[Original Research]

CHEST

A Multicenter Randomized Trial of a Checklist for Endotracheal Intubation of Critically Ill Adults

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BACKGROUND: Hypoxemia and hypotension are common complications during endotracheal intubation of critically ill adults. Verbal performance of a written, preintubation checklist may prevent these complications. We compared a written, verbally performed, preintubation checklist with usual care regarding lowest arterial oxygen saturation or lowest systolic BP experienced by critically ill adults undergoing endotracheal intubation.

METHODS: A multicenter trial in which 262 adults undergoing endotracheal intubation were randomized to a written, verbally performed, preintubation checklist (checklist) or no preintubation checklist (usual care). The coprimary outcomes were lowest arterial oxygen saturation and lowest systolic BP between the time of procedural medication administration and 2 min after endotracheal intubation.

RESULTS: The median lowest arterial oxygen saturation was 92% (interquartile range [IQR], 79-98) in the checklist group vs 93% (IQR, 84-100) with usual care ($P = .34$). The median lowest systolic BP was 112 mm Hg (IQR, 94-133) in the checklist group vs 108 mm Hg (IQR, 90-132) in the usual care group ($P = .61$). There was no difference between the checklist and usual care in procedure duration (120 vs 118 s; $P = .49$), number of laryngoscopy attempts (one vs one attempt; $P = .42$), or severe life-threatening procedural complications (40.8% vs 32.6%; $P = .20$).

CONCLUSIONS: The verbal performance of a written, preprocedure checklist does not increase the lowest arterial oxygen saturation or lowest systolic BP during endotracheal intubation of critically ill adults compared with usual care.

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ABBREVIATIONS: IQR = interquartile range; Sp_{O_2} = arterial oxygen saturation

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Endotracheal intubation is a commonly performed procedure during the care of critically ill adults,[1-3] and complications occur in as many as one-third of patients.[1,2,4,5] Hypoxemia and hypotension, the most common procedural complications, are associated with operator inexperience and inadequate preparation.[2,6,7]

The transfer of expert knowledge and best evidence to the bedside critical care provider via a checklist intervention improves quality of care, procedural performance, and patient outcomes.[8-14] The high rate of procedural complications during endotracheal intubation and the low cost of a checklist intervention make this a promising target for improvement of procedural performance. Nontechnical preparation for intubation[15] using a checklist has been used for operating room intubations[16]; however, the utility in critically ill patients with acute physiologic derangements is unclear. In observational studies of critically ill adults, preintubation checklists have either had no association with improved outcomes[17] or had an association with reduced procedural complications.[4]

To address this uncertainty, we conducted a multicenter, prospective, randomized trial comparing the effect of a written, verbally performed, preintubation checklist (checklist) with usual care on procedural complications during endotracheal intubation of critically ill adults. We hypothesized that the lowest arterial oxygen saturation (Sp_{O_2}) or systolic BP during intubation would be higher with the checklist intervention.

Materials and Methods

The Checklists and Upright Positioning in Endotracheal Intubation Trial was a prospective, multicenter, randomized trial of a written, verbally performed, preintubation checklist compared with usual care for endotracheal intubation of critically ill adults. At three study sites, the trial was factorialized to also compare the ramped with sniffing intubating position during endotracheal intubation, the results of which have been reported separately.[18] The protocol was approved by the institutional review boards at all sites with a waiver of informed consent (e-Table 1).

Study Patients

Between July 22, 2015, and July 19, 2016, all patients (≥ 18 years of age) undergoing endotracheal intubation by a pulmonary/critical care medicine fellow or anesthesiology resident in the five participating ICUs were enrolled (e-Table 1). Patients were excluded if awake intubation was planned, intubation was so emergent that a randomization envelope could not be obtained, or treating clinicians felt a specific preintubation checklist or patient positioning was needed (Fig 1).

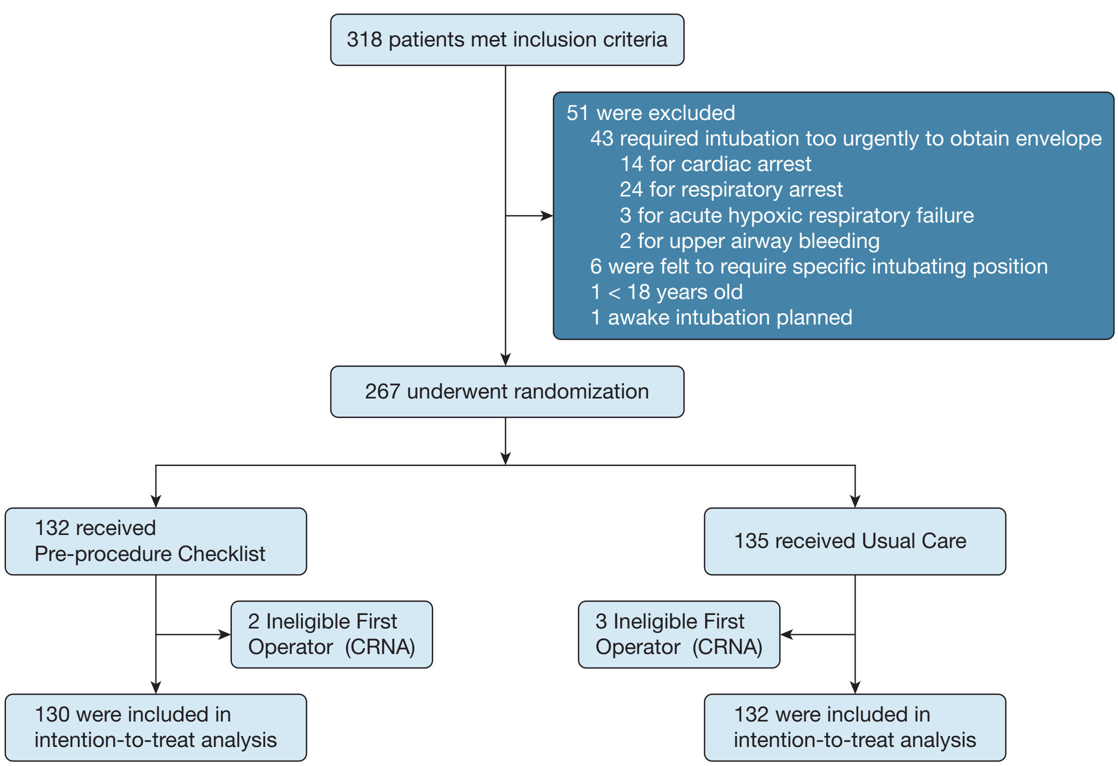

Figure 1 – *Patient screening, randomization, and follow-up. CRNA = Certified Registered Nurse Anesthetist.*

Randomization and Blinding

Patients were randomly assigned in a 1:1 ratio to use of a verbally performed, written, preintubation checklist or usual care via random permuted blocks of 4, 8, and 12, stratified by study site. Study assignment was concealed until after the decision had been made to intubate and the patient was enrolled in the trial.

Study Interventions

For patients assigned to the checklist group, a printed checklist (e-Fig 1) was read aloud by a nurse or physician uninvolved in the performance of the procedure, with each item met by a verbal response from the operator. The checklist intervention included 10 items recommended by guidelines or airway experts as preparatory steps that should always be performed prior to intubation. The derivation of the checklist intervention is described in detail in the e-Appendix 1. The checklist could be performed anytime between enrollment and the administration of procedural medications. Operators could abort the performance of the checklist and proceed with intubation if required for the safe management of the patient. In the usual care group, no written checklist was available. All other aspects of the procedure were at the discretion of the clinical team.

Data Collection

Study end points were collected by independent observers who were present in the patient's room but not participating in the procedure. To confirm the accuracy of the data collected by the independent observers, the primary investigators concurrently assessed the same end points for a convenience sample of 11% of study intubations.

Measurement of Outcomes

The coprimary outcomes were the lowest Spo_2 and lowest systolic BP between procedural medication administration and 2 min after endotracheal intubation. Secondary outcomes included a composite of life-threatening complications, time from induction to successful intubation, change in Spo_2 and systolic BP from induction, number of laryngoscopy attempts required for intubation, Cormack and Lehane grading of the glottic view,[19] ventilator-free days, ICU-free days, and in-hospital mortality. Description of the sample size calculation and statistical analysis can be found in e-Appendix 2.

Results

Of 318 critically ill adults intubated during the study period, 267 were enrolled and randomized to either checklist or usual care (Fig 1). For five patients, the planned operator changed to a Certified Registered Nurse Anesthetist after randomization, leaving a total of 262 patients analyzed.

Baseline and Procedural Characteristics

Patients randomized to the checklist (n = 130) and usual care (n = 132) were similar at baseline (Table 1). Operators included 27 pulmonary and critical care medicine fellows and 19 anesthesiology residents. The checklist and usual care groups did not differ regarding the specialty training or prior intubation experience of the operator. Postrandomization procedural characteristics are presented in e-Table 2.

In the patients randomized to the checklist group, all 10 checklist items were performed and verbalized in 81% of patients. In the 19% of patients in the checklist group who did not have all 10 items completed, only three patients were missing more than one checklist item because of increasing urgency of the procedure (e-Table 3). To assess for the separation in the study groups regarding the intervention of the verbal performance of a checklist and to assess for penetrance of the intervention into the usual care group, we used the 11% convenience sample of enrolled patients in which the procedure was also observed by study staff. The rate of performance and verbalization of each checklist item was higher in the checklist group than the usual care group (Fig 2).[20]

Primary Outcome

There was no significant difference in the lowest Spo_2 between patients randomized to the checklist group (median, 92%; interquartile range [IQR], 79-98) and the usual care group (93%; IQR, 84-100; $P = .34$) (Fig 3). Similarly, there was no significant difference in lowest systolic BP between the checklist (112 mm Hg; IQR, 94-133) and usual care groups (108 mm Hg; IQR, 90-132; $P = .61$) (Fig 3). Results were similar in analyses adjusting for age, BMI (kg/m^2), Acute Physiology and Chronic Health Evaluation II score, and previous total intubating experience of the operator at the time of intubation (e-Table 4). In a convenience sample of 30 (11%) patients, values for the lowest Spo_2 and systolic BP recorded concurrently by the independent observer and the primary investigators were strongly correlated (Spo_2 Spearman $\rho = 0.99$, $P < .001$; systolic BP Spearman $\rho = 0.99$, $P < .001$) (e-Fig 2).

For 24 patients assigned to the checklist group, the full checklist could not be completed because of either (1) the increasing urgency of the procedure (2/24) or (2) other unknown reasons (22/24). The most common incomplete checklist item was the difficult airway evaluation (16/24) (e-Table 3). In a prespecified, per-protocol analysis of the 106 patients with all checklist items completed compared with usual care, there remained no difference between groups in the primary outcomes (e-Table 5). Additionally, when the five patients intubated by Certified Registered Nurse Anesthetists were added back to the analysis, there was no difference in any of the primary or secondary outcomes (e-Table 6).

TABLE 1] Patient and Operator Characteristics at Baseline

Characteristic	Checklist (n = 130)	Usual Care (n = 132)
Age, y	56 (47-63)	58 (47-68)
Men	87 (66.9)	78 (59.1)
White race	82 (63.1)	102 (77.3)
APACHE II score	21.5 (18-26.2)	22 (18-26)
BMI, kg/m^2	26.9 (23.8-32.2)	27.4 (23.8-33.4)
Active ICU diagnoses		
Sepsis	57 (43.8)	50 (37.9)
Septic shock	39 (30)	38 (28.8)
Pneumonia	44 (33.8)	33 (25)
Altered mental status	39 (30)	44 (33.3)
Gastrointestinal blood loss	23 (17.7)	23 (17.4)
Cardiogenic shock	6 (4.6)	2 (1.5)
Hemorrhagic shock	9 (6.9)	5 (3.8)
ARDS	12 (9.2)	15 (11.4)
Active comorbidities complicating intubation		
Vomiting	2 (1.5)	2 (1.5)
Witnessed aspiration	3 (2.3)	4 (3)
Upper gastrointestinal bleeding	5 (3.8)	7 (5.3)
Epistaxis or oral bleeding	1 (0.8)	0 (0)
Airway mass or infection	1 (0.8)	2 (1.5)
Head or neck radiation	1 (0.8)	0 (0)
BMI > 30 kg/m^2	39 (30)	47 (35.6)
Limited neck mobility	5 (3.8)	3 (2.3)
Limited mouth opening	6 (4.6)	2 (1.5)
OSA	15 (11.5)	13 (9.8)
None	66 (50.8)	64 (48.4)
MACOCHA score[a]	2 (1-6)	NA
Indication for intubation		
Hypoxic respiratory failure	75 (57.7)	72 (54.5)
Altered mental status	46 (35.3)	53 (40.1)
Facilitate another procedure	13 (10)	21 (15.9)
Hypercarbic respiratory failure	22 (16.9)	19 (14.4)
Impending airway collapse	17 (13.1)	19 (14.4)
Hemodynamics	13 (10)	15 (11.4)
Vasopressor use in 6 h prior	24 (18.5)	28 (21.2)
Bipap use in 6 h prior	39 (30)	42 (31.8)
Reintubation in last 24 h	18 (13.8)	17 (12.9)
Lowest MAP prior to intubation, mm Hg	66 (57-80)	66 (54-78)
Lowest pH in 6 h prior (n = 108)	7.30 (7.23-7.41)	7.33 (7.2-7.42)
Highest $Paco_2$ in 6 h prior (n = 108)	44 (34-64)	47 (35-65)
Lowest $Paco_2$ in 6 h prior (n = 108)	84 (66-109)	71 (58-96)
Spo_2 at induction, %	99 (95-100)	99 (94-100)
Systolic BP at induction, mm Hg	119 (104-137)	120 (101-144)

(Continued)

TABLE 1] (Continued)

Characteristic	Checklist (n = 130)	Usual Care (n = 132)
Operator characteristics		
No. of months of specialty training completed at the time of the intubation	23 (14-33)	23 (13-33)
No. of total prior intubations by operators at the time of intubation	60 (35-90)	57 (32-90)
Pulmonary/critical care medicine fellow operator	119 (91.5)	120 (90.9)

Data are given as median (25th percentile-75th percentile), No. (%), or as otherwise indicated. APACHE = Acute Physiology and Chronic Health Evaluation; Bipap = bilevel positive airway pressure; MAP = mean arterial pressure; NA = not applicable.
[a]MACOCHA scores were only calculated as part of the checklist intervention.

Secondary Outcomes

Use of a preintubation checklist did not decrease the number of laryngoscopy attempts, shorten the time to intubation, or improve glottic view (Table 2). There was no difference in a composite of severe, life-threatening procedural complications between the checklist (40.8%) and usual care group (32.6%, $P = .20$). There was no difference in ventilator-free days, ICU-free days, and in-hospital mortality (e-Fig 3, Table 2).

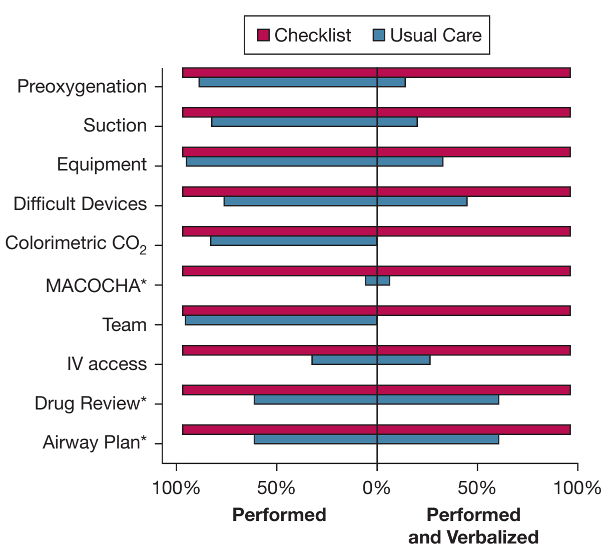

Figure 2 – *Rate of performance and verbalization of checklist items by study group. In a 10% convenience sample of enrolled patients, study investigators recorded the performance of each item included on the checklist. Each of the 10 checklist items is listed on the y-axis, and the rate of performance of each item is listed on the x-axis. In the checklist group, the rate of performance and verbalization (right side) of each checklist item was significantly higher than the usual care group. * = three checklist items required verbalization for them to be considered performed; therefore, the rates are the same on the right and left sides; colorimetric CO_2 = colorimetric carbon dioxide detector; MACOCHA = difficult airway assessment scoring system*[19] *used in the checklist intervention.*

Heterogeneity of Treatment Effect

There was no significant difference in the lowest SpO_2 or systolic BP between the checklist and usual care groups in any of the prespecified subgroups (e-Fig 4). Continuous variables arbitrarily dichotomized into subgroups were also analyzed as continuous variables to examine for a heterogenous treatment effect with no significant effect modification identified (e-Figs 5, 6). For cases in which the time to endotracheal intubation was longer, lowest SpO_2 appeared to be higher in the checklist group than with the usual care group (P value for interaction = .06) (e-Fig 5). To assess for contamination of the usual care group by exposure to the checklist intervention during the study, we compared the checklist and usual care groups among the 66 study intubations in which the operator had never previously seen the checklist (lowest SpO_2 92% vs 96%, $P = .26$; lowest systolic BP 111 vs 106 mm Hg, $P = .57$)

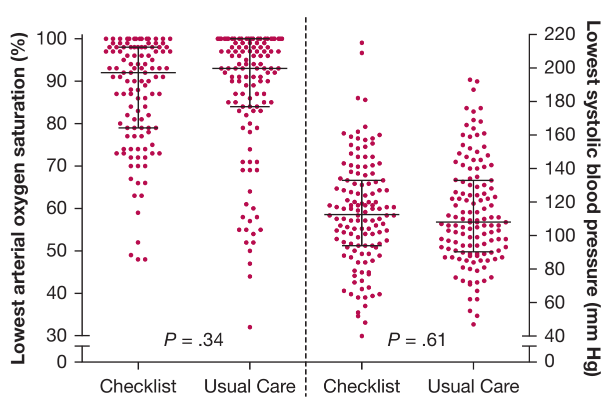

Figure 3 – *Lowest arterial oxygen saturation and systolic BP by study group. The coprimary outcomes of lowest arterial oxygen saturation (left y-axis) and lowest systolic BP (right y-axis) between induction and 2 min after successful endotracheal intubation are displayed for patients randomized to usual care or the preprocedure checklist. Horizontal bars = median and interquartile range.*

TABLE 2] Secondary Clinical Outcomes for the Checklist vs Usual Care Groups

Secondary Outcome	Checklist (n = 130)	Usual Care (n = 132)	*P* value[a]
Change in Spo_2 from baseline, %	−4 (−16 to 0)	−2 (−11.5 to 0)	.12
Change in systolic BP from baseline, mm Hg	−1 (−17 to 0)	−6 (−23 to 0)	.50
First pass success	102 (78.5)	108 (81.8)	.54
Time from induction to intubation, s	120 (79 to 187)	118 (75 to 197)	.49
No. of laryngoscopy attempts	1 (1 to 1)	1 (1 to 1)	.42
In-hospital mortality	57 (43.8)	59 (44.7)	.90
Ventilator-free days	13 (0-24)	15 (0-25)	.39
ICU-free days	5 (0-21)	2 (0-22)	.80
Best Cormack and Lehane[19] view obtained on first attempt			.45
Grade I	57 (43.8)	70 (53)	
Grade II	47 (36.2)	42 (31.8)	
Grade III	22 (16.9)	18 (13.6)	
Grade IV	4 (3.1)	2 (1.5)	
Airway difficulty description			.27
Easy	96 (73.8)	103 (78)	
Moderate	20 (15.4)	21 (15.9)	
Difficult	14 (10.8)	7 (5.3)	
Severe life-threatening complications	53 (40.8)	43 (32.6)	.20
Died within 1 h of intubation	1 (0.8)	1 (0.7)	> .99
Cardiac arrest	4 (3.1)	3 (2.3)	.72
Severe cardiovascular collapse (new systolic BP < 65 mm Hg)	8 (6.2)	5 (3.8)	.40
Severe cardiovascular collapse (new or increased vasopressor)	21 (16.2)	24 (18.2)	.74
Severe hypoxia (Spo_2 < 80%)	34 (26.8)	26 (20)	.23
Other procedure-related complications			
Aspiration	1 (0.8)	2 (1.5)	> .99
Esophageal intubation	7 (5.4)	4 (3)	.38
Airway trauma	0 (0)	0 (0)	
Heart rate < 40 beats per minute	1 (0.8)	2 (1.5)	> .99
Other complication	7 (5.4)	8 (6.1)	> .99

Data are given as median (25th percentile to 75th percentile), No. (%), or as otherwise indicated. Spo_2 = arterial oxygen saturation.
[a]Mann-Whitney *U* test or Fisher exact test.

and over the course of the trial as exposure to the checklist intervention accrued (e-Fig 7; e-Table 7).

Discussion

This multicenter randomized trial comparing a written, verbally performed, preintubation checklist with usual care during endotracheal intubation of critically ill adults found no difference between groups in lowest Spo_2 or systolic BP. The lack of effect persisted across all subgroups of patients and operators, and after adjustment for potential confounders. Generalizability of these findings may be limited by the content of the checklist used in this study, the manner in which the checklist was verbalized between an observer and operator in training, and frequent performance of checklist items during usual care in the study ICUs. Different results might be seen with a checklist containing items specifically directed at improving physiologic parameters, addressing the technical and cognitive aspects of the procedure, a setting with infrequent performance of checklist items in usual care, or a setting of community-based hospitals.

Checklist interventions have been used in the ICU to implement the best evidence, expert recommendations,[8,12,14,21] teamwork, and communication.[22] The assurance that essential components of care are not omitted and the collaborative environment created are proposed mechanisms for improvements in quality and outcomes observed in past studies.[8,12,14,21] Checklist use in the ICU to prepare for the performance of a procedure has also been shown to improve clinical outcomes in academic settings with trainees as proceduralists.[12] Given the high intubation complication rates, inexperienced operators, and a team approach to the procedure, preparation of both the operator and other team members with a verbal preintubation checklist is an intervention commonly used in practice. The current checklist intervention resulted in a high rate of preparatory steps completed; however, this did not translate into improved outcomes. Preprocedure intubation checklists consisting of different items and use in different institutions, including smaller community-based hospitals, should still be studied to determine if they improve patient outcomes.

The results of this trial are in contrast with a prior study demonstrating an associated reduction in hypoxemia and hypotension with a preintubation checklist.[4] There are several potential explanations for this difference. The prior study included multiple items not commonly performed in usual care that could improve BP (fluid loading and norepinephrine administration) and Spo_2 (preoxygenation with noninvasive ventilation[23]), whereas our checklist was composed of items reported by airway experts as almost always performed and guideline-recommended steps to be performed prior to every intubation that do not necessarily affect Spo_2 or BP. The prior study was also an observation of a control phase followed by an intervention phase in which numerous biases are possible, including that the procedural proficiency of operators increased over this time period. Finally, the penetrance of the checklist items in the usual care (control) period was low and increased significantly with the introduction of a checklist, whereas our trial showed that the penetrance of some checklist items was high in usual care.

Given that all the checklist items are part of operator training and standard preparation steps for intubation, we expected to find frequent performance of some items in the usual care group. Therefore, the experiments we aimed to perform with this trial were as follows: (1) verbal performance of a written, preprocedure checklist compared with usual care, which could include nonverbalized performance of checklist items, and (2) all checklist items being performed compared with checklist items intermittently or never performed. The rate of verbal performance of each checklist item was greater in the checklist group vs the usual care group. Additionally, all checklist items were performed in 81% of patients randomized to the checklist group. Furthermore, in 19 of the 24 incomplete checklists, only 1 item was missing. Therefore, in the current multicenter trial of trainees intubating critically ill adults, the verbal performance of a preintubation checklist composed of items recommended by experts and guidelines results in an almost always performance of checklist items, but without improvement in procedural or patient-centered outcomes. To maximize external validity, the pragmatic design aimed to describe the effectiveness of a checklist intervention rather than using a checklist intervention with infrequently performed preparatory steps applied to highly protocolized care.

There are a number of strengths of this trial. The large sample size, use of multiple centers, wide spectrum of operator experience, and pragmatic nature of the intervention add to the external validity of the trial. The specific use of only trainees in this trial is important because this is the less-experienced operator population, which a checklist intervention would theoretically benefit. The trial achieved a high adherence to checklist items recommended by airway experts and guidelines to be routinely performed in practice. Use of independent observers to collect the primary outcomes limits observer bias, blinding of group assignment until after enrollment limits selection bias, and randomization balances potential confounders.

There are limitations to this trial. Randomization of the unblinded intervention occurred at the patient level, which could allow operators to learn the checklist and then contaminate any subsequent usual care intubations with the intervention. To assess for contamination of the usual care group, we analyzed the primary outcomes as they occurred with operators' previous exposures to the checklist and found consistent results between study groups when operators had never seen the checklist vs each additional checklist use. This trial was conducted in centers in which the performance of some checklist items in usual care was similar compared with the checklist intervention, which may limit any differences seen between study groups. The sample size in this trial is not large enough to definitively determine if a checklist intervention affects the rate of less common but severe procedural complications. Patient and operator characteristics were balanced at baseline; however, data regarding the operators' cognitive and technical procedural abilities were not collected and these may also influence the primary outcomes. Although a multifaceted process was used to derive the items included in the checklist, items included may only prepare the operator for the nontechnical aspects of the procedure[15] and indirectly influence the primary outcomes, which may be more related to a patient's underlying pathophysiology or the technical performance of the procedure.

Conclusions

Among critically ill adults undergoing endotracheal intubation by operators in training, the verbal performance of a preprocedure checklist increases adherence to recommended preparatory steps but does not decrease procedural complications or improve clinical outcomes compared with usual care in tertiary care, academic ICUs.

Acknowledgments

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Additional information: The e-Appendix, e-Figures, and e-Tables can be found in the Supplemental Materials section of the online article.

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