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Title: A quality improvement initiative to increase the safety of pediatric emergency airway management.

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What is already known about the topic: Emergency airway management is a low frequency, high risk procedure. Multiple individual strategies have been proposed to improve its safety, though it is unclear if their use in combination is feasible and effective.

What this study adds: The overall safety of emergency airway management can be improved through quality improvement measures.

SUMMARY (ABSTRACT):

Background: Emergency airway management is commonly associated with life-threatening hypoxia and hypotension which may be preventable.

Aim: To reduce the frequency of intubation-related hypoxia and hypotension.

Methods: A prospective quality improvement study conducted over 4 years in the Emergency Department of The Royal Children's Hospital, Melbourne, Australia. A pre-intervention cohort highlighted safety gaps and was used to design study interventions, including: an emergency airway algorithm, standardized airway equipment, a pre-intubation checklist and equipment template, end-tidal carbon dioxide monitoring, post-intubation team debriefing, and multi-disciplinary team training. Following implementation, a post-intervention cohort was used to monitor the impact of study interventions on clinical process and patient outcome. Process measures were: use of a pre-intubation checklist, verbalization of an airway plan, adequate resuscitation prior to intubation, induction agent dose titration, use of apneic oxygenation, and use of end-tidal carbon dioxide to confirm endotracheal tube position. The primary outcome measure was first pass success rate without hypoxia or hypotension. Potential harms from study interventions were monitored.

Results: Forty-six intubations were included over one calendar year in the post-intervention cohort (compared to 71 in the pre-intervention cohort). Overall clinical uptake of the 6 processes measures was 85%. First pass success rate without hypoxia

or hypotension was 78% in the post-intervention cohort compared to 49% in the pre-intervention cohort (absolute risk reduction: 29.0%; 95% confidence interval 12.3-45.6%, number needed to treat: 3.5). No significant harms from study interventions were identified.

Conclusion: Quality improvement initiatives targeting emergency airway management may be successfully implemented in the Emergency Department, and are associated with a reduction in adverse intubation-related events.

Keywords: Child; Pediatric; Emergency Service, Hospital; Intubation, Intra-tracheal; Patient Safety; Quality Assurance, Health Care; Task Performance and Analysis

INTRODUCTION

Emergency airway management outside of the operating room (OR) is a high-risk procedure. It is frequently associated with adverse events, and those adverse events are more likely to result in permanent disability or death than those which occur in the OR (1). Hypoxia and hypotension in particular have been reported in up to 1/3 of patients (2), are associated with poor neurological outcome, and are the strongest predictors of airway-related death (1, 3-6). More than 1 intubation attempt is the strongest predictor of hypoxia during the peri-intubation period (7). As such, first pass success without hypoxia or hypotension should be the aim of all emergency airway management.

Initiatives to reduce the adverse event rate during non-OR emergency airway management have been implemented in emergency departments (EDs) and intensive care units (ICUs) with some success (8). Reduced rates of desaturation and improved first pass success rates have been observed following the implementation of several systems changes, including: airway algorithms, checklist use, pre-procedural physiological resuscitation, standardized team and equipment preparation, planning for unsuccessful attempts, use of apnoeic oxygenation, restricting airway providers to senior medical staff or to those having undergone specific airway training, use of end-tidal carbon dioxide ($EtCO_2$) monitoring to confirm correct endotracheal tube (ETT) placement, and post-event debriefing (Table 1) (9-13). Potential harms from airway

interventions have not been monitored. No studies have examined the impact of airway interventions on the incidence of hypotension during the peri-intubation period, and none have reported the impact on first pass success without hypoxia or hypotension.

The aim of this study was to use quality improvement (QI) methodology to improve the combined rate of first pass success without hypoxia or hypotension during intubation in the pediatric emergency department.

METHODS

Design: The Model for Improvement framework was used for study design (14); identifying process, outcome, and balancing measures relevant to non-OR emergency airway management (Table 2) (15). Definitions for: intubation attempt, desaturation, gastric distension, hypotension, aspiration, cardiac arrest, external laryngeal manipulation (ELM), difficult intubation, difficult laryngoscopy, and apneic oxygenation were as previously described (2).

Setting: The Royal Children's Hospital (RCH), Melbourne, Australia is a 340 bed quaternary level pediatric (children 0-18 years of age) hospital with an annual ED census of >90 000. The study was conducted over a 4-year time period; the pre-intervention cohort was identified in the ED prospectively over the calendar year 2013, interventions were developed and implemented hospital-wide over the following 2 years, and a post-intervention cohort was identified in the ED prospectively over the calendar year 2016.

Defining the problem: Emergency airway management was identified as a high-risk procedure through evaluation of the pre-intervention cohort (2). Balancing measures were used to monitor for potential harms from study interventions, including: gastric distention, poor face mask seal, and aspiration of gastric contents.

Analysis: Data were entered into Microsoft Excel 2010 (Microsoft, Redmond, WA, USA). Descriptive statistics were performed on demographic data. The difference in first pass success without hypoxia or hypotension between pre and post-intervention cohorts was compared using absolute risk reduction (ARR) and number needed to treat (NNT) and reported with 95% confidence intervals (CI). Statistical analysis was performed using STATA 14 (StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP).

RESULTS

Forty-six intubations were performed in the post-intervention cohort, and 71 pre-intervention. Data was captured for all intubations. The median age of the post-intervention cohort was 3 years (IQR 16 months-9 years), with 9/46 (20%) <1year of age. In the pre-intervention cohort, the median age was 3 years (IQR 10months-11 years), with 18/71 (25%) <1year of age (2). Diagnostic categories comparing pre- and post-intervention cohorts are presented in Table 3.

Process measures: Overall adherence to the 6 process measures was 85% in the post-intervention cohort (Figure 1). Three instances of checklist non-use were identified. These occurred due to team leader unfamiliarity on 2 occasions, and perceived time critical nature of intubation in 1 patient. One intubation occurred without a clear

airway plan being verbalized due to the presence of multiple senior medical staff and lack of clear team leadership. Post-intubation debrief identified one patient who was unable to be adequately resuscitated prior to intubation, and one patient who had inadequate dose titration of induction agent. One patient was intubated without apneic oxygenation due to airway practitioner unfamiliarity. $EtCO_2$ was used to confirm ETT position in all patients over the study period.

Outcome measures: The primary outcome of the combined incidence of first pass success without hypoxia or hypotension in the post-intervention cohort was 78% compared to 49% in the pre-intervention cohort (ARR 29.0%; 95% CI 12.3-45.6%, NNT 3.5) (Figure 2).

The first pass success rate in the post-intervention cohort was 36/46 (78%) compared with 55/71 (78%) in the pre-intervention cohort. In the post-intervention cohort, two intubation attempts were required to successfully intubate the trachea in 7/46 (15%) patients, and 3 intubation attempts in 3/46 (7%), compared to 11/71 (15%) and 5/71 (7%), respectively, in the pre-intervention cohort. Changes in the process of intubation between unsuccessful and successful attempts were: suctioning of oral secretions or blood in 6 patients, change of operator in 5 patients, use of a bougie in 3 patients, and the use of ELM in 2 patients. Laryngoscope type (direct vs indirect), style (curved vs straight), and size did not change between attempts, and patient position changes were not reported between attempts.

Difficult laryngoscopy occurred in 2 patients in the post-intervention cohort. Laryngoscopic view was improved using ELM on both occasions. Two patients in the

post-intervention cohort were intubated using the Glidescope® video laryngoscope on the first attempt, and no C&L airway grade could be assigned.

Four of forty-six patients (8%) in the post-intervention cohort had hypoxic adverse events compared to ten of seventy-one (14%) in the pre-intervention cohort. All hypoxic adverse events in the post-intervention cohort occurred in patients requiring >1 intubation attempt. Two patients had initial first pass success without hypoxia, with subsequent accidental extubation as the ETT was being secured. One patient was extubated due to progressive post-intubation hypoxia and an equivocal $EtCO_2$ trace, but was retrospectively thought to have had right main-stem bronchus intubation with pulse oximeter delay. The last hypoxic adverse event occurred following successful passage of an oversized bougie, with subsequent inability to load the correctly sized ETT.

No patient in the post-intervention group had a hypotensive adverse event over the study period, compared to 15/71 (21%) in the pre-intervention cohort.

The frequency of methods used to avoid hypoxia and hypotension between pre and post-intervention cohorts are listed in Table 4.

Balancing measures: The following potential harms from study interventions were identified in the post-intervention cohort: 1 patient developed gastric distension requiring decompression, 1 patient had nasal cannulae removed during the apneic period due to poor face mask seal despite the use of 2-person technique, and 1 patient had nasal cannulae removed during the apneic period due to epistaxis. There were no

episodes of aspiration. None of these events were associated with hypoxia or hypotension.

DISCUSSION

We demonstrated an improvement in the combined outocome of first pass success without hypoxia or hypotension following the implementation of QI initiatives. No significant harms from study interventions were identified.

We observed no change in first pass success rate between pre and post-intervention cohorts. Study interventions were based on the finding that anatomically difficult airways were uncommon in the pre-intervention cohort, and that laryngoscopic view could be improved with changes in position, equipment, technique, or operator (2). Therefore, the focus of our QI interventions were not only on improving the technical skill of the airway operator, but included strategies to address the physiologically and situationally difficult airway (16). Airway skills were taught on task trainers during multidisciplinary team training and reinforced during OR training (16); despite this training, competency at intubation through study interventions could not be assured. This may have contributed to the lack of improvement in first pass success rate observed between cohorts. Finally, airway interventions emphasized maintaining oxygenation during the peri-intubation period. This may have resulted in early discontinuation of intubation attempts in an effort to avoid desaturation, resulting in a lower first pass success rate than had the airway operator persevered with the intubation attempt.

We observed a reduction in the frequency of hypoxia as an adverse event between pre and post- intervention cohorts. Interventions aimed at reducing the frequency of hypoxic adverse events included: patient positioning 20 degrees head up, pre-oxygenation using positive end-expiratory pressure (PEEP), apneic oxygenation using positive airway pressure / PEEP via face mask / t-piece, and nasal cannula oxygenation during laryngoscopy (17-20). The frequency of use of apneic oxygenation was higher in the post-intervention cohort, which may have improved peri-intubation oxygenation. Additionally, hypoxic adverse events did not result from failure of pre- or apneic oxygenation, but occurred due to other technical factors. Two patients with hypoxic adverse events were initially intubated successfully without hypoxia, with subsequent accidental extubation as the ETT was being secured. Another had incorrect equipment size contribute to transient hypoxia (due to the use of a bougie that was too large to load an appropriately-sized ETT), and the last had transient hypoxia not prevented by the use of a saturation stop point of ≤93% due to pulse oximeter delay.

We observed a significant reduction in the incidence of hypotension between pre- and post-intervention cohorts. Interventions aimed at reducing the frequency of hypotension were components of the pre-intubation checklist, and included: pre-loading patients at risk of hypotension with fluid bolus therapy, starting an inotrope or vasopressor infusion for persisting circulatory failure despite fluid bolus therapy, having a "rescue" dose of inotrope drawn up prior to induction of anesthesia, and titrating the dose of induction agent to the patients physiology (21-24). Induction agent choice and dose were left at the discretion of the treating team. More patients were pre-treated with fluid bolus therapy, were administered ketamine as an induction

agent, and had dose titration of induction agent in the post-intervention cohort compared to the pre-intervention cohort, which may have contributed to the observed reduction in peri-intubation hypotension.

LIMITATIONS

This was a pragmatic study testing the effectiveness of multiple interventions in broad routine clinical practice. The contribution of individual elements of our study interventions were difficult to assess because they were implemented together as a bundle. This methodology was necessary as all of the study interventions were co-dependent. Though pre and post- intervention cohorts were both identified over one calendar year and had similar known characteristics, there may have been unknown characteristics that differed between groups and contributed to study findings. We observed an unexplained reduction in total number of departmental intubations over the study period. It is possible that increased use of non-invasive respiratory support in the form of heated, humidified high-flow nasal cannula oxygen therapy for respiratory failure over the study period may have contributed to the reduction in total number of ED intubations (25), and a concurrent anti-epileptic medication trial may have reduced the intubation rate for convulsive status epilepticus. We observed no change in the frequency of transfer of patients to the OR for urgent intubation over the study period (26). Two of the process measures recorded (adequacy of resuscitation and appropriate dose titration of induction agent) were prone to outcome / hindsight bias. Lastly, it is possible that changes in patient management other than the study interventions occurred between cohorts and contributed to the study results.

CONCLUSION

Quality improvement initiatives targeting emergency airway management using the NAP4 framework are associated with an improvement in first pass success without hypoxia or hypotension in the pediatric ED.

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DISCLOSURES

ETHICS: The study was approved by The Royal Children's Hospital Human Research Ethics Committee (HREC 32250A).

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CONFLICT OF INTEREST: None of the authors have any declared conflicts of interest.

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Figure 1. Adherence to quality improvement process measures in the post-intervention study group

Figure 2. Adverse intubation-related outcomes in pre and post-intervention study cohorts.

Table 1. Summary of quality improvement initiatives targeting emergency airway management

Study	Patient group	Setting	Quality improvement interventions	Main findings
Kerrey 2015	Pediatric	ED	checklist, pilot-copilot model, video laryngoscopy only, restricted airway providers	16% desaturation rate vs 33% in historic controls
Jaber 2010	Adult	ICU	Pre-oxygenation using positive airway pressure, 2 operators, rapid sequence intubation, use of cricoid force, end-tidal carbon dioxide monitoring	21% composite life-threatening adverse events vs 34% in historic controls
Fogg 2016	Mixed	ED	training, algorithm, checklist, restricted providers, combined direct/video laryngoscope, bougie, apneic oxygenation	11% desaturation vs 15% in historic controls 93% first pass success vs 83% in historic controls
Mayo 2011	Adult	ICU	checklist, combined team approach, CRM tactics, post-event debrief	14% desaturation, no comparison group 6% hypotension, no comparison group 62% first pass success, no comparison group
Mosier 2015	Adult	ICU	simulation based training curriculum (recognition of difficult airway, pre-procedural resuscitation, team / equipment preparation, planning for failure, use of a difficult airway algorithm)	First pass success 82% vs 74% in historic controls Desaturation 17% vs 23% in historic controls

Table 2. Quality improvement measures undertaken to improve the safety of emergency airway management.

Study interventions	Process measures	Outcome measures	Balancing measures
Airway algorithm Standardized equipment Checklist Template End-tidal carbon dioxide monitor Team training Post-event debrief	Checklist use Airway plan Physiologic resuscitation Dose titration of induction agent Use of apneic oxygenation End-tidal carbon dioxide use	First pass success without hypoxia or hypotension	Gastric distension Poor face mask seal Aspiration of gastric contents

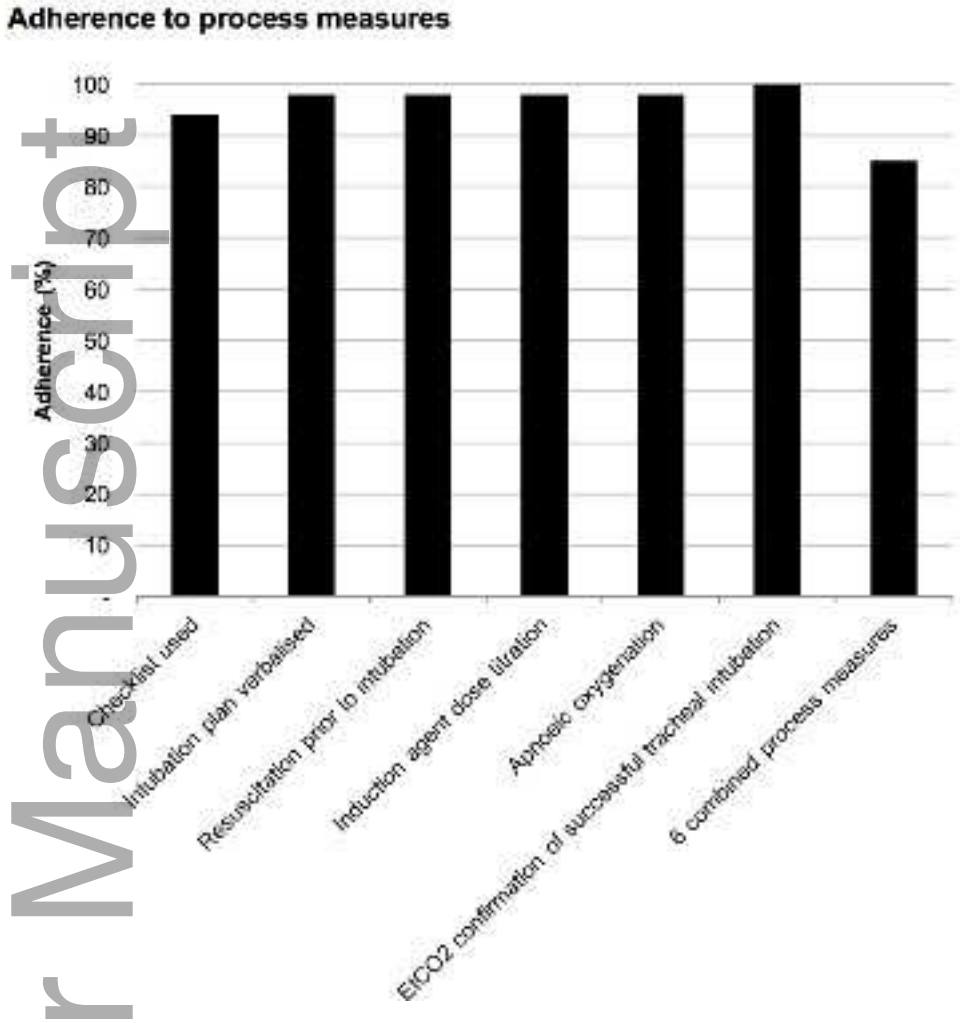
Table 3. Diagnostic categories of patients requiring emergency airway management

	Diagnostic category	Historic control n (%)	Intervention group n (%)
Medical	Seizure	22 (31)	14 (30)
	Respiratory failure	11 (16)	5 (11)
	Sepsis	7 (10)	3 (7)
	Cardiac arrest	5 (7)	2 (4)
	Stroke/ Intra-cranial hemorrhage	4 (6)	2 (4)
	Overdose / Ingestion	3 (4)	3 (7)
	Altered mental status- not overdose	2 (3)	8 (17)
	Airway obstruction	1 (1)	1 (2)
	Cardiac failure	1 (1)	0 (0)
Trauma	Head injury- threatened airway	9 (13)	6 (13)
	Combative/ agitated due to trauma	4 (6)	1 (2)
	Burn / inhalation	2 (3)	1 (2)
Total (n)		**71(100)**	**46(100)**

Table 4. Frequency of use of measures to avoid hypoxia and hypotension during the peri-intubation period in the intervention group compared with a historic cohort.

	Intervention	**Historic Cohort (n=71); n (%)**	**Intervention Group (n=46); n (%)**
Measures to avoid hypoxia	Pre-oxygenation with positive airway pressure	67 (94)	35 (76)
	Apneic oxygenation	38 (54)	46 (100)
Measures to avoid hypotension	Fluid bolus	31 (44)	37 (80)
	Inotrope / vasopressor infusion	3 (4)	6 (13)
	Induction agent (dose: mg/kg; median, IQR)	Ketamine: 22 (31) Dose: 2.0 (1.8-2.0) Propofol: 13 (18) Dose: 2.0 (1.2-2.4) Thiopentone: 11 (16) Dose: 3.0 (2.0-3.0) Fentanyl: 8 (11) Dose*: 2.0 (1.5-3.1) Combination: 10 (14) Inhalational: 0 (36) No induction agent: 6 (8)	Ketamine: 33 (72) Dose: 1.5 (1.0-2.0) Propofol: 3 (7) Dose: 2 (1.0-5.0) Thiopentone: 3 (7) Dose: 2.5 (1.5-5.0) Fentanyl: 0 (0) Dose*: n/a Combination: 2 (4) Inhalational: 2 (4) No induction agent: 3 (7)

*Fentanyl dose is in mcg/kg



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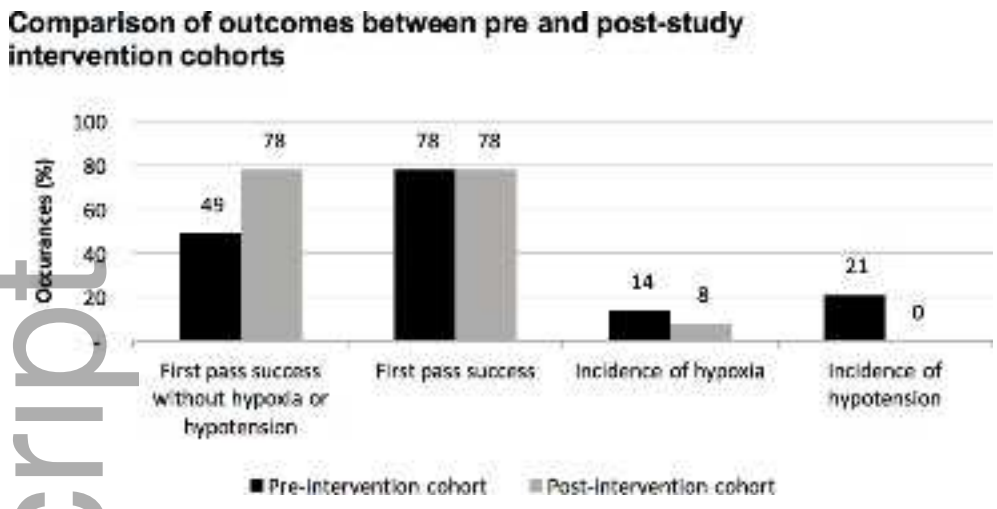

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