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# Impact of a pre-procedural checklist on complications in emergency endotracheal intubation: a prospective cohort study

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**ABSTRACT**

***Introduction:***
Emergency endotracheal intubation (ETI) is high-risk. Pre-procedural checklists may enhance safety, but evidence in emergency ETI is limited. This preliminary, exploratory study evaluated a checklist's impact on ETI complications and mortality.

***Materials and Methods:***
This prospective cohort study enrolled adult Emergency Department (ED) patients requiring emergency ETI (August 2021-December 2022). A control group (pre-checklist) was compared to an intervention group (post 12-point checklist implementation and training). Data on procedure-related complications and 24-hour mortality were collected and analyzed using relative risks.

***Results:***
131 patients (control n=68, checklist n=63) were included. The overall composite complication rate was similar (RR 1.01, p=0.90), potentially masking individual effects. Checklist use was associated with reduced aspiration (RR 0.36, p=0.045) but an unexpected increase in post-intubation hypoxia (RR 3.24, p=0.004); reasons, possibly procedural delays or altered team dynamics, require further investigation. Other individual complications and 24-hour mortality (RR 1.38, p=0.22) showed no significant differences.

***Conclusion:***
In this underpowered, preliminary, and exploratory study, a pre-procedural checklist did not significantly reduce overall ETI complications. The observed decrease in aspiration alongside increased hypoxia warrants cautious interpretation and underscores the complexity of checklist implementation in emergency airway management. Further research with larger sample sizes is crucial to optimize checklist design and confirm its impact on patient safety.

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## *Introduction*

Emergency endotracheal intubation (ETI), while often life-saving, is a high-risk procedure associated with a significant incidence of complications, including hypoxia, aspiration, hypotension, esophageal intubation, and traumatic injury, which can contribute to increased morbidity and mortality (1,2). Given the time-sensitive and often chaotic nature of emergency situations, procedural errors during ETI are not uncommon, even in experienced hands. Strategies to mitigate these risks and enhance patient safety during emergency ETI are therefore of paramount importance (3). The adoption of standardized checklists has emerged as a promising approach to improve the safety and reliability of complex medical procedures across various clinical settings (4). Checklists have been shown to reduce errors and improve outcomes in diverse fields, from aviation to surgery, by ensuring adherence to essential steps and promoting a culture of safety (5,6). In airway management, pre-procedural checklists have been advocated as a tool to standardize preparation, optimize equipment readiness, and enhance team coordination, potentially leading to a reduction in procedure-related complications (7).

However, the evidence regarding the effectiveness of checklists in the specific context of emergency ETI remains limited and somewhat inconsistent (8). While some studies suggest that checklists can improve adherence to recommended guidelines and reduce specific complications, their impact on the broad spectrum of ETI-related adverse events and mortality is less clear, particularly given the modest effect sizes typically observed with such interventions in real-world emergency settings. Furthermore, the dynamic and unpredictable nature of emergency airway management may present unique challenges to the straightforward application of checklists, potentially impacting their effectiveness in this setting. This preliminary and exploratory study aims to contribute to the understanding of the role of pre-procedural checklists in the context of emergency ETI.

The purpose of this study was to evaluate whether the routine implementation of a standardized 12-point preprocedural checklist for endotracheal intubation in adult patients presenting with medical emergencies can reduce complications and in-hospital mortality. The primary objective was to assess if the use of this checklist decreases the incidence of procedure-related complications, including hypoxia, bradycardia, hypotension, esophageal intubation, cardiac arrest, traumatic intubation (comprising dental, laryngeal, and tracheal trauma), aspiration, pneumothorax, multiple intubation attempts, and unplanned or accidental extubation. The secondary objective was to determine whether the checklist affects in-hospital mortality rates at 24 hours post-procedure.

## *Materials and Methods*

Study Design

This prospective cohort study was conducted with adult patients (≥18 years) in the emergency department at Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, spanning from August 2021 to December 2022. The protocol was approved by the Institute Ethics Committee of PGIMER, Chandigarh (Ref. No.-INT/IEC/2021/SPL-1749). Initially, patients in the control group were recruited over the first six months of the study before the preprocedural checklist was introduced. Following this, emergency physicians and nurses underwent a one-week training session on the checklist. The checklist was then routinely implemented for all endotracheal intubations. Training was reiterated every two months by the investigator to reinforce correct usage. During the intervention phase, each checklist element was verbally confirmed as completed by the attending nurse and acknowledged by the attending physician prior to proceeding with intubation. However, formal quantitative monitoring of adherence rates for each checklist item or a detailed assessment of implementation fidelity beyond this verbal confirmation process was not systematically performed, which is a limitation of this study. Subsequently, the checklist cohort was recruited over the following six months. All intubations throughout the study period were performed by emergency medicine residents, with rapid sequence intubation

(RSI) consistently employed as the preferred method.

**Participants**

The study population comprised adult patients (≥18 years) requiring emergency intubation at PGIMER during the designated timeframe. Patients were screened based on specified inclusion criteria, including those with neurological emergencies, cardiovascular emergencies, acute or chronic kidney disease with pulmonary edema or uremic encephalopathy, gastrointestinal bleeding, hepatic encephalopathy, sepsis, envenomation or intoxication, anaphylaxis, or respiratory failure. Exclusion criteria were pregnant women, terminal illnesses (e.g., disseminated malignancy), patients in cardiac arrest, COVID-19 positive patients, trauma patients, and surgical emergencies. Written informed consent was obtained from the participants' legally authorized representatives (LAR) or next of kin.

**Sample Size Calculation and Power Considerations**

The initial sample size calculation aimed to detect a large reduction in complication rates from an anticipated 9.2% in the control group to 1.2% in the checklist group, targeting 80% power ($\alpha = 0.05$), which yielded a required sample size of 266 participants. This represented an anticipated absolute risk reduction of 8% (a relative risk reduction of nearly 87%). It is acknowledged that this assumed effect size was unrealistically large, as most complex interventions like checklists in emergency settings typically yield more modest effect sizes (e.g., 10–30% relative risk reduction) (9,10). Due to logistical time constraints within the defined study period (August 2021 to December 2022), the recruitment target was revised, and a total of 131 participants were ultimately enrolled (68 control, 63 intervention). This reduction of over 50% from the original target significantly limits the statistical power of the study. With the achieved sample size, the study was underpowered to detect small to moderate effect sizes for the primary composite outcome and particularly for less frequent individual complications. This underpowering increases the likelihood of Type II errors (false negatives) for outcomes where no statistically significant difference was found. Consequently, the study findings should be interpreted as preliminary and hypothesis-generating, and non-significant results should not be taken as evidence of no effect.

**Intervention**

Patients presenting to the Emergency Department who required endotracheal intubation were screened, and those meeting inclusion criteria were invited to participate following informed consent. The checklist was implemented without altering the treatment protocols determined by the treating physicians according to standard procedures. After the initial six months of the control period, large printed copies of the checklist were displayed in the Emergency Department. Education was provided to all staff through live sessions, webinars, and meetings, emphasizing the checklist's potential to reduce complications. Each checklist element was verbally confirmed by the attending nurse and acknowledged by the attending physician. The checklist included essential safety elements such as patient identification, indication for intubation, adequate positioning (flexion of the neck and extension of the head at the atlanto-occipital joint), preoxygenation, attachment and optimization of monitors for blood pressure, ECG, and pulse oximetry, apnoeic oxygenation, reliable IV access, suction functionality, intubation equipment check and backup, drugs for intubation and post-intubation sedation, and failed airway equipment (Supplement 1) (11). Video laryngoscopes and capnography were initially considered for inclusion in this checklist; however, they were excluded due to their limited availability in primary and secondary care centers (12). This decision was made to ensure broader generalizability of the study results across diverse clinical settings.

**Outcomes**

Primary outcomes included any of the following procedure-related complications: hypoxia, bradycardia, hypotension, esophageal intubation, cardiac arrest, traumatic intubation, aspiration, pneumothorax, multiple intubation attempts, and unplanned extubation. Definitions for these outcomes were specific: hypoxia was defined as oxygen saturation < 92% measured by fingertip pulse oximetry at

5 minutes and 30 minutes after induction drugs were administered; bradycardia was a heart rate < 60 beats per minute; hypotension was a systolic blood pressure < 90 mmHg at the same time points; esophageal intubation was identified by auscultation or capnography; cardiac arrest was defined as the absence of central pulses requiring cardiopulmonary resuscitation; traumatic intubations included dental, laryngeal, or tracheal trauma; pneumothorax was diagnosed via chest X-ray; aspiration observed during laryngoscopy or suctioning; multiple intubation attempts were defined as two or more attempts; and unplanned extubation referred to accidental displacement of the tube before planned extubation. The secondary outcome included in-hospital mortality at 24 hours post-procedure. The choice of 24-hour mortality is recognized as a relatively early endpoint, which may not fully reflect longer-term impacts of the intervention.

**Data collection**

Outcome data were collected by the primary investigator and included patient demographics, comorbidities, baseline vitals, and reasons for any non-compliance with the checklist. The outcomes were assessed at 5 minutes, 30 minutes, and 24 hours post-intubation. Follow-up included checking patient status through medical records in cases of loss of follow-up.

**Statistical analysis**

Statistical analysis was conducted using R program. Descriptive statistics summarized categorical data in percentages and proportions, while continuous variables were expressed as means/standard deviations or medians/interquartile ranges. Relative risks for primary and secondary outcomes were reported with a 95% confidence interval. Differences between the checklist and control groups were analyzed using the Chi-square test and Fisher's Exact test, with statistical significance set at a p-value of <0.05. No adjustments for multiple comparisons (e.g., Bonferroni correction) were made for the analysis of multiple secondary outcomes. Given the exploratory nature of this study and the limited sample size, this approach was chosen, but it increases the risk of spurious significant findings (Type I error). Therefore, all p-values, especially for secondary outcomes, should be interpreted with caution.

## *Results*

A total of 144 participants were assessed for eligibility in the study. We excluded thirteen participants due to the following reasons: age less than 18 years (n=6), cardiac arrest prior to intubation (n=4), and withdrawal of consent (n=3). Consequently, we enrolled 131 patients in the study. The cohort was divided into 68 participants in the control group during the first six months and 63 participants in the checklist group during the subsequent six months. Table 1 presents the baseline characteristics of the study participants, divided into control (N=68) and intervention (N=63) groups.

**Table 1.** Baseline Characteristics of the study participants

| Characteristic | Overall N = 131[1] | Control group N = 68[1] | Intervention group N = 63[1] | p-value[2] |
|---|---|---|---|---|
| Age, in years | 50 (35 – 61) | 50 (39 – 61) | 50 (28 – 62) | 0.50 |
| Gender | | | | 0.76 |
| Female | 37 / 131 (28%) | 20 / 68 (29%) | 17 / 63 (27%) | |
| Male | 94 / 131 (72%) | 48 / 68 (71%) | 46 / 63 (73%) | |
| Diabetes mellitus | 22 / 131 (17%) | 10 / 68 (15%) | 12 / 63 (19%) | 0.51 |
| Hypertension | 40 / 131 (31%) | 27 / 68 (40%) | 13 / 63 (21%) | 0.018 |
| Chronic kidney disease | 9 / 131 (6.9%) | 7 / 68 (10%) | 2 / 63 (3.2%) | 0.17 |
| Coronary artery disease | 6 / 131 (4.6%) | 3 / 68 (4.4%) | 3 / 63 (4.8%) | >0.99 |
| Chronic liver disease | 10 / 131 (7.6%) | 3 / 68 (4.4%) | 7 / 63 (11%) | 0.19 |
| History of smoking | 29 / 131 (22%) | 12 / 68 (18%) | 17 / 63 (27%) | 0.20 |
| History of alcohol consumption | 34 / 131 (26%) | 14 / 68 (21%) | 20 / 63 (32%) | 0.15 |
| Cerebrovascular accident | 5 / 131 (3.8%) | 4 / 68 (5.9%) | 1 / 63 (1.6%) | 0.37 |
| Hypothyroidism | 4 / 131 (3.1%) | 2 / 68 (2.9%) | 2 / 63 (3.2%) | >0.99 |
| No comorbidities | 38 / 131 (29%) | 20 / 68 (29%) | 18 / 63 (29%) | 0.92 |
| Indication of Intubation | | | | 0.001 |
| Cardiovascular illness | 3 / 131 (2.3%) | 2 / 68 (2.9%) | 1 / 63 (1.6%) | |
| Gastrointestinal disease | 14 / 131 (11%) | 4 / 68 (5.9%) | 10 / 63 (16%) | |
| Neurological illness | 63 / 131 (48%) | 42 / 68 (62%) | 21 / 63 (33%) | |
| Renal disease | 9 / 131 (6.9%) | 5 / 68 (7.4%) | 4 / 63 (6.3%) | |
| Respiratory illness | 27 / 131 (21%) | 13 / 68 (19%) | 14 / 63 (22%) | |
| Others | 15 / 131 (11%) | 2 / 68 (2.9%) | 13 / 63 (21%) | |
| Experience of the physician | | | | 0.10 |
| Less than one year | 94 / 131 (72%) | 53 / 68 (78%) | 41 / 63 (65%) | |
| more than one year | 37 / 131 (28%) | 15 / 68 (22%) | 22 / 63 (35%) | |

[1]Median (IQR); n / N (%) [2]Wilcoxon rank sum test; Pearson's Chi-squared test; Fisher's exact test

The median age was 50 years in both groups, with no significant difference (p=0.50). Gender distribution was similar, with 28% females and 72% males overall (p=0.76). Key comorbidities included diabetes mellitus (17%), hypertension (31%), and chronic kidney disease (6.9%). Notably, hypertension was significantly more prevalent in the control group (40%) compared to the intervention group (21%) (p=0.018). The primary indications for intubation (as broad categories) varied significantly between groups (p=0.001), with neurological illness being the most common (48%), followed by respiratory illness (21%). The experience of the physicians performing the intubations was predominantly less than one year (72%), with no significant difference between groups (p=0.10). Control and Intervention groups were comparable in most baseline characteristics, except for a significantly higher prevalence of hypertension in the control group and differences in the overall distribution of primary intubation indications. Supplement 2 (Table 3) provides a detailed breakdown of these indications.

Supplement 2- Table 3. Indications for intubation among study participants

| **Characteristic** | **Overall N = 131[1]** | **Control group N = 68[1]** | **Intervention group N = 63[1]** | **p-value[2]** |
|---|---|---|---|---|
| Neurological disease | | | | 0.41 |
| Altered sensorium causes unknown | 25 / 63 (40%) | 16 / 42 (38%) | 9 / 21 (43%) | |
| Intracranial Hemorrhage | 11 / 63 (17%) | 9 / 42 (21%) | 2 / 21 (9.5%) | |
| Meningitis | 3 / 63 (4.8%) | 1 / 42 (2.4%) | 2 / 21 (9.5%) | |
| Neuromuscular illness | 3 / 63 (4.8%) | 3 / 42 (7.1%) | 0 / 21 (0%) | |
| Seizures | 9 / 63 (14%) | 7 / 42 (17%) | 2 / 21 (9.5%) | |
| Stroke | 10 / 63 (16%) | 5 / 42 (12%) | 5 / 21 (24%) | |
| Subarachnoid Hemorrhage | 2 / 63 (3.2%) | 1 / 42 (2.4%) | 1 / 21 (4.8%) | |
| Respiratory disease | | | | 0.55 |
| Type 1 respiratory failure | 15 / 27 (56%) | 8 / 13 (62%) | 7 / 14 (50%) | |
| Type 2 respiratory failure | 12 / 27 (44%) | 5 / 13 (38%) | 7 / 14 (50%) | |
| Cardiovascular disease | | | | 0.33 |
| Heart failure | 1 / 3 (33%) | 0 / 2 (0%) | 1 / 1 (100%) | |
| Myocardial infarction | 2 / 3 (67%) | 2 / 2 (100%) | 0 / 1 (0%) | |
| Renal disease | | | | 0.52 |
| Acute/Chronic kidney disease | 5 / 9 (56%) | 2 / 5 (40%) | 3 / 4 (75%) | |
| Uremic encephalopathy | 4 / 9 (44%) | 3 / 5 (60%) | 1 / 4 (25%) | |
| Gastrointestinal disease | | | | >0.99 |
| Hepatic encephalopathy | 12 / 14 (86%) | 4 / 4 (100%) | 8 / 10 (80%) | |
| Upper Gastrointestinal bleeding | 2 / 14 (14%) | 0 / 4 (0%) | 2 / 10 (20%) | |
| Others | | | | 0.57 |
| Drug intoxication/withdrawal | 6 / 15 (40%) | 1 / 2 (50%) | 5 / 13 (38%) | |
| Envenomation | 5 / 15 (33%) | 0 / 2 (0%) | 5 / 13 (38%) | |
| Hanging | 1 / 15 (6.7%) | 0 / 2 (0%) | 1 / 13 (7.7%) | |
| Metabolic | 2 / 15 (13%) | 1 / 2 (50%) | 1 / 13 (7.7%) | |
| Sepsis | 1 / 15 (6.7%) | 0 / 2 (0%) | 1 / 13 (7.7%) | |
| [1]n / N (%) | | | | |
| [2]Fisher's exact test; Pearson's Chi-squared test | | | | |

While the overall distribution of broad indication categories differed significantly (Table 1, p=0.001), further analysis of the specific sub-types within these categories (as shown in Supplement 2) did not reveal statistically significant differences for individual sub-types between the control and intervention groups (all $p > 0.05$ for individual sub-type comparisons). The overall composite rate of procedure-related

complications was similar between the checklist and control groups (73% vs 72%; Relative Risk [RR] 1.01, 95% Confidence Interval [CI] 0.82-1.25; p=0.90) (Table 2).

**Table 2.** Primary and Secondary Outcomes

| Complications | Control (N=68) n(%)* | Checklist (N=63) n(%)* | RR# (95% CIα) | P value |
|---|---|---|---|---|
| Primary Outcome: Overall Complications | 49 (72%) | 46 (73%) | 1.01 (0.82-1.25) | 0.9 |
| Equipment Failure | 3 (4.4%) | 6 (9.5%) | 2.16 (0.564-8.27) | 0.31 |
| Hypoxia | 6 (8.82%) | 18 (28.5%) | 3.24 (1.37-7.64) | 0.004 |
| Multiple Attemptsβ | 14 (20.6%) | 5 (7.9%) | 0.38 (0.15-1.01) | 0.07 |
| Hypotension | 16 (23.5%) | 24 (38%) | 1.62 (0.951-2.76) | 0.07 |
| Bradycardia | 10 (14.7%) | 7 (11.1%) | 0.75 (0.3-1.86) | 0.72 |
| Aspiration | 15 (22.05%) | 5 (7.93%) | 0.36 (0.14-0.93) | 0.045 |
| Intubation Related Trauma | 16 (23.5%) | 12 (19%) | 0.81 (0.41-1.57) | 0.53 |
| Esophageal Intubation | 5 (7.35%) | 3 (4.8%) | 0.65 (0.16-2.60) | 0.72 |
| Pneumothorax | 0 (0%) | 1 (1.58%) | - | 0.48 |
| Unplanned Extubation | 9 (13.2%) | 7 (11.1%) | 0.84 (0.33-2.12) | 0.91 |
| Cardiac Arrest with ROSCΔ | 14 (20.6%) | 5 (7.93%) | 0.38 (0.14-1.01) | 0.07 |
| Secondary outcome: In Hospital Mortality @ 24 hours | 18 (26.5%) | 23 (36.5%) | 1.38 (0.82-2.3) | 0.22 |

This composite outcome, however, masked differing effects on individual complications. Specifically, the implementation of the checklist was associated with a statistically significant reduction in aspiration events (checklist 7.93% vs control 22.05%; RR 0.36, 95% CI 0.14-0.93; p=0.045). Conversely, a statistically significant and threefold higher incidence of post-intubation hypoxia was observed in the checklist group compared to the control group (checklist 28.5% vs control 8.82%; RR 3.24, 95% CI 1.37-7.64; p=0.004). This finding for hypoxia should be interpreted cautiously given the multiple outcomes tested without correction, the sample size limitations, and the exploratory nature of the study. No statistically significant differences were found between the groups for unplanned extubation (checklist 11.1% vs control 13.2%; RR 0.84, 95% CI 0.33-2.12; p=0.91), intubation-related trauma (checklist 19% vs control 23.5%; RR 0.81, 95% CI 0.41-1.57; p=0.53), hypotension (checklist 38% vs control 23.5%; RR 1.62, 95% CI 0.95-2.76; p=0.07), equipment failure (checklist 9.5% vs control 4.4%; RR 2.16, 95% CI 0.56-8.27; p=0.31), multiple intubation attempts (checklist 7.9% vs control 20.6%; RR 0.38, 95% CI 0.15-1.01; p=0.071), cardiac arrest with return of spontaneous circulation [ROSC] (checklist 7.93% vs control 20.6%; RR 0.38, 95% CI 0.14-1.01; p=0.071), bradycardia (checklist 11.1% vs control 14.7%; RR 0.75, 95% CI 0.3-1.86; p=0.72), oesophageal intubation (checklist 4.8% vs control 7.35%; RR 0.65, 95% CI 0.16-2.60; p=0.720), or pneumothorax (checklist 1.58% vs control 0%; p=0.481). In-hospital mortality at 24 hours also showed no significant difference between the groups (checklist 36.5% vs control 26.5%; RR 1.38, 95% CI 0.82-2.3; p=0.22).

## *Discussion*

This prospective, exploratory cohort study, conducted in a busy emergency department at a tertiary care center in India, evaluated the impact of a standardized 12-point pre-procedural checklist on complications associated with emergency endotracheal intubation (ETI). Our primary finding was that the routine implementation of a pre-procedural checklist did not result in a statistically significant reduction in the overall composite of procedure-related complications. This null finding for the primary outcome, considered in the context of the study's limited statistical power due to a smaller-than-planned sample size, suggests that in our setting, the checklist did not demonstrate a measurable impact on the broad range of immediate complications associated with emergency ETI. However, a clinically meaningful effect, particularly a modest one, cannot be definitively ruled out.

It is crucial to acknowledge that the composite primary outcome encompassed a heterogeneous group of complications, and its overall stability may mask clinically important differential effects on individual

outcomes, potentially understating their individual clinical significance. While the checklist was designed to address multiple aspects of pre-procedural preparation, its impact was not uniform. Indeed, when examining individual components, we observed a mixed picture. Notably, the checklist was associated with a statistically significant reduction in aspiration events. Aspiration is a clinically important complication of ETI, linked to aspiration pneumonitis and pneumonia (13). The checklist elements addressing preoxygenation, suction readiness, and patient positioning likely contributed to this benefit by promoting safer airway management practices prior to laryngoscopy (14,15). This finding aligns with evidence that checklists can improve adherence to specific safety measures and reduce targeted errors (16).

However, this potential benefit regarding aspiration was counterbalanced by an unexpected increase in post-intubation hypoxia in the checklist group. Hypoxia is a critical peri-intubation event associated with significant morbidity and mortality (17,18). This paradoxical finding is clinically concerning and warrants careful interpretation, particularly given the study's sample size, the testing of multiple secondary outcomes without adjustment (which increases the risk of a spurious Type I error), and the lack of a definitive mechanistic explanation. Several hypotheses could be explored in future research. The process of completing the checklist itself, if not seamlessly integrated, might have inadvertently prolonged pre-procedure time, including apnea duration, contributing to desaturation, especially in critically ill patients with limited physiological reserve (19). It is also possible that an emphasis on checklist completion led to delays in initiating intubation or a 'checklist fixation' phenomenon, where focus on the checklist detracted from dynamic patient assessment and timely intervention (the 'checklist paradox') (20). For example, if preoxygenation was performed as per checklist but was inadequate for a patient with very low physiological reserve, the team might have proceeded with intubation feeling falsely secure due to checklist completion, rather than proactively optimizing preoxygenation further or considering alternative strategies (21). Alternatively, the observed increase in hypoxia could be an artifact of detection bias (e.g., increased vigilance in the checklist group) or due to unmeasured confounding variables. Without further data on procedural timings, detailed fidelity of checklist use, and team factors, these remain speculative. The non-significant findings for other individual complications within the primary outcome – including traumatic intubation, hypotension, esophageal intubation, cardiac arrest, multiple intubation attempts, unplanned extubation, pneumothorax, equipment failure, and bradycardia – further contribute to the overall null result for the composite primary outcome. Given the study's limited power, these non-significant results should not be interpreted as definitive evidence of no effect; rather, the study may have been inadequately powered to detect small to moderate, yet potentially clinically relevant, differences in these less frequent events (potential Type II error). The non-significant findings for these individual complications and 24-hour mortality further underscore the complexity of improving outcomes in emergency ETI using a checklist-based intervention alone (22). Emergency ETI is a complex, multi-factorial intervention, and a 12-point checklist may be insufficient to address all sources of variability and potential errors.

**Limitations**

Our study has several important limitations. Firstly, as an exploratory investigation with a sample size of 131 participants, substantially reduced from the initial target of 266 due to pragmatic time constraints, the study was underpowered to definitively detect small to moderate effects for both the primary composite outcome and individual, less frequent complications. The initial power calculation was based on an overly optimistic effect size. This underpowering increases the risk of Type II errors, meaning that true effects of the checklist may have been missed for outcomes reported as non-significant. Secondly, the study's single-center design limits generalizability. The quasi-

experimental design, with sequential cohort recruitment, is susceptible to temporal confounding and the Hawthorne effect. Thirdly, while training on the checklist was provided and verbal confirmation of its use was part of the protocol, we did not conduct formal, quantitative assessments of checklist implementation fidelity or adherence rates for each item. This lack of detailed fidelity monitoring makes it difficult to ascertain the degree to which the checklist was consistently and correctly used, which could impact the observed outcomes. Fourthly, multiple secondary outcomes were assessed without statistical adjustment for multiple comparisons. This approach, while chosen for an exploratory study, increases the probability of Type I errors (spurious significant findings), and thus the unexpected increase in hypoxia must be interpreted with particular caution.

Fifthly, the choice of 24-hour mortality as an endpoint serves as an early indicator; it may not fully reflect longer-term impacts. A more nuanced analysis of causes of death or ICU length of stay might provide more useful clinical information in future, larger studies. Our study, conducted with intubations performed by emergency medicine residents with varying levels of experience, reflects real-world clinical practice in a busy emergency department, but also introduces heterogeneity that could mask the potential benefits of the checklist. The exclusion of video laryngoscopy and capnography from the checklist, while intended to enhance generalizability to resource-limited settings, might also have limited the checklist's potential to reduce complications such as esophageal intubation and traumatic intubation in more complex airways (23,24).

## *Conclusion*

In this preliminary and exploratory prospective cohort study, the implementation of a 12-point pre-procedural checklist for emergency ETI in adult medical patients did not demonstrate a statistically significant reduction in the overall composite rate of procedure-related complications. The study was underpowered due to a smaller than planned sample size, which was based on an initially optimistic effect size estimation; this limits definitive conclusions, especially regarding non-significant findings. While a reduction in aspiration was observed, this was accompanied by an unexpected increase in post-intubation hypoxia. This hypoxia finding requires cautious interpretation due to potential methodological limitations, including the risk of a spurious association from multiple outcome testing without adjustment, and warrants further dedicated investigation into potential underlying mechanisms such as procedural delays. These divergent results for individual complications highlight the importance of not relying solely on composite outcomes in such evaluations. The findings underscore the complexities of implementing checklist-based interventions in the dynamic emergency airway management setting. Further, adequately powered research, including fidelity assessment and consideration of procedural timings, is essential to rigorously evaluate the true impact of checklists, optimize their design and integration, and understand their influence on specific complications and overall patient safety in emergency ETI.

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## *References*

1. Mort TC. The incidence and risk factors for cardiac arrest during emergency tracheal intubation: a justification for incorporating the ASA Guidelines in the remote location. J Clin Anesth. 2004 Nov;16(7):508–16.
2. Lentz S, Grossman A, Koyfman A, Long B. High-Risk Airway Management in the Emergency Department. Part I: Diseases and Approaches. J Emerg Med. 2020 Jul;59(1):84–95.
3. Yang TH, Shao SC, Lee YC, Hsiao CH, Yen CC. Risk factors for peri-intubation cardiac arrest: A systematic review and meta-analysis. Biomed J. 2024 Jun 1;47(3):100656.
4. van Klei WA, Hoff RG, van Aarnhem EEHL, Simmermacher RKJ, Regli LPE, Kappen TH, et al. Effects of the introduction of the WHO "Surgical Safety Checklist" on in-hospital mortality: a cohort study. Ann Surg. 2012 Jan;255(1):44–9.
5. Clay-Williams R, Colligan L. Back to basics: checklists in aviation and healthcare. BMJ Qual Saf. 2015 Jul 1;24(7):428–31.
6. Treadwell JR, Lucas S, Tsou AY. Surgical checklists: a systematic review of impacts and

implementation. BMJ Qual Saf. 2014 Apr 1; 23(4): 299–318.
7. Higgs A, McGrath BA, Goddard C, Rangasami J, Suntharalingam G, Gale R, et al. Guidelines for the management of tracheal intubation in critically ill adults. Br J Anaesth. 2018 Feb;120(2):323–52.
8. Turner JS, Bucca AW, Propst SL, Ellender TJ, Sarmiento EJ, Menard LM, et al. Association of Checklist Use in Endotracheal Intubation with Clinically Important Outcomes: A Systematic Review and Meta-analysis. JAMA Netw Open. 2020 Jul 1;3(7):e209278.
9. Biau DJ, Kernéis S, Porcher R. Statistics in Brief: The Importance of Sample Size in the Planning and Interpretation of Medical Research. Clin Orthop. 2008 Sep;466(9):2282–8.
10. Jones S, Carley S, Harrison M. An introduction to power and sample size estimation. Emerg Med J EMJ. 2003 Sep; 20(5): 453–8.
11. Winters BD, Gurses AP, Lehmann H, Sexton JB, Rampersad CJ, Pronovost PJ. Clinical review: checklists - translating evidence into practice. Crit Care Lond Engl. 2009;13(6):210.
12. Steel A, Haldane C, Cody D. Impact of videolaryngoscopy introduction into prehospital emergency medicine practice: a quality improvement project. Emerg Med J EMJ. 2021 Jul; 38(7):549–55.
13. Marik PE. Aspiration pneumonitis and aspiration pneumonia. N Engl J Med. 2001 Mar 1; 344(9):665–71.
14. Benumof JL. Preoxygenation: best method for both efficacy and efficiency. Anesthesiology. 1999 Sep;91(3):603–5.
15. Prakash S, Rapsang AG, Mahajan S, Bhattacharjee S, Singh R, Gogia AR. Comparative Evaluation of the Sniffing Position with Simple Head Extension for Laryngoscopic View and Intubation Difficulty in Adults Undergoing Elective Surgery. Anesthesiol Res Pract. 2011; 2011: 297913.
16. Pronovost P, Needham D, Berenholtz S, Sinopoli D, Chu H, Cosgrove S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. N Engl J Med. 2006 Dec 28;355(26):2725–32.
17. Bodily JB, Webb HR, Weiss SJ, Braude DA. Incidence and Duration of Continuously Measured Oxygen Desaturation During Emergency Department Intubation. Ann Emerg Med. 2016 Mar 1;67(3):389–95.
18. Pourmand A, Robinson C, Dorwart K, O'Connell F. Pre-oxygenation: Implications in emergency airway management. Am J Emerg Med. 2017 Aug 1;35(8):1177–83.
19. McKown AC, Casey JD, Russell DW, Joffe AM, Janz DR, Rice TW, et al. Risk Factors for and Prediction of Hypoxemia during Tracheal Intubation of Critically Ill Adults. Ann Am Thorac Soc. 2018 Nov;15(11):1320–7.
20. Urbach DR. The Checklist Paradox. Ann Surg. 2017 Dec;266(6):930–1.
21. Sakles JC. Maintenance of Oxygenation During Rapid Sequence Intubation in the Emergency Department. Acad Emerg Med. 2017; 24(11): 1395–404.
22. Taryle DA, Chandler JE, Good JT, Potts DE, Sahn SA. Emergency room intubations--complications and survival. Chest. 1979 May; 75(5): 541–3.
23. Sheikh S, Shamim F. Video Laryngoscopy in Emergency Airway Management - a Paradigm Shift from 'I' to 'We'; a Letter to Editor. Arch Acad Emerg Med. 2022 Mar 20;10(1):e22.
24. Nagler J, Krauss B. Capnography: a valuable tool for airway management. Emerg Med Clin North Am. 2008 Nov;26(4):881–97, vii.