Research Square

Preprints are preliminary reports that have not undergone peer review.
They should not be considered conclusive, used to inform clinical practice,
or referenced by the media as validated information.

C-MAC videolaryngoscope-guided versus standard digital insertion of the ProSeal™ laryngeal mask airway: a randomised controlled trial comparing the D-blade and Macintosh blade

Chonchaya Tangnopphapaton
Chulalongkorn University
Narathip Toosakul
Chulalongkorn University
Kornkamon Yuwapattanawong
kornkamon.y@chula.ac.th

Chulalongkorn University

Research Article

Keywords: Laryngeal mask airway, ProSeal, Videolaryngoscopy, C-MAC, D-blade, Fibreoptic assessment, Randomised controlled trial

Posted Date: November 26th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-11439670/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License

Additional Declarations: No competing interests reported.

Abstract

Background

The ProSeal™ laryngeal mask airway (LMA) is frequently malpositioned when inserted using the standard digital technique. Videolaryngoscopic guidance may improve positioning, but the most suitable blade is unknown. We compared ProSeal LMA positioning after C-MAC videolaryngoscope-guided insertion with a D-blade or a size 3 Macintosh blade with that after standard digital insertion.

Methods

In this single-centre, three-arm, parallel-group randomised controlled trial, 150 adults with American Society of Anesthesiologists physical status I or II undergoing elective surgery were randomly allocated (1:1:1) to ProSeal LMA insertion guided by the C-MAC D-blade (Group D), guided by the C-MAC size 3 Macintosh blade (Group M) or performed using the standard digital technique (Group S). The primary outcome was optimal positioning, defined as a fibreoptic score of 4 and assessed by a blinded investigator. Secondary outcomes included first-attempt success, insertion time, ease of orogastric tube insertion, haemodynamic responses and postoperative airway complications.

Results

All 150 randomised patients were included in the analysis. Optimal positioning was achieved in 31/50 patients (62%) in Group D, 25/50 (50%) in Group M and 7/50 (14%) in Group S ($P < 0.001$); compared with Group S, the absolute difference was 48% (95% CI 29.6–62.0%) for Group D and 36% (95% CI 17.9–51.1%) for Group M. Positioning did not differ significantly between Groups D and M ($P = 0.444$). First-attempt success (84%, 96% and 88% in Groups S, D and M, respectively; $P = 0.131$) and insertion time ($P = 0.432$) did not differ significantly among the groups. Orogastric tube insertion was easier in both videolaryngoscope groups than in Group S ($P = 0.005$), and sore throat scores at 24 h were lower ($P = 0.015$). Haemodynamic variables did not differ significantly among the groups.

Conclusions

C-MAC videolaryngoscope-guided insertion with either the D-blade or the size 3 Macintosh blade improved ProSeal LMA positioning compared with the standard digital technique, without prolonging insertion time. Positioning did not differ significantly between the two blades.

Trial registration:

Australian New Zealand Clinical Trials Registry (ANZCTR), ACTRN12624000528550. Retrospectively registered on 28 April 2024. https://www.anzctr.org.au/ACTRN12624000528550.aspx

Background

The laryngeal mask airway (LMA) is widely used for airway management during general anaesthesia, both in spontaneously breathing patients and in those receiving positive-pressure ventilation [1, 2]. The ProSeal™ LMA (Teleflex Medical, Athlone, Ireland) is a second-generation supraglottic airway device. Its double cuff improves the oropharyngeal seal, and its drain tube reduces the risk of gastric insufflation and pulmonary aspiration [3, 4].

With the standard digital technique, the first-attempt insertion success rate is lower for the ProSeal LMA than for the Classic™ LMA (82% vs. 91%) [5]. Device-specific problems, including downfolding of the epiglottis, folding of the distal cuff, impaction against the posterior pharyngeal wall and incomplete seating of the cuff tip in the hypopharynx, can cause failed or delayed insertion or malposition [5].

Several alternative insertion techniques have been described, but most are performed blindly [6–11]. When insertion is guided by a Macintosh laryngoscope, the device passes over the tongue and beneath the epiglottis with little soft-tissue resistance. However, direct laryngoscopy may provoke haemodynamic and airway reflex responses and may cause pharyngeal or oesophageal trauma [12–15].

A videolaryngoscope provides a better view of the glottis than a direct laryngoscope because its camera is positioned closer to the larynx. Videolaryngoscopic guidance may therefore help to position supraglottic airway devices accurately [16], which may improve ventilation and reduce airway trauma [17]. The C-MAC® videolaryngoscope (Karl Storz, Tuttlingen, Germany) can be used with a size 3 Macintosh-type blade or a hyperangulated D-blade. To our knowledge, no randomised controlled trial has compared these two blades with the standard digital technique for ProSeal LMA insertion.

Fibreoptic assessment is the reference standard for confirming LMA position [16]. We hypothesised that ProSeal LMA insertion guided by the C-MAC D-blade would achieve optimal positioning (a fibreoptic score of 4 [18]) more often than insertion guided by the C-MAC size 3 Macintosh blade or the standard digital technique. The primary objective was to compare the rate of optimal ProSeal LMA positioning among the three techniques. The secondary objectives were to compare first-attempt success, insertion time, ease of orogastric tube insertion and haemodynamic responses to insertion. We also assessed harms, including blood staining of the device and postoperative sore throat, hoarseness and dysphagia.

Methods

Trial design and ethics

This was a prospective, single-centre, three-arm, parallel-group randomised controlled trial with 1:1:1 allocation, conducted at King Chulalongkorn Memorial Hospital, Bangkok, Thailand, between May 2023

and December 2024. The study was approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University (IRB No. 310/66) and was conducted in accordance with the Declaration of Helsinki. The trial is reported in accordance with the CONSORT 2025 statement.

The trial was retrospectively registered with the Australian New Zealand Clinical Trials Registry on 28 April 2024 (ACTRN12624000528550; https://www.anzctr.org.au/ACTRN12624000528550.aspx). Registration was delayed because of an administrative oversight: the investigators were unaware that registration was required before enrolment of the first participant, and the trial was registered promptly once this was identified. The primary and secondary outcomes, eligibility criteria and planned analyses were prespecified in the protocol approved by the Institutional Review Board before recruitment began, and none was modified after enrolment started. The trial protocol and statistical analysis plan are available from the corresponding author on request. All participants gave written informed consent before enrolment.

Patients and members of the public were not involved in the design, conduct, reporting or dissemination plans of this trial.

Participants

We included adults aged 18–65 years with American Society of Anesthesiologists (ASA) physical status I or II who were scheduled for elective surgery in the supine or lithotomy position under general anaesthesia with a ProSeal LMA.

The exclusion criteria were:

- a known or predicted difficult airway, defined as any of the following: a history of difficult airway management, an interincisor distance < 3 cm, modified Mallampati class III or IV, or limited neck extension;
- body mass index (BMI) > 35 kg/m²;
- increased risk of pulmonary aspiration (e.g. gastro-oesophageal reflux disease or hiatus hernia);
- oropharyngeal pathology or loose teeth;
- upper respiratory tract infection within the preceding 2 weeks;
- pre-existing sore throat, hoarseness or dysphagia;
- significant cardiovascular disease (e.g. coronary artery disease or poorly controlled hypertension); and
- allergy or contraindication to any study drug.

Randomisation and allocation concealment

Participants were randomly assigned in a 1:1:1 ratio to one of three groups:

- **Group D:** ProSeal LMA insertion guided by the C-MAC videolaryngoscope with a D-blade;
- **Group M:** ProSeal LMA insertion guided by the C-MAC videolaryngoscope with a size 3 Macintosh blade;
- **Group S:** ProSeal LMA insertion using the standard digital technique.

A research coordinator generated the allocation sequence by computer using unstratified block randomisation with a fixed block size of six. The coordinator, who had no role in recruitment, treatment or outcome assessment, also prepared sequentially numbered, opaque, sealed envelopes containing the allocation cards. After induction of anaesthesia, an investigator who was not involved in enrolment or outcome assessment opened the next envelope in the sequence and informed the attending anaesthetist of the allocated insertion technique.

Blinding

Because of the nature of the interventions, the anaesthetists who inserted the device could not be blinded to group allocation. Participants were blinded to group allocation because all insertions were performed after induction of general anaesthesia and allocation was not disclosed until completion of the 24-h postoperative follow-up.

Outcome assessors were blinded wherever possible. An investigator unaware of group allocation (KY) performed the fibreoptic assessment of device position. This investigator remained outside the operating theatre during insertion and entered only after the videolaryngoscope had been removed. An assistant who was present during insertion, and therefore not blinded, recorded insertion time, first-attempt success, ease of orogastric tube insertion and haemodynamic variables. The other investigators unaware of group allocation (CT and NT) assessed blood staining of the device after removal and recorded postoperative airway complications, including sore throat, hoarseness and dysphagia. The data analyst was also blinded, and group labels remained coded until the primary analysis was complete.

Study procedures

Standard monitoring, including electrocardiography, non-invasive blood pressure measurement and pulse oximetry, was applied before induction of anaesthesia. After preoxygenation with 100% oxygen at 6 $L \cdot min^{-1}$ for 3 min, anaesthesia was induced with intravenous propofol 1.5–2.5 $mg \cdot kg^{-1}$, fentanyl 0.5–1 $\mu g \cdot kg^{-1}$ and succinylcholine 0.5 $mg \cdot kg^{-1}$. Patients were then ventilated via a facemask with sevoflurane 3–4% for approximately 45 s. ProSeal LMA insertion was attempted once an adequate depth of anaesthesia had been achieved, as indicated by loss of the eyelash reflex, jaw relaxation, apnoea and absence of spontaneous movement. An additional dose of propofol (1–1.5 $mg \cdot kg^{-1}$) was administered before each subsequent insertion attempt.

The size of the ProSeal LMA was selected according to body weight: size 3 for ≤ 50 kg, size 4 for > 50–70 kg and size 5 for > 70–100 kg. Before insertion, the cuff was fully deflated and its posterior surface was lubricated. All insertions were performed by experienced anaesthetists, each with more than 50 previous ProSeal LMA insertions. A maximum of three insertion attempts was permitted; if insertion was unsuccessful after three attempts, the trachea was intubated and the event was recorded.

In Group S, the ProSeal LMA was inserted using the standard digital technique with the patient's head in the sniffing position [19]. In Groups D and M, the C-MAC videolaryngoscope fitted with the allocated blade was introduced in the midline until the epiglottis and vallecula were visualised. The epiglottis was then elevated, and the ProSeal LMA was advanced into the hypopharynx under videolaryngoscopic guidance until its distal tip was aligned with the upper oesophageal opening.

After successful placement, the cuff pressure was adjusted to 60 cmH_2O using a cuff manometer. Anaesthesia was maintained with sevoflurane at 1.0–1.2 minimum alveolar concentration (MAC) in approximately 50% oxygen in air, with spontaneous ventilation preserved. Intravenous ondansetron 4–8 mg was administered 15–30 min before the end of surgery. The ProSeal LMA was removed when the patient was fully awake, breathing adequately and obeying commands, and the device was then inspected for visible blood staining.

Outcomes

The primary outcome was the proportion of participants with optimal ProSeal LMA positioning, defined as a fibreoptic score of 4 on the scale described by Brimacombe and Berry [18]. The investigator (KY) performed the assessment within 1 min of confirming effective ventilation and before surgical incision. A 5-mm FLEX intubation video endoscope (model 11303 BNXK; Karl Storz, Tuttlingen, Germany) was passed through the airway tube to the level of the mask aperture, and the view was graded as follows:

- Score 4: only the vocal cords visible;
- Score 3: vocal cords and posterior epiglottis visible;
- Score 2: vocal cords and anterior epiglottis visible;
- Score 1: vocal cords not visible.

A score of 4 was taken to indicate optimal positioning, and scores of 1–3 were classified as suboptimal.

The secondary outcomes were first-attempt insertion success, insertion time, ease of orogastric tube insertion, haemodynamic responses to insertion, visible blood staining of the device, and postoperative sore throat, hoarseness and dysphagia. Insertion time was defined as the time from the moment the anaesthetist picked up the ProSeal LMA to the appearance of the first capnographic waveform. The ease of orogastric tube insertion was graded as easy, difficult or impossible. Haemodynamic variables were recorded before induction of anaesthesia, immediately before ProSeal LMA insertion and at 1, 3 and 5 min after insertion. Sore throat, hoarseness and dysphagia were assessed at 1 h (in the post-

anaesthesia care unit [PACU]) and 24 h after surgery. Sore throat was assessed using an 11-point numerical rating scale (NRS), on which 0 indicated no pain and 10 the worst pain imaginable; the scale was explained to patients beforehand, and they were asked to report the number that best reflected their pain at the time of assessment. Hoarseness and dysphagia were each graded as 0 (none), 1 (mild) or 2 (severe).

Sample size

The sample size was calculated using the formula for comparing two independent proportions. In a previous study by Wiryana et al. [20], optimal LMA positioning was achieved in 17% of patients with the standard digital technique and in 79.2% of those with videolaryngoscope-guided insertion using a Macintosh blade. A pilot study of 12 participants (four per group) was conducted to inform the calculation; pilot participants were not included in the main analysis. On the basis of the pilot data and expert consultation, an absolute difference of 30% (80% vs. 50%) was considered the minimal clinically important difference. With a two-sided α of 0.05, a power of 80% and a continuity correction, 45 participants per group were required. To allow for a dropout rate of 10%, 50 participants were enrolled in each group, giving a total sample size of 150.

No interim analyses were planned or performed, and no stopping rules were applied.

Statistical analysis

Continuous variables are presented as mean ± standard deviation (SD) or median (interquartile range [IQR]), as appropriate, and categorical variables as number (%). Continuous variables were compared among the three groups using one-way analysis of variance (ANOVA) or the Kruskal–Wallis test, and categorical variables using the chi-square test. Ordinal outcomes, including the fibreoptic score, the number of insertion attempts and postoperative symptom scores, were compared using the Kruskal–Wallis test. Fisher's exact test (Fisher–Freeman–Halton extension for three groups) was used instead of the chi-square test for categorical variables with small expected cell counts and for first-attempt success and the proportion of easy orogastric tube insertions. Haemodynamic variables were compared among the groups at each time point using one-way ANOVA.

When the overall test was significant ($P < 0.05$), pairwise comparisons were performed. Fibreoptic scores were compared between each pair of groups using the Kruskal–Wallis test, and the proportion of easy orogastric tube insertions (easy vs. difficult or impossible) using the chi-square test. Pairwise differences in postoperative airway complications were estimated using Fisher's protected least significant difference procedure, which controls the familywise type I error rate when three groups are compared, and are reported as mean differences or differences in proportions with 95% confidence intervals (CIs). 95% CIs for proportions, and absolute differences in the proportion of participants with optimal positioning are reported with 95% CIs calculated using the Wilson score method. All randomised

participants were analysed in the group to which they were allocated. A two-sided $P < 0.05$ was considered statistically significant. Analyses were performed using Stata version 18 (StataCorp LLC, College Station, TX, USA). There were no missing data for the primary or secondary outcomes; therefore, no imputation was required. No subgroup or sensitivity analyses were performed.

Results

Participant characteristics

Between May 2023 and December 2024, 150 patients were assessed for eligibility; all were eligible, agreed to participate and were randomised (n = 50 per group). Recruitment ended when the planned sample size was reached. All participants received the allocated intervention, none was lost to follow-up, and all were included in the final analysis (Fig. 1). Baseline characteristics are summarised in Table 1. Most participants were women (138/150, 92%), with a mean (SD) age of 46.7 (11.4) years and a mean (SD) BMI of 23.1 (3.9) kg/m²; 62% (93/150) were classified as ASA physical status I. Gynaecological surgery was the most common procedure (89/150, 59%), followed by breast (51/150, 34%) and urological (10/150, 7%) surgery. Demographic characteristics, airway assessments (Mallampati classification, thyromental distance and mouth opening), type of surgery, and durations of surgery and anaesthesia did not differ significantly among the groups (all $P > 0.05$).

Primary outcome

The distribution of fibreoptic scores differed significantly among the three groups ($P < 0.001$; Fig. 2). Optimal ProSeal LMA positioning (fibreoptic score 4) was achieved in 31/50 (62%) patients in Group D and 25/50 (50%) in Group M, compared with 7/50 (14%) in Group S. Compared with Group S, the absolute difference in the proportion with optimal positioning was 48% (95% CI 29.6–62.0%) for Group D and 36% (95% CI 17.9–51.1%) for Group M; the difference between Groups D and M was 12% (95% CI −7.2 to 30.0%). Fibreoptic scores were significantly better in both videolaryngoscope-guided groups than in Group S (both $P < 0.001$), with no significant difference between Groups D and M ($P = 0.444$). In Group S, most patients had a score of 2 (19/50, 38%) or 3 (18/50, 36%), and the vocal cords could not be seen (score 1) in 6/50 (12%) patients, compared with 1/50 (2%) in each videolaryngoscope group.

Secondary outcomes

The ProSeal LMA was successfully inserted within three attempts in all 150 patients, and no patient required tracheal intubation (Table 2). The first-attempt success rate was highest in Group D (96%, 48/50; 95% CI 86.5–98.9%), followed by Group M (88%, 44/50; 95% CI 76.2–94.4%) and Group S (84%, 42/50; 95% CI 71.5–91.7%), but the difference among the groups was not statistically significant ($P = 0.131$). A third attempt was required in only one patient each in Groups S and M. Insertion time was also

similar among the groups, with median (IQR) values of 30 (26–39) s in Group S, 33.5 (27–42) s in Group D and 33 (27–45) s in Group M (*P* = 0.432; Fig. 3).

The ease of orogastric tube insertion differed significantly among the groups (*P* = 0.018; Table 2). Insertion was graded as easy in 28/50 (56%; 95% CI 42.3–68.8%) patients in Group S, 42/50 (84%; 95% CI 71.5–91.7%) in Group D and 39/50 (78%; 95% CI 64.8–87.2%) in Group M (*P* = 0.005). Insertion was impossible in 3/50 (6%) patients in Group S and 2/50 (4%) in Group M, but in none in Group D. In pairwise comparisons of the proportion of easy insertions, orogastric tube insertion was easier in Group D (*P* = 0.002) and Group M (*P* = 0.019) than in Group S, with no significant difference between Groups D and M (*P* = 0.444).

Systolic, diastolic and mean arterial pressures and heart rate did not differ significantly among the three groups at any time point (all *P* > 0.05; Additional file 1: Table S1). In all groups, blood pressure decreased gradually after induction of anaesthesia, whereas heart rate remained relatively stable. Vasopressor treatment was required infrequently: in three patients in Group S (one at 1 min and two at 3 min after LMA insertion) and one patient in Group M (at 5 min), with no significant difference among the groups (*P* = 0.329–1.000).

Harms

Blood staining of the ProSeal LMA was observed in 17/50 (34%) patients in Group S, 9/50 (18%) in Group D and 14/50 (28%) in Group M, with no significant difference among the groups (*P* = 0.188; Table 3). Sore throat scores (NRS) were similar among the groups at 1 h (*P* = 0.364) but differed significantly at 24 h (*P* = 0.015). In pairwise comparisons at 24 h, sore throat scores were higher in Group S than in Group D (mean difference 0.60; 95% CI 0.16 to 1.04; *P* = 0.007) and Group M (mean difference 0.44; 95% CI 0.00 to 0.88; *P* = 0.048), with no significant difference between Groups D and M (*P* = 0.469; Additional file 1: Table S2). Hoarseness and dysphagia were infrequent, and their scores did not differ significantly among the groups at either time point.

Discussion

In this randomised controlled trial, C-MAC videolaryngoscope-guided insertion of the ProSeal LMA with either the D-blade or the size 3 Macintosh blade achieved optimal positioning (fibreoptic score of 4) significantly more often than the standard digital technique. Optimal positioning was most frequent with the D-blade, although the difference between the two blades was not statistically significant. First-attempt success and insertion time were similar among the three groups. Together, these findings suggest that direct visualisation of the supraglottic structures during insertion substantially improves the position of the device without compromising insertion efficiency.

Optimal positioning of the ProSeal LMA is essential to ensure adequate ventilation and to minimise airway-related adverse events. The blind digital technique described by Brain [19] remains the most

widely used insertion method; however, insertion is not always smooth, and repeated attempts may cause airway trauma. Malposition after digital insertion is mainly attributed to downfolding of the epiglottis, folding of the distal cuff, impaction against the posterior pharyngeal wall and incomplete seating of the cuff tip in the hypopharynx [5]. Because the digital technique is performed blindly, these problems cannot be recognised or corrected during insertion, and most alternative techniques share this limitation [6–11]. Videolaryngoscopic guidance addresses each of these mechanisms: the blade lifts the epiglottis away from the path of the cuff, and the operator can direct the distal tip along the posterior pharyngeal wall towards the upper oesophageal opening under continuous vision. This is consistent with the view that visual guidance allows more accurate positioning of supraglottic airway devices [16].

Our primary findings are consistent with those of previous trials of videolaryngoscope-guided insertion using the C-MAC system. Ozgul et al. [17], who also used the C-MAC D-blade to guide ProSeal LMA insertion, reported optimal positioning (fibreoptic score 4) in 75% of patients with videolaryngoscopic guidance, compared with 25% with the digital technique; the corresponding rates in our study were 62% and 14%. Similarly, Wiryana et al. [20], who used the C-MAC with a Macintosh blade to insert the Classic LMA, reported optimal positioning in 79% of patients with videolaryngoscopic guidance and in 17% with the classic blind technique. In children, C-MAC-guided placement of the i-gel reduced malposition (Brimacombe score 1 or 2) from 49% to 8% and increased oropharyngeal leak pressure [21]. Thus, in our study and in previous adult trials [17, 20], no more than one in four devices inserted blindly was optimally positioned, even though every device in our study provided effective ventilation before fibreoptic assessment. The pattern of suboptimal scores in Group S supports the mechanisms described above: the epiglottis was visible within the mask aperture in 74% of patients in this group (scores 2 and 3), and the vocal cords could not be seen at all in 12%, compared with 2% in each videolaryngoscope group. A very similar distribution was reported after digital insertion by Ozgul et al. (scores 2 and 1 in 37% and 10% of patients, respectively) [17], suggesting that incomplete advancement of the cuff and epiglottic downfolding, rather than failure of insertion itself, account for most malpositions.

Not all studies have shown a benefit of visual guidance. Simsek et al. [22] found no significant difference in fibreoptic grade between videolaryngoscope-guided and blind insertion of the LMA Classic, although oropharyngeal leak pressure was higher after guided insertion. Studies of insertion guided by a direct laryngoscope have also produced conflicting results: Campbell et al. [14] reported appropriate positioning in 91.5% of patients with direct visual placement, compared with 42% with blind insertion, whereas Chandan et al. [13], using the same fibreoptic scoring system, found no significant difference between the two techniques. These discrepancies may reflect differences in device design, laryngoscope type and operator experience. The ProSeal LMA, with its larger double cuff and drain tube, is more prone than the Classic LMA to folding of the distal cuff and impaction in the hypopharynx [5], and it may therefore benefit more from visual guidance. In addition, the wider view of the hypopharynx provided by a videolaryngoscope may explain why our results are closer to those of Campbell et al. than to those of Chandan et al.

Optimal positioning was achieved in 62% of patients with the D-blade and 50% with the Macintosh blade. This 12-percentage-point difference was not statistically significant, and its 95% CI (− 7.2 to 30.0%) was wide. To our knowledge, no previous study has compared the two blades directly. The rate with the D-blade was comparable to the 75% reported by Ozgul et al. with the same blade [17], whereas the rate with the Macintosh blade was lower than the 79% reported by Wiryana et al. [20], who inserted the smaller, single-cuff Classic LMA. The hyperangulated D-blade may elevate the epiglottis more effectively and provide a more complete view of the hypopharynx, but our trial was powered to detect a difference between videolaryngoscope-guided and digital insertion, not between the two blades. A clinically relevant advantage of the D-blade can therefore be neither confirmed nor excluded, and a larger trial would be needed to address this question.

Improved positioning was not achieved at the expense of insertion efficiency. The ProSeal LMA was inserted within three attempts in all patients, and no patient required tracheal intubation. First-attempt success in Group S (84%) was similar to the 82% previously reported for digital insertion of the ProSeal LMA [5], and it was numerically higher with the D-blade (96%) and the Macintosh blade (88%), although these differences were not statistically significant. Previous trials found significantly higher first-attempt success with C-MAC guidance, at the cost of a longer insertion time. Ozgul et al. reported a higher first-attempt success rate and an insertion time of approximately 38 s with videolaryngoscopic guidance, compared with 28 s with the digital technique [17]; Wiryana et al. reported first-attempt success in 100% and 89% of patients, respectively [20]; and in children, C-MAC guidance increased first-attempt success from 69% to 86% but prolonged insertion by approximately 7 s [21]. In our study, median insertion times differed by no more than 3.5 s among the groups (30 s in Group S, 33.5 s in Group D and 33 s in Group M). This difference from previous studies may reflect our definition of insertion time, which ended at the first capnographic waveform and therefore included any adjustment needed to achieve ventilation after blind insertion, as well as the experience of our operators. Because the first-attempt success rate with the digital technique was already high in our study, the trial had limited power to detect a further improvement.

The results for orogastric tube insertion are consistent with the fibreoptic findings and support their clinical relevance. Insertion was graded as easy in 84% of patients in Group D and 78% in Group M, compared with 56% in Group S, and insertion was impossible in 6% of patients in Group S and 4% in Group M but in none in Group D. Ozgul et al. similarly reported more successful orogastric tube insertion after videolaryngoscope-guided placement than after digital insertion [17]. The drain tube of the ProSeal LMA is designed to lie at the upper oesophageal opening, where it allows gastric access and venting and reduces the risk of gastric insufflation and pulmonary aspiration [3, 4]. Difficult or failed orogastric tube passage therefore suggests that the distal cuff is folded or incompletely seated in the hypopharynx, the same malpositions that were identified fibreoptically more often in Group S. Accurate positioning under videolaryngoscopic guidance may thus improve the protective function of the drain tube as well as the fibreoptic view.

Postoperative airway morbidity was low in all groups. Sore throat scores at 24 h were lower in both videolaryngoscope groups than in Group S, with mean differences of 0.60 and 0.44 points on a 0–10 numerical rating scale for Groups D and M, respectively, whereas scores at 1 h did not differ. Previous studies did not find a difference in sore throat: Ozgul et al. reported a similar incidence at 1 h and 24 h after videolaryngoscope-guided and digital insertion [17], and Wiryana et al. observed sore throat in only one patient after blind insertion and in none after guided insertion [20]. Because these studies recorded sore throat as present or absent, whereas we used a graded scale, our study may have detected smaller differences in severity; however, the differences were less than 1 point, and their clinical importance is uncertain. Visible blood staining of the device was observed less often in Group D (18%) than in Group S (34%) or Group M (28%), but this difference was not statistically significant. The direction of this finding is consistent with previous reports of less blood staining after videolaryngoscope-guided insertion, which reached statistical significance in the study by Wiryana et al. (0% vs. 9.4%) [20] but not in the study by Ozgul et al. [17]. Hoarseness and dysphagia were infrequent in all groups. A plausible explanation for these findings is that guided insertion reduces contact between the device and the posterior pharyngeal wall and the number of repositioning manoeuvres. Overall, the results indicate that the laryngoscope blade did not cause additional airway trauma, contrary to concerns raised for laryngoscope-guided insertion [12–15].

Similarly, videolaryngoscopy did not provoke a measurable haemodynamic response. Systolic, diastolic and mean arterial pressures and heart rate did not differ among the groups at any time point, in agreement with the findings of Ozgul et al., who reported similar heart rate and mean arterial pressure after videolaryngoscope-guided and digital insertion [17]. The gradual decrease in blood pressure observed after induction in all groups is more likely to reflect the effects of the anaesthetic agents than the insertion technique. Vasopressor treatment was required in only four patients, none of whom were in Group D. Unlike tracheal intubation, videolaryngoscope-guided placement of a supraglottic airway does not require the device to pass through the vocal cords, which may explain why the stimulus was well tolerated under the anaesthetic technique used in this study.

Taken together, these results have practical implications. Because a ProSeal LMA that ventilates adequately after digital insertion is frequently malpositioned, clinicians cannot rely on successful ventilation alone to confirm optimal placement. Videolaryngoscopic guidance with either blade improved positioning and facilitated orogastric tube insertion without prolonging insertion or increasing airway morbidity, and it may therefore be considered when accurate positioning and a functioning drain tube are particularly important, or when digital insertion has failed. Further studies should evaluate this technique in patients with difficult airways, in less experienced operators and with clinically relevant end points such as oropharyngeal leak pressure and ventilation quality.

This study has several limitations. First, it was a single-centre trial, and all devices were inserted by experienced anaesthetists; the results may not apply to less experienced operators. Second, the anaesthetists who inserted the device and the assistant who recorded insertion time, first-attempt success, ease of orogastric tube insertion and haemodynamic variables could not be blinded, which may

have introduced detection bias for these outcomes. Third, most participants were women of normal body weight undergoing gynaecological or breast surgery, and patients with a known or predicted difficult airway were excluded, which limits generalisability to other populations, including patients with difficult airways, in whom videolaryngoscopic guidance might be most useful. Fourth, the trial was not powered for the secondary outcomes or for the comparison between the two blades, and multiple secondary comparisons were performed; these results should therefore be regarded as exploratory. Finally, the trial was registered retrospectively, although the outcomes and analyses were prespecified in the approved protocol and were not changed after enrolment began.

Conclusions

ProSeal LMA insertion guided by the C-MAC videolaryngoscope with either a D-blade or a size 3 Macintosh blade achieved optimal fibreoptic positioning more often than the standard digital technique, without prolonging insertion time. Videolaryngoscopic guidance also facilitated orogastric tube insertion and was associated with less sore throat at 24 h. Positioning did not differ significantly between the two blades.

Abbreviations

ANOVA: analysis of variance; ANZCTR: Australian New Zealand Clinical Trials Registry; ASA: American Society of Anesthesiologists; BMI: body mass index; CI: confidence interval; CONSORT: Consolidated Standards of Reporting Trials; IQR: interquartile range; IRB: Institutional Review Board; LMA: laryngeal mask airway; MAC: minimum alveolar concentration; NRS: numerical rating scale; PACU: post-anaesthesia care unit; SD: standard deviation

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University (IRB No. 310/66) and was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants before enrolment.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analysed during the current study, including de-identified individual participant data, the data dictionary and the statistical code, are available from the corresponding author on reasonable request. The trial protocol and statistical analysis plan are also available from the corresponding author on request.

Competing interests

The authors declare that they have no competing interests.

Funding

This study was supported by the Ratchadapiseksompotch Fund, Faculty of Medicine, Chulalongkorn University (Grant No. RA65/002). The funder had no role in the design of the study; the collection, analysis or interpretation of data; or the writing of the manuscript.

Authors' contributions

KY: conceptualisation, funding acquisition, investigation, methodology, project administration, writing – original draft, and writing – review and editing. CT: data curation, formal analysis, investigation, visualisation and writing – original draft. NT: data curation, formal analysis, investigation and writing – original draft. All authors read and approved the final manuscript.

Acknowledgements

Not applicable.

References

1. Seet E, Rajeev S, Firoz T, Yousaf F, Wong J, Wong DT, Chung F. Safety and efficacy of laryngeal mask airway Supreme versus laryngeal mask airway ProSeal: a randomized controlled trial. Eur J Anaesthesiol. 2010;27:602–7. https://doi.org/10.1097/EJA.0b013e32833679e3.
2. Francksen H, Bein B, Cavus E, Renner J, Scholz J, Steinfath M, Tonner PH, Doerges V. Comparison of LMA Unique, Ambu laryngeal mask and Soft Seal laryngeal mask during routine surgical procedures. Eur J Anaesthesiol. 2007;24:134–40. https://doi.org/10.1017/S0265021506001219.
3. Brimacombe J, Keller C. The ProSeal laryngeal mask airway: a randomized, crossover study with the standard laryngeal mask airway in paralyzed, anesthetized patients. Anesthesiology. 2000;93:104–9. https://doi.org/10.1097/00000542-200007000-00019.

4. Keller C, Brimacombe J. Mucosal pressure and oropharyngeal leak pressure with the ProSeal versus laryngeal mask airway in anaesthetized paralysed patients. Br J Anaesth. 2000;85:262–6. https://doi.org/10.1093/bja/85.2.262.
5. Brimacombe J, Keller C, Fullekrug B, Agrò F, Rosenblatt W, Dierdorf SF, Garcia de Lucas E, Capdevila X, Brimacombe N. A multicenter study comparing the ProSeal and Classic laryngeal mask airway in anesthetized, nonparalyzed patients. Anesthesiology. 2002;96:289–95. https://doi.org/10.1097/00000542-200202000-00011.
6. Brimacombe J, Keller C, Judd DV. Gum elastic bougie-guided insertion of the ProSeal laryngeal mask airway is superior to the digital and introducer tool techniques. Anesthesiology. 2004;100:25–9. https://doi.org/10.1097/00000542-200401000-00008.
7. Hwang JW, Park HP, Lim YJ, Do SH, Lee SC, Jeon YT. Comparison of two insertion techniques of ProSeal laryngeal mask airway: standard versus 90-degree rotation. Anesthesiology. 2009;110:905–7. https://doi.org/10.1097/ALN.0b013e31819b5d40.
8. Chen HS, Yang SC, Chien CC, Spielberger J, Hung KC, Chung KC. Insertion of the ProSeal laryngeal mask airway is more successful with the Flexi-Slip stylet than with the introducer. Can J Anaesth. 2011;58:617–23. https://doi.org/10.1007/s12630-011-9506-6.
9. El Beheiry H, Wong J, Nair G, Chinnappa V, Arora G, Morales E, Chung F. Improved esophageal patency when inserting the ProSeal laryngeal mask airway with an Eschmann tracheal tube introducer. Can J Anaesth. 2009;56:725–32. https://doi.org/10.1007/s12630-009-9141-7.
10. Koay CK, Yoong CS, Kok P. A randomized trial comparing two laryngeal mask airway insertion techniques. Anaesth Intensive Care. 2001;29:613–5. https://doi.org/10.1177/0310057X0102900609.
11. Sorbello M, Petrini F. Supraglottic airway devices: the search for the best insertion technique or the time to change our point of view? Turk J Anaesthesiol Reanim. 2017;45:76–82. https://doi.org/10.5152/TJAR.2017.67764.
12. Nalini KB, Shivakumar S, Archana S, Sandhya Rani DC, Mohan CV. Comparison of three insertion techniques of ProSeal laryngeal mask airway: a randomized clinical trial. J Anaesthesiol Clin Pharmacol. 2016;32:510–4. https://doi.org/10.4103/0970-9185.194774.
13. Chandan SN, Sharma SM, Raveendra US, Rajendra Prasad B. Fiberoptic assessment of laryngeal mask airway placement: a comparison of blind insertion and insertion with the use of a laryngoscope. J Maxillofac Oral Surg. 2009;8:95–8. https://doi.org/10.1007/s12663-009-0025-8.
14. Campbell RL, Biddle C, Assudmi N, Campbell JR, Hotchkiss M. Fiberoptic assessment of laryngeal mask airway placement: blind insertion versus direct visual epiglottoscopy. J Oral Maxillofac Surg. 2004;62:1108–13. https://doi.org/10.1016/j.joms.2003.10.014.
15. Kim GW, Kim JY, Kim SJ, Moon YR, Park EJ, Park SY. Conditions for laryngeal mask airway placement in terms of oropharyngeal leak pressure: a comparison between blind insertion and laryngoscope-guided insertion. BMC Anesthesiol. 2019;19:4. https://doi.org/10.1186/s12871-018-0674-6.

16. Van Zundert AA, Kumar CM, Van Zundert TC. Malpositioning of supraglottic airway devices: preventive and corrective strategies. Br J Anaesth. 2016;116:579–82. https://doi.org/10.1093/bja/aew104.
17. Ozgul U, Erdil FA, Erdogan MA, Begec Z, Colak C, Yucel A, Durmus M. Comparison of videolaryngoscope-guided versus standard digital insertion techniques of the ProSeal™ laryngeal mask airway: a prospective randomized study. BMC Anesthesiol. 2019;19:244. https://doi.org/10.1186/s12871-019-0915-3.
18. Brimacombe J, Berry A. A proposed fiber-optic scoring system to standardize the assessment of laryngeal mask airway position. Anesth Analg. 1993;76:457.
19. Brain AI. The laryngeal mask—a new concept in airway management. Br J Anaesth. 1983;55:801–5.
20. Wiryana M, Van Zundert AAJ, Sinardja K, Senapathi TGA, Aribawa IGNM, Sidemen IGPS, Soedarso DT. Accuration insertion LMA with video laryngoscope compare with classic technique. SOJ Anesthesiol Pain Manag. 2017;4:1–4.
21. Kumar R, Bihani P, Mohammed S, Syal R, Bhatia P, Jaju R. Comparison of clinical performance of C-MAC video laryngoscope guided vs blind placement of i-gel® in paediatric patients: a randomized controlled open-label trial. Turk J Anaesthesiol Reanim. 2023;51:347–53. https://doi.org/10.4274/TJAR.2023.221010.
22. Simsek T, Saracoglu A, Sezen O, Cakmak G, Saracoglu KT. Blind vs. video-laryngoscope-guided laryngeal mask insertion: a prospective randomized comparison of oropharyngeal leak pressure and fiberoptic grading. J Clin Monit Comput. 2022;36:1249–55. https://doi.org/10.1007/s10877-022-00841-1.

Tables

Table 1 Baseline demographic and clinical characteristics of participants

Characteristic	Group S (n = 50)	Group D (n = 50)	Group M (n = 50)	*P* value
Sex, female, n (%)	47 (94)	44 (88)	47 (94)	0.443
Age (years), mean ± SD	47.1 ± 11.3	44.9 ± 12.1	48.1 ± 10.7	0.374
Weight (kg), mean ± SD	59.5 ± 10.5	56.9 ± 10.5	58.8 ± 11.4	0.468
Height (cm), mean ± SD	159.9 ± 5.3	158.4 ± 6.4	157.9 ± 4.8	0.186
BMI (kg/m^2), mean ± SD	23.3 ± 4.1	22.6 ± 3.5	23.6 ± 4.3	0.477
ASA physical status, n (%)				0.712
I	31 (62)	33 (66)	29 (58)	
II	19 (38)	17 (34)	21 (42)	
Mallampati class, n (%)				0.061
I	26 (52)	35 (70)	24 (48)	
II	24 (48)	15 (30)	26 (52)	
Thyromental distance, n (%)				0.235
> 4 cm	48 (96)	50 (100)	47 (94)	
≤ 4 cm	2 (4)	0 (0)	3 (6)	
Mouth opening, n (%)				0.064
> 3 cm	43 (86)	49 (98)	47 (94)	
≤ 3 cm	7 (14)	1 (2)	3 (6)	
Unrestricted head extension, n (%)	50 (100)	50 (100)	50 (100)	–
Type of surgery, n (%)				0.489
Breast	20 (40)	17 (34)	14 (28)	
Gynaecological	27 (54)	28 (56)	34 (68)	
Urological	3 (6)	5 (10)	2 (4)	
Duration of surgery (min), median (IQR)	34 (19–49)	28.5 (19–40)	25 (17–43)	0.615
Duration of anaesthesia (min), median (IQR)	52 (40–75)	46.5 (40–62)	46 (37–75)	0.649

Values are presented as mean ± standard deviation (SD) or median (interquartile range, IQR) for continuous variables, and n (%) for categorical variables. *P* values were calculated using one-way ANOVA or the Kruskal–Wallis H test for continuous variables, and the chi-square test for categorical variables. Statistical significance was defined as $P < 0.05$.

Group S, ProSeal LMA insertion using the standard digital technique; Group D, ProSeal LMA insertion guided by the C-MAC videolaryngoscope with a D-blade; Group M, ProSeal LMA insertion guided by the C-MAC videolaryngoscope with a size 3 Macintosh blade. ASA, American Society of Anesthesiologists; BMI, body mass index; IQR, interquartile range; LMA, laryngeal mask airway; SD, standard deviation; –, not applicable (no variation between groups).

Table 2 ProSeal LMA and orogastric tube insertion outcomes

Characteristic	Group S (n = 50)	Group D (n = 50)	Group M (n = 50)	*P* value
ProSeal LMA insertion				
Number of insertion attempts, n (%)				0.140[b]
1	42 (84)	48 (96)	44 (88)	
2	7 (14)	2 (4)	5 (10)	
3	1 (2)	0 (0)	1 (2)	
First-attempt success, n (%) [95% CI]	42 (84) [71.5–91.7]	48 (96) [86.5–98.9]	44 (88) [76.2–94.4]	0.131[a]
Overall success (≤ 3 attempts), n (%) [95% CI]	50 (100) [92.9–100]	50 (100) [92.9–100]	50 (100) [92.9–100]	–
Insertion time (s), median (IQR)	30 (26–39)	33.5 (27–42)	33 (27–45)	0.432[b]
Tracheal intubation required, n (%)	0 (0)	0 (0)	0 (0)	–
Orogastric tube insertion				
Ease of insertion, n (%)				0.018[a]
Easy [95% CI]	28 (56) [42.3–68.8]	42 (84) [71.5–91.7]	39 (78) [64.8–87.2]	0.005[c,d]
Difficult	19 (38)	8 (16)	9 (18)	
Impossible	3 (6)	0 (0)	2 (4)	

Values are presented as n (%), n (%) [95% confidence interval, CI] or median (interquartile range, IQR). 95% CIs for proportions were calculated using the Wilson score method. Statistical significance was defined as $P < 0.05$.

[a]Chi-square test. [b]Kruskal–Wallis H test. [c]Fisher–Freeman–Halton exact test. [d]Proportion of easy insertions (easy vs. difficult or impossible); pairwise comparisons (chi-square test): Group S vs Group D, $P = 0.002$; Group S vs Group M, $P = 0.019$; Group D vs Group M, $P = 0.444$.

Group S, ProSeal LMA insertion using the standard digital technique; Group D, ProSeal LMA insertion guided by the C-MAC videolaryngoscope with a D-blade; Group M, ProSeal LMA insertion guided by the C-MAC videolaryngoscope with a size 3 Macintosh blade. CI, confidence interval; IQR, interquartile range; LMA, laryngeal mask airway; –, not applicable (no variation between groups).

Table 3 Postoperative airway complications

Variable	Group S (n = 50)	Group D (n = 50)	Group M (n = 50)	*P* value
Blood staining on device, n (%)	17 (34)	9 (18)	14 (28)	0.188[a]
Sore throat score, median (IQR)				
1 h (PACU)	1 (0–4)	1 (0–3)	0.5 (0–3)	0.364[b]
24 h	0 (0–2)	0 (0–0)	0 (0–1)	0.015[b,c]
Hoarseness score, median (IQR)				
1 h (PACU)	0 (0–0)	0 (0–0)	0 (0–0)	0.466[b]
24 h	0 (0–0)	0 (0–0)	0 (0–0)	0.475[b]
Dysphagia score, median (IQR)				
1 h (PACU)	0 (0–0)	0 (0–0)	0 (0–0)	0.554[b]
24 h	0 (0–0)	0 (0–0)	0 (0–0)	0.703[b]

Values are presented as n (%) or median (interquartile range, IQR). Sore throat was graded using a 0–10 numerical rating scale (NRS; 0, no pain; 10, worst pain imaginable), and hoarseness and dysphagia were graded as 0 (none), 1 (mild) or 2 (severe). Time points refer to time after surgery. Statistical significance was defined as $P < 0.05$.

[a]Chi-square test. [b]Kruskal–Wallis H test. [c]Pairwise comparisons at 24 h: Group S vs Group D, $P = 0.007$; Group S vs Group M, $P = 0.048$; Group D vs Group M, $P = 0.469$. All pairwise comparisons are shown in Additional file 1: Table S2.

Group S, ProSeal LMA insertion using the standard digital technique; Group D, ProSeal LMA insertion guided by the C-MAC videolaryngoscope with a D-blade; Group M, ProSeal LMA insertion guided by the C-MAC videolaryngoscope with a size 3 Macintosh blade. IQR, interquartile range; LMA, laryngeal mask airway; PACU, post-anaesthesia care unit.

Figures

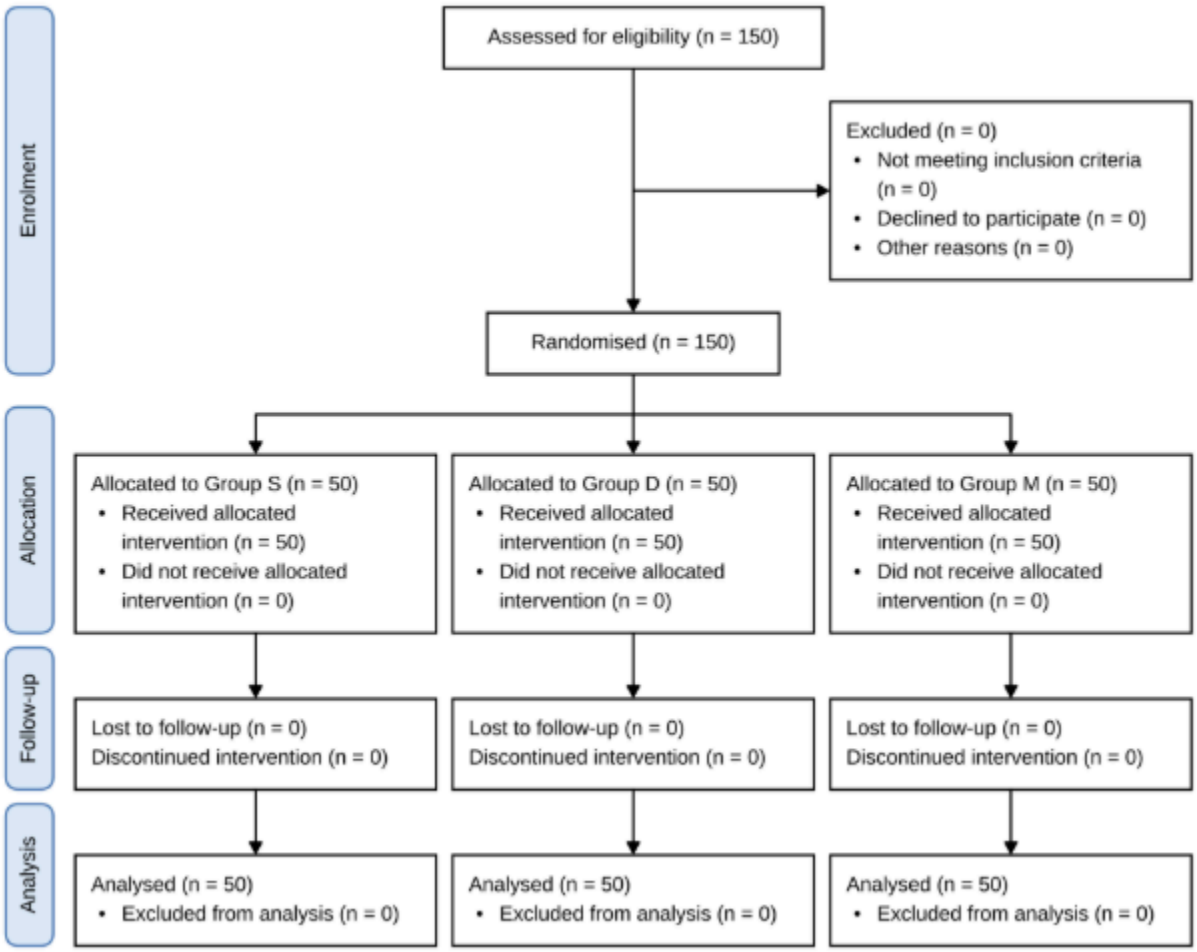


Figure 1

CONSORT flow diagram of participant enrolment, allocation, follow-up and analysis. Group S, standard digital technique; Group D, C-MAC videolaryngoscope with a D-blade; Group M, C-MAC videolaryngoscope with a size 3 Macintosh blade.

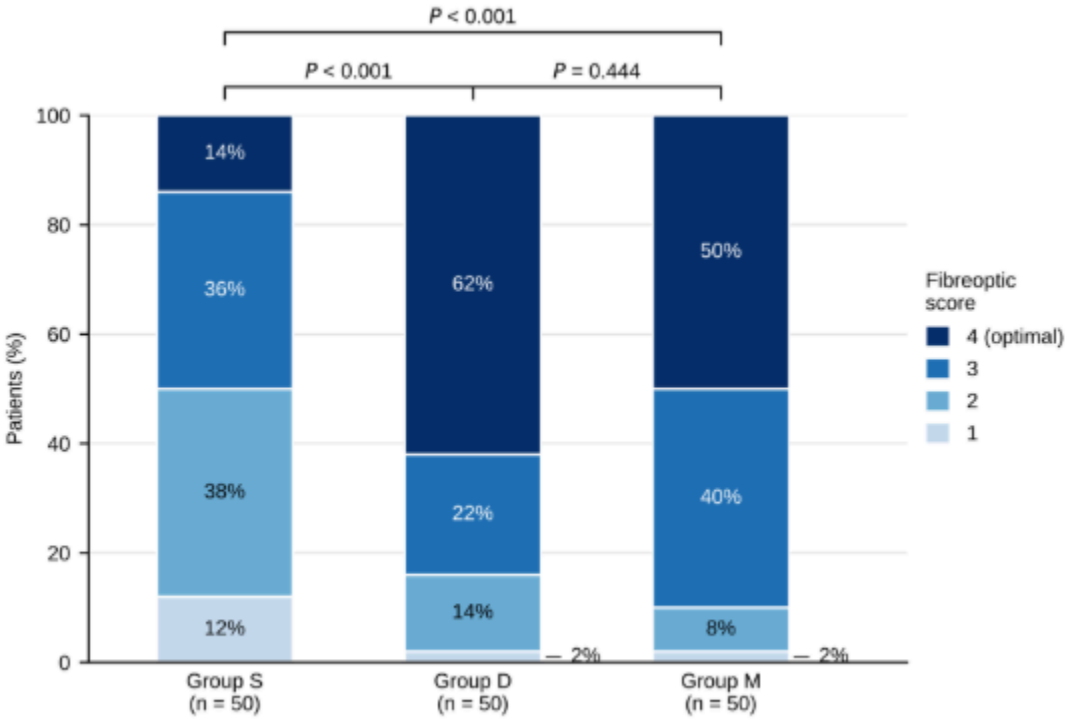


Figure 2

Fibreoptic assessment of ProSeal LMA position in the three study groups

Stacked bars show the percentage of patients with each fibreoptic score (Brimacombe scale), from 1 to 4: 1, vocal cords not seen; 2, vocal cords plus anterior epiglottis seen; 3, vocal cords plus posterior epiglottis seen; 4, only vocal cords seen (optimal positioning). Numbers of patients for scores 1/2/3/4 were 6/19/18/7 in Group S, 1/7/11/31 in Group D and 1/4/20/25 in Group M (n = 50 per group). The distribution of scores differed significantly among the three groups (Kruskal–Wallis test, *P*< 0.001). Brackets show pairwise comparisons between groups using the Kruskal–Wallis test. *P* < 0.05 was considered statistically significant. Group S, standard digital technique; Group D, C-MAC videolaryngoscope with a D-blade; Group M, C-MAC videolaryngoscope with a size 3 Macintosh blade. LMA, laryngeal mask airway.

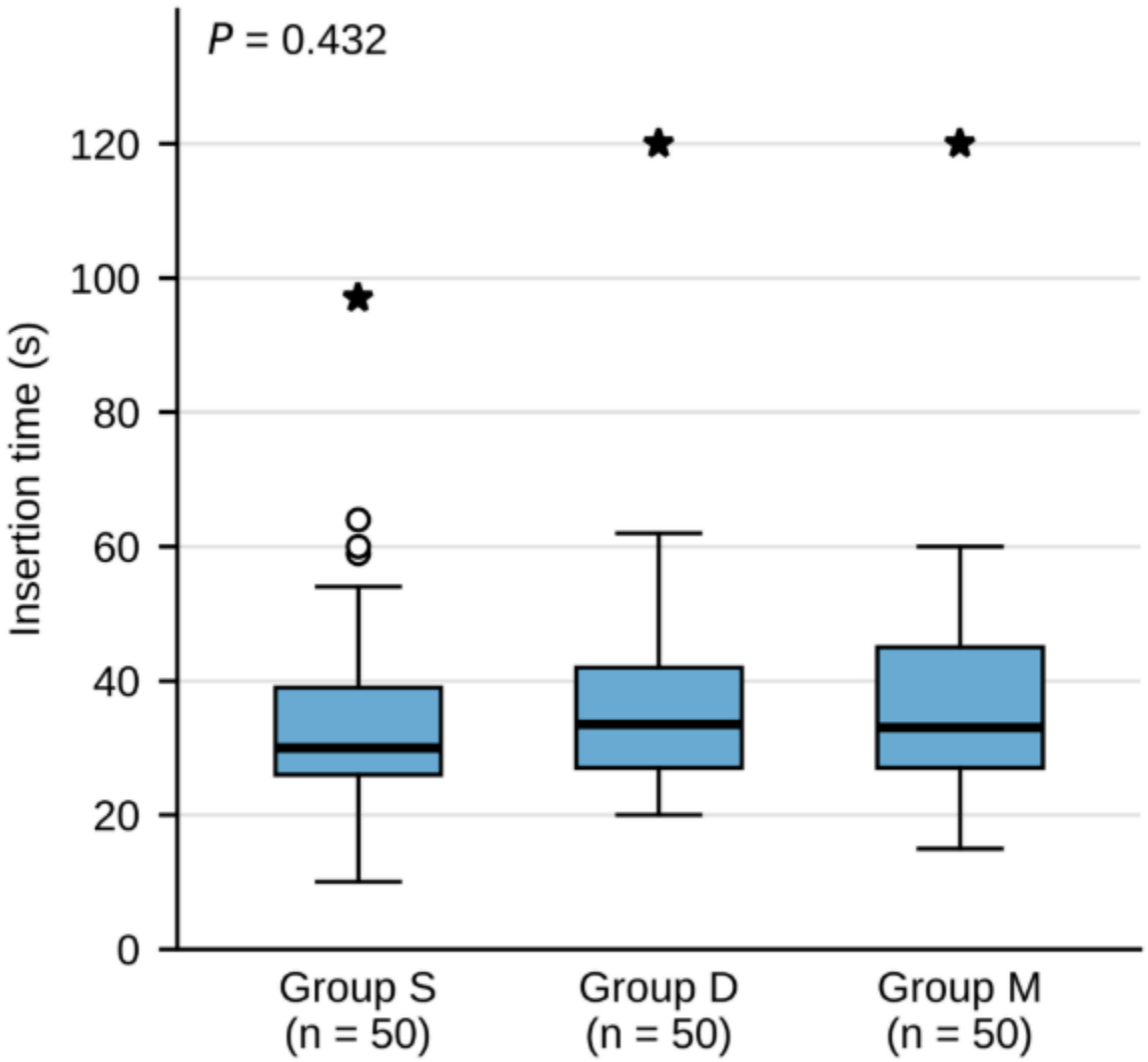


Figure 3

ProSeal LMA insertion time in the three study groups

Box plots show the median (horizontal line) and interquartile range (box) of insertion time. Whiskers extend to the most extreme values within 1.5 times the interquartile range; circles indicate outliers (1.5–3 times the interquartile range beyond the box) and asterisks indicate extreme values (more than 3 times the interquartile range beyond the box). Median (IQR) insertion times were 30 (26–39) s in Group S, 33.5 (27–42) s in Group D and 33 (27–45) s in Group M. There was no significant difference among the groups (Kruskal–Wallis test, *P* = 0.432). Group S, standard digital technique; Group D, C-MAC videolaryngoscope with a D-blade; Group M, C-MAC videolaryngoscope with a size 3 Macintosh blade. IQR, interquartile range; LMA, laryngeal mask airway.