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Title: Quality of bag mask ventilation in critically ill children

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Structured Abstract (250 words max)

Purpose
To characterize the quality of Bag Mask Ventilation (BMV) delivered to critically ill children and to evaluate the association of BMV quality on the occurrence of adverse tracheal intubation-associated events (TIAEs) and severe oxygen desaturation during tracheal intubation (TI).

Scope
BMV is a fundamental skill for acute care providers but is difficult to perform in critically ill children. There is a concern that low-quality BMV is common, contributing to severe oxygen desaturation and physiologic derangement in critically ill children.

Methods
We measured key components of BMV quality in critically ill children using a Respiratory Function Monitor (RFM): Expiratory Tidal Volume (TVe), Peak Inspiratory Pressure (PIP), % leak around the mask, presence of upper airway obstruction. We defined high-quality breath as all components being within the target.

Results
Due to COVID-19, our data collection has been delayed. To date, we enrolled 70 children with evaluable RFM data (target goal:84). Our interim analysis included 31 children with a median age of 54 months (IQR: 20-114) and a median weight of 16.7 kg (IQR: 10.5-32.6); 55% were male gender. TVe was median 8.8 mL/kg (IQR 4.8-16.2), with TVe at target range (4-12 mL/kg) in 40.6%. PIP was median 24.7 cmH2O (IQR: 20.5-32.9) and was at target range (≤25 cmH2O) in 51%. The % leak median was 22.3% (IQR: 0-65.8), and the measure was at target range (<40%) in 58.8%. Desaturation (SpO2<80%) or adverse TIAEs occurred in 5/20 (25%) of children with high-quality breath<50%, whereas 0/11 of children with high-quality breath≥50% had oxygen desaturation (SpO2<80%) or adverse TIAEs.

Key Words
mask ventilation, quality, child, critically ill, adverse events, oxygen desaturation

Purpose
Our goals are to characterize the quality of BMV delivered to critically ill children and to evaluate the association of quality of BMV on the occurrence of adverse TIAE, severe oxygen desaturation, and brain oxygen desaturation during TI procedures.

Scope
Airway management with Tracheal Intubation (**TI**) in critically ill children is an important life-saving procedure with known high risk. We identified and reported that 20% of TI are associated with adverse TI-associated events (**TIAE**s) and 14% are associated with severe oxygen desaturation (defined as SpO2<80% for children with baseline SpO2>90%) using our National Emergency Airway Registry for Children (NEAR4KIDS), a multicenter quality improvement (QI) database of 41 pediatric ICUs. These children who suffered adverse TIAE or severe desaturation had a longer duration of mechanical ventilation and ICU stay. Implementation of a multidisciplinary checklist decreased these event rates by only 4% since 2013, remaining far from ideal. Current ongoing QI interventions have targeted the implementation of apneic oxygenation and video laryngoscopy (to improve visualization of the larynx) to minimize TIAE and oxygen desaturation. However, we have not yet targeted a critical skill: bag mask ventilation (**BMV**). Insufficient BMV and oxygen reserve before laryngoscopy may cause immediate oxygen desaturation during TI laryngoscopy, which leads to short laryngoscopy procedure time and physiologic derangement, such as hypotension. Poor BMV with excessive pressure and inadequate relief of upper airway obstruction is also associated with gastric inflation and emesis. BMV is considered a fundamental resuscitative skill for all acute care providers but is difficult to perform in critically ill children due to challenging patient anatomy and physiology (e.g., difficult airway anatomy, upper airway obstruction, poor lung compliance). Although anesthesiologists routinely provide BMV to their patients, critical care providers infrequently perform BMV. There *is a critical gap in knowledge* about the quality and effectiveness of BMV in critically ill children in the ICU. There is a substantial concern that low-quality BMV is common, which may contribute to severe oxygen desaturation, physiologic derangement, and *end-organ hypoxia*: brain oxygen desaturation during TI in critically ill children.

Method
Study Design, Data Sources/Collection
We are conducting a prospective observational study to assess the quality of BMV provided in critically ill children in a large pediatric ICU. With our institutional review board approval, the quality of BMV data collection is performed using a noninvasive Respiratory Function Monitor (RFM) at the time of tracheal intubation. The overwhelming majority of TI in the pediatric ICU involves BMV as a part of the TI procedure.
Noninvasive brain regional oxygen measurement (NIRS) probe is also placed during the BMV. For each TI, encounter processes and outcomes are collected using an existing local quality improvement data collection as a part of the National Emergency Airway Registry for Children (NEAR4KIDS). After the procedure, BMV quality data are downloaded from RFM for further analyses. The bedside BMV procedure logs that capture the provider intervention (e.g., laryngoscope attempt, airway insertion) were also collected at the time of TI procedure.

Interventions
None

Measures
Bag mask ventilation quality
Our standard clinical flow/pressure sensor and quantitative capnometer is placed between the face mask and flow-inflating bag. Each key component of BMV quality: **TVe** (patient received

tidal volume, as opposed to inspiratory tidal volume, which includes the leak around the mask), **PIP**, % leak around the mask, presence/absence (*relief*) of upper airway obstruction (manifested by high PIP and low expiratory TV, high % leak) was collected. We defined low-quality BMV if any of the following were present: **TVe**<4 mL/kg or >12 mL/kg, excessive PIP above 25 cmH2O when adequate TVe (4-12 mL/kg) is achieved at lower PIP, % leak calculated as (inspiratory TV-TVe)/inspiratory TV greater than 40%, and failure to relieve upper airway obstruction. These thresholds are derived from previously published neonatal resuscitation studies[22-24]. We *a priori* defined that those breaths with all parameters within the targeted range would be considered high-quality breaths, whereas those breaths with any parameter outside the targeted range were considered non-high-quality breaths.

Data analyses
For our specific aim 1: To characterize key modifiable components of BMV quality during TI procedures in critically ill children using a Respiratory Function Monitor (RFM), modifiable components of BMV quality---expiratory Tidal Volume (**TVe**), Peak Inspiratory Pressure (**PIP**), % leak around the mask, presence/absence of upper airway obstruction (manifested by low TVe, high PIP, high % leak--- are summarized. We classified each breath as low vs. high quality based on the criteria described above. Because breaths data are clustered within each patient, we used the proportion of high-quality breaths per patient for patient-level analyses.

For our specific aim 2: To evaluate the association of the quality of BMV with the occurrence of adverse TIAEs, severe oxygen desaturation (defined as SpO2<80%), and brain tissue regional oxygen desaturation, we evaluated the association of the proportion of high-quality breaths per patient with patient-level outcomes. Our primary outcome was the occurrence of adverse TIAEs or severe oxygen desaturation (SpO2<80%) during TI procedure.

Limitation
Due to COVID-19 restriction, we experienced a substantial delay in data collection due to fewer children being seen in the ICU during the first 6 months and staff restriction during the pandemic (March 11, 2020, to December 28, 2021). Airway management, especially TI procedure and BMV, are considered high-risk aerosol-generating procedures, and rules are in place to limit the number of providers at the bedside for children with COVID-positive or unknown status.

Results

Principal findings and Outcomes
Due to the COVID-19 pandemic during the study period, our data collection has been delayed. To date, we enrolled 70 children with evaluable RFM data (target enrollment goal: 84 with evaluable data). We conducted an interim analysis that included 31 children. Our study cohort had a median age of 54 months (IQR: 20-114) and a median weight of 16.7 kg (IQR: 10.5-32.6); the male/female rates were 55%/45%. Indications for a TI procedure were respiratory failure (42%), procedure (61%), shock (6%), and neuromuscular weakness (6%).
The TVe median was 8.8 mL/kg (IQR 4.8-16.2), TVe was at target range (4-12 mL/kg) in 40.6%. The PIP median was 24.7 cmH2O (IQR: 20.5-32.9), and the PIP was at target range (≤25 cmH2O) in 51%. The % leak median was 22.3% (IQR: 0-65.8), and it was at target range (<40%) in 58.8%. Desaturation (SpO2<80%) or adverse TIAEs occurred in 5/20 (25%) of children with high-quality breath<50%, whereas 0/11 of children with high-quality breath≥50% had oxygen desaturation (SpO2<80%) or adverse TIAEs.
The proportion of high-quality breaths was 37.5% (1,051/2,806) among TIs without desaturation or TIAEs versus 30.0% (195/651) among TIs with desaturation or TIAEs (p<0.001).

There was a substantial pause of BMV during laryngoscopy as a part of TI procedure. The median duration was 59.5 sec (IQR:44-84 sec) for the first attempt (n=30, one patient is missing this data), 68 sec (IQR:42-72 sec) for the second attempt (n=9), and 39.5 sec (IQR: 39-51 sec) for the third attempt (n=6). The brain tissue oxygen saturation data analyses are ongoing.

Discussion

In the current study, we aimed to characterize the quality of BMV provided in critically ill children who received TI procedures in the ICU. Our preliminary findings indicate that poor-quality BMV is common and may be associated with the poorer patient outcomes: adverse TIAEs and oxygen desaturation.

This finding is significant, because our previous studies showed that the adverse TIAEs and oxygen desaturation events during TI procedure are also associated with a longer duration of mechanical ventilation, longer ICU stay, and more ICU mortality. We also recently evaluated commonly performed BMV mitigation techniques and documented various levels of success (e.g., supraglottic or adjunct airway use success rate for improving BMV: 73%, provider change: 80%).

We plan to complete a final data analysis and use this observational study data for future RO1 application. With this preliminary study result, we are informed that the quality of BMV given to critically ill children is suboptimal, and there is substantial room for improvement. Poor quality of BMV may be associated with poor patient outcomes. Future quality improvement work should target the high quality of BMV using simulation, real-time feedback, and effective coaching.

Conclusion

Our preliminary analyses of the data suggested the poor quality of BMV is pervasive and may be associated with patient outcomes. The data collection was delayed due to COVID-19. The completion of full data analyses will further quantify the safety gap in the current pediatric ICU practice.

Significance

BMV is an essential, life-saving skill performed for critically ill children. Yet, the BMV quality measured by a Respiratory Function Monitor revealed a high proportion of poor-quality BMV breaths. These poor-quality breaths may be associated with poor patient outcomes for critically ill children.

Implications

Quality of BMV for critically ill children should be measured and intervened.

Future quality improvement studies should include educational and innovative interventions to improve the quality of BMV in critically ill children.

Publications

Daly Guris RJ, Doshi A, Boyer DL, Good G, Gurnaney HG, Rosenblatt S, McGowan N, Widmeier K, Kishida M, Nadkarni V, Nishisaki A, Wolfe HA. Just-in-Time Simulation to Guide Workflow Design for Coronavirus Disease 2019 Difficult Airway Management. Pediatr Crit Care Med. 2020 Aug;21(8):e485-e490. PMID: 32459793; PMCID: PMC7288785.