Published in final edited form as:

Anesth Analg. 2018 July ; 127(1): 151–156. doi:10.1213/ANE.0000000000002621.

Safety and Effectiveness of a Novel Facemask for Positive Pressure Ventilation

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Abstract

BACKGROUND: Manual positive pressure ventilation is an essential skill in a variety of clinical situations. The C&E technique is commonly used with standard facemasks to provide effective ventilation. The Tao mask is a novel design that allows a more ergonomic grip. A seal between the mask and face is made with downward pressure of the palm, centered on the mask, and jaw lift is achieved with 4 fingers centered under the mandible. The purpose of this study was to evaluate the safety and effectiveness of the Tao mask compared to a standard mask before and after the administration of neuromuscular blockade (NMB) using 2 previously established ventilation scales.

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DISCLOSURES
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Conflict of Interest: None.
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Contribution: This author helped design the study, analyze and interpret the data, and write the manuscript.
Conflict of Interest: None.
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Conflict of Interest: None.
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Conflict of Interest: None.
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Conflict of Interest: None.
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Conflict of Interest: None.
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Conflict of Interest: R. D. Warters is the inventor of the Tao mask. He did not participate in the collection or analysis of data.
This manuscript was handled by: Avery Tung, MD, FCCM.

Clinical trial number: Pro00047645.

Implications Statement: This study demonstrates equivalent safety and superior effectiveness of a novel facemask for positive pressure ventilation.

METHODS: One hundred fifty-two patients >18 years of age who were scheduled for general anesthesia were recruited. All care team members were shown a brief instructional video on the use of the Tao mask. After induction of general anesthesia with a standardized protocol, each patient was ventilated with both the standard (Vital Signs #082510) and Tao masks and effectiveness was measured using the Han and Warters scales. This process was repeated after NMB. The sequence of masks was determined with a random-number generator.

RESULTS: Tao mask ventilation scores were significantly better than standard mask scores on both the Han scale and the Warters scale before the administration of NMB ($P < .001$ for both). Tao mask scores were also significantly better than standard mask scores on the Warters scale after the administration of NMB ($P < .001$). However, there was no significant difference on the Han scale between the 2 mask types after NMB ($P = .180$). On the Warters scale, there were significantly fewer patients who were difficult to ventilate with the Tao mask than the standard mask before NMB (18 vs 40; $P < .001$) and after NMB (8 vs 17; $P = .005$). No adverse events were reported with either mask.

CONCLUSIONS: Our results indicate that the Tao mask demonstrated equivalent safety and superior effectiveness compared to a standard mask. The study design favored the standard mask because all participating practitioners had multiple years of experience with the standard mask and no prior experience with the Tao mask. Since the incidence of inadequate mask ventilation goes up significantly with inexperienced operators, the improved effectiveness of the Tao mask could be even more profound with novice operators. (Anesth Analg 2018;127:151–6)

Manual positive pressure ventilation via facemask is commonly utilized in a wide variety of clinical settings including operating rooms, emergency departments, hospital wards, and ambulances. Positive pressure ventilation can be life-saving for patients who are hypoxic, hypercapnic, or apneic. Although mask ventilation skills are routinely taught, even the most skilled and experienced anesthesiologists struggle to effectively mask ventilate approximately 5% of patients.[1] The incidence of ineffective mask ventilation increases substantially with less experienced clinicians. De Regge et al[2] showed that 84% of emergency room nurses were not able to perform adequate mask ventilation. Another study by Elling and Politis[3] found that >50% of emergency medical technicians were unable to successfully ventilate a mannequin.

The effective use of standard facemask requires the simultaneous establishment of a seal between the mask and face and the lifting of the jaw. The preferred mask grip is the C&E technique.[4] In our experience, the grip required to establish the face seal and jaw lift simultaneously is awkward and difficult to teach.

The Tao mask (Figure 1) is based on a novel design that allows a more ergonomic grip in place of the C&E technique. With the Tao mask, downward pressure with the palm of the hand centered on the mask provides the seal between the face and the mask. All 4 fingers align under the jaw to provide jaw lift (Figure 2).

The primary goal of this study is to compare the safety and effectiveness of the novel mask (Tao mask) to that of a standard facemask (Vital Signs #082510) using previously published ventilation scales (Han and Warters scales[5,6]) before and after the administration of neuromuscular blockade (NMB).

METHODS

This study was approved by the institutional review board at the Medical University of South Carolina, and written informed consent was obtained from each patient.

Study Overview

Patients scheduled for surgery requiring general endotracheal anesthesia were eligible for enrollment in this study. Inclusion criteria were age >18 years and surgery requiring general endotracheal anesthesia. Exclusion criteria included increased risk for aspiration of gastric contents, need for awake intubation, previously established airway devices, and allergy to study medications.

The care team consisted of an attending anesthesiologist and a certified registered nurse anesthetist. All care team members were provided a brief instructional video on the use of the Tao mask. No additional instruction was provided.

After induction of general anesthesia with a standardized protocol, each patient was ventilated with both the standard and Tao masks and effectiveness was measured using the Han and Warters scales. This process was repeated after the administration of rocuronium. The sequence of masks was determined with a random-number generator.

Preoperative airway assessment was based on the metrics used by Langeron et al[1] and included the following:

- Mallampati classification
- Thyromental distance, in millimeters, measured with the patient in a sitting position and the head in full extension.
- Mouth opening measured as the interincisor distance, in millimeters
- Macroglossia estimated on a subjective basis
- Micrognathia estimated on a subjective basis
- Assessment of dentition
- Presence of a beard
- Body mass index (BMI)
- History of snoring
- Subjective assessment by the anesthesiologist of anticipated difficult mask ventilation

Intraoperative Management

Premedication included midazolam 1–4 mg intravenous (IV) and fentanyl 1–2 µg/kg IV. In the operating room, the patients were placed supine, in the sniffing position (neck flexed, head extended), and standard American Society of Anesthesiologists monitors were applied. Additional monitoring was allowed at the discretion of the attending anesthesiologist based on the patient's medical condition and the procedure planned. Patients were preoxygenated with 100% oxygen for 2–3 minutes before induction. Fresh gas flow consisted of oxygen at 10 L/min. Propofol 1–3 mg/kg IV was administered for induction.

Grading of Mask Ventilation

On loss of the eyelid reflex, the certified registered nurse anesthetist ventilated the patient with the designated mask with a goal of generating a tidal volume (TV) of 5 mL/kg. The attending anesthesiologist graded the mask ventilation using the Han and Warters scales (Appendices A and B). The second mask was then evaluated in the same manner. Rocuronium (0.6 mg/kg) was then administered, and after 2 minutes, ventilation with both masks was again evaluated in the same order.

Adverse Events

All intraoperative adverse events are recorded and monitored in the Medical University of South Carolina Research Electronic Data Capture Quality Improvement Database. The following airway-related events are recorded: anticipated or unanticipated difficult intubation, inability to intubate, inability to ventilate, unplanned extubation, laryngospasm, process requiring postoperative reintubation, dental injury, hypoxemia with arterial oxygenation saturation <85%, laryngospasm, and airway trauma. The database exists for the purpose of quality assurance and improvement and is reviewed monthly by a multidisciplinary panel of physicians, nurses, and technicians.

Statistical Analysis

This study is a crossover trial where all participants were asked to ventilate patients with both the Tao and the standard masks before and after NMB. Descriptive statistics were calculated for study patient characteristics. Before examining differences between the 2 masks, we conducted tests for carryover effect using a Wilcoxon rank sum test approach.[7] The difference in scores between mask types on each patient was then compared using a Wilcoxon rank sum test approach as described by Wellek and Blettner[7] to test the null hypothesis that the differences in scores are equal to zero. McNemar test was also used to evaluate agreement between the 2 masks in terms of whether or not a patient was deemed difficult to ventilate.

As a secondary analysis, we examined the association of patient characteristics on ventilation scores both before and after NMB. Note the change in score was condensed into 2 categories: (1) better and (2) same or worse, due to the limited number of participants who scored worse using the Tao mask. Univariate association of ventilation scores with all categorical patient characteristics was evaluated using a χ^2 or Fisher exact approach, and associations between ventilation scores with all continuous variables were evaluated using a 2-sample *t* test approach. All analyses were conducted in SAS v9.4 (SAS Institute, Cary, NC).

Power Analysis

The study sample size was estimated using previously reported average (1.8) and standard distribution (1.6) for Warters ventilation scores. We estimated a 20% reduction (0.36) in these scores using the Tao mask. The result of the calculation to yield 5% alpha is a sample size of 156 patients.

RESULTS

One hundred fifty-two patients were enrolled. Patient characteristics overall and by randomization groups are reported in Table 1. The mean age of patients in the study was 55 ± 17 years, and the mean BMI was 29.7 ± 7.9 kg/m^2. A majority of patients (81%) were Mallampati class I or II. Patient characteristics were similar between the randomization groups although patients masked using the Tao mask first were significantly older than patients masked using the regular mask first ($P = .039$). No adverse events were reported with either mask type.

Raw ventilation scores and score differences by mask type before and after NMB are reported in Table 2. Before examining differences between the Tao and regular masks, we evaluated for carryover effect. There was no significant carryover effect before or after administration of NMB on either the Han or Warters scales (baseline Han scale $P = .151$; baseline Warters scale $P = .432$; post-NMB Han scale $P = .798$; post-NMB Warters scale $P = .763$). Tao mask ventilation scores were significantly lower than standard mask scores on both the Han scale and the Warters scale before the administration of NMB ($P < .001$ for both). Tao mask scores were also significantly lower than standard mask scores on the Warters scale after the administration of NMB ($P < .001$). However, there was no significant difference on the Han scale between the 2 mask types after NMB ($P = .180$).

We also examined the impact of mask sequence to ensure that the improvement in scores using the Tao mask was not due to a learning effect. Before NMB, the Warters scores were significantly lower for the Tao mask, regardless of the order in which the masks were used (standard first: $P < .001$ and Tao first: $P = .018$). However, the Han scores were only significantly lower for the Tao mask when the standard mask was used first ($P < .001$). After NMB, only the Warters scores were significantly lower for the Tao mask and this improvement was significant regardless of the order in which the masks were used (standard first: $P < .001$ and Tao first: $P = .016$).

Table 3 shows the proportion of patients who were easy or difficult to ventilate pre- and post-NMB with the 2 masks on the 2 ventilation scales. Difficult mask ventilation is defined as score of ≥3 on both ventilation scales. The Han scale did not show any significant difference in the number of easy to ventilate and difficult to ventilate patients between the standard and Tao masks before ($P = .157$) or after NMB ($P = 1.0$). However, significantly more patients were easy to ventilate with the Tao mask but difficult to ventilate with the standard mask on the Warters scale both before ($P < .001$) and after NMB ($P = .005$).

Specifically, before NMB, of the 40 patients classified as difficult by the Warters scale using the standard mask, 22 of the 40 (55%) were classified as easy using the Tao mask. Only 2 of the 20 patients classified as difficult using the Tao mask were classified as easy using the standard mask. After NMB, only 8 of 17 (47%) patients classified as difficult using the standard mask were classified as difficult with the Tao mask.

As a secondary analysis, we evaluated the effect of patient characteristics on the ventilation scores of the Tao and standard masks using the Han and Warters scales (Table 4). No patient characteristics were associated with superior ventilation scores for the standard mask.

On the Han scale before NMB, patients were easier to ventilate with the Tao mask if they had a receding mandible ($P = .030$) or when they snored ($P = .014$). On the Warters scale before NMB, receding mandible ($P < .001$) and snoring ($P = .002$) were also associated with significantly easier ventilation as were higher BMI ($P = .018$), higher Mallampati class ($P = .003$), and anticipated difficult mask ventilation ($P < .001$). On the Han scale after NMB, patients were easier to ventilate with the Tao mask if they had a higher Mallampati class ($P = .032$) or when they snored ($P = .047$). On the Warters scale after NMB, patients were easier to ventilate with the Tao mask if they had a higher Mallampati class ($P = .029$) or macroglossia ($P = .036$) and when difficult mask ventilation was anticipated ($P = .022$).

DISCUSSION

Our data indicate that the novel Tao mask is associated with equivalent safety and improved effectiveness compared to the standard mask. No adverse events were reported with either mask type. The Tao mask performed significantly better than the standard mask before the administration of NMB using both the Han and Warters ventilation scales. After the administration of NMB, the Tao mask performed significantly better than the standard mask on the Warters scale, but not the Han scale. This discrepancy is not surprising given the lack of sensitivity of the Han scale and the previous finding that mask ventilation is facilitated by NMB.[6]

The Han scale is a 4-point scale that lacks sensitivity. The scale fails to define “ventilated,” “difficult,” and “inadequate.” In contrast, the Warters scale is a 10-point scale and adequate ventilation is defined as a TV of 5 mL/kg. Points are added based on specific adjuncts needed to achieve the target TV. Our group has previously demonstrated that NMB facilitates mask ventilation.[6] Therefore, we would expect to see less of a difference between the 2 masks after NMB and we would expect the Han scale to be less likely to detect a difference between the masks due to its lower sensitivity.

Both the Han and Warters scales define difficult ventilation as a score of 3 or higher.[5,6] Using the Warters scale, there was a significantly lower number of patients who were difficult to ventilate with the Tao mask than the standard mask before (18 vs 40) and after NMB (8 vs 17) (Table 3). Thus the number of difficult mask ventilations with the Tao mask was less than half of those with the standard mask.

The decreased incidence of “difficult” mask ventilation with the Tao mask is more significant given that the study design favored the standard mask. All participating practitioners had multiple years of experience with the standard mask and no prior experience with the Tao mask. It is quite possible that the difference in efficacy between the masks will increase as clinicians gain experience with the novel mask. Further, since the incidence of inadequate mask ventilation goes up significantly with inexperienced operators,[2,3,8] the improved efficacy of the Tao mask could be even more profound with novice operators. Future studies should test this hypothesis.

Langeron et al[1] identified a variety of factors associated with difficult mask ventilation. We used the same metrics as Langeron et al[1] to evaluate the effect of patient characteristics on the relative efficacy of the Tao and standard masks. Several patient characteristics correlate positively with improved performance of the Tao mask compared to the standard mask on both the Han and Warters scales (Table 4). It is therefore possible that the improved effectiveness of the Tao mask is more pronounced in patients who are more difficult to ventilate. Importantly, no patient characteristics were associated with improved performance of the standard mask over the Tao mask.

We also evaluated the impact of mask sequence on ventilation scores. On the Warters scale, the Tao mask was significantly better before and after NMB regardless of mask sequence. On the Han scale, the Tao mask scored significantly better before NMB and only when the standard mask was used first. We believe that this is explained by the lack of sensitivity of the Han scale as well as a possible learning effect. We postulate that it was easier to use the second mask, because the mask operator gained familiarity with each patient while using the first mask.

We believe that the improved performance of the Tao mask, despite the fact that the clinicians lacked experience with this novel mask, is explained by the ergonomic grip leading to (1) an improved mask–face seal and (2) a symmetrical, midline jaw lift. The Tao mask design allows the palm to be placed in the center of the mask, providing a superior seal between the mask and face compared to the “C&E” grip. The Tao mask design also allows 4 fingers to align under the center of the chin to provide midline lift. This yields superior jaw lift compared to the off-center jaw lift by 3 fingers with the “C&E” technique. In our experience, the improved ergonomics become more pronounced as mask difficulty increases.

Our study has several limitations. The primary one is the number of patients enrolled. Although the study was powered adequately to distinguish the relative efficacy of the mask types, larger patient numbers would have provided more granularities. The incidence of difficult mask ventilation is low with experienced practitioners, so greater patient numbers would have been needed to draw more specific conclusions regarding the relative performance of the masks in difficult to ventilate patients. The same is true for impossible mask ventilation that occurs with such a low incidence (0.15%),[9] that we are unable to comment on the performance of the Tao mask under these circumstances. Finally, none of the participants had any experience with the Tao mask, as they had been using the standard mask for several years. Recruiting airway novices for the study would have been difficult and ethically challenging. An ongoing simulation laboratory study with inexperienced airway providers (second-year medical students) using both masks will hopefully address this shortcoming.

In conclusion, this study demonstrates equivalent safety and superior performance of the Tao mask despite a trial design that favors the standard mask due to the extensive user experience with the standard mask. Future studies should evaluate the performance of the Tao mask relative to standard masks in patients with risk factors for difficult mask ventilation, with novice operators and with clinicians with small hands.

Funding:

This study was supported by the Department of Anesthesia and Perioperative Medicine, Medical University of South Carolina. Tao masks were provided by Tao Life Sciences LLC.

APPENDIX

APPENDIX A.

Han Scale

Grade 0	Ventilation by mask not attempted
Grade 1	Ventilated by mask
Grade 2	Ventilated by mask with oral airway or other adjuvant
Grade 3	Difficult mask ventilation (inadequate, unstable, or requiring 2 practitioners)
Grade 4	Unable to mask ventilate

APPENDIX B.

Warters Scale

The goal is to generate a tidal volume ≥5 mL/kg	
• Oral or nasal airway: 1 point	
• Peak inspiratory pressure	20–25: 1 point
	25–30: 2 points
	30: 3 points
	Unable to generate PIP >30: 3 points
• 2 person ventilation: 2 points	
• TV <5 mL/kg: 2 points	
• Unable to ventilate: 2 points	

Abbreviations: PIP, peak inspiratory pressure; TV, tidal volume.

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KEY POINTS

Question:

- Does a novel facemask offer any benefits over a standard facemask before and after neuromuscular blockade?

Findings:

- The novel facemask is associated with equivalent safety and improved effectiveness compared to the standard mask.

Meaning:

- The novel facemask offers improved effectiveness due to an ergonomic grip that provides a superior mask–face seal and midline jaw lift.

Figure 1.
Tao mask.

Figure 2.
Proper hand position for ventilation with the Tao mask.

Table 1.

Baseline Patient Characteristics Across All Patients and by Randomization Group

	All Patients (n = 152)	Regular Then Tao (n = 76)	Tao Then Regular (n = 76)	*P*
Gender (male)	67 (44.1)	31 (40.8)	36 (47.4)	.513
Age (y)	54.9 (16.9)	52.1 (17.3)	57.7 (16.0)	.039
BMI (kg/m^2)	29.7 (7.85)	30.2 (8.64)	29.2 (7.00)	.443
Mallampati class				.313
I	36 (24.3)	19 (25.3)	17 (23.3)	
II	84 (56.8)	39 (52.0)	45 (61.6)	
III	27 (18.2)	17 (22.7)	10 (13.7)	
IV	1 (0.68)	0 (0.00)	1 (1.37)	
Macroglossia	28 (18.4)	14 (18.4)	14 (18.4)	1.000
Receding mandible	26 (17.1)	17 (22.4)	9 (11.8)	.132
Edentulous	12 (7.89)	6 (7.89)	6 (7.89)	1.000
Beard	27 (17.8)	10 (13.2)	17 (22.4)	.203
Snore	52 (34.2)	24 (31.6)	28 (36.8)	.608
Anticipated DMV	39 (25.7)	20 (26.3)	19 (25.0)	1.000

ontinuous variables are reported as mean (SD) and categorical variables as n (%). *P* values are for the difference between randomization groups.

Abbreviations: BMI, body mass index; DMV, difficult mask ventilation.

Table 2.

Raw Ventilation Scores and Score Differences by Mask Type Before and After NMB

		Han Score		Han Score	
Timing	Mask Type	Mean (SD)	Median (25%, 75%)	Mean (SD)	Median (25%, 75%)
Pre-NMB	Standard	1.38 (0.60)	1 (1, 2)	1.70 (1.66)	1 (1, 3)
	Tao	1.22 (0.52)	1 (1, 1)	1.30 (1.42)	1 (0, 2)
	Difference	0.15 (0.43)[a]	0 (0, 0)[a]	0.39 (0.76)[a]	0 (0, 1)[a]
Post-NMB	Standard	1.23 (0.51)	1 (1, 1)	1.14 (1.22)	1 (0, 2)
	Tao	1.20 (0.49)	1 (1, 1)	0.86 (1.16)	1 (0, 1)
	Difference	0.03 (0.24)	0 (0, 0)	0.28 (0.58)[a]	0 (0, 1)[a]

Differences are calculated by taking the ventilation score using the standard mask and subtracting the score using the Tao mask. Data are presented as mean (SD) and as median (25th, 75th percentile).

Abbreviations: NMB, neuromuscular blockade; SD, standard deviation.

[a] $P < .001$

Table 3.

Difficulty of Mask Ventilation Based on Han Scores and Warters Scores by Mask Type Before and After NMB

Score Source	Pre-NMB	*P*	Post-NMB	*P*
Han scores				
Easy by both standard and Tao masks	143 (94.1)	.157	148 (97.4)	1.00
Difficult by both standard and Tao masks	7 (4.61)		4 (2.63)	
Easy with Tao mask, difficult with standard mask	2 (1.32)		0 (0.00)	
Easy with standard mask, difficult with Tao mask	0 (0.00)		0 (0.00)	
Warters scores				
Easy by both standard and Tao masks	110 (72.4)	<.001	135 (88.8)	.005
Difficult by both standard and Tao masks	18 (11.8)		9 (5.92)	
Easy with Tao mask, difficult with standard mask	22 (14.5)		8 (5.26)	
Easy with standard mask, difficult with Tao mask	2 (1.32)		0 (0.00)	

alues are reported as n (%). *P* values are based on McNemar test of agreement with a significant value indicating that more participants report difficulty with the standard mask but not with the Tao mask compared to those who report difficulty with the Tao mask but not the standard mask.

Abbreviation: NMB, neuromuscular blockade.

Table 4.

Comparison of Patient Characteristics by Whether or Not Ventilation Scores Improved Using the Tao Versus Standard Mask on the Han Scale and on the Warters Scale Before and After NMB

	Han Score			Warters Score		
Pre-NMB	**Same or Worse (n = 129)**	**Better (n = 23)**	***P***	**Same or Worse (n = 101)**	**Better (n = 51)**	***P***
BMI	29.5 (7.92)	31.0 (7.48)	.407	28.6 (7.37)	31.8 (8.41)	.018
Mallampati class			.236			.003
I	34 (27.2)	2 (8.70)		31 (31.3)	5 (10.2)	
II	68 (54.4)	16 (69.6)		55 (55.6)	29 (59.2)	
III	22 (17.6)	5 (21.7)		12 (12.1)	15 (30.6)	
IV	1 (0.80)	0 (0.00)		1 (1.01)	0 (0.00)	
Macroglossia (yes)	25 (19.4)	3(13.0)	.572	25 (19.4)	3 (13.0)	.572
Receding mandible (yes)	18 (14.0)	8 (34.9)	.030	9 (8.91)	17 (33.3)	<.001
Snore (yes)	39 (30.2)	13 (56.5)	.014	26 (25.7)	26 (51.0)	.002
Anticipated DMV (yes)	30 (23.3)	9 (39.1)	.108	17 (16.8)	22 (43.1)	<.001

	Han Score			Warters Score		
Post-NMB	**Same or Worse (n = 145)**	**Better (n = 7)**	***P***	**Same or Worse (n = 111)**	**Better (n = 41)**	***P***
BMI	29.6 (7.99)	31.1 (3.97)	.624	29.1 (7.60)	31.2 (8.42)	.151
Mallampati class			.032			.029
I	34 (24.1)	2 (28.6)		30 (27.8)	6 (15.0)	
II	83 (58.9)	1 (14.3)		63 (58.3)	21 (52.5)	
III	23 (16.3)	4 (57.1)		14 (13.0)	13 (32.5)	
IV	1 (0.71)	0 (0.00)		1 (0.93	0 (0.00)	
Macroglossia (yes)	27 (18.6)	1 (14.3)	1.000	16 (14.4)	12 (29.3)	.036
Receding mandible (yes)	24 (16.6)	2 (28.6)	.343	18 (16.2)	8 (19.5)	.632
Snore (yes)	47 (32.4)	5 (71.4)	.047	37 (33.3)	15 (36.6)	.708
Anticipated DMV (yes)	35 (24.1)	4 (57.1)	.072	23 (20.7)	16 (39.0)	.022

Continuous variables are reported as mean (SD) and categorical variables as n (%). *P* values are for the test of association between patient characteristics with improvement on the Han scale or Warters scale using the Tao compared to the standard mask before and after NMB.

Abbreviations: BMI, body mass index; DMV, difficult mask ventilation; NMB, neuromuscular blockade.