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Associations of Stylet Use during Neonatal Intubation with Intubation Success, Adverse Events, and Severe Desaturation: A Report from NEAR4NEOS

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Keywords
Neonatal intubation · Stylet · Tracheal intubation-associated events · Airway injury · Difficult airway

Abstract
Introduction: Intubations are frequently performed procedures in neonatal intensive care units (NICU) and delivery rooms (DR). Unsuccessful first attempts are common as are tracheal intubation-associated events (TIAEs) and severe desaturations. Stylets are often used during intubation, but their association with intubation outcomes is unclear. ***Objective:*** To compare intubation success, rate of relevant TI-

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AEs, and severe desaturations in neonates intubated with and without stylets. ***Methods:*** Tracheal intubations of neonates in the NICU or DR from 16 centers between October 2014 and December 2018, performed by neonatology or pediatric providers, were collected from the NEAR4NEOs international registry. Primary oral intubations with a laryngoscope were included in the analysis. First-attempt success, the occurrence of relevant TIAEs, and severe oxygen desaturation (≥20% saturation drop from baseline) were compared between intubations performed with versus without a stylet. Logistic regression with generalized estimate equations was used to control for covariates and clustering by sites. ***Results:*** Out of 5,292 primary oral intubations, 3,877 (73%) utilized stylets. Stylet use varied considerably across the centers with a range between 0.5 and 100%. Stylet use was not associated with first-attempt intubation success, esophageal intubation, mainstem intubation, or severe desaturations after controlling for confounders. Patient size was associated with these outcomes and much more predictive of success. ***Conclusions:*** Stylet use during neonatal intubation was not associated with higher first-attempt intubation success, fewer relevant TIAEs, or less severe desaturations. These data suggest that stylets can be used based on individual preference, but stylet use may not be associated with better intubation outcomes.

Introduction

Intubations are frequently performed procedures in neonatal intensive care units (NICU) and delivery rooms (DR). Unsuccessful first-intubation attempts are common as are adverse tracheal intubation-associated events (TIAEs) and severe desaturations [1, 2]. Successful first-attempt neonatal intubations are associated with fewer TIAEs and improved neonatal and pediatric outcomes [1–4]. Stylets are commonly used in an attempt to improve intubation success. A stylet is a malleable metal wire coated in plastic which can be inserted into the lumen of an endotracheal tube (ETT) with the intent of providing rigidity to the ETT to assist in passing it through the vocal cords during endotracheal intubation [5]. Current Neonatal Resuscitation Program (NRP) guidelines do not recommend routine use of a stylet for endotracheal intubation [6]. However, in a national survey of neonatal airway providers, the majority reported using a stylet with most or all of their intubations based on the belief that stylet use improved intubation success rates [7].

Despite their common use, there is limited evidence investigating the effects of stylet use on neonatal intubation outcomes [8]. In the only small randomized trial investigating stylets in neonatal intubations, trainees were randomized to either use a stylet or intubate without a stylet on their first attempt. This study found stylets did not affect first-attempt intubation success rates or upper airway trauma [8].

The use of a stylet in an ETT presents potential risks. There are numerous case reports of stylet-related adverse outcomes including torn or perforated airways and retained broken stylet pieces [9–13]. In a national survey of neonatal airway providers, 78% had experienced or witnessed an adverse event resulting from stylet use with the most common issue being accidental dislodgement of the ETT during stylet removal necessitating yet another intubation to secure an airway. However, 71% of respondents felt stylets were "generally safe" [7].

Severe oxygen desaturation, defined as a decrease of at least 20% from baseline, is common during neonatal intubation [1, 2]. Severe desaturations have been shown in a multicenter study to occur in 48% of intubations performed in the NICU and 31% of intubations performed in the DR [1]. One proposed potential benefit for using stylets during intubation is a decrease in the time to achieving successful ETT placement. If stylets facilitate ease of ETT placement, they could theoretically reduce intubation time and thus decrease the frequency of desaturation events.

The goal of this study was to examine associations between stylet use during neonatal intubation with intubation success, adverse events, and severe desaturations using a prospectively collected large quality improvement research database. We hypothesized that stylet use during intubation would be associated with improved first-attempt success rates, fewer severe desaturations, but an increased incidence of relevant TIAEs such as airway injury.

Methods

Setting

This study uses data collected from 16 academic NICU [1].

Design

Data were extracted from the NEAR4NEOs database, a multisite international collaborative that prospectively collects information on all intubations occurring within the NICU and DR for participating sites [1]. All tracheal intubation events performed by direct or video laryngoscopy in the NICU or DR in the NEAR4NEOS database between October 2014 and December 2018 were

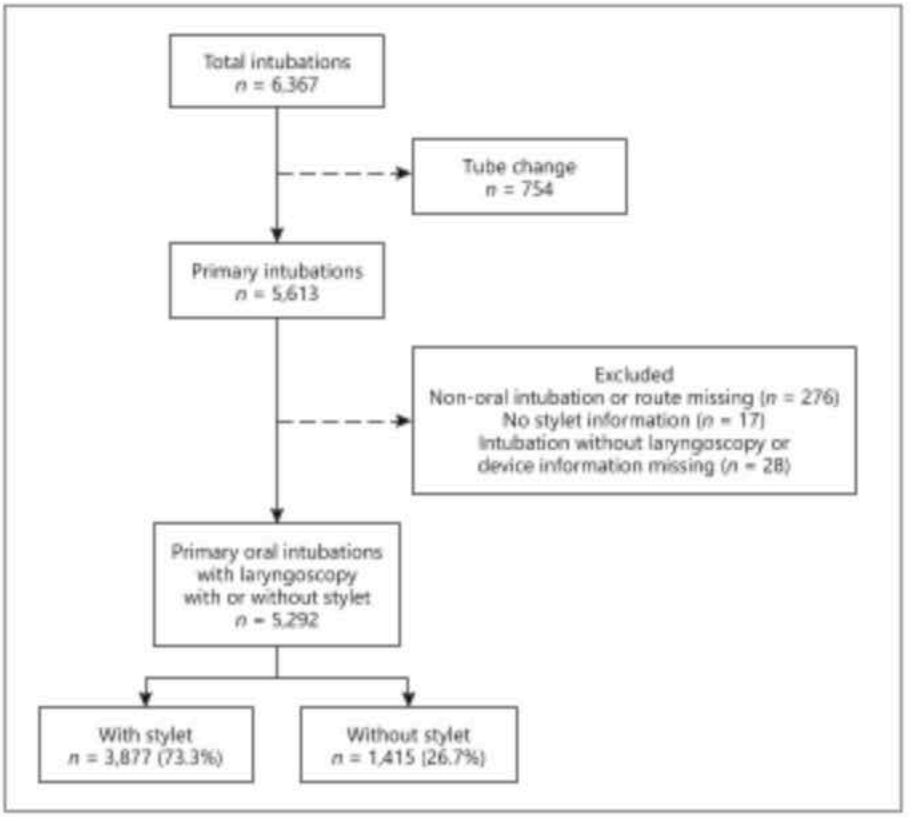

Fig. 1. Study enrollment diagram.

included. Data were collected at each institution on a standardized form following collaborative operational definitions, deidentified and verified for completeness and accuracy by a designated and trained study personnel, and entered into a centralized online secure database, REDCap. The institutional review board at each participating site approved the study with a waiver of informed consent for the use of patient data.

Definitions

First-attempt intubation success was defined as placement of an ETT in the trachea by the first airway provider on their initial attempt. An intubation course was defined as all the intubation attempts performed on the same patient on a given date with 1 course of medication and one intubation method. Patient demographics included weight at the time of intubation, birth and corrected gestational age, and comorbidities. Intubation demographics included the indication, airway device utilized, medications administered, and the first-attempt provider's discipline. Intubations occurring outside of the NICU or DR, intubations via the nasal route, and those in which the ETT was exchanged were excluded. Intubations performed by non-neonatology and non-general-pediatric providers, such as anesthesia providers, were excluded. Stylet use was counted only if utilized on the first attempt. Stylet use was at the discretion of the provider and/or unit practice.

Adverse TIAEs relevant to stylet use included airway injury, esophageal intubation with immediate or delayed recognition, mainstem intubation confirmed on X-ray, and pneumothorax related to the intubation attempt as determined by the clinical team. Airway injury was defined as any damage to the upper or lower airway and included lacerations, abrasions, and perforations. Severe oxygen desaturations were defined as a decrease of 20% or more from the preintubation baseline oxygen saturation.

Outcome Measures

The primary outcome was first-attempt success. Secondary outcomes included the adverse TIAEs relevant to stylets: airway injury, esophageal intubation, mainstem bronchial intubation, and pneumothorax as well as oxygen desaturation ≥20% [1].

Statistics

A priori power calculation was performed with simulation. To detect a clinically meaningful difference of 10% (first-attempt success 60% with stylet use and 50% without stylet use) with the variance of center level random effect = 0.287, the power was estimated as >99%. The variance of center level random effect was assumed based on the use of stylet in the current dataset.

Statistical analyses were performed using STATA 16.0 (StataCorp, College Station, TX, USA). Descriptive statistics were used to present the demographic data as number and percentages for categorical variables and as medians and interquartile ranges for nonparametric, continuous data. The relationships between patient, provider, and practice characteristics with the occurrence of stylet use were analyzed using univariable analysis with Pearson's χ^2 or Fisher's exact test for dichotomous variables or Wilcoxon rank-sum for numeric variables. The clinical impact of stylet use was assessed by univariate analysis with the occurrence of pre-

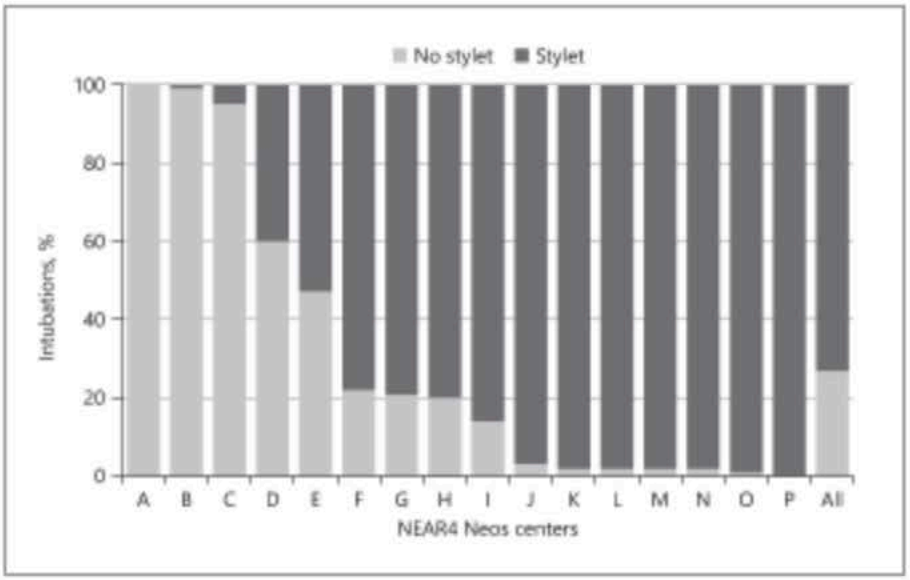

Fig. 2. Use of stylets for intubation by the NEAR4NEOS center.

specified TIAEs: TIAEs (airway injury, esophageal intubation, mainstem intubation, and pneumothorax) and severe oxygen desaturation. The independent effect of stylet use on the first-attempt success rate (primary outcome) and secondary outcomes of specific TIAEs and severe oxygen desaturation was determined by the generalized estimate equation multivariable logistic regression model while controlling for patient, provider, and practice factors. Intrasite association of outcomes was accounted for by fitting exchangeable correlation structures in the generalized estimate equation models, with robust standard errors based on the "sandwich" covariance matrix. Covariates were included in the multivariable model when there was an association with stylet use at $p < 0.05$ in the univariable analysis.

Results

Demographics and Factors Associated with Stylet Use

Out of 5,292 primary oral intubations from 16 institutions, 3,877 (73%) utilized a stylet (Fig. 1). Stylet use varied considerably across the centers with a range of 0.5–100% (Fig. 2). Stylet use varied by many patient factors (Table 1). There was no difference in stylet use between NICU and DR. A stylet was used more often in lower weight infants and at a younger age. Stylets were used more often in infants with acute respiratory failure. Stylets were used less often in infants with congenital anomalies and neurologic diagnoses. Stylets were more often used during intubations for oxygen failure, surfactant administration, and DR resuscitations. Intubations for ventilation failure, procedures, and replacement of ETTs after unplanned extubations were more often performed without stylets. Among intubations with a stylet, neonatology fellows were more likely the first-attempt providers, while intubations without stylets more often had nurse practitioners, physician assistants, and hospitalists as the first-attempt providers. Sedation and paralysis were less often used in the stylet group. Video laryngoscopy was less often used in the stylet group.

Stylet Use and Outcomes

The first-attempt success rate was lower in the stylet group in the univariate analysis: 47.7 versus 51.0%, $p = 0.03$. Stylet use was not associated with first-attempt success (adjusted odds ratio 1.12, 95% confidence interval: 0.68–1.85, $p = 0.664$) after controlling for differences in patient, practice, and provider factors and clustering for the study site (Table 2). First-attempt success was more likely to occur in infants who weighed >1.5 kg, in intubations utilizing both sedative and paralytic medications, and in intubations performed by nonresidents.

Unadjusted analysis of relevant TIAEs showed significantly more esophageal intubations, mainstem bronchial intubations, and oxygen desaturation (≥20%) in the stylet group (Table 3). Multivariate analysis of other TIAEs and oxygen desaturation did not reveal significant independent association with stylets (all $p > 0.05$).

Airway Injury Cases

The cases with airway injury ($n = 23$) were of lower weight (median current weight 1,110 g [IQR: 815–1,880] vs. median 1,640 g [IQR: 920–2,900] for infants without airway injuries) with a higher proportion of airway/craniofacial anomaly (21.7 vs. 4.6%, $p = 0.004$) (Table 4).

Table 1. Patient, provider, and practice characteristics among tracheal intubations with versus without stylet use

Patient characteristics (N = 5,292)	Stylet (n = 3,877)	Without stylet (n = 1,415)	p value
Current weight, median (IQR), g	1,500 (890–2,780)	2,060 (1,000–3,100)	**<0.0001**
Birth gestational age, median (IQR), weeks	28 (25–35)	30 (26–36)	**<0.0001**
Age at time of intubation, median (IQR), days	1 (0–22)	4 (0–42)	**<0.0001**
Comorbidities, n (%)			
Acute respiratory failure	2,557 (66.0)	805 (56.9)	**<0.001**
Chronic respiratory failure	648 (16.7)	222 (15.7)	0.373
Congenital anomaly requiring surgery	355 (9.2)	212 (15.0)	**<0.001**
Congenital heart disease	235 (6.1)	132 (9.3)	**<0.001**
Neurologic impairment	211 (5.4)	98 (6.9)	**0.042**
Sepsis	177 (4.6)	71 (5.0)	0.491
Airway/craniofacial anomaly	171 (4.4)	78 (5.5)	0.094
Acquired surgical condition	120 (3.1)	27 (1.9)	**0.020**
Intubation indications, n (%)			
Oxygenation failure	1,115 (28.8)	354 (25.0)	**0.007**
Ventilation failure	1,051 (27.1)	446 (31.5)	**0.002**
Apnea and bradycardia	637 (16.5)	213 (15.1)	0.227
Surfactant administration	1,030 (26.6)	229 (16.2)	**<0.001**
DR clinical indication	814 (21.0)	234 (16.5)	**<0.001**
Procedure	271 (7.0)	157 (11.1)	**<0.001**
Unplanned extubation	323 (8.3)	154 (10.9)	**0.004**
Upper airway obstruction	157 (4.1)	45 (3.2)	0.144
Shock	107 (2.8)	33 (2.3)	0.391
First attempt provider, n (%)			
Pediatric resident	553 (14.3)	185 (13.1)	**<0.001**
Neonatology fellow	1,423 (36.7)	467 (33.0)	
Neonatology attending	166 (4.3)	114 (8.1)	
Nurse practitioner/physician assistant/hospitalist	1,327 (34.2)	547 (38.7)	
RT	249 (6.4)	16 (1.1)	
Others (subspecialists)	157 (4.1)	86 (6.1)	
Location, DR	1,039 (26.8)	368 (26.0)	0.564
Vagolytic use	1,550 (40.0)	758 (53.6)	**<0.001**
Premedication use, n (%)			
No sedation or paralysis	1,945 (50.2)	513 (36.3)	**<0.001**
Sedation only	602 (15.5)	120 (8.5)	
Sedation and paralysis	1,315 (33.9)	776 (54.8)	
Paralysis only	15 (0.4)	6 (0.4)	
Video laryngoscopy	760 (19.6)	468 (33.1)	**<0.001**

RT, respiratory therapist; DR, delivery room. p values of < or = 0.05 are in bold.

There was a 5-fold difference in airway injury rates when stylets were used (n = 21, 0.5% with stylets vs. n = 2, 0.1% without stylets) that did not reach statistical significance (p = 0.06) (Table 3).

Discussion

We examined associations between stylet use during neonatal intubation with intubation success, adverse events, and severe desaturations. In this large sample of infant intubations, we found that even though stylets were used in nearly 75% of intubation attempts, there was significant variation with some centers using them nearly universally, and others almost never. While stylet use varied considerably between patients and providers, stylet use was not associated with first-attempt intubation success, adverse events, or severe desaturations after controlling for patient, provider, and practice factors and clustering by site. To the authors' knowledge, this is the largest study to date examining the associations of stylet use and neonatal intubation outcomes.

Table 2. Multivariate analysis of association of stylet use with first-attempt success

Variable	Odds ratio	95% confidence interval	*p* value
Stylet use	1.12	0.68–1.85	0.664
Current weight >1.5 kg	1.37	1.13–1.67	**0.002**
Birth gestational age ≥28 weeks	1.14	0.93–1.41	0.206
Intubation after 1st day of life	0.97	0.74–1.28	0.837
Comorbidities			
Congenital heart disease	0.93	0.76–1.14	0.461
Congenital anomaly requiring surgery	1.00	0.81–1.22	0.977
Neurologic impairment	0.95	0.76–1.20	0.675
Acute respiratory failure	1.05	0.96–1.15	0.302
Surgery for acquired disorder	0.78	0.39–1.54	0.472
Indication for intubation			
Oxygen failure	1.08	0.89–1.30	0.422
Procedure	1.18	0.93–1.50	0.177
Ventilation failure	0.92	0.78–1.08	0.304
Surfactant administration	0.88	0.77–1.01	0.063
Unplanned extubation	1.43	1.00–2.06	0.051
Diagnosis requiring intubation in DR	1.02	0.81–1.29	0.847
First-attempt provider			
Resident	Reference		
Fellow	3.10	2.33–4.11	**<0.001**
Neonatology attending	5.16	3.14–8.50	**<0.001**
Nurse practitioner/physician assistant/hospitalist	2.64	1.89–3.67	**<0.001**
RT	2.73	1.79–4.15	**<0.001**
Others (subspecialist)	2.55	1.81–3.59	**<0.001**
Vagolytic use[$]	1.10	0.92–1.31	0.296
Premedication			
No sedative or paralytic	Reference		
Sedative only	0.60	0.45–0.79	**<0.001**
Sedative and paralytic	1.49	1.12–2.03	**0.009**
Paralysis only	0.87	0.26–2.93	0.823
Video laryngoscopy^	1.20	0.86–1.68	0.276

RT, respiratory therapist; DR, delivery room. *p* values of < or = 0.05 are in bold. [$] Vagolytic includes atropine. ^ Reference is direct laryngoscopy.

We did not find an association between stylet use and first-attempt intubation success, which is consistent with prior studies. In the only published randomized control trial of stylets for neonatal intubation, there was no association with success, but the overall trial was small (n = 232) and occurred at a single center [8]. Despite the current practice of frequent stylet utilization, the NRP does not recommend routine use of stylets, and there are little data to support the use of stylets during neonatal intubation [6]. The reasons for their popularity could lie in the perceived value of the stiffness of the ETT, or in intubation training itself, with comfort and belief of presumed efficacy passed from one generation of providers to the next. Comfort with a particular stiffness or bend in the ETT may make intubating without a stylet feel different and unfamiliar, leaving the laryngoscopist feeling less confident or safe in their procedural ability. As this study allowed each laryngoscopist and site to choose whether they used a stylet, the impact of individual laryngoscopist's performance with and without a stylet could not be evaluated.

We found an increased number of airway injury when stylets were used; however, the reported number of airway injury cases was small, and the detailed description of the events was not reported. This makes the analysis less informative than desired. The cases with airway injury were of lower weight and had higher proportion of airway/craniofacial anomaly. Multivariate analysis did not show an independent significant association between stylet use and the relevant TIAEs often described in the

Table 3. The association of stylet use and adverse outcomes

	Univariate analysis			Multivariate analysis (compared to without stylet)	
	stylet, *n* (%)	without stylet, *n* (%)	*p* value	odds ratio (95% confidence interval)	*p* value
Airway injury	21 (0.5)	2 (0.1)	0.058	Not performed	na
Esophageal intubation	469 (12.1)	108 (7.6)	**<0.001**	1.29 (0.83–2.02)	0.251
Mainstem bronchial intubation	76 (2.0)	15 (1.1)	**0.026**	1.44 (0.62–3.34)	0.397
Pneumothorax	15 (0.4)	3 (0.2)	0.431	Not performed	na
Oxygen desaturation ≥20%	1,714 (49.5)	595 (45.3)	**0.010**	1.11 (0.85–1.46)	0.438

Multivariable analyses utilized logistic regression to control for the patient, provider, and practice characteristics associated with the use of stylet and clustering by sites. Refer to the section Methods for details. na, not applicable. *p* values of < or = 0.05 are in bold.

Table 4. Airway injury cases ($N = 23$)

Patient characteristics	Stylet ($n = 21$)	Without stylet ($n = 2$)	Total ($N = 23$)
Current weight, median (IQR), g	1,140 (900–1,880)	580 (560–600)	1,110 (815–1,880)
Birth gestational age, median (IQR), weeks	27 (25–32)	23.5 (23–24)	27 (24–32)
Age at time of intubation, median (IQR), days	7 (0–18)	1 (0–2)	2 (0–18)
Comorbidities, *n* (%)			
Airway/craniofacial anomaly	5 (23.8)	0 (0)	5 (21.7)
Acquired surgical condition	1 (4.8)	0 (0)	1 (4.4)
Intubation indications, *n* (%)			
Oxygenation failure	9 (42.9)	2 (100)	11 (47.8)
Ventilation failure	6 (28.6)	1 (50.0)	7 (30.4)
Surfactant administration	5 (23.8)	1 (50.0)	6 (26.1)
DR clinical indication	2 (9.5)	1 (50.0)	3 (13.0)
Unplanned extubation	1 (4.8)	0 (0)	1 (4.4)
Upper airway obstruction	2 (9.5)	0 (0)	2 (8.7)
Shock	2 (9.5)	0 (0)	2 (8.7)
First-attempt provider, *n* (%)			
Pediatric resident	3 (14.3)	0 (0)	3 (13.4)
Neonatology fellow	10 (47.6)	2 (100)	12 (52.7)
Neonatology attending	1 (4.8)	0 (0)	1 (4.4)
Nurse practitioner/physician assistant/hospitalist	5 (23.8)	0 (0)	5 (21.7)
RT	2 (9.5)	0 (0)	2 (8.7)
Others (subspecialists)	0 (0)	0 (0)	0 (0)
Location, DR, *n* (%)	2 (9.5)	1 (50.0)	3 (13.0)
Premedication use, *n* (%)			
No sedation or paralysis	7 (33.3)	1 (50.0)	8 (34.8)
Sedation only	7 (33.3)	0 (0)	7 (30.4)
Sedation and paralysis	7 (33.3)	1 (50.0)	8 (34.8)
Paralysis only	0 (0)	0 (0)	0 (0)
Video laryngoscopy, *n* (%)	3 (14.3)	0 (0)	3 (13.0)

RT, respiratory therapist; DR, delivery room.

literature. As the case reports in the literature described, there remain some potential risks involved with stylet use [9–13]. Tracheal perforations are extremely rare events and might require case-control studies to evaluate their relationship with stylets, but the overall low number of airway injuries in this large data set provides some reassurance that these are uncommon outcomes, occurring in <1% of intubations [7]. However, there remain some potential risks involved in their use. There is significant variation in how providers place stylets within ETTs with some placing the stylet more distal or at the level of the Murphy eye to facilitate increased tube stiffness [14]. This practice may potentially increase the risk of the stylet tip positioned beyond the tip of the ETT and injure delicate airway tissue or break off. There are numerous case reports describing airway or ETT obstruction caused by the retained plastic sheath from a stylet, and endoscopic removal of retained stylet components can be especially difficult in premature neonates with small airways [9–13]. Many laryngoscopists bend the ETT and stylet complex which may increase the risk of shearing of the plastic coating resulting in retained stylet components. There is a need to train clinical staff on a standardized placement of the tip of the stylet within the ETT to minimize the risk of perforations and breakage.

In this study, stylet use was not associated with severe desaturations. Infants with significant respiratory system compromise are most at risk for severe desaturation during intubation attempts due to their poor respiratory reserve. A longer duration of intubation is likely to result in more severe desaturation. Stylet use is often believed to shorten intubation attempts, which would result in fewer severe desaturation events. Unfortunately, the NEAR4NEOS database does not include intubation duration as a metric, so we are unable to report on the impact that stylet use has on the duration of intubation. Since stylet use was not associated with a difference in odds of severe desaturation in multivariate analysis, we speculate the overall impact of stylet use on intubation duration may be small.

Currently, neonatologists routinely use conventional stylets consisting of a metal wire covered in a plastic sheath. However, there are reports in the otolaryngology and anesthesia literature of alternative stylets. Stylets with built-in cameras are utilized by otolaryngologists to facilitate intubation of patients with difficult airways. Anesthesia literature has also investigated the use of light wands, a type of lighted stylet, in children undergoing elective surgery [15]. There is room for innovation regarding alternative stylets designed specifically for the neonatal population.

This study has some limitations. While the data were prospectively collected, the stylet use was not randomized. A larger proportion of intubation with stylets is attempted by trainees (51% done by residents or fellows) compared to intubations without stylets (46% attempted by residents or fellows), potentially influencing success rates and adverse TIAEs. Sedation and paralysis were used together more often in intubations without stylets, and their use was associated with a higher first-attempt success rate in the multivariable analysis, as reported before [16]. Similarly, the stylet use was more common in an anticipated difficult airway in some situation. It is also possible that providers reported more airway injuries when a stylet was used during intubation, which may have been due to an ascertainment or reporting bias. An additional limitation is that the severity of airway injuries was not captured on the data collection form, making the interpretation of the potential airway harm difficult. Despite these limitations, this is one of the largest studies investigating the use of stylets for infant intubations and provides valuable data on a diverse neonatal population in the NICU and DR.

Conclusions

For intubations in the NICU and DR, stylet use was not associated with a higher first-attempt success rate. Stylet use was highly variable across the institutions. Stylet use was not associated with relevant adverse events (airway injury, esophageal intubation, mainstem bronchial intubation, and pneumothorax). Consideration should be used when deciding whether to use a stylet during neonatal intubation given the potential risk of injuries associated with stylet use. Further studies may address the effectiveness of stylet use in both intubation success and adverse events using a pragmatic randomized control design.

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Statement of Ethics

This study was granted ethical exemptions from written consent due to the deidentified nature of the QI data by each of the 16 contributing sites' Ethical Review Boards. This is included in the

section Methods as follows: "The institutional review board at each participating site approved the study with a waiver of informed consent for the use of patient data."

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

Drs. Gray, Rumpel, and Brei drafted the work, contributed to conception of the work, and approved the final version. Drs. Krick, Glass, DeMeo, Barry, Johnston, Moussa, Jung, Quek, Mehrem, Singh, Kim, and Zenge contributed to acquisition of data for the work, revised it critically, and approved of the final version. Ms. Napolitano and Tisnic contributed to acquisition of the data, revised the drafted work, and approved the final version. Ms. Shults contributed to analysis and interpretation of the data, revised the work, and approved the final version. Drs. Ades and Nadkarni contributed to the design of the work and critical revisions and approved of the final version. Drs. Sawyer, Foglia, and Nishisaki contributed to the conception and design, interpretation of the data, drafting, and revisions and approved the final version. All authors agree to be accountable for all aspects of the work.

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