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Sex Disparities in Applied Force on Maxillary Incisors Among Novices During Laryngoscopy Using a High-Fidelity Simulator: A Prospective Observational Study

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Endotracheal intubation (ETI) is a common and crucial intervention. Whether the performance of ETI differs according to the sex of the laryngoscopist remains unclear. The aim of this study was to assess sex disparities in markers of ETI performance among novices using a high-fidelity simulator. This prospective observational study was conducted from April 2017 to March 2019 in a public medical university. In total, 209 medical students (4th and 5th grade) without clinical ETI experience were recruited. Of the 209 students, 64 (30.6%) were female. The participants used either a Macintosh direct laryngoscope or C-MAC video laryngoscope in combination with a stylet or gum-elastic bougie to perform ETI on a high-fidelity simulator. The primary endpoint was the maximum force applied on the maxillary incisors during laryngoscopy. The secondary endpoint was the time to ETI. The implanted sensors in the simulator automatically quantified the force and time to ETI. The maximum force applied on the maxillary incisors was approximately 30% lower in the male than female group for all laryngoscopes and intubation aids examined (all P < 0.001). Similarly, the time to ETI was approximately 10% faster in the male than female group regardless of the types of laryngoscopes and intubation aids used (all P < 0.05). In this study, male sex was associated with a lower maximum force applied on the maxillary incisors during both direct and indirect laryngoscopy performed by novices. A clinical study focusing on sex differences in ETI performance is needed to validate our findings.

INTRODUCTION

Endotracheal intubation (ETI) is a life-saving procedure that is commonly performed in the emergency department and is one of the most essential skills in which emergency physicians must become competent. ETI is also a complex procedure that can be fraught with errors and severe complications including esophageal intubation, hypoxemia, bradycardia, dysrhythmia, upper airway injury, and even cardiac arrest (1, 2). Of these ETI-related adverse events, dental injury and hemodynamic alterations are known to be associated with excess force applied on the oral structures during laryngoscopy (3, 4). Glottic exposure with minimal force is therefore important for safer ETI.

With the continuous increase in the number of females in the medical work force, the need to evaluate sex-related differences in clinical performance has become increasingly important. Previous studies from other fields of medicine have demonstrated that female medical students show higher performance in communication skills and medical interview skills (5), whereas male medical students show higher performance in certain surgical skills and cardiopulmonary resuscitation (6, 7). However, whether ETI performance differs according to the sex of the laryngoscopist remains unclear. Biological differences between females and males might result in differences in ETI performance, especially when performed by inexperienced laryngoscopists. Since junior residents perform more than 30% of ETI procedures in modern emergency departments (1, 4), this clinical question warrants investigation. In addition, if such differences are present, it would be beneficial to consider sex differences when designing future ETI educational programs. We therefore conducted a prospective observational simulation-based study to assess sex disparities in markers of ETI performance by novices.

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MATERIALS AND METHODS

Study design, setting, and participants

This prospective observational simulation-based study was carried out from April 2017 to March 2019 at a public medical university in Japan. After approval by the Institutional Review Board at Fukushima Medical University (no. 2991), we recruited 4th- and 5th-grade medical students who had no clinical experience with ETI. Written informed consent was obtained from each participant. The research protocol conforms to the Declaration of Helsinki.

Devices

The laryngoscopes used in this study were a Macintosh direct laryngoscope (DL) with a No. 3 blade (Smiths Medical; Minneapolis, MN, USA) and a C-MAC video laryngoscope (VL) with a No. 3 blade and monitor (Karl Storz; Tuttlingen, Germany). A Portex® stylet (Smiths Medical) and a gum-elastic bougie (GEB) (Portex® Tracheal Tube Introducer, 15-Fr; Smiths Medical) were used as the intubation aids. Portex® tracheal tubes with an internal diameter of 7.0 mm (Smiths Medical) were lubricated with Airway Lubricant Spray (Laerdal Medical; Stavanger, Norway) before laryngoscopy, and a bag valve mask (Laerdal Medical) was placed within hand's reach of the participant.

Simulator

The forces applied on the maxillary incisors and tongue during ETI attempts were measured using a high-fidelity airway management simulator (Difficult Airway Management Simulator Evaluation System; Kyoto Kagaku; Kyoto, Japan). The implanted sensors in the simulator automatically recorded the forces applied on its incisors and tongue during laryngoscopy. The "normal airway" mode of the simulator without restricted mouth opening and cervical mobility was selected in this study because novices are less likely to perform ETI in patients with a difficult airway. The time to ETI, defined as the time from the first contact with the device until the first successful lung ventilation, was also recorded automatically by the implanted sensors in the simulator.

Simulation scenario and study protocol

One of the investigators (Y.O.) gave a standardized lecture to all participants before they attempted ETI. This included oral instructions on ETI preparation and how to use each device, as well as a demonstration of the intubation technique with each device. For acclimatization, each participant was then allowed to practice achieving one successful ETI with each laryngoscope and airway adjunct on the simulator. After this training session, the simulation study was initiated: each participant was asked to perform ETI on the simulator using the 1) Macintosh DL and stylet, 2) Macintosh DL and GEB, 3) C-MAC VL and stylet, and 4) C-MAC VL and GEB. To mitigate the learning curve effect, the order of the ETI method was randomized for each participant by an online program (Research Randomizer, available at www.randomizer.org).

Outcome measures

The primary endpoint was the maximum applied force on the maxillary incisors during ETI attempts. The secondary endpoints were the maximum applied force on the tongue during ETI attempts and the time to ETI. The participants were also asked to score the glottic view at each intubation attempt using the Cormack–Lehane grading system (8) as grade 1 (most of the glottic opening can be seen), grade 2A (the glottic opening can be partially seen), grade 2B (only the posterior extremity of the glottis or only the arytenoid cartilages are visible), grade 3 (only the epiglottis but no portion of the glottis is visible), or grade 4 (neither the glottis nor the epiglottis can be seen).

Power analysis

Previous studies estimated that the force on the maxillary incisors in a manikin ranged from 0 to 183 N depending on the laryngoscope used, airway adjuncts used, experience of the laryngoscopist, and the degree of difficulty (9–13). These highly diverse data prevent precise sample size estimation in advance. Furthermore, because almost no previous studies have examined sex-related differences in applied forces on the maxillary incisors during laryngoscopy, an a priori estimation of the effect of sex on our primary endpoint was not possible. We therefore decided to use collectable data during the study period.

Statistical analysis

The statistical analysis plan was determined a priori. Differences in continuous variables between the two groups were compared using the Mann–Whitney U test because of the non-normal distribution of the data. Between-group differences in ordinal scales, such as the Cormack–Lehane grades, were also compared using the Mann–Whitney U test. All statistical analyses were performed using GraphPad Prism 9 (GraphPad Software; San Diego, CA, USA). A P value of <0.05 was considered statistically significant.

RESULTS

Study participants

In total, 209 medical students were enrolled in this study (Figure 1). Of these 209 students, 64 (30.6%) were female. All participants received the intended standardized lecture, performed ETI according to the research protocol, and were included in the analysis. The participants' mean age was 23.9 ± 2.2 years in the male group and 23.3 ± 1.4 years in the female group.

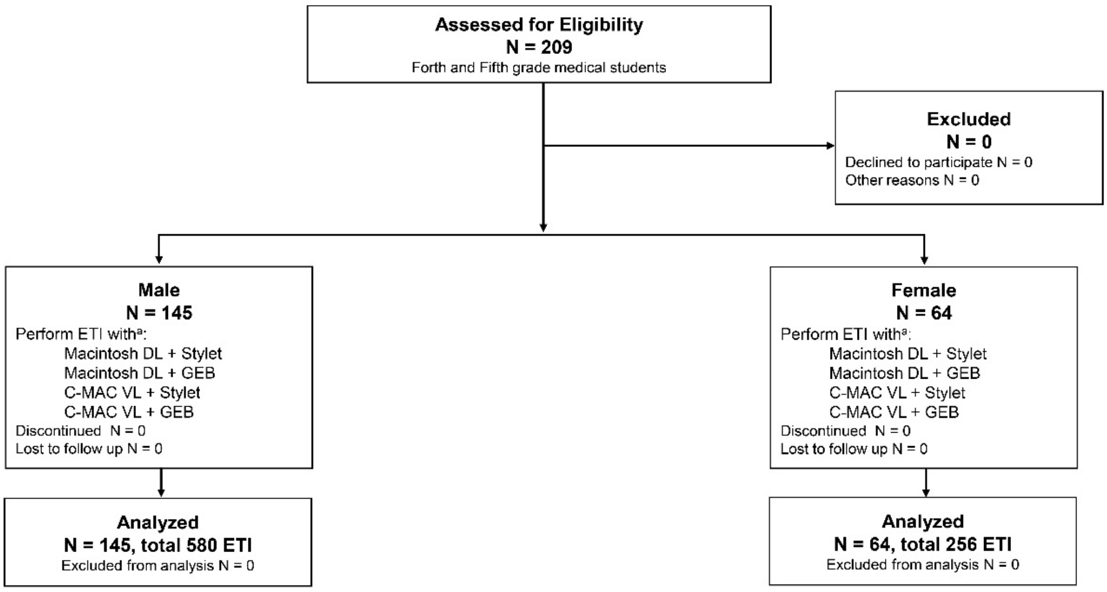

Figure 1. Participant flow diagram

DL, direct laryngoscope; ETI, endotracheal intubation; GEB, gum-elastic bougie; VL,video laryngoscope.

[a]To minimize the learning curve effect, the order of the ETI method was randomized for each participant.

Primary outcome

As shown in Figure 2, the median maximum force applied on the maxillary incisors was approximately 30% lower in the male than female group for all laryngoscopes and intubation aids examined (Macintosh DL + stylet: male 37.0 N vs. female 48.0 N; Macintosh DL + GEB: male 32.0 N vs. female 42.0 N; C-MAC VL + stylet: male 34.0 N vs. female 45.0 N; C-Mac VL + GEB: male 33.0 N vs. female 45.0 N; all $P < 0.001$).

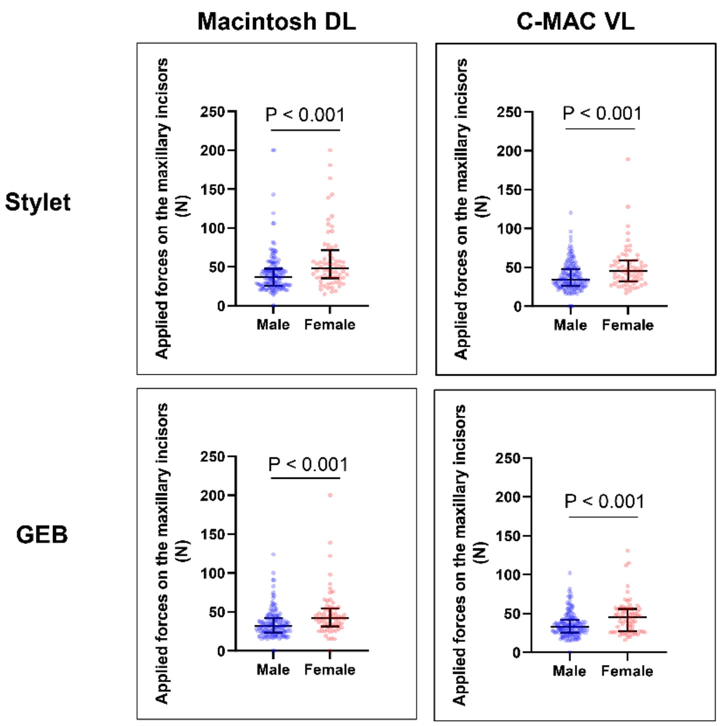

Figure 2. Comparison of maximum applied force on maxillary incisors by sex of the laryngoscopists
The column scatter plots represent the data distribution (circles), median (horizontal bar), and interquartile range (vertical bar). The P values were derived from the Mann–Whitney U test.
Male participants, n = 145; female participants, n = 64.
DL, direct laryngoscope; GEB, gum-elastic bougie; VL, video laryngoscope.

Other outcomes of interests

The force applied on the tongue was similar between the male and female groups, regardless of the types of laryngoscopes and intubation aids used (Figure 3).

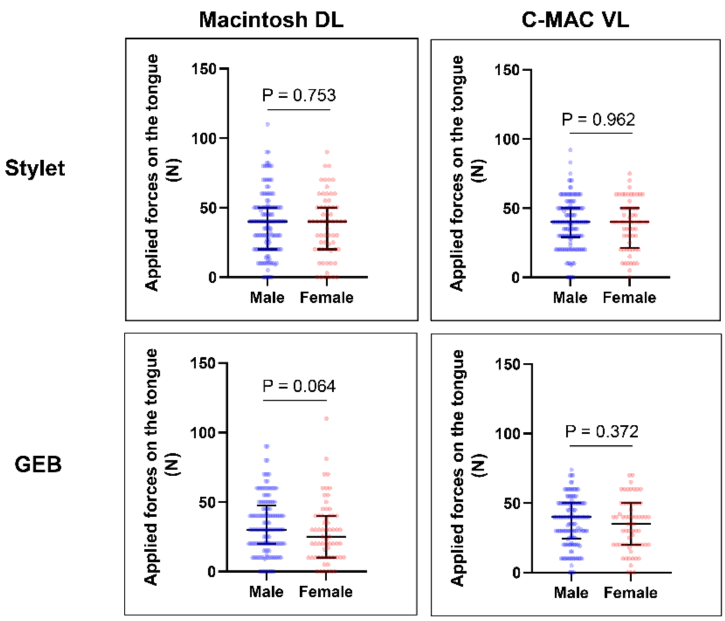

Figure 3. Comparison of maximum applied force on tongue by sex of the laryngoscopists
The column scatter plots represent the data distribution (circles), median (horizontal bar), and interquartile range (vertical bar). The P values were derived from the Mann–Whitney U test.
Male participants, n = 145; female participants, n = 64.
DL, direct laryngoscope; GEB, gum-elastic bougie; VL, video laryngoscope.

The median time to ETI was approximately 10% faster in the male than female group, regardless of the types of laryngoscopes and intubation aids used (Macintosh DL + stylet: male 31.0 s vs. female 35.8 s; Macintosh DL + GEB: male 35.2 s vs. female 42.4 s; C-MAC VL + stylet: male 27.2 s vs. female 30.5 s; C-Mac VL + GEB: male 32.8 s vs. female 36.0 s; all P < 0.05; Figure 4).

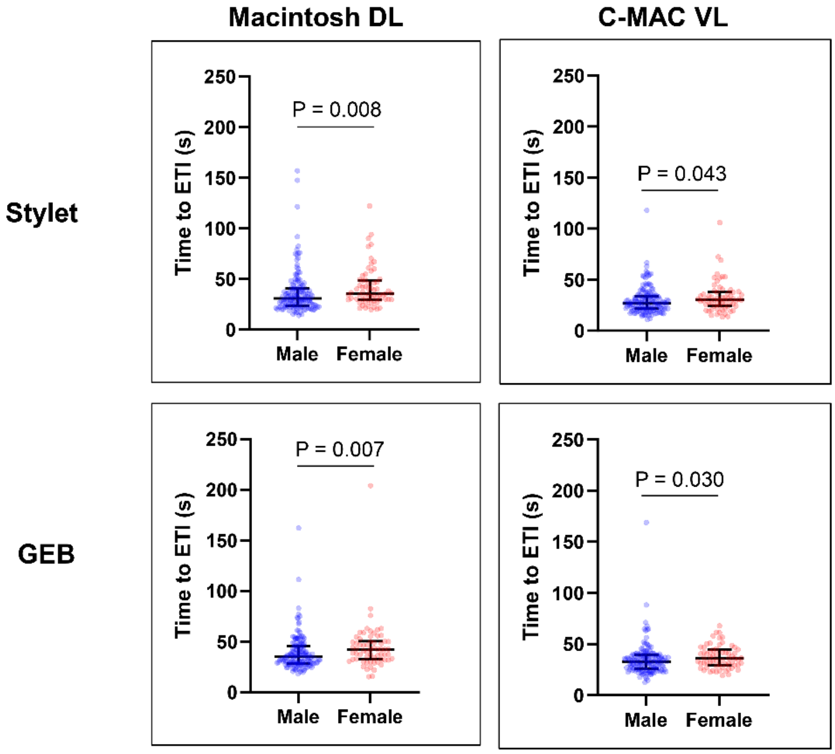

Figure 4. Comparison of time to ETI by sex of the laryngoscopists
The time to ETI was defined as the time from the first contact with the device until the first successful lung ventilation. The column scatter plots represent the data distribution (circles), median (horizontal bar), and interquartile range (vertical bar).
The P values were derived from the Mann–Whitney U test.
Male participants, n = 145; female participants, n = 64.
DL, direct laryngoscope; ETI, endotracheal intubation; GEB, gum-elastic bougie; VL, video laryngoscope.

The distribution of the Cormack–Lehane laryngoscopic views was similar between the male and female groups for all types of laryngoscopes and intubation aids used (Figure 5).

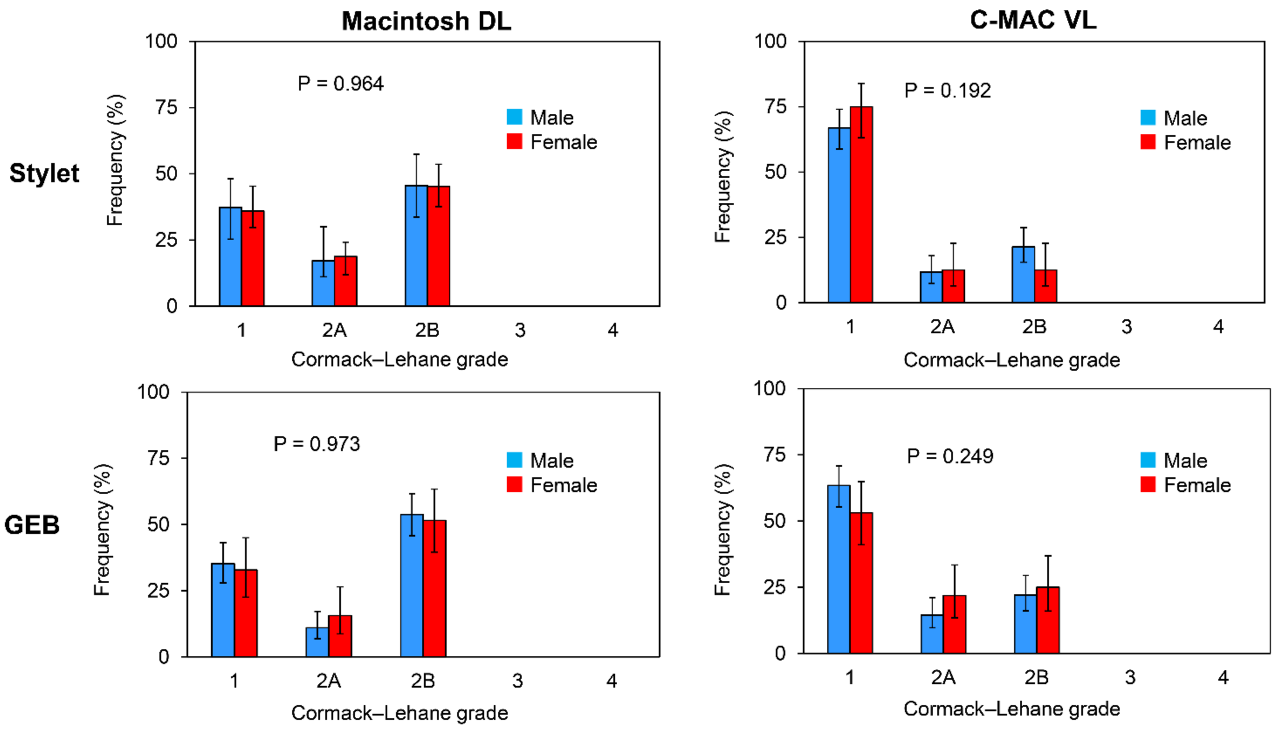

Figure 5. Distribution of Cormack–Lehane laryngoscopic view by sex of the laryngoscopists
Error bar represents the 95% confidence interval.
Male participants, n = 145; female participants, n = 64.
The P values were derived from the Mann–Whitney U test.
DL, direct laryngoscope; GEB, gum-elastic bougie; VL,video laryngoscope.

DISCUSSION

This prospective observational study using a high-fidelity simulator found that male sex was associated with reduced force applied on the maxillary incisors as compared with female counterparts during laryngoscopy both with the Macintosh DL and C-MAC VL and both combined with a stylet and GEB. Male sex was also associated with a 10% faster time to ETI than female sex.

The present study showed that compared with female laryngoscopists, male laryngoscopists could complete ETI with approximately 30% less force applied on the oral structures during both direct and indirect laryngoscopy. Successful laryngoscopy requires a complex interaction of medical knowledge, physical strength, procedural confidence, coordination, and visuospatial awareness (14). Sex-related differences in such parameters are known to exist. For example, males are generally more accurate than females in visuospatial coordination tasks (15), which might result in improved ETI abilities. A previous study showed that male medical students tended to outperform female students in surgical skills, which also require visuospatial coordination (6). To achieve satisfactory glottic exposure, the blade of the laryngoscope must be used to elevate the tongue, mandible, epiglottis, and soft tissue. On average, males are taller, heavier, and physically stronger than females. It is possible that such biological differences mean that males can more easily generate force to lift the tongue, mandible, epiglottis, and soft tissue with lower applied force on the maxillary incisors than their female counterparts until refinement of the technique occurs with increasing experience. Similar results were observed in a previous study that investigated the sex disparities in cardiopulmonary resuscitation performance: compared with female medical students, male medical students were more likely to achieve the appropriate chest compression depth due to the physical strength differences between the sexes (16). In addition, there is also a general trend that male practitioners show higher confidence with procedural skills than their female counterparts. For example, one study showed that male pediatric interns had higher initial confidence in ETI than female interns (17). Self-confidence plays an important role when performing complex medical interventions (18). Although the current study design (observational study) cannot prove causality, we believe that some combination of such differences might have resulted in the observed findings. On the basis of our findings, senior physicians may need to be aware of sex-related differences when supervising ETI performed by novices. As the use of a VL or GEB is known to be associated with decreased force applied on the oral structures during laryngoscopy (11, 12, 19), such intubation aids may be helpful for novices, especially for female novices. Our results also provide a rationale to test the sex-related effects on ETI performance, including the effects on ETI time, applied forces on the oral structures during laryngoscopy, and ETI-related complications in the clinical setting, as recently demonstrated in other fields of medicine (20).

Excess force applied on the oral structures during laryngoscopy can be a risk factor for airway-related adverse events such as dental injury, bradycardia, and dysrhythmia (3, 4). To safely perform ETI, it is important to achieve glottic exposure with minimal force. A previous study showed that the forces generated during ETI of a manikin and a human were similar (21). The mean lifting force during ETI attempts measured by a strain gauge attached to the blade of the laryngoscope was 28.8 N in human patients and 26.6 N on a simulator (21), both of which were comparable to the force recorded in our study. We therefore believe that the approximately 30% difference in force applied on the maxillary incisors between the male and female participants in the present study is clinically meaningful.

This study involved medical students with no clinical ETI experience to prevent bias caused by different levels of ETI experience. However, this limits the generalizability of our results to more experienced laryngoscopists. Future studies should examine whether the sex-related differences in ETI performance detected by this study still exist in more mature and experienced physicians. According to our clinical impression, it is likely that experienced female and male laryngoscopists do not differ in the performance of ETI. However, because less experienced medical professionals such as junior residents commonly perform ETI in the emergency department (1, 4) and operating room, we believe that the clinical implication of our study is still important. Our results suggest that future educational programs designed to teach ETI should consider sex differences.

This study had three major limitations. First, we did not calculate the sample size in advance. As described in the Methods section, a priori estimation of precise sample size was not possible because of disparities with previous data (9–13). However, the post hoc power calculation demonstrated that the power of our study was sufficient (power >0.90) for the primary outcome examined. We believe that our study can be used in effect size estimation for future clinical studies.

Second, as with any simulation-based study, it may not be possible to extrapolate our findings to clinical settings. In real-world settings, several factors may interrupt ETI attempts (e.g., overwhelming stress in living patients, a noisy and uncontrolled environment, secretions and bleeding), but such factors could not be replicated in this simulation study. Our findings therefore require confirmation in a future clinical study. However, it is difficult to quantitatively measure the force applied on the oral structures during ETI, especially when supervising novices. Before performing direct clinical evaluations, we must first validate our clinical question using the simulator.

Third, the outcome assessments were not blinded. Since the same researchers were involved in study planning, data collection, outcome measurement, and statistical analysis, there is a theoretical risk of biased assessment. However, all primary and secondary outcomes except for the glottic view were automatically quantified by the implanted sensor in the simulator. This objective measurement system mitigates this concern.

Despite these limitations, our findings are the first to demonstrate the association between sex differences and the force applied on the oral structures during laryngoscopy. Our data should stimulate further studies to clarify sex-related differences in airway management. Future efforts should be made to identify ways to dissolve the observed differences between the sexes.

In conclusion, this prospective observational study using a high-fidelity simulator found that male sex was associated with lower maximum force applied on the maxillary incisors during both direct and indirect laryngoscopy performed by novices. A clinical study focusing on sex-related differences in ETI performance is needed to validate our findings. For better ETI education, the supervisors may need to consider sex differences.

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