

Comparison of direct and indirect epiglottis lifting techniques using the McGRATH TM MAC video laryngoscope on the incidence of intubation-related complications: a randomized controlled trial

Aki Hirai

Wakayama Medical University School of Medicine

Hirotsugu Kanda

hkanda@wakayama-med.ac.jp

Wakayama Medical University School of Medicine

Akihiro Suzuki

Jichi Medical University

Tanat Chotijarumaneewong

Jichi Medical University

Tomoyuki Kawamata

Wakayama Medical University School of Medicine

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Abstract

Background:

During video laryngoscopy (VL), the epiglottis can be lifted either indirectly from the vallecula or directly by placing the blade beneath it. Although direct lifting improves vocal cord visualization, whether these techniques differ in intubation-related complications remains unclear. This multicenter randomized controlled trial investigated whether direct epiglottis lifting using the McGrath™ MAC VL increases intubation-related complications compared with indirect lifting.

Methods:

This multicenter, open-label, randomized controlled trial was conducted at two hospitals. Adult patients scheduled for elective surgery requiring tracheal intubation were screened; after exclusion of 96 patients, 938 were randomized to direct (n = 464) or indirect lifting (n = 474). The modified intention-to-treat population comprised 899 patients (direct, n = 445; indirect, n = 454). The primary outcome was a composite of hoarseness, postoperative sore throat, hypoxemia, aspiration, dental injury, and epiglottal displacement. Secondary outcomes included individual complications, intubation conditions, and hemodynamic responses. Subgroup analyses by anesthesiologist experience were performed.

Results:

The primary composite outcome did not differ between groups (direct 42.9% vs. indirect 41.9%; $P = 0.787$). Individual complications were comparable. Epiglottal displacement occurred exclusively in the direct group (4.5% vs. 0%). External laryngeal manipulation (backward upward rightward pressure [BURP]) was required less frequently in the direct group (6.3% vs. 10.4%; $P = 0.030$). Intubation conditions and hemodynamic responses did not differ between groups. Subgroup analysis showed no significant differences in the primary composite outcome across experience groups.

Conclusion:

Direct and indirect epiglottis lifting did not differ in intubation-related complications. Direct epiglottis lifting reduced the need for BURP. However, epiglottal displacement occurred exclusively with direct lifting.

Trial registration

UMIN Clinical Trials Registry (Registration No UMIN000055803).

Introduction

Video laryngoscopes (VLs) enable visualization of the vocal cords without requiring alignment of the oral, pharyngeal, and laryngeal axes. VLs have improved intubation success rates [1] and reduced intubation-related airway trauma [2] compared with conventional direct laryngoscopes. Additionally, VLs tend to attenuate hemodynamic responses during laryngoscopy compared with conventional direct laryngoscopes. [3] Different VLs have similar performance regarding intubation time and intubation success rates in comparative studies. [4] Recent clinical evidence and updated airway guidelines increasingly suggest that VLs should be considered a first-line approach to facilitate tracheal intubation in both routine and difficult airway management. [5]

Two techniques are used to lift the epiglottis during VL-assisted intubation: indirect epiglottis lifting, in which the tip of the blade is positioned in the vallecula to elevate the epiglottis, and direct epiglottis lifting, in which the tip of the blade is positioned beneath the epiglottis to directly elevate it. Although a previous study demonstrated that direct epiglottis lifting significantly improved vocal cord visualization compared with indirect epiglottis lifting using the AceScope™ (Acemedical Co., Seoul, Korea), [6] it remains unclear whether the two techniques differ in the incidence of intubation-related complications during VL-assisted intubation. Intubation-related complications may include dental trauma, [7, 8] hypoxemia, [8] and soft tissue injury. [7] Additionally, increasing attention has been directed to epiglottal displacement (i.e., epiglottic folding, downfolding, or prolapse) caused by the laryngoscope blade. [9–12] The McGRATH™ MAC VL (Medtronic, Minneapolis, MN, USA) has been extensively evaluated. [13, 14] Therefore, we performed an open-label, randomized controlled trial to compare the overall incidence of intubation-related complications between direct and indirect epiglottis lifting using the McGRATH™ MAC VL. We hypothesized that direct epiglottis lifting, because it involves direct manipulation of the epiglottis, would be associated with a higher incidence of intubation-related complications than indirect epiglottis lifting.

Materials and Methods

Study Design

The open-label, prospective superiority, parallel-group randomized controlled trial was performed at two hospitals, Wakayama Medical University Hospital and Jichi Medical University Hospital from December 2024 to May 2025. Ethical approval was obtained from the Ethics Committee of Wakayama Medical University Hospital (No. 4257) and Jichi Medical University Hospital (No. J 24-050). The study protocol was registered in the University Hospital Medical Information Network Clinical Trials Registry and contact information to request the full-text clinical trial information is available (UMIN000055803, principal investigator: Aki Hirai; first posted October 10, 2024). This manuscript adheres to the applicable Consolidated Standards of Reporting Trials (CONSORT) guidelines (Fig. 1). No changes to the trial protocol were made after trial commencement. The trial protocol and the pre-specified statistical analysis plans were approved by our institutional ethics review board and are documented in the

IRB-approved study protocol. These documents are available from the corresponding author upon reasonable request. Patients or members of the public were not involved in the design, conduct, reporting, or dissemination plans of this trial.

Patients and Randomization

Patients were screened for potential enrollment. In accordance with the study protocol, the inclusion criteria were as follows: (1) age $\geq$ 18 years; (2) scheduled to receive general anesthesia for elective surgery; (3) American Society of Anesthesiologists physical status class I–III; (4) ability to understand the study and provide written informed consent; and (5) planned oral endotracheal intubation. Participants were excluded if they met any of the following criteria: (1) suspected difficult intubation or difficult mask ventilation, as determined by the anesthesiologist's overall clinical assessment; (2) cervical spondylosis; (3) gastroesophageal reflux disease; (4) epiglottic cysts; and (5) body mass index $> 35 \text{ kg/m}^2$. After obtaining written informed consent, patients were randomly allocated into the direct epiglottis lifting group (the direct group) or the indirect epiglottis lifting group (the indirect group) on the basis of the epiglottis lifting technique, using a computer-generated permuted block randomization sequence (variable block size with 1:1 allocation). The random allocation sequence was generated by an independent statistician (K.W.). Allocation was performed using a web-based central randomization system. The enrolling anesthesiologist accessed the system to obtain the group assignment only after confirming patient eligibility and obtaining written informed consent, ensuring that neither the enrolling nor the allocating personnel had prior access to the allocation sequence.

Intervention

The physicians who performed tracheal intubation in this study comprised board-certified anesthesiologists, anesthesiology fellows (with > 1 year of clinical experience in anesthesiology), and anesthesiology residents (2-6 months of clinical experience in anesthesiology). Anesthesiology residents performed tracheal intubation under the supervision of a board-certified anesthesiologist. All physicians also practiced both direct and indirect epiglottis lifting with the McGRATH™ MAC VL using tracheal intubation manikins beforehand.

Protocol

For each patient undergoing anesthesia, a preoperative airway assessment was performed in addition to standard history taking and physical examination. The airway assessment comprised the Mallampati classification (class I - IV), maximum mouth opening (cm), thyromental distance (cm), and the presence of edentulism, snoring, or sleep apnea syndrome. Monitors during general anesthesia comprised electrocardiography, noninvasive blood pressure, invasive blood pressure, percutaneous oxygen saturation, processed EEG monitoring, neuromuscular monitoring and capnography. Patients were placed supine with the head in a neutral position; head elevation and ramping were per the anesthesiologist's preference. After preoxygenation (100% oxygen, 6 L/min) until expired oxygen concentration reached $\geq 80\%$, remifentanyl (0.1-0.3 $\mu\text{g/kg/min}$) or fentanyl (1-2 $\mu\text{g/kg}$), followed

by propofol (1 - 2 mg/kg) and rocuronium (0.6 mg/kg, with additional doses if needed) after loss of consciousness. Once the train-of-four ratio reached 0, the vocal cords were visualized using the allocated epiglottis lifting technique and the trachea was orally intubated; BURP was applied as determined at the discretion of the intubator if the glottis was inadequately visualized. Tube size (internal diameter) was 7.0 - 7.5 mm for female and 7.5 - 8.0 mm for male patients, with a malleable stylet shaped into the standard two-curve configuration. [15] Successful intubation was defined by confirmation of an end-tidal carbon dioxide waveform on capnography, and cuff pressure was set at 20 - 30 cmH₂O. A failed first attempt was followed by a second attempt after 1 minute of face-mask oxygenation. Patients were followed for intubation-related adverse events for 24 hours after extubation.

Outcome Measures

The primary outcome was the incidence of a composite of intubation-related complications, comprising hoarseness, postoperative sore throat, hypoxemia, aspiration, dental injury, and epiglottal displacement. The composite endpoint was selected to provide an overall assessment of the safety of tracheal intubation by capturing postoperative upper-airway symptoms, structural or mechanical injury, and peri-intubation respiratory complications. [9, 16, 17] The presence of hoarseness and postoperative sore throat were evaluated the day after surgery by an observer who was blinded to the epiglottis lifting technique during tracheal intubation. Hoarseness was assessed using a clinically based 4-point ordinal scale adapted from a previous study investigating postoperative laryngeal morbidity using the McGrath™ MAC VL after tracheal intubation. [18] Scores were defined as follows: 0 = none, 1 = patient complaint, 2 = objectively hoarse, and 3 = loss of voice. A score ≥ 1 was considered indicative of postoperative hoarseness. The intensity of postoperative sore throat was rated on a numerical rating scale from 0 to 10 (0: no sore throat, 10: worst pain imaginable), with a score ≥ 1 defining a sore throat. Hypoxemia was defined as percutaneous oxygen saturation < 90% during intubation. Aspiration was defined as visible gastric or oropharyngeal contents in the pharynx during intubation on the basis of the clinical findings. Dental injury was defined as any new tooth or dental prosthesis damage attributable to intubation assessed immediately after orotracheal intubation. Epiglottal displacement, also referred to as epiglottic inversion, downward displacement, or prolapse, is an unexpected complication that can occur during tracheal intubation or the insertion of supraglottic airway devices. [9] We categorized epiglottal displacement into the following four distinct types: [9] Grade 0 represents the normal condition. Grade 1 is characterized by lateral displacement, which may occur in either direction. Grade 2 indicates partial folding; a portion of the epiglottis is visible. Grade 3 denotes complete folding. Epiglottal displacement was evaluated during and after tracheal intubation, and Grade 1–3 indicated a complication. When epiglottal displacement occurred during blade insertion, the blade was repositioned by placing its tip into the vallecula to restore the epiglottis to its normal anatomical position and achieve adequate glottic exposure.[11] When epiglottal displacement occurred during tracheal tube advancement, the tube was withdrawn and reinserted after correction of the epiglottal position. Because a single patient could experience more than one component of the composite primary outcome, each patient was classified according to the presence or absence of the composite outcome, defined as the

occurrence of at least one of its component events; patients were not counted more than once regardless of how many components they experienced. The same presence/absence approach was applied to each individual component when analyzed separately.

Secondary outcomes comprised the incidence of each component of the primary composite outcome, the incidence of BURP, the first-pass success rate of tracheal intubation, time to successful tracheal intubation (defined as the time from discontinuation of oxygen administration to confirmation of an end-tidal carbon dioxide waveform on capnography), the number of intubation attempts until success, and hemodynamic variability at 1 minute after intubation. Regarding the number of intubation attempts, a single attempt was defined as the interval from laryngoscope insertion in the pharynx until either successful tracheal intubation or withdrawal of the laryngoscope from the pharynx following a failed attempt. Hemodynamic variability was defined as the changes in systolic blood pressure, mean blood pressure, and heart rate between the values recorded immediately before the start of intubation and those recorded 1 minute after successful tracheal intubation.

Sample Size Calculation

Because no reliable estimate of the overall incidence of the prespecified composite of intubation-related complications was available, the sample size was calculated using postoperative hoarseness as a representative and relatively frequent component of the composite outcome. Assuming a two-sided significance level of 0.05, a power of 80%, and reported incidences of hoarseness of 12.9% and 20.0%, [19] a minimum of 365 patients per group was required. Because a composite outcome defined by the occurrence of any of its components would be expected to occur at least as frequently as an individual component, this sample size was considered conservative with respect to the anticipated overall event frequency. Allowing for an anticipated dropout rate of approximately 5%, the target enrollment was set at 400 patients per group. No interim analyses or stopping rules were prespecified.

Statistical Analysis

Patient background data are presented as median [interquartile range], since normality (Shapiro-Wilk test) was not met, or as frequency and percentage for nominal variables. Categorical variables, including the primary endpoint, were compared using Fisher's exact test; continuous variables were compared using the Wilcoxon rank-sum (Mann-Whitney U) test.

The primary analysis was conducted in the modified intention-to-treat (mITT) population (all randomized patients with available primary outcome data; no imputation for missing data); a per-protocol set (PPS) analysis excluding major protocol violations served as a sensitivity analysis. Odds ratios with 95% confidence intervals were calculated for categorical outcomes; the Haldane-Anscombe correction (adding 0.5 to each cell) was applied where zero-cell counts occurred (hypoxemia, epiglottal displacement). A prespecified subgroup analysis stratified by anesthesiologist experience, selecting a priori as a clinically relevant intubator-related factor, was conducted to explore its impact on the primary outcome. A prespecified interaction test between anesthesiologist experience and lifting technique was

also performed to assess whether the effect of the lifting technique on the primary outcome varied across experience groups.

A two-sided significance level of 0.05 was used, and all analyses were performed using JMP Pro version 18.0.0 (SAS Institute Inc., Cary, NC, USA), according to the prespecified statistical analysis plan. De-identified data and analysis code are available from the corresponding author upon reasonable request.

Results

From December 2024 to May 2025, we assessed 1034 patients for eligibility, of whom 938 (90.7%) eligible patients were randomly allocated to the direct group (n = 464) or indirect group (n = 474). A CONSORT flow diagram is presented in Fig. 1. During follow-up, 19 patients in the direct group and 20 patients in the indirect group were excluded due to unavailability of primary outcome data, resulting in 899 patients (direct, n = 445; indirect, n = 454) included in the mITT population for the primary analysis. Subsequently, 13 patients in the direct group and 7 in the indirect group were excluded from the mITT population due to protocol deviations, leaving 879 patients (n = 432 in the direct group and n = 447 in the indirect group) in the per-protocol set (PPS), which was analyzed as a sensitivity analysis. Overall, 703 patients (351 in the direct group and 352 in the indirect group) were enrolled from Wakayama Medical University Hospital and 196 patients (94 in the direct group and 102 in the indirect group) were enrolled from Jichi Medical University Hospital. The ratios of group allocation were comparable between the two hospitals, and there were no significant differences in the patients' demographic data between the groups (Table 1). Surgical procedures and patient positioning, with other intraoperative and perioperative variables that are suggested to be associated with postoperative throat symptoms, [18–21] are summarized in Supplemental Digital Content¹. PPS analysis of the patients' demographic data demonstrated no significant differences between the groups similar to the mITT analysis (Supplemental Digital Content 2).

Table 1

Comparison of demographic data and airway-related variables between the two epiglottis lifting groups

Characteristic	Direct lifting method (n = 445)	Indirect lifting method (n = 454)	P value
Physician			0.447
Resident	122 (27.4%)	140 (30.8%)	
Fellow	184 (41.4%)	186 (41.0%)	
Board-certified anesthesiologist	139 (31.2%)	128 (28.2%)	
Age (y)	68 (55–76)	67 (53–76)	0.486
Sex			0.205
Male	223 (50.1%)	208 (45.8%)	
Female	222 (49.9%)	246 (54.2%)	
Height (cm)	160.8 (153.5–168)	159.9 (153.4–166.6)	0.188
Weight (kg)	61.6 (52–69.2)	60.8 (53.1–69.9)	0.853
BMI (kg/m²)	23.4 (20.9–26.0)	23.5 (21.1–26.7)	0.262
ASA classification			0.388
I/II/III	48 (10.8%)/351 (78.9%)/46 (10.3%)	50 (11.0%)/369 (81.3%)/35(7.7%)	
Airway evaluations			
Mallampati class	200 (45.2%)/190 (42.9%)/	208 (45.8%)/196 (43.2%)/	0.974
1/2/3/4	44 (9.9%)/9 (2.0%)	41 (9.0%)/9 (2.0%)	
Maximum mouth opening (cm)	4.8 (4–5.5)	4.8 (4–5.5)	0.662
Thyromental distance (cm)	7.5 (6.8–8)	7.3 (6.9–8)	0.603
Presence of edentulism	115 (25.9%)	112 (24.7%)	0.701
Snoring	160 (36.0%)	140 (30.8%)	0.104
SAS	41 (9.2%)	36 (7.9%)	0.552
Data are expressed as number (%) or median (interquartile range).			
mITT: modified intention-to-treat (primary analysis).			
BMI: body mass index, ASA: American Society of Anesthesiologists, SAS: sleep apnea syndrome			

Primary Outcome

The incidence of the composite of intubation-related complications did not differ significantly between the groups, with 42.9% in the direct group and 41.9% in the indirect group (odds ratio: 1.04, 95% confidence interval: 0.80–1.36; absolute risk difference: +1.1%, 95% CI: –5.4% to +7.5%; $P = 0.787$) (Table 2). PPS analysis was consistent (Supplemental Digital Content 3).

Table 2
Primary outcome

Outcomes	Direct lifting method (n = 445)	Indirect lifting method (n = 454)	Direct vs Indirect OR (95% CI)	Direct vs Indirect ARD (95% CI)	P value
Incidence of the composite of intubation-related complications	191 (42.9%)	190 (41.9%)	1.04 (0.80– 1.36)	+ 1.1% (– 5.4% to + 7.5%)	0.787
Data are expressed as number (%). OR: odds ratio, CI: confidence interval; ARD: absolute risk difference (Direct minus Indirect). ARD 95% CI calculated using normal approximation.					
mITT: modified intention-to-treat (primary analysis).					

Secondary Outcomes

The incidences of other components of the primary outcome, namely hoarseness, sore throat, hypoxemia, aspiration, and dental injury, did not differ between the two groups (Table 3). The median sore throat score was 0 in both groups, indicating minimal severity. Epiglottal displacement occurred in 20 patients (4.5%) in the direct group (Grade 1: 10; Grade 2: 7; Grade 3: 3) and in none in the indirect group. Regarding intubation conditions, time to successful tracheal intubation and number of intubation attempts until success were comparable between the lifting groups. The incidence of BURP was lower in the direct group than in the indirect group (6.3% vs. 10.4%; $P = 0.030$) (Table 4). Hemodynamic changes associated with the intubation procedure were also comparable between the two groups (Table 4). Similarly, PPS analyses were consistent (Supplemental Digital Content 4 and 5).

Table 3
Secondary outcomes-1: each component of the primary outcome

Outcomes	Direct lifting method (n = 445)	Indirect lifting method (n = 454)	Direct vs Indirect OR (95% CI)	Direct vs Indirect ARD (95% CI)	P value
Hoarseness Score ≥ 1	114 (25.6%)	116 (25.5%)	1.00 (0.74–1.35)	+ 0.1% (– 5.6% to + 5.8%)	1.00
=0	331 (74.4%)	338 (74.5%)			
=1	79 (17.8%)	90 (19.8%)			
=2	35 (7.9%)	26 (5.7%)			
=3	0 (0%)	0 (0%)			
Sore throat NRS ≥ 1	120 (27.0%)	119 (26.2%)	1.04 (0.77–1.40)	+ 0.8% (– 5.0% to + 6.5%)	0.821
Median NRS	0 (0–1)	0 (0–1)			0.816
Hypoxemia	0 (0%)	2 (0.44%)	0.203 (0.010–4.243) *	–0.4% (– 1.1% to + 0.2%)	0.500
Aspiration	0 (0%)	0 (0%)	N/A	N/A	1.00
Dental injury	0 (0%)	0 (0%)	N/A	N/A	1.00
Epiglottal displacement ≥ 1	20 (4.5%)	0 (0%)	43.794 (2.640–726.383) *	+ 4.5% (+ 2.6% to + 6.4%)	< 0.0001
=0	425 (95.5%)	454 (100%)			
=1	10 (2.2%)	0 (0%)			
=2	7 (1.6%)	0 (0%)			
=3	3 (0.7%)	0 (0%)			
Data are expressed as number (%) or median (interquartile range). OR: odds ratio, CI: confidence interval; ARD: absolute risk difference (Direct minus Indirect); NRS: numerical rating scale. ARD 95% CI calculated using normal approximation.					
mITT: modified intention-to-treat (primary analysis). *Haldane–Anscombe correction.					

Table 4
Secondary outcomes-2: intubation conditions and hemodynamic changes

Outcomes	Direct lifting method (n = 445)	Indirect lifting method (n = 454)	Direct vs Indirect OR (95% CI)	Direct vs Indirect ARD (95% CI)	P value
Intubation conditions					
Intubation time (seconds)	48 (37–62)	46 (37–58)			0.282
Number of intubation attempts until success	One: 428 (96.2%) Two: 15 (3.4%) Three: 2 (0.4%)	One: 446 (98.2%) Two: 7 (1.5%) Three: 1 (0.2%)			0.172
BURP (%)	28 (6.3%)	47 (10.4%)	0.58 (0.36–0.95)	–4.1% (– 7.7% to – 0.5%)	0.030
Hemodynamic changes					
Changes in Heart rate (beats/min)	+ 8 (1–18)	+ 6.5 (0–16)			0.172
Changes in sBP (mmHg)	+ 13 (0–29)	+ 12 (– 1–25.3)			0.152
Changes in dBP (mmHg)	+ 9 (– 1–21)	+ 7 (– 1–19)			0.111
Changes in mBP (mmHg)	+ 10.7 (0–23.3)	+ 8.7 (– 0.3–20.7)			0.113
Data are expressed as number (%) or median (interquartile range). OR: odds ratio, CI: confidence interval; ARD: absolute risk difference (Direct minus Indirect). ARD 95% CI calculated using normal approximation.					
BURP: backward upward rightward pressure. mITT: modified intention-to-treat (primary analysis)					

Subgroup analysis

Subgroup analysis stratified by anesthesiologist experience revealed no statistically significant differences in the primary composite outcome within any experience group (Table 5). However, the prespecified interaction test showed that the effect of lifting technique on the primary outcome differed

significantly according to anesthesiologist experience (P for interaction = 0.025; Table 5), and PPS analysis was consistent (Supplemental Digital Content 6).

Table 5
Subgroup analysis of the incidence of the primary outcome by resident, fellow, and board-certified anesthesiologist

Variable	Direct lifting method (n = 445)	Indirect lifting method (n = 454)	Direct vs Indirect OR (95% CI)	Direct vs Indirect ARD (95% CI)	P value	P for interaction
Resident	59/122 (48.4%)	52/140 (37.1%)	1.58 (0.97– 2.60)	+ 11.2% (– 0.7% to + 23.2%)	0.080	0.025
Fellow	61/184 (33.2%)	79/186 (42.5%)	0.67 (0.44– 1.03)	–9.3% (– 19.2% to + 0.5%)	0.069	
Board- certified	71/139 (51.1%)	59/128 (46.1%)	1.22 (0.75– 1.98)	+ 5.0% (– 7.0% to + 17.0%)	0.463	
OR: odds ratio, CI: confidence interval; ARD: absolute risk difference (Direct minus Indirect). ARD 95% CI calculated using normal approximation. mITT: modified intention-to-treat (primary analysis).						

Discussion

The principal finding of the present study is that the incidence of a composite of intubation-related complications did not differ between indirect and direct epiglottis lifting techniques.

Primary outcome and its components

Because individual complications alone may not fully reflect the overall clinical impact of airway manipulation, a composite endpoint comprising clinically relevant airway-related events was prespecified to provide a comprehensive assessment of intubation-related safety, consistent with previous airway studies using composite intubation-related outcomes. [16, 17] Contrary to our initial hypothesis, the composite incidence of hoarseness, sore throat, hypoxemia, aspiration, dental injury, and epiglottal displacement was approximately 42% in both groups. Although this approach captured a broad range of intubation-related adverse events and increased the overall event frequency compared with evaluating uncommon complications individually, the composite outcome was largely driven by the relatively frequent symptoms of hoarseness and sore throat. In contrast, epiglottal displacement occurred less frequently and exclusively in the direct lifting group. Therefore, the absence of a significant

difference in the composite outcome should not be interpreted as indicating equivalent risks for each individual complication.

Postoperative hoarseness and sore throat were the most frequent components of the composite outcome and were generally mild. The reported incidence of postoperative sore throat after tracheal intubation ranges widely from 12.1% to 70% [22–25], and previous studies using indirect epiglottis lifting with the McGRATH™ MAC VL have reported rates of approximately 20%. [18] Similarly, post-intubation hoarseness has been reported in 15.9%–55% of patients. [26–28] The incidences observed in the present study (hoarseness: 25.5% in both groups; sore throat: 26.4% and 25.7% in the direct and indirect groups, respectively) were within these reported ranges. Postoperative throat symptoms may be influenced by multiple factors, including mechanical irritation by the tracheal tube, mucosal ischemia, cuff pressure, and duration of vocal cord exposure, [29] in addition to the epiglottis lifting technique itself.

Potentially serious intubation-related complications, including hypoxemia, aspiration, and dental injury, were uncommon and did not differ significantly between the two groups. Hypoxemia occurred in only two patients. Considering that the intubators included anesthesiologists with varying levels of experience, including residents, the low incidence of these events suggests that serious peri-intubation complications were uncommon with either technique under elective, controlled conditions.

Epiglottal displacement occurred exclusively in the direct epiglottis lifting group, with an incidence of 4.5%. Although its clinical significance remains uncertain, it should be recognized as a potential technique-specific adverse event associated with direct epiglottis lifting. Epiglottic folding was carefully assessed and promptly corrected when identified; however, if left uncorrected, it may lead to ischemia and swelling of the epiglottis, [30] potentially resulting in airway obstruction. [31, 32] When using the direct lifting technique, the epiglottis should be lifted from the dorsal side to prevent downfolding. [11] Therefore, careful observation of the epiglottis during intubation and confirmation of its normal position during laryngoscope withdrawal are warranted when direct lifting is used. [9]

Clinical implications of direct epiglottis lifting technique

Regarding intubation conditions, the time to successful intubation and number of intubation attempts were similar between the two lifting techniques. Notably, the need for BURP was significantly lower with the direct lifting technique compared to the indirect lifting technique, suggesting that the direct lifting technique improved glottic visualization, consistent with a previous report. [6] This potential advantage in laryngeal exposure may be clinically beneficial in situations requiring optimization of the glottic view. An interaction between anesthesiologist experience and lifting technique was observed in the subgroup analysis; however, no statistically significant difference between techniques was observed within any individual experience group. Therefore, this finding should be interpreted cautiously and considered exploratory and hypothesis-generating. Taken together, the direct epiglottis lifting technique may provide better glottic visualization without an apparent increase in overall intubation-related complications.

However, attention should be paid to epiglottal displacement, as it was the only component that differed between the two techniques.

Limitations

The present study has several limitations. First, this trial was not designed as an equivalence or noninferiority study; therefore, the absence of a statistically significant difference should not be interpreted as evidence of equivalence. Second, the composite primary outcome included events with differing frequencies, clinical importance, and mechanistic relationships to the lifting technique, and the sample size was based on postoperative hoarseness rather than the composite outcome itself. Third, all intubations were performed under elective, controlled conditions, limiting generalizability to emergency settings or patients with impaired visualization. Fourth, patients with anticipated difficult airways were excluded. Finally, anesthesiologists were not blinded to the lifting technique, potentially introducing performance bias.

Conclusion

In conclusion, no significant difference was observed in the composite incidence of intubation-related complications between direct and indirect epiglottis lifting using the McGRATH™ MAC VL. Direct lifting required less frequent BURP but was associated with epiglottal displacement, warranting careful confirmation of epiglottic position when this technique is used.

Abbreviations

BURP, backward upward rightward pressure

CONSORT, Consolidated Standards of Reporting Trials

VL, video laryngoscope

Declarations

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Declaration of Interest:

The authors declare no conflicts of interest.

Authors' contributions:

AH and HK designed and conducted the research. AH performed the data collection and analysis and wrote the manuscript. HK had primary responsibility for the final content. HK, AS, and TC critically reviewed the manuscript and provided feedback on each subsequent version. TK supervised the study and wrote, reviewed, and edited the manuscript. All authors read and approved of the final manuscript.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Wakayama Medical University Hospital (No. 4257) and Jichi Medical University Hospital (No. J 24-050). Written informed consent was obtained from all participants before enrollment. All procedures were performed in accordance with relevant guidelines and regulations, including the Declaration of Helsinki.

Availability of data and materials

De-identified participant data, the statistical analysis code, and additional study materials are available from the corresponding author upon reasonable request.

Consent for publication

Not Applicable.

Clinical trial registration number: UMIN000055803

https://center6.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000063783

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Data Availability: De-identified participant data, the statistical analysis code, and additional study materials are available from the corresponding author (H.K.; hkanda@wakayama-med.ac.jp) upon reasonable request.

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Figures

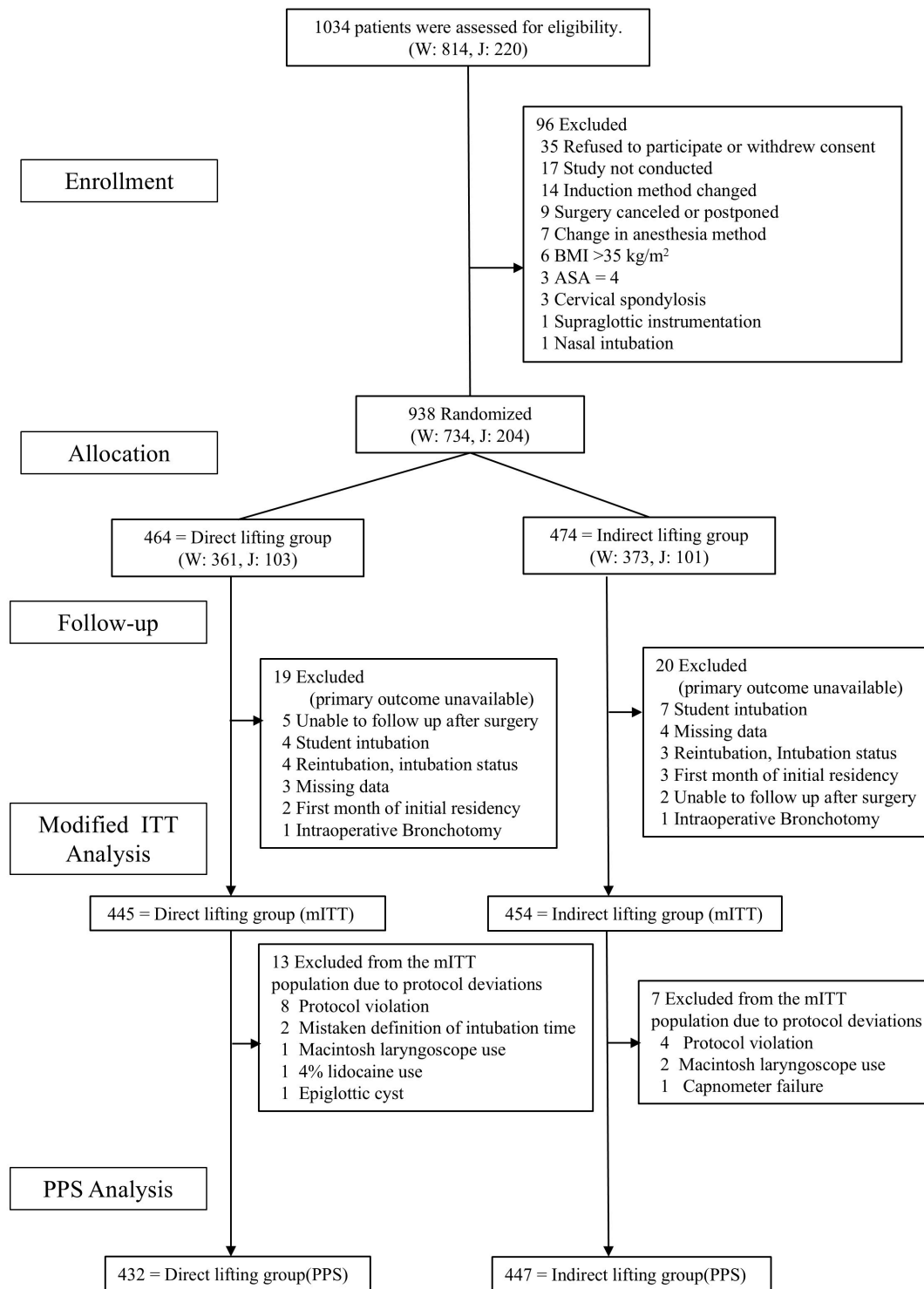


Figure 1

CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

W: Wakayama Medical University, J: Jichi Medical University, BMI: body mass index, ASA: American Society of Anesthesiologists

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