine [7,11,12]. Fourth, we cannot rule out the possibility that our proposed model may not perform as well when applied to surgical procedures not included in the NSQIP-P CPT list. This limitation may limit the generalizability of our prognostic model to surgical procedures like cardiac, transplant or vascular. Fifth, we recognize that FTR is a composite definition and is thus limited by potential differences in the distribution of its component variables. Furthermore, we cannot determine the hospital or patient level factors that underlie the post-complication rescue process, i.e. some patients with severe disease may not want to be rescued and some disease and complications are simply “rescue resistant.” Sixth, we must underscore the fact that despite the excellent performance of our risk scoring index, no risk scoring system can reliably predict which patients will deteriorate or succumb to their disease. A prognostic scoring system is by design an “early warning system” that may help identify the subset of patients that require close monitoring. Finally, our definition of failure to rescue was based on the 30-day mortality and, therefore, did not capture events that occur on or after 31 days following the operation. Despite these limitations, our definition of failure to rescue is consistent with previous studies, that have defined “failure to rescue” based on 30-day postoperative mortality [12,41,42].

4. Conclusion

We found that half of failure-to-rescue cases occurred in a subset of high-risk children who had the greatest preoperative comorbidities burden. We developed a prognostic index that demonstrated an excellent discrimination and calibration, with which to accurately identify these high-risk children. Successful identification of high-risk children may provide surgeons with a window of opportunity to implement aggressive monitoring and therapeutic systems to prevent pediatric postsurgical mortality. Institutions may also utilize the derived prognostic index to benchmark their performance, and thus focus on continuous quality improvement.

Declaration of competing interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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