Head-Elevated Patient Positioning Decreases Complications of Emergent Tracheal Intubation in the Ward and Intensive Care Unit

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BACKGROUND: Based on the data from elective surgical patients, positioning patients in a back-up head-elevated position for preoxygenation and tracheal intubation can improve patient safety. However, data specific to the emergent setting are lacking. We hypothesized that back-up head-elevated positioning would be associated with a decrease in complications related to tracheal intubation in the emergency room environment.

METHODS: This retrospective study was approved by the University of Washington Human Subjects Division (Seattle, WA). Eligible patients included all adults undergoing emergent tracheal intubation outside of the operating room by the anesthesiology-based airway service at 2 university-affiliated teaching hospitals. All intubations were through direct laryngoscopy for an indication other than full cardiopulmonary arrest. Patient characteristics and details of the intubation procedure were derived from the medical record. The primary study endpoint was the occurrence of a composite of any intubation-related complication: difficult intubation, hypoxemia, esophageal intubation, or pulmonary aspiration. Multivariable logistic regression was used to estimate the odds of the primary endpoint in the supine versus back-up head-elevated positions with adjustment for a priori-defined potential confounders (body mass index and a difficult intubation prediction score [*M*allampati, obstructive sleep *A*pnea, *C*ervical mobility, mouth *O*pening, *C*oma, severe *H*ypoxemia, and intubation by a non-*A*nesthesiologist score]).

RESULTS: Five hundred twenty-eight patients were analyzed. Overall, at least 1 intubation-related complication occurred in 76 of 336 (22.6%) patients managed in the supine position compared with 18 of 192 (9.3%) patients managed in the back-up head-elevated position. After adjusting for body mass index and the *M*allampati, obstructive sleep *A*pnea, *C*ervical mobility, mouth *O*pening, *C*oma, severe *H*ypoxemia, and intubation by a non-*A*nesthesiologist score, the odds of encountering the primary endpoint during an emergency tracheal intubation in a back-up head-elevated position was 0.47 (95% confidence interval, 0.26–0.83; $P = 0.01$).

CONCLUSIONS: Placing patients in a back-up head-elevated position, compared with supine position, during emergency tracheal intubation was associated with a reduced odds of airway-related complications. (Anesth Analg 2016;122:1101–7)

Emergency tracheal intubation (ETI) performed outside of the operating room (OR) is an essential and lifesaving procedure. In contrast to airway management in the context of elective surgical patients, the incidence of difficult intubation (DI) and other airway-related complications (e.g., hypoxemia, hypotension, esophageal intubation, and aspiration) is significantly greater.[1–4] A multistep process for rapid induction/intubation to "…counteract regurgitation by gravity…prevent postural hypotension…[and] support the head in the sniffing position for intubation" was reported by Stept and Safar[5] 45 years ago. Most recently, Jaber et al.[6] reported that a 10-point bundled intervention surrounding many aspects of ETI significantly reduced life-threatening events such as severe circulatory collapse and severe oxygen desaturation during the first hour after intubation. Patient positioning was not included in their list of interventions.

Studies involving normal weight as well as obese surgical patients suggest that preoxygenation is improved and apnea time prolonged when patients are in a back-up head-elevated (BUHE) versus supine position.[7–11] Significantly improved glottic views on direct laryngoscopy (DL) have also been reported with patients positioned in a BUHE versus supine position.[12] With few exceptions, it would seem that placing patients in a BUHE position to be a simple maneuver, which would provide an added element of safety during an ETI procedure. However, data regarding its efficacy in reducing ETI-related complications are lacking. Thus, we hypothesized that BUHE positioning, compared with supine positioning, would be associated with a lower occurrence of ETI-related complications.

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METHODS

Setting

The University of Washington Human Subjects Division approved this study with a waiver of informed consent. Two large academic medical centers affiliated with the

University of Washington (Seattle, WA) provide 866 licensed beds, the only level I trauma center servicing a 5-state area (Washington, Wyoming, Alaska, Montana, and Idaho) and 150 adult intensive care unit (ICU) beds for medical, transplant, cardiac and cardiothoracic, trauma, surgical, burn, and neurosciences. Medical coverage for all locations is provided 24 hours a day, 7 days a week by intensivist-led teams, which include an attending physician, a fellow, and senior and junior-level residents. The departments of surgery, anesthesiology, and internal medicine all provide trainees and attending physicians.

Out-of-operating room airway management in all locations other than the emergency department (ED; ward, ICU, remote locations such as radiology suites, etc.) is performed by a preassigned anesthesia airway team comprising an anesthesia trainee or nurse anesthetist and an attending anesthesiologist. Within the ED, primary responsibility for emergency airway management is shared between board-certified emergency medicine-trained physicians and their trainees and the anesthesiology service depending on the type of admission (medical, surgical, or trauma). Regardless, the anesthesia-based airway team is available as backup via a universal paging system 24 hours, 7 days per week. In both situations, 2 operators are mandated. In addition, members of the department of respiratory therapy and bedside nurses familiar with emergency procedures attend all intubations. On the ward or in other remote locations such as radiology or the outpatient clinic areas, dedicated "rapid response" nurses also attend and assist with intubations as part of a dedicated rapid response team. When intubations occur in the ED or ICU, the unit bedside nurses attend and assist.

Eligibility Criteria

Eligible patients had to have been tracheally intubated outside the OR or postoperative recovery area at some time during their hospital stay. In addition, initial intubation attempts had to have been made using DL. Patients younger than 18 years, those intubated for cardiopulmonary arrest, those intubated in the ED, or where initial intubation attempts were made using a technique other than DL such as video laryngoscopy or flexible fiberoptic endoscopy were excluded. For patients who subsequently underwent reintubation during the same hospitalization, only the first intubation procedure was considered.

Data Collection

All intubation procedures generate a structured procedure note. Discrete fields in the note, which are completed by the provider(s), include details of the intubation such as the providers present and their experience level, the diagnosis, an external airway examination, the patient positioning for intubation, the initial intubation technique, the laryngeal views attained, the number of intubation attempts performed, and any complications. In general, if a certified registered nurse anesthetist or anesthesia trainee performs an ETI, they complete the electronic procedure note, which is then sent to the supervising attending anesthesiologist for review and final signature. At their discretion, the note can be revised to better reflect actual events. All discrete fields from the intubation procedure note as well as demographic variables not included in the intubation note (age, sex, height, weight, body mass index [BMI], and the unit where the intubation took place) are captured by the hospital's Caradigm Intelligence Platform (Caradigm USA LLC, Seattle, WA) and made available through a comprehensive out-of-OR intubation Structured Query Language-based reporting tool. For information not contained in the intubation note, but necessary to calculate the predicted intubation difficulty score, the electronic medical record was used to examine preanesthesia clinic notes, moderate sedation evaluation forms, respiratory therapy documents, electronic medical record-generated problem lists, diagnoses on discharge summaries, and nursing vital sign documentation during the peri-intubation period. In particular, the respiratory therapist(s) attending the intubation completes a separate quality improvement form, primarily intended as a safeguard against underreporting by the operators, but also to supplement missing data regarding complicated procedures. This form contains similar details as the intubation note regarding number of attempts at intubation, equipment used, and any complications. The time taken to secure the airway is not measured precisely to the minute but estimated to be from the start of induction to the time that the tube is confirmed by end-tidal gas detection and only recorded if >10 minutes in duration. These forms are manually collected and entered by the Department of Anesthesiology's dedicated quality improvement nurse into an electronic spreadsheet for later examination. All data abstraction was conducted by 2 of the study authors (SK and AMJ). The medical records of adult patients tracheally intubated at Harborview and the University of Washington Medical Centers between November 2013 and April 2015 were included.

Study End Points and Definitions

The primary study endpoint was the occurrence of a composite of any intubation-related complication (DI, hypoxemia, esophageal intubation, or pulmonary aspiration) associated with the intubation procedure among patients intubated in either the supine or the head-elevated position. DI was defined as ≥3 attempts at intubation, airway management of >10 minutes duration,[13] or the need for a surgical airway in accordance with previous investigations.[2,3,6,14,15] Hypoxemia was defined as a pulse oximetry reading <90% during or within 15 minutes of intubation if it had been >90% before induction.[3] Pulmonary aspiration was defined as immediate peri-induction observation of gastric contents at the glottic opening or in the endotracheal tube.[16] Intubating position was defined by the angle of the back above the horizontal as either supine (<30°) or head elevated (≥30°). The use of a towel or pillows to generate a "sniffing position" without sufficient back elevation above the horizontal was still considered supine positioning. Head elevation to ≥30° was accomplished using the patient's bed or stretcher as shown in Figure 1. Towels or pillows were supplemented as needed to achieve the positioning unless contraindicated by spine precautions or not feasible based on the patient's underlying anatomy. For intubations, which took place on the patient's electronic hospital bed, the angle of back elevation in relationship to the horizontal is visually displayed. Back elevation was estimated when the intubation took place on a stretcher. Predicted intubation difficulty was assessed using the MACOCHA score,[14] which stands

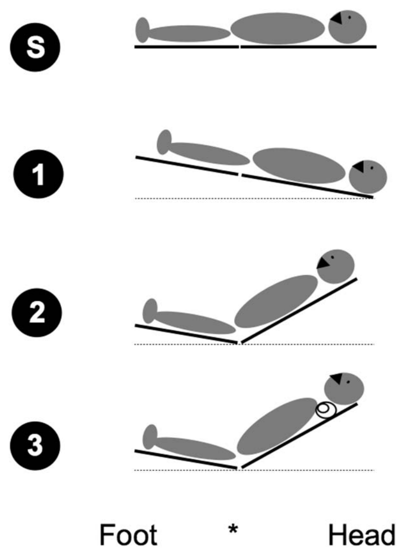

Figure 1. Graphic representation of how providers are instructed to position the patient in the 30° back-up head-elevated (BUHE) position. The patient's head should be even with the top of the mattress of the bed so, if necessary, the patient is briefly placed in the Trendelenburg position to facilitate movement toward the head of the bed (1). With the patient still in the Trendelenburg position, the back is raised at least 30° above the horizontal (2) and the head is placed in the "sniffing position" using towels or a towel roll (depicted) or pillows until the external auditory meatus is level with the sternal notch (3). S = flat supine position. *Break in the bed. –A horizontal reference.

for *M*allampati, obstructive sleep *A*pnea, *C*ervical mobility, mouth *O*pening, *C*oma, severe *H*ypoxemia, and intubation by a non-*A*nesthesiologist. The score ranges from 0 to 12 with increasing values associated with greater odds of DI. Values assigned for each of the score items is as follows: Mallampati ≥3, 5 points; obstructive sleep apnea, 2 points; limited cervical mobility, 1 point; mouth opening <3 cm, 1 point; coma defined as a Glasgow coma score ≤8, 1 point; severe hypoxemia defined as a saturation of ≤80% at the time of intubation, 1 point; and intubation by a nonanesthesiologist, 1 point. The score was derived from prospectively collected data from 1000 consecutive intubations in 42 ICUs. Data collected included patient characteristics, reason for ICU admission and intubation, operator experience, patient's hemodynamic status, airway examination, intubation characteristics, and any intubation-related complications. It was subsequently validated externally in another 400 consecutive intubations from 18 other ICUs. The reported area under the curve for the simplified 7-item score was 0.89 (95% confidence interval [CI], 0.86–0.93) with a sensitivity of 73%, a specificity of 89%, a negative predictive value of 98%, and a positive predictive value of 36%. Scores >3 have been used to predict DI.[15]

To account for differences in the care models between Europe and North America, we substituted "junior operator" for "nonanesthesiologist" in our calculation. A junior operator was one with <12 months of anesthesia-specific airway training. Thus, all anesthesia trainees before the start of their second clinical anesthesia year were considered junior. In contrast, all nurse anesthetists, anesthesia trainees at or beyond their second clinical anesthesia year, anesthesia fellows, and attendings were considered senior.

Statistical Analysis

Baseline demographic and clinical variables were compared between patients intubated in the supine and head-elevated positions using a 2-sample Student *t* test with the assumption of unequal variances (Satterthwaite degrees of freedom) for continuous variables and χ^2 tests for categorical variables. Multivariable logistic regression was used to estimate the odds of the composite end point occurring during intubation in the supine and head-elevated positions. Models were adjusted for BMI as a continuous linear variable and the MACOCHA score as categorical variable, both a priori-defined potential confounders. We performed separate sensitivity analyses to explore the association between (1) patient position and DI and (2) patient position and the occurrence of an intubation-related complication other than DI (hypoxemia, esophageal intubation, and/or pulmonary aspiration), adjusting for the same confounders.

In addition, to account for potential practice changes other than positioning that might have benefitted patients undergoing ETI during the study period, we ran separate models including year of intubation. We also adjusted for operator experience as a separate covariate to verify robustness of our results. A 2-sided α <0.05 was considered statistically significant. Statistical analyses were performed using STATA statistical software, version 12.0 (StataCorp, College Station, TX).

RESULTS

Five hundred twenty-eight patients were analyzed (Fig. 2). Thirty-two patients met the definition for difficult to intubate. Almost all of these (30/32 [93%]) were considered difficult based on requiring ≥3 attempts at intubation; 23 underwent 3 attempts, 6 underwent 4 attempts, and 1 underwent 5 attempts culminating in a surgical airway. Of these, the GlideScope® GVL video laryngoscope (Verathon, Inc., Bothell, WA) was used alone for airway rescue in 50% (15/30) and in combination with a fiberoptic bronchoscope in 3 (10%) additional patients. In the remaining 12 (40%) patients, DL was the only laryngoscopic technique attempted. A single-use 15-Fr 70-cm coude tip tracheal tube introducer (SunMed, Grand Rapids, MI) was used to facilitate intubation in 3 (25%) of these cases. Two additional patients met the definition for difficult based on performance of a surgical airway after the initial attempt at intubation by DL. No patient was considered difficult based on the intubation procedure requiring >10 minutes as the only criteria. The differences between patients intubated in the supine and head-elevated positions are presented in Table 1. The proportion of patients who had a Spo_2 <80% at the time of intubation (9.4% vs 6.8%, *P* = 0.43) or limited cervical spine motion (10.1% vs 10.3%, *P* = 1.0) were similar between groups. However, more patients in the head-elevated group had a Glasgow Coma Scale <8 (15.1% vs 29.3%, *P* = 0.04) and were intubated by a senior operator (66% vs 93%, *P* < 0.01).

Overall, at least 1 intubation-related complication occurred in 76 of 336 (22.6%) patients managed in the supine position compared with 18 of 192 (9.3%) managed in the BUHE position. After adjusting for BMI and the MACOCHA score, head-elevated versus supine positioning was associated with significantly lower odds of reaching the primary endpoint (odds ratio = 0.42; 95% CI, 0.23–0.77;

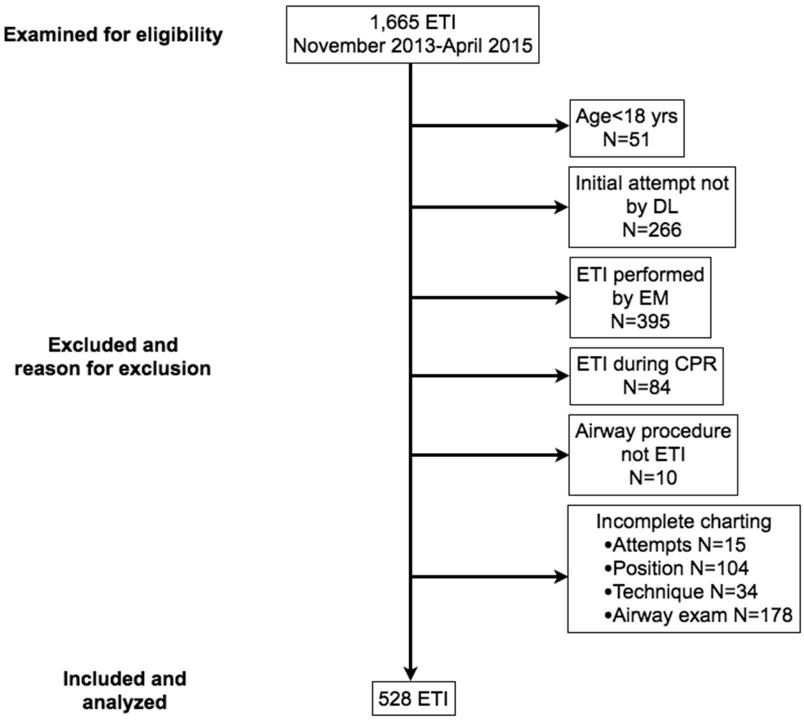

Figure 2. Reasons for exclusion of patient from final analysis. CPR = cardiopulmonary resuscitation; DL = direct laryngoscopy; EM = emergency medicine; ETI = emergency tracheal intubation.

Table 1. Characteristics of Patients, Operators, and Intubations, Which Occurred in the Supine Versus Head-Elevated Position

	Overall (*N* = 528)	Supine (*N* = 336)	HOB elevated (N = 192)	*P* value
Age (y)	57 ± 16	57 ± 16	58 ± 16	0.6585
Sex				
M	332 (63)	198 (59)	134 (67)	0.0149
F	196 (37)	138 (41)	58 (33)	
BMI (kg/m^2)				
<30	330 (63)	205 (61)	125 (65)	0.4004
>30	198 (37)	131 (39)	67 (35)	
Reason for intubation				
Hypoxia	201 (38)	120 (36)	81 (42)	0.1321
Hypercarbia	54 (10)	36 (11)	18 (9)	
Airway protection	192 (36)	122 (36)	70 (36)	
Both	64 (12)	43 (13)	21 (11)	
Other	14 (3)	13 (4)	1 (0.5)	
Year performed				
2013	48 (9)	34 (10)	14 (7)	0.1271
2014	388 (73)	237 (71)	151 (79)	
2015	92 (18)	65 (19)	27 (14)	
Operator experience[a]				
Junior	126 (24)	113 (34)	13 (7)	<0.0001
Senior	402 (76)	223 (66)	179 (93)	
MACOCHA score				
<3	447 (85)	271 (81)	176 (92)	0.0006
>3	81 (15)	65 (19)	16 (8)	
Glottic view	1 (1–1 [1–4])	1 (1–2 [1–4])	1 (1–1 [1–4])	0.0049
Attempts	1 (1–1 [1–5])	1 (1–1 [1–5])	1 (1–1 [1–3])	0.0585
Complications				
Hypoxemia	66 (12.5)	54 (17)	12 (6.3)	0.6352
Aspiration	10 (1.9)	8 (2.3)	2 (1)	
Esophageal	8 (1.5)	5 (1.5)	3 (1.5)	
DI	32 (6)	26 (7.7)	6 (3)	

Data are presented as *n* (%), mean ± SD, or median (interquartile range [full range]) unless otherwise noted.

BMI = body mass index; DI = difficult intubation; HOB = head of bed; MACOCHA score = *M*allampati, obstructive sleep *A*pnea, *C*ervical mobility, mouth *O*pening, *C*oma, severe *H*ypoxemia, and intubation by a non-*A*nesthesiologist score; M = male; F = female.

[a]A total of 61 operators performed the 528 intubations. The range of intubations per operator was 1–16. No single operator performed >3% of intubations. The top 5 operators performed the following number (%) of intubations: operator 1: 16 (3%); operator 2: 16 (3%); operator 3: 15 (2.8%); operator 4: 15 (2.8%); and operator 5 (2.5%).

$P = 0.005$). In sensitivity analyses, the odds ratio for DI was 0.88 (95% CI, 0.24–3.21; $P = 0.848$), whereas the odds for a composite of hypoxemia, aspiration, or esophageal intubation was 0.41 (95% CI, 0.22–0.76; $P = 0.005$; Table 2). Finally, in addition, controlling for operator experience and the year of intubation, in addition to MACOCHA and BMI, did not alter results significantly (Table 2).

DISCUSSION

Our main finding is that ETI performed in a BUHE position was associated with lower odds of encountering an intubation-related complication compared with supine positioning when taking into account body habitus and predicted difficulty. In the OR environment, this finding is not novel. Indeed, a number of investigators have previously reported a beneficial effect of BUHE positioning during the induction of anesthesia, which include better preoxygenation resulting in longer apnea times[7–11] as well as improved glottic visualization during DL.[12] Lee et al,[12] in 40 patients, randomly performed laryngoscopy in either the supine or a 25° head-elevated position. The percentage glottic opening score was improved by approximately 25% in the head-elevated position compared with the flat supine position. During ETI, such an improvement may be the difference between a straightforward uncomplicated intubation and one that is difficult and/or complicated. However, this benefit is not supported by our analysis, because we found that the associated reduction in intubation-related complications was driven by fewer episodes of hypoxemia, esophageal intubation, and/or pulmonary aspiration rather than DI. Two principle reasons likely account for this finding. DI was uncommon in our series and, thus, our study may have been underpowered to detect a difference with DI as an isolated outcome. Alternatively, or in combination with the former, specific risk factors that place the patient at an increased risk for DI may not be modifiable by patient position, whereas complications such as hypoxemia, esophageal intubation, and pulmonary aspiration may be modified. In addition to the theoretic benefit of BUHE position on oxygen reserves,[17] such positioning stands to reduce the risk of passive gastric regurgitation and pulmonary aspiration.

A number of risk assessment scores have been studied for their ability to identify an otherwise unanticipated DI in OR patients.[18–22] With respect to ETI, however, they are severely limited insofar as an extensive examination of external airway features is often not possible.[23] Some have even suggested that the external airway examination is of questionable value.[24] Therefore, one strength of our study was to incorporate a validated prediction score, specific to ETI outside the OR, as a covariate in our analyses. Although other studies have previously reported on outcomes of ETI in critical care,[1–4,16,25] none has presented outcomes adjusting for predicted difficulty.

Our study has several limitations. The intubation data are self-reported and subject to reporting bias. Indeed, our reported incidence of DI is 6%. Videolaryngoscopes, specifically a variety of different glidescopes (GlideScope AVL Reusable, GlideScope AVL Single Use, and GlideScope Ranger Reusable; Verathon, Inc.), are available for use in several out-of-OR locations. The availability of such advanced airway devices could have introduced a selection bias away from patients suspected or known to have a difficult airway, explaining, in part, our low rates of observed DI with DL. Alternatively, or in combination with the former explanation, intubations performed by experienced operators, all of whom are sufficiently practiced in DL, might have driven down the DI rate. However, our DI rates are consistent with previous prospective cohort studies, which report rates of 6.6% to 13.2%.[1–3,16] Our reported incidence of aspiration and esophageal intubation, approximately 2% each, are also similar to previous reports.[3,16,25] Importantly, the position in which the patient was preoxygenated and subsequently intubated could have been mistakenly recorded. Providers are regularly instructed as to the definition of what constitutes a BUHE position; the head of the bed at >30°, but we cannot guarantee that the patient was in such a position. Patients in whom the degrees of head elevation were estimated could have been close to but not >30° (e.g., 20°–25°). Because most patients are intubated in the supine position and extra time and effort are required to position the patient with their head elevated, we believe that it is less likely that providers incorrectly identified patient position in the record as head-elevated when they were actually supine. We also acknowledge that patients listed as supine could have been slightly elevated (e.g., 10°). Also, because of the retrospective nature of our study, we have limited insight into why some patients were positioned with the head elevated and others were not. In fact, MACOCHA scores were higher in the supine than head-elevated group, so we are left to wonder why practitioners would make the effort to position patients in the head-elevated position if not for concern over anticipated airway difficulty. Severe hemodynamic instability or presumed intracranial hypertension might affect the practitioner's choice of positioning. Hypotension, defined as a systolic blood pressure <90 mm Hg within 15 minutes of the peri-intubation period, is a complication

Table 2. Logistic Regression Models

Model[a,b]	Odds ratio	SE	z statistic	P value	95% confidence interval
Model 1: Endpoint = composite	0.4247	0.1302	−2.79	0.005	0.2329–0.7746
Model 2: Endpoint = adverse event	0.4082	0.1292	−2.83	0.005	0.2195–0.7591
Model 3: Endpoint = difficult intubation	0.8812	0.5860	−0.19	0.848	0.2420–3.208
Additional sensitivity analyses					
Model 4: Model 1 + adjustment for operator experience	0.4951	0.1601	−2.17	0.030	0.2627–0.9332
Model 5: Model 1 + adjustment for year of intubation	0.4409	0.1364	−2.65	0.008	0.2404–0.8086

MACOCHA score = *M*allampati, obstructive sleep *A*pnea, *C*ervical mobility, mouth *O*pening, *C*oma, severe *H*ypoxemia, and intubation by a non-*A*nesthesiologist score.
[a]All models adjusted for MACOCHA score as a categorical variable and body mass index as a continuous linear variable.
[b]No evidence of interaction between patient position and MACOCHA ($P = 0.613$) or patient position and body mass index ($P = 0.889$).

field in our structure procedure note. Among our study cohort, the occurrence of hypotension in patients intubated in the supine and BUHE positions was similar, 53 of 336 (15.8%) and 31 of 192 (16.1%), respectively. However, because we did not record the preintubation blood pressures, we cannot determine whether hemodynamic instability may have biased practitioners toward one intubating position or whether the BUHE position might more commonly result in a meaningful decrease in postinduction blood pressure. Future prospective data will need to be collected. However, only 3% of patients in our cohort were intubated for an indication of shock or intracranial hypertension (listed in Table 1 as "other").

Obesity and severe hypoxemia at intubation were also similar between groups. However, we did note that senior operators intubated a larger proportion of patients in the BUHE position than their junior colleagues. This could have been because of heightened clinical suspicion for airway difficulty or ETI-related complications not captured by a prediction score. However, separate analyses adjusting for operator experience alone still yielded intubating position as an independent predictor of complications. Alternatively or in combination, this may represent a learning effect. At our institution, we teach trainees that all ETI should be performed in the BUHE position unless contraindicated. Therefore, it would be expected that as residents advance through their training and gain greater experience in ETI, they would be more likely to include positioning as part of their preintubation checklist. This was not confirmed by adding the year in which a patient was intubated as a covariate in the regression model. Also, the fact that only 15% of our study cohort was predicted to be a DI (MACOCHA score ≥3) suggests a potential selection bias for lower risk patients. On one hand, this could limit the external validity of our results to the highest risk patients. On the other hand, our findings would suggest that use of the BUHE position for ETI may allow improved safety, even in the relatively lower risk critically ill patient population. The reader will note that we did not specifically take into account several potential confounders such as admitting diagnosis, severity of illness, preintubation vital signs, or individual elements of the airway examination. Rather, we used the MACOCHA score, which was developed taking these factors into account.[14] Intubations, which were performed by our emergency medicine colleagues, were excluded from our cohort. Our rationale was to limit unmeasured confounding that could result from operator experience. Finally, we acknowledge the inherent limitations of observational data and that residual, unmeasured confounding may persist.

We have shown an association between intubating position and ETI-related complications. This must not to be confused with a causal relationship, which our study design does not allow us to infer. Our findings require confirmation in a prospective randomized controlled trial. However, we believe that placing patients in a BUHE position is a relatively easy maneuver to perform, optimizes conditions for a variety of airway management techniques, including ventilation by facemask, extraglottic airways, videolaryngoscopy, and flexible fiberoptic endoscopy, has no associated cost, is easily understood and executed by the staff, and requires no advanced technology or power source other than the bed. Thus, outside of patients in whom its use is contraindicated, we suggest the BUHE position for undergoing ETI.

DISCLOSURES

Name: Nita Khandelwal, MD, MS.
Contribution: This author contributed to study design, data analysis, and manuscript preparation.
Attestation: Nita Khandelwal approved the final manuscript and attests to the integrity of the original data and the analysis reported in this manuscript.
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Contribution: This author helped conduct the study and prepare the manuscript.
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Attestation: Steven H. Mitchell approved the final manuscript.
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Contribution: This author contributed to study design, conduct of the study, data collection, data analysis, and manuscript preparation.
Attestation: Aaron M. Joffe approved the final manuscript, attests to the integrity of the original data and the analysis reported in this manuscript, and is the archival author.
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