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Clinical outcomes following implementation of a management bundle for esophageal atresia with distal tracheoesophageal fistula☆

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ABSTRACT

Background/Purpose: This study evaluated compliance with a multi-institutional quality improvement management protocol for Type-C esophageal atresia with distal tracheoesophageal fistula (EA/TEF).
Methods: Compliance and outcomes before and after implementation of a perioperative protocol bundle for infants undergoing Type-C EA/TEF repair were compared across 11 children's hospitals from 1/2016–1/2019. Bundle components included elimination of prosthetic material between tracheal and esophageal suture lines during repair, not leaving a transanastomotic tube at the conclusion of repair (NO-TUBE), obtaining an esophagram by postoperative-day-5, and discontinuing prophylactic antibiotics 24 h postoperatively.
Results: One-hundred seventy patients were included, 40% pre-protocol and 60% post-protocol. Bundle compliance increased 2.5-fold pre- to post-protocol from 17.6% to 44.1% ($p < 0.001$). After stratifying by institutional compliance with all bundle components, 43.5% of patients were treated at low-compliance centers (<20%), 43% at medium-compliance centers (20–80%), and 13.5% at high-compliance centers (>80%). Rates of esophageal leak, anastomotic stricture, and time to full feeds did not differ between pre- and post-protocol cohorts, though there was an inverse correlation between NO-TUBE compliance and stricture rate over time ($\rho = -0.75$, $p = 0.029$).
Conclusions: Compliance with our multi-institutional management protocol increased 2.5-fold over the study period without compromising safety or time to feeds and does not support the use of transanastomotic tubes.
Level of Evidence: Level II.
Type of Study: Treatment Study.

Esophageal atresia (EA) with tracheoesophageal fistula (TEF) is a congenital anomaly that has seen significant improvement in outcomes over the last century due to advancements in surgical techniques and perioperative care [1]. The mortality of EA/TEF in the U.S. has dropped to less than 10%, and with that decrease the focus on postoperative morbidity and long-term outcomes has advanced to the forefront of interest

☆ How this paper will improve care: Implementation of a multi-institutional, evidence-based protocol for EA/TEF patients is safe, feasible, and allows for data-driven practice changes with decreased variability in care. We found protocol compliance challenging and no benefit in routine trans-anastomotic tube use.

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by the discipline of pediatric surgery [2]. However, no strong evidence-based guidelines exist for the surgical management of EA/TEF, and recent multi-institutional studies have identified a high degree of practice variability in the perioperative management of these patients [3].

Recent retrospective review of surgical techniques and postoperative outcomes in the management of proximal EA with distal TEF (Type C EA/TEF) by the Midwest Pediatric Surgery Consortium (MWPSC) identified areas of practice variation that were significantly correlated with postoperative outcomes or at variance with surgical best practices [4]. First, the interposition of prosthetic material (such as fibrin glue or synthetic mesh) between tracheal and esophageal suture lines during EA repair was independently associated with an increase in postoperative esophageal leak rate. Second, leaving a transanastomotic (TA) tube in the esophagus at the conclusion of EA repair was independently associated with an increased incidence of postoperative esophageal stricture. Third, there was significant variation in the use and timing of postoperative esophagrams, which had implications for when patients were able to start enteral feeds. Finally, duration of postoperative prophylactic antibiotic usage was highly variable and did not meet the Surgical Care Improvement Project (SCIP)-Inf-3 measure of discontinuing prophylactic antibiotics within 24 h postoperatively to minimize antimicrobial resistance, side effects, and cost [5].

To address these areas of practice variability, an EA/TEF surgical management protocol was developed and implemented using quality improvement methodology within the participating institutions of the MWPSC. The purpose of this study was to evaluate compliance with the protocol bundle and compare patient outcomes before and after protocol implementation.

1. Methods

1.1. Patients and study design

A prospective observational cohort study of infants who underwent definitive surgical repair of Type C EA/TEF before and after implementation of a quality improvement management protocol was performed across 11 participating children's hospitals of the MWPSC. Institutional review board approval was obtained from participating sites prior to patient enrollment. All infants with Type C EA/TEF diagnosed within 30 days of life who underwent definitive surgical repair of their defect by 6 months of life between 1/1/2016 and 1/1/2019 were included. Exclusion criteria were other types of EA or TEF, mortality prior to surgical intervention, and definitive repair performed at an institution outside of the MWPSC. Patients were identified during regular review of administrative hospital and practice databases using diagnostic codes for Type C EA/TEF (ICD-9750.3) and procedure codes for esophageal reconstruction with or without ligation of TEF (ICD-9 CM 31.73, 42.51, 42.85, 42.89, 43.19; CPT 43314 or 43313) at each institution during the study period and eligibility was confirmed via review of the medical record.

Study data were collected via chart review on a rolling basis and managed using Research Electronic Data Capture (REDCap™) software hosted at the Medical College of Wisconsin [6]. Data elements included patient demographics, management bundle compliance, perioperative characteristics, and postoperative outcomes. All data were validated centrally and at individual institutions for completeness and accuracy.

1.2. Quality improvement management bundle

A standardized management bundle was defined with consensus from all participating institutions based on modifiable areas of practice variation identified on prior retrospective review with the aim of improving surgical outcomes following Type C EA/TEF repair. The bundle consisted of four components – 1) eliminating interposition of prosthetic material between tracheal and esophageal suture lines during EA repair (NO-PROS), 2) discontinuing the use of TA-tubes at the conclusion of repair (NO-TUBE), 3) obtaining an esophagram by postoperative-day-5 (EGRAM = 5), and 4) discontinuing prophylactic antibiotics within 24 h postoperatively (ABX < 24) (Fig. 1). While all four bundle components were encouraged, a compliance goal of 80% across all institutions was adopted for combined NO-PROS + NO-TUBE with the aims of decreasing postoperative anastomotic leak and stricture rates. Standardizing compliance with EGRAM = 5 was hypothesized to reduce time to starting enteral feeds without increasing anastomotic leak rate, and compliance with ABX < 24 was suspected to have no effect on postoperative infectious complications while limiting unnecessary antibiotic usage. To account for clinical or system barriers to obtaining an esophagram on postoperative-day-5 (POD5) or discontinuing antibiotics within 24 h, a number of exceptions were included in the protocol that if met would still allow for compliance. The exceptions for EGRAM = 5 included clinical concern for patient condition precluding an esophagram, radiology unavailable to perform the study, and initiating feeds within 5 days postoperatively without obtaining a routine esophagram. The exception for ABX < 24 was con-

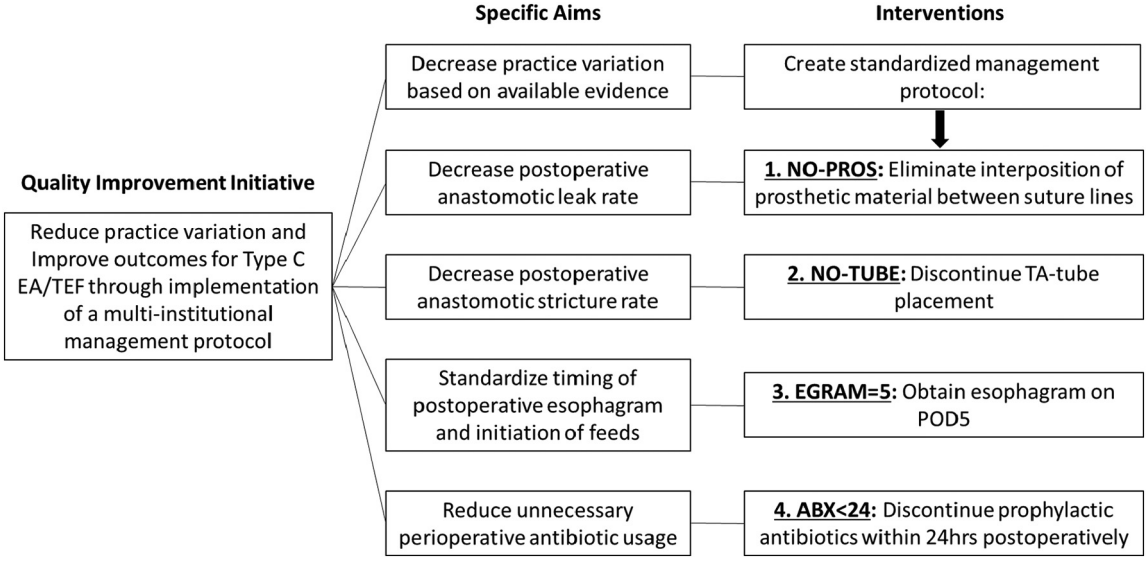

Fig. 1. Specific aims and associated interventions developed to address the esophageal atresia with tracheoesophageal fistula (EA/TEF) quality improvement initiative. TA-tube, transanastomotic tube; POD5, postoperative day 5.

tinuation of antibiotics for any therapeutic reason such as documentation of active infection or sepsis rule-out.

The goal was for each institution to collect baseline pre-protocol data during the initial 12 months of the study, and to then implement the 4-component management bundle in early 2017. Patients were individually designated into pre- or post-protocol cohorts based on the specified date of bundle implementation at their respective institutions. Institutional bundle compliance was biannually audited and reviewed during in-person meetings of the MWPSC, allowing for regular feedback to institutions.

1.3. Outcomes

The primary outcome measure was change in bundle compliance pre- to post-protocol implementation, both overall and by individual institution. Secondary outcome measures included short-term postoperative anastomotic leak and stricture rates, time to enteral feeds, and surgical site infection (SSI) within 30-days postoperatively stratified by institutional bundle compliance. Other outcomes of interest were in-hospital mortality, postoperative complications, and hospital length of stay (LOS). Postoperative anastomotic leak was defined as any esophageal leak identified on esophagram within 30 days postoperatively. Anastomotic stricture was defined as postoperative esophageal narrowing requiring dilation within 60 days postoperatively. Other postoperative complications included anastomotic dehiscence, urinary tract infection, sepsis, and multi-system organ failure within 30 days of EA repair.

1.4. Data analysis

Statistical analysis was performed using R version 3.6.0 (R Foundation for Statistical Computing, http://www.R-project.org) and STATA version 16.0 (StataCorp, 2019, Stata Statistical Software; College Station, TX, USA). Patient characteristics and outcomes were described through summary statistics, using median with interquartile range for continuous variables and frequency with percentage for categorical variables. Comparative analyses were performed using Fisher's exact test for categorical variables, Wilcoxon rank-sum test for continuous and ordinal variables between two groups, and Kruskal–Wallis test for continuous and ordinal variables between more than two groups. Time to feeds were analyzed using Kaplan–Meier survival curves and log-rank tests to compare survival distributions between groups. Data were first stratified by treatment pre- or post-protocol implementation, and secondarily by protocol bundle compliance adjusting for institution as random effect. Rates of individual compliance with NO-PROS + NO-TUBE, 30-day postoperative anastomotic leak, and 60-day postoperative anastomotic stricture were stratified by 6-month time intervals after adjusting for patients lost to follow-up within the observation window, and cross-correlations between variables were measured with Spearman's rank order correlation coefficient (ρ).

A post hoc adjusted subgroup analysis was performed to evaluate risk of postoperative anastomotic stricture using multivariable Cox proportional hazards regression. A priori variables included in the regression model were defined by consensus and had a p-value <0.05 on univariate analysis. These variables included institutional compliance with NO-TUBE ($<20\%$, 20–80%, $>80\%$), urgency of the procedure (emergent vs non-emergent), intraoperative use of vasopressors, and long esophageal gap length. Thoracoscopic repair was also identified as a significant variable on univariate analysis, however it demonstrated collinearity with NO-TUBE compliance so was not included in the model. Further, the regression analysis was limited to the subset of patients that survived to 60-day follow-up and that had undergone EA repair as their first operation, excluding those that had a prior gastrostomy tube placement or fistula ligation. A p-value less than 0.05 was considered statistically significant.

2. Results

2.1. Patient demographics and perioperative characteristics

A total of 170 patients with Type C EA/TEF were included in this study, with 40% (n = 68) managed pre-protocol implementation and 60% (n = 102) managed post-protocol implementation. Pre- and post-protocol cohorts had overall similar demographics and preoperative characteristics, though the pre-protocol cohort had higher rates of associated anomalies affecting the head and airway (p = 0.036 and 0.004, respectively) (Table 1**).** The majority of patients underwent definitive EA repair as their first operation (88.2%). Of those that did not undergo EA repair as their first operation, 95% (19/20) had a gastrostomy tube placed prior to repair and 65% (13/20) underwent initial fistula ligation. Thoracoscopic repair was performed in 15.3%. The rate of long esophageal gap length (defined as three or more vertebral bodies identified on preoperative contrast study or bronchoscopy) was 10.2%. Nearly all patients (90.6%) were started on acid suppression medication (H_2 blocker or proton pump inhibitor) postoperatively.

2.2. Protocol bundle compliance

Compliance rates for the entire four-component bundle increased 2.5-fold from 17.6% pre-protocol to 44.1% post-protocol ($p < 0.001$) **(**Fig. 2**).** There were significant increases in compliance for each individ-

Table 1
Demographics and perioperative characteristics.

	All patients (N = 170)	Pre-protocol (N = 68)	Post-protocol (N = 102)	p-Value
Gender (% male)	91 (53.5)	37 (54.4)	54 (52.9)	0.88[e]
Gestational age (weeks); median [IQR]	37 [35, 39]	37 [35.8, 39]	37 [35, 39]	0.37[w]
Birth weight (kg); median [IQR]	2.5 [2, 3.1]	2.6 [2.1, 3]	2.4 [2, 3.1]	0.47[w]
Race				0.78[e]
White/Caucasian	130 (76.5)	53 (77.9)	77 (75.5)	
Black/African American	14 (8.2)	5 (7.4)	9 (8.8)	
Asian/Pacific Islander	7 (4.1)	2 (2.9)	5 (4.9)	
Hispanic/Latino	6 (3.5)	4 (5.9)	2 (2)	
Multiracial	5 (2.9)	1 (1.5)	4 (3.9)	
Other	4 (2.4)	2 (2.9)	2 (2)	
Unknown	4 (2.4)	1 (1.5)	3 (2.9)	
EA/TEF prenatally suspected	33 (19.4)	12 (17.6)	21 (20.6)	0.7[e]
Associated anomalies				
Cardiac (clinically significant)	71 (41.8)	27 (39.7)	44 (43.1)	0.75[e]
Musculoskeletal	57 (33.7)	26 (38.8)	31 (30.4)	0.32[e]
Genitourinary	57 (33.5)	24 (35.3)	33 (32.4)	0.74[e]
Gastrointestinal	34 (20)	16 (23.5)	18 (17.6)	0.43[e]
Head	29 (17.1)	17 (25)	12 (11.8)	**0.036[e]**
Chromosomal	27 (16)	15 (22.1)	12 (11.9)	0.09[e]
Airway/pulmonary	26 (15.7)	17 (26.2)	9 (8.9)	**0.004[e]**
Definitive EA repair performed at 1st operation	150 (88.2)	62 (91.2)	88 (86.3)	0.47[e]
ASA score; median [IQR]	4 [3, 4]	3.5 [3, 4]	4 [3, 4]	0.45[w]
Weight at operation (kg); median [IQR]	2.5 [2.14, 3.06]	2.6 [2.2, 3.02]	2.5 [2.1, 3.1]	0.44[w]
Mechanically ventilated prior to OR	49 (28.8)	20 (29.4)	29 (28.4)	>0.99[e]
Emergent procedure	14 (8.3)	9 (13.2)	5 (5)	0.09[e]
Long esophageal gap length	17 (10.2)	6 (8.8)	11 (11.1)	0.14[e]
Thoracoscopic EA repair	26 (15.3)	6 (8.8)	20 (19.6)	0.08[e]
Postoperative vasopressor requirement	21 (12.4)	7 (10.3)	14 (13.7)	0.64[e]
Postoperative acid suppression	154 (90.6)	60 (88.2)	94 (92.2)	0.43[e]

All numerical values documented in number (%) unless otherwise stated.
Statistical tests: [w] Wilcoxon rank-sum, [e] Fisher's exact.
Abbreviations: IQR, interquartile range; EA/TEF, esophageal atresia with tracheoesophageal fistula; ASA, American Society of Anesthesiologists; OR, operating room.

ual bundle component in the post-protocol cohort (all $p < 0.01$) except for NO-PROS, as the interposition of prosthetic material was rarely used in either cohort (6% pre-protocol vs 3% post-protocol, $p = 0.44$). Of the patients that were considered compliant with EGRAM = 5, overall 57/106 (53.8%) had a documented exception (73.3% of the pre-protocol cohort vs 46.2% of the post-protocol cohort, $p = 0.017$), with the most common exceptions being patient condition (49.1%) and radiology unavailable due to a weekend or holiday (38.6%). Of the patients that were considered compliant with ABX < 24, overall 12/117 (10.3%) had a documented exception (15.8% of the pre-protocol cohort vs 7.6% of the post-protocol cohort, $p = 0.2$), with the most common exceptions being concern for esophageal leak (50%) and treatment in the setting of maternal chorioamnionitis (16.7%). Bundle compliance varied considerably by institution for all components both pre- and post-protocol implementation as demonstrated in Fig. 3**.** Combined NO-TUBE + NO-PROS compliance increased significantly from 44.1% to 64.7% ($p = 0.01$) over the entire two-year period following protocol implementation. When evaluated over six-month intervals, there was a sharp rise in NO-TUBE + NO-PROS compliance from a baseline of 36% in the first 6 months of the study to a peak of 87% in the 6-month period following protocol implementation **(**Fig. 4**).** This was followed by a steady decline in compliance over the remaining 18 months of the study period to a trough of 50% in the second half of 2018.

2.3. Postoperative outcomes

The overall incidence of anastomotic leak within 30 days postoperatively was 24.7%, and there were no differences in leak rates between pre- and post-protocol cohorts (23.5% pre-protocol vs 25.5% post-protocol, $p = 0.86$) **(**Table 2**).** Similarly, there were no differences in postoperative anastomotic stricture rates between the two cohorts and the overall incidence of stricture requiring dilation within 60 days postoperatively was 30% (27.9% pre-protocol vs 31.4% post-protocol, $p = 0.73$). All other outcomes were equivalent between the pre- and post-protocol cohorts, though there was a trend toward shorter time to full enteral feeds in the post-protocol cohort (19 days to full feeds pre-protocol vs 13 days post-protocol, $p = 0.07$). The overall SSI rate was 3.5% (2.9% pre-protocol vs 3.9% post-protocol, $p > 0.99$).

When evaluating anastomotic leak and stricture rates over 6-month intervals, both varied over time **(**Fig. 4**).** The stricture rate initially decreased from a peak of 39% in the first 6 months of the study to a trough of 20% during the 6-month period following protocol implementation when NO-PROS + NO-TUBE compliance was high (87%). This was followed by a gradual increase in stricture rate up to 35% over the remaining 18 months of the study period when NO-PROS + NO-TUBE compliance fell to 50%. There was significant cross-correlation between NO-PROS + NO-TUBE compliance and stricture rate over time ($\rho = -0.75$, $p = 0.029$). There was a similar trend in anastomotic leak rate (peak of 38% in the first 6 months, trough of 17% in the year following protocol implementation), however it was not significantly cross-correlated with NO-PROS + NO-TUBE compliance over time ($\rho = -0.54$, $p = 0.11$).

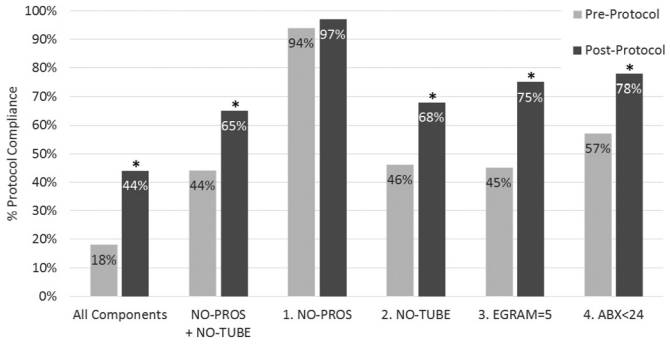

Fig. 2. Rates of protocol compliance stratified by pre- and post-protocol implementation for all bundle components combined, NO-PROS + NO-TUBE, and each individual bundle component (NO-PROS, NO-TUBE, EGRAM = 5, ABX < 24). The black stars represent statistically significant differences between pre- and post-protocol cohorts (all $p < 0.05$).

To further evaluate the effects of bundle compliance on postoperative outcomes, results were stratified by low, medium, and high compliance with all bundle components controlling for institution as random effect. Overall, 43.5% of patients were treated at low-compliance centers (compliance rate < 20%), 43% were treated at medium-compliance centers (compliance rate 20–80%), and 13.5% were treated at high-compliance centers (compliance rate > 80%) (Table 3**).** There were no differences in anastomotic leak or stricture rates based on institutional compliance ($p = 0.14$ and 0.42 for leak and stricture, respectively). Time to initiation of enteral feeds was 2 days shorter in the low-compliance cohort (5 days vs 7 days in medium and high-compliance cohorts; $p = 0.014$), however time to reach full enteral feeds and number of days on total parenteral nutrition (TPN) were equivalent across compliance cohorts ($p = 0.53$ and 0.57 for days to full feeds and days on TPN, respectively). Further, there were institutional differences in a number of perioperative characteristics when stratifying by compliance. Long esophageal gap length was more prevalent in high-compliance centers (17.4% vs 11.4% and 6.8% in medium and low compliance centers; $p = 0.006$), as was thoracoscopic EA repair (47.8% vs 17.8% and 2.7% in medium and low compliance centers; $p < 0.001$) and postoperative requirement of vasopressors (26.1% vs 15.1% and 5.4% in medium and low compliance centers; $p = 0.015$).

Because of these unanticipated institutional differences in perioperative characteristics, we performed a post hoc multivariable regression analysis to evaluate the risk of anastomotic stricture adjusting for factors as described in Section 1.4. Patients that underwent gastrostomy tube placement or fistula ligation as a separate procedure prior to definitive EA repair ($n = 20$) were excluded from this analysis as they represent a clinically unique subset of patients that undergo delayed repair. A total of 147 patients were included in the regression analysis with a stricture rate of 29.3% ($n = 43$). The variables selected for the regression were institutional compliance with NO-TUBE, emergent procedure, intraoperative vasopressor requirement, and esophageal gap length **(**Table 4**).** There were no differences in adjusted risk of postoperative anastomotic stricture based on institutional NO-TUBE compliance (aHR 0.45, 95%CI 0.18–1.17, $p = 0.1$ for compliance 20–80%; aHR 0.5, 95%CI 0.18–1.4, $p = 0.19$ for compliance >80%).

3. Discussion

This study sought to evaluate adherence to an evidence-based management protocol for Type C EA/TEF and to compare postoperative outcomes before and after protocol implementation in a multi-institutional cohort of pediatric surgeons. We found that bundle compliance increased 2.5-fold following protocol implementation (from 17.6% to 44.1%), resulting in decreased variability in patient care. Despite a significant increase in bundle compliance, adherence to the protocol was difficult to maintain over the duration of the study period and compliance varied considerably by institution. There were no significant differences in postoperative outcomes of interest (anastomotic leak, anastomotic stricture, time to reach full enteral feeds, or infectious complications) before or after protocol implementation or when stratified by institutional protocol compliance. However, there was a significant inverse correlation between compliance with not leaving a TA-tube postoperatively and rate of anastomotic stricture. Overall, implementation of the management bundle was safe and may be associated with a decreased risk of postoperative anastomotic stricture. These results highlight the difficulties in shifting and maintaining practice patterns based on best-available evidence.

In this era of utilizing quality and safety benchmarking to improve healthcare system performance and control costs, there has been a push toward protocol-driven medicine [7,8]. This concept has moved into the realm of surgery, with pathways and protocols aimed at

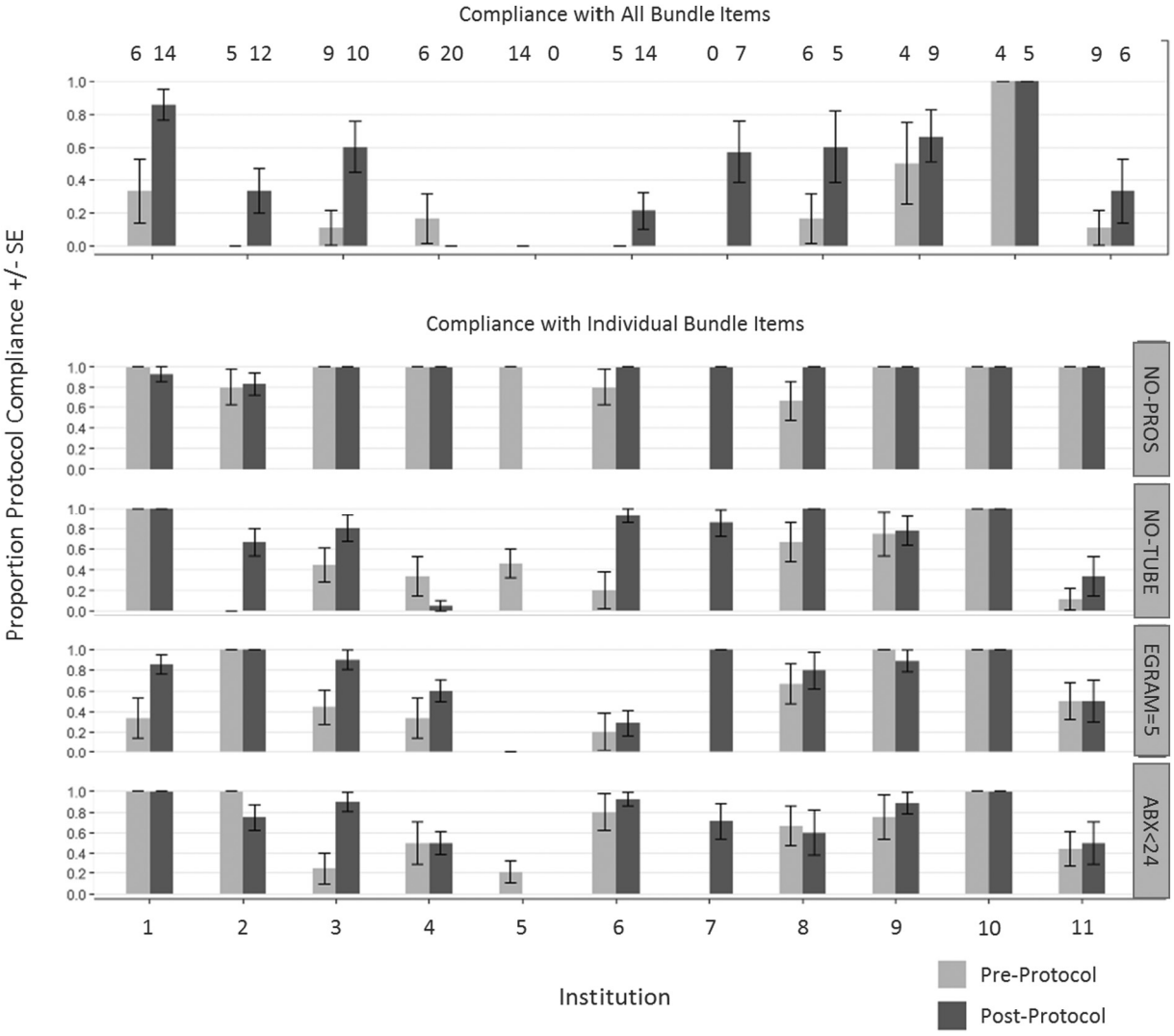

Fig. 3. Rates and standard errors (SE) of protocol compliance for each of the 11 participating institutions stratified by pre-and post-protocol implementation for all bundle components combined and each individual bundle component (NO-PROS, NO-TUBE, EGRAM = 5, ABX < 24).

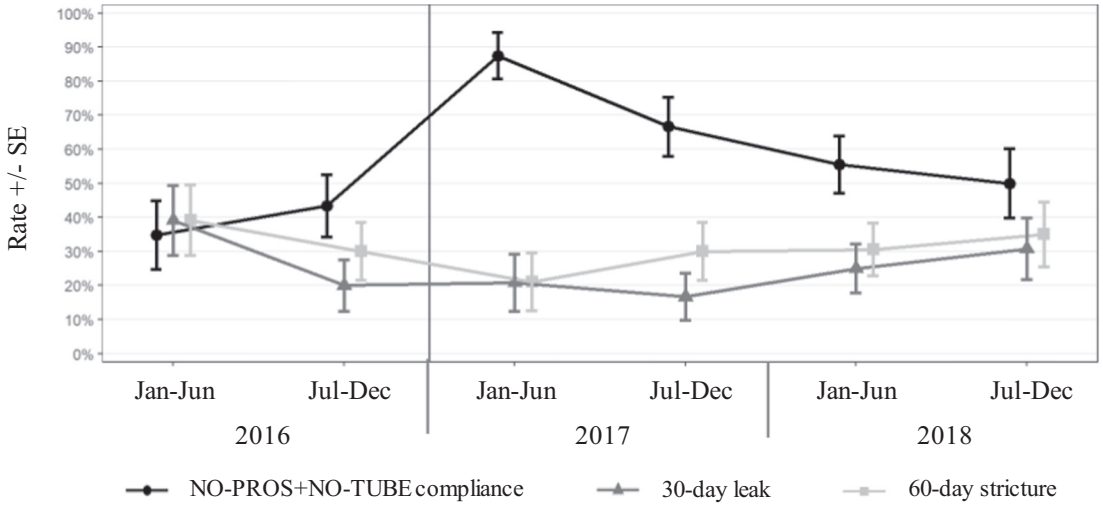

Fig. 4. Rates and standard errors (SE) of NO-PROS + NO-TUBE compliance, 30-day postoperative anastomotic leak, and 60-day postoperative anastomotic stricture over time by 6-month intervals. The vertical line represents the timing of protocol implementation.

Table 2
Pre- vs post-protocol postoperative outcomes.

	Pre-protocol (N = 68)	Post-protocol (N = 102)	p-Value
Anastomotic leak within 30 days	16 (23.5)	26 (25.5)	0.86[e]
Anastomotic stricture within 60 days	19 (27.9)	32 (31.4)	0.73[e]
Days to first enteral feed; median [IQR]	7 [7, 8]	6 [5, 7]	0.33[L]
Days to full enteral feeds; median [IQR]	19 [14, 23]	13 [12, 16]	0.07[L]
Days on TPN; median [IQR]	14 [10, 21]	13 [9, 25]	0.63[w]
Surgical site infection	2 (2.9)	4 (3.9)	>0.99[e]
Esophageal dehiscence	0	1 (1)	>0.99[e]
Urinary tract infection	3 (4.4)	6 (5.9)	0.74[e]
Sepsis	1 (1.5)	4 (3.9)	0.65[e]
Multi-system organ failure	1 (1.5)	0	0.4[e]
Hospital LOS (days); median [IQR]	36 [21, 76]	40 [18, 72]	0.79[w]
Mortality (in-hospital)	3 (4.4)	4 (3.9)	>0.99[e]

All numerical values documented in number (%) unless otherwise stated.
Statistical tests: [w] Wilcoxon rank-sum, [e] Fisher's exact, [L] log-rank.
Abbreviations: IQR, interquartile range; TPN, total parenteral nutrition; LOS, length of stay.

Table 4
Cox regression analysis of postoperative anastomotic stricture*

	aHR	95% CI	p-Value
Institutional compliance - NO-TUBE			
<20%	Ref.		
20–80%	0.45	(0.18, 1.17)	0.1
>80%	0.5	(0.18, 1.4)	0.19
Emergent procedure	0.91	(0.31, 2.63)	0.86
Intraoperative vasopressors	1.18	(0.52, 2.7)	0.69
Long esophageal gap length			
No	Ref.		
Yes	1.08	(0.33, 3.58)	0.9
Unknown	0.62	(0.25, 1.57)	0.32

N = 147, Events = 43.
Abbreviations: aHR, adjusted hazard ratio; CI, confidence interval.
* Excludes patients that underwent a separate operation prior to esophageal atresia repair and deaths prior to 60-day follow-up.

reducing surgical site infections, cutting costs, and reducing hospital length of stay to name a few [9–11]. While evidence-based practice changes can show significant results when high compliance is achieved, there are barriers to implementing and maintaining these quality improvement (QI) measures. In our study, compliance was highest immediately following protocol implementation, however dropped off over the remainder of the study period. Further, compliance varied considerably by institution. Though this study did not directly capture the reasons for non-compliance with the bundle elements, discussions within the MWPSC both during and after the study period identified a number of areas for future improvement. To address institutional variability, there were certain institutions where specific surgeons outside of the MWPSC working group were not comfortable with implementing elements of the bundle despite direct evidence from prior investigations that supported the protocol recommendations. This was especially true for the use of TA-tubes. Resistance to shifting surgical dogma based on available evidence is common among surgeons. A recent American Pediatric Surgical Association (APSA) member survey evaluated participation in national quality improvement/patient safety programs and found that only 68% of respondents utilize the data from these programs to change their practice when they have access to it [7]. The barriers to utilization included lack of knowledge, time or resources; difficulty interpreting the data; and belief that the data were not useful. One benefit of large, multi-institutional studies such as ours is that they add further data to existing literature which may ultimately change the practice patterns of those who are later adopters of new techniques. Future QI studies performed by the MWPSC will ensure that each individual participating surgeon is educated regarding the rationale and evidence supporting the protocol recommendations, and is committed to following the recommendations where clinically appropriate. Identifying stakeholders that may be resistant to a proposed change and engaging them early is a key step in the process of QI project development and is known to have a significant impact on the ultimate

Table 3
Perioperative characteristics and postoperative outcomes stratified by institutional compliance with all bundle components.

All patients (N = 170)	Institutional compliance: All bundle components			p-Value
	<20% (N = 74)	20–80% (N = 73)	>80% (N = 23)	
Perioperative characteristics				
Esophageal continuity achieved at 1st operation	69 (93.2)	62 (84.9)	19 (82.6)	0.17[e]
Clinically significant cardiac anomaly	35 (47.3)	29 (39.7)	7 (30.4)	0.34[e]
ASA score; median [IQR]	4 [3, 4]	4 [3, 4]	4 [3, 4]	0.99[k]
Weight at operation (kg); median [IQR]	2.53 [2.2, 3.1]	2.49 [1.96, 3.2]	2.64 [2.3, 2.9]	0.75[k]
Emergent procedure	6 (8.1)	6 (8.2)	2 (9.1)	>0.99[e]
Long esophageal gap length	5 (6.8)	8 (11.4)	4 (17.4)	**0.006[e]**
Thoracoscopic EA repair	2 (2.7)	13 (17.8)	11 (47.8)	**<0.001[e]**
Postoperative vasopressor requirement	4 (5.4)	11 (15.1)	6 (26.1)	**0.015[e]**
Postoperative outcomes				
Anastomotic leak within 30 days	14 (18.9)	19 (26)	9 (39.1)	0.14[e]
Anastomotic stricture within 60 days	25 (33.8)	18 (24.7)	8 (34.8)	0.42[e]
Days to first enteral feed; median [IQR]	5 [4, 7]	7 [6, 9]	7 [5, 11]	**0.014[L]**
Days to full enteral feeds; median [IQR]	14 [10, 19]	13 [10, 28]	15 [11, 21]	0.53[L]
Days on TPN; median [IQR]	13 [10, 19]	16 [13, 21]	15 [13, 23]	0.57[k]
Surgical site infection	2 (2.7)	3 (4.1)	1 (4.3)	0.74[e]
Esophageal dehiscence	0	1 (1.4)	0	0.57[e]
Urinary tract infection	2 (2.7)	6 (8.2)	1 (4.3)	0.28[e]
Sepsis	0	5 (6.8)	0	**0.032[e]**
Multi-system organ failure	0	1 (1.4)	0	>0.99[e]
Hospital LOS (days); median [IQR]	35 [19, 67]	49 [20, 82]	44 [22, 68]	0.43[k]
Mortality (in-hospital)	3 (4.1)	4 (5.5)	0	0.77[e]

All numerical values documented in number (%) unless otherwise stated.
Statistical tests: [e] Fisher's exact, [k] Kruskal-Wallis, [L] log-rank.
Abbreviations: IQR, interquartile range; ASA, American Society of Anesthesiologists; EA, esophageal atresia; TPN, total parenteral nutrition; LOS, length of stay.

success of the project [12,13].

Our study demonstrated difficulties with adherence to the protocol bundle over time, as compliance with NO-PROS + NO-TUBE increased substantially in the first 6 months following protocol implementation to above our goal of 80%, but then quickly dropped over the remaining 2 years of the study period. Quality improvement studies that maintain high compliance over time share a number of common elements. First is in-depth and repeated education on the protocol elements for all stakeholders throughout the study period [9,12–14]. A limitation of our study was that the protocol implementation process consisted of a single PowerPoint™ presentation prior to protocol roll-out, and then relied on centralized biannual audits and feedback to individual institutions regarding protocol compliance and associated patient outcomes. This process made it difficult to ensure that all surgical faculty, including new staff and trainees, at each participating institution were properly on-boarded regarding the rationale and evidence supporting the protocol elements. Another hallmark of successful long-term QI initiatives is the ability to evaluate compliance and outcomes over time on a frequently rolling basis [9,14]. If compliance begins to slip, the study team can quickly identify the issue and work to correct it in real-time. In our study, audits were performed on a biannual basis, thus delaying identification of and feedback regarding protocol non-compliance to individual sites. Further, the major outcomes of our study – postoperative esophageal leaks and strictures – often occurred weeks after initial compliance data were collected for a specific patient, making it difficult to identify and act on potential differences in outcomes based on institution or protocol adherence. Another possible reason for the drop in compliance over time is that site-specific but not surgeon-specific compliance data were captured, preventing direct feedback to and benchmarking of individual surgeons. In the future, incorporating a process of site as well as surgeon-specific review of study cases on a more frequent basis, reinforcement of the protocol elements over the length of the study, and engagement of all contributing staff members from study conception to conclusion would predictably improve adherence over time [12]. Further study is needed to fully elucidate the barriers to implementation and maintenance of quality improvement protocols within multi-institutional surgical collaboratives such as ours.

The postoperative outcome measures we were most interested in evaluating based on protocol compliance in this study were anastomotic leak and stricture rates. We found an overall 25% rate of leak and 30% rate of stricture in this prospective cohort, highlighting the contemporary significance of these postoperative complications in patients undergoing EA repair. Because overall compliance with NO-PROS was so high both pre- and post-protocol implementation, we were unable to make any conclusions regarding the effect of interposing prosthetic material between tracheal and esophageal suture lines during EA repair. However, leak rates did not differ before or after implementation of the entire bundle, lending support to the hypothesis that, even though there was no significant benefit, the proposed protocol bundle is safe to implement in this study population. In regards to the effect of TA-tubes on esophageal stricture rate, recent retrospective data from the MWPSC and others have demonstrated significant reductions in postoperative strictures when TA-tubes are not used [4,15,16]. Despite these findings, a 2019 European Reference Network on Rare Inherited and Congenital Anomalies (ERNICA) consensus statement found that 80% of participating representatives agreed that TA-tubes should be routinely inserted during EA repair [17]. One common concern regarding the elimination of TA-tubes during EA repair is that it will result in delays starting feeds and discontinuing parenteral nutrition [18]. Our data demonstrated no differences in stricture rates when stratified by pre- or post-protocol implementation, by institutional protocol compliance, or after adjusting for possible confounders. However, there was a significant inverse correlation between NO-PROS + NO-TUBE compliance and stricture rate when evaluated over time. Also, when combined compliance with not leaving a TA-tube and obtaining an esophagram on POD5 was high, there were no differences in time to full feeds or days on TPN compared to the lower compliance cohorts. Taken together, these findings support the conclusions that not leaving a TA-tube during EA repair is safe, and may lower the risk of postoperative anastomotic stricture. Adding this study to the body of literature demonstrating an increased risk of stricture with TA tubes, there seems to be no compelling reason to justify their use.

Despite the benefits of using a regional surgical collaborative to implement a quality improvement management protocol, there were a number of limitations to this study. First were the difficulties with protocol implementation and auditing across multiple institutions that were discussed above. Further, there were some areas of perioperative practice variation that were not accounted for in the protocol bundle, and that had changed since our group's retrospective review finished 2 years prior. These included a higher rate of thoracoscopic repairs – this study had an overall 15% rate of thoracoscopic repair compared to 9% in the retrospective review, and in this study the increase in thoracoscopic approach was limited to the institutions that were highly compliant with the protocol bundle. Also, there was a higher proportion of patients treated in compliance with the bundle elements even before formal protocol implementation had occurred. For example, compliance with NO-TUBE was 39% prior to protocol implementation in this study, compared to 21% in the retrospective review. These recent practice changes make it difficult to adjust for confounding variables and to determine associations with protocol elements. The limitations discussed here highlight the need for future well-designed, well-controlled QI studies that allow for identification of barriers to protocol adherence and maintenance in real-time.

In conclusion, this study demonstrated a 2.5-fold increase in protocol compliance following implementation of an EA/TEF QI management bundle within a regional surgical collaborative. Despite a significant increase in protocol compliance from pre- to post-protocol, the subsequent drop in compliance over time and variability between institutions highlight the barriers to implementation of and adherence to quality improvement initiatives across multiple institutions. Overall, implementation of our management bundle appears safe and our findings do not support the routine use of TA-tubes.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jpedsurg.2020.09.049.

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