

# Comparison of the efficacy of Macintosh laryngoscope-guided insertion of I-gel™ with the conventional blind insertion technique - A randomised study

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## ABSTRACT

**Background and Aims:** This study was designed to compare the efficacy of Macintosh laryngoscope-guided insertion of I-gel™ with the conventional blind insertion technique. **Methods:** A total of 156 adult patients scheduled to undergo elective surgery under general anaesthesia were included. All participants were randomly divided into two groups; I-gel™ was inserted with conventional blind and Macintosh laryngoscopic-guided technique in group A and B respectively. The primary objective of the study was to determine the incidence of optimal positioning in both the groups based on fibreoptic bronchoscope score of the glottic view. Oropharyngeal leak pressure, haemodynamic parameters and insertion characteristics were also compared. Categorical data were presented as ratio or percentage, continuous data were presented as mean ± standard deviation or median (95% confidence interval). The strength of association between insertion technique and the anatomical fit of the device was calculated by relative risk ratio. **Results:** Fibreoptic scores were significantly better in laryngoscope-guided insertion group when compared to the blind insertion group ( $P < 0.0001$ ). The incidence of malposition was 3.85% in the laryngoscopic insertion group and 39.4% in the blind insertion ( $P < 0.0001$ ). Oropharyngeal leak pressure was higher in laryngoscope-guided insertion group than in blind insertion group ( $26.89 \pm 3.37$  cm H<sub>2</sub>O versus  $24.42 \pm 3.00$  cm H<sub>2</sub>O;  $P < 0.0001$ ). Other insertion characteristics except time taken to insert the device were comparable in both groups. **Conclusion:** When compared to the standard blind insertion technique, laryngoscope-guided insertion of I-gel™ results in better alignment with the laryngeal inlet providing a proper anatomical fit and better airway seal pressure.

**Key words:** Bronchoscope, endotracheal intubation, general anaesthesia, laryngoscope

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## INTRODUCTION

Supraglottic airway (SGA) devices are a well-established tool in the armamentarium of anaesthesiologists involved in airway management. According to National Audit Project-4 (NAP-4), 56% of surgeries under general anaesthesia are performed using SGAs.<sup>[1]</sup> Less invasive than endotracheal intubation, SGAs are now especially popular in outpatient surgeries as well as rescue devices in management of airway crisis.<sup>[2]</sup>

I-gel™ (Intersurgical, Wokingham, Berkshire, UK), a second-generation SGA device provides a cuffless

perilaryngeal sealing mechanism. It can be inserted easily with minimal risk of tissue compression, and its in-built bite block and a reinforced tip, provides

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a more patent airway. Blind insertion technique as described by Brain is most widely used to insert I-gel™ and other SGAs. Imaging studies and studies based on the clinical evaluation of performance, fiberoptic and ultrasound examination, have consistently shown the suboptimal placement when SGAs are inserted blindly, with the incidence of malposition ranging from 50-80%.<sup>[3,4]</sup> Malpositioning of SGA can lead to various complications such as gastric insufflation, increased chances of aspiration, insufficient tidal volume, air leak, airway obstruction, blood staining of device, tissue trauma and nerve injuries.<sup>[5]</sup> Under vision I-gel™ insertion techniques have been described to maximise their intended function and to achieve ideal anatomic position.<sup>[6]</sup>

We hypothesised that the readily available Macintosh laryngoscope could be used as an effective tool to improve success rate when I-gel™ is used to secure the airway, in settings where advanced airway equipments like videolaryngoscope, etc., are not available. In the present study, we aimed to compare the accuracy and efficacy of Macintosh laryngoscope-guided under vision insertion technique of I-gel™ with the standard blind insertion technique in terms of fiberoptic bronchoscope (FOB) grading of the glottic view and oropharyngeal leak pressure (OPLP) measurements.

## METHODS

Following the institutional ethics committee approval (SNMC/IEC/2021/plan/386) and registering the trial in the Clinical Trials Registry of India (CTRI/2021/05/033457), the study was conducted at a tertiary care centre from May 2021 to October 2021. A total of 156 patients, of either gender [American Society of Anesthesiologists (ASA) physical status I and II, age 21-50 years, body mass index (BMI) 18 to 25kg/m<sup>2</sup>], scheduled to undergo elective surgical procedures in the supine position were studied. Patients with anticipated difficult airway (Mallampati score >2 or mouth opening <3 cm), morbid obesity, patients with active upper respiratory tract infection, patients at risk of gastric aspiration, pregnant patients and the patients requiring active neurosurgical intervention were excluded. The principles of the Declaration of Helsinki were followed while conducting the study.

Participants were randomised using block randomisation technique into two groups, Group A and Group B; with 78 study participants in each group. In Group A, I gel™ was inserted by the

conventional blind insertion technique and in Group B, it was inserted under vision using the Macintosh laryngoscope. All patients were examined during the pre-operative visit, one day prior to surgery and were advised to remain nil per oral (NPO) as per Indian Society of Anaesthesiologists (ISA) fasting guidelines.<sup>[7]</sup> In the operation theatre (OT), pulse oximetry (SpO<sub>2</sub>), non-invasive blood pressure (NIBP), electrocardiogram (ECG) were attached, an 18G peripheral venous cannula was secured and baseline reading of vital parameters were recorded. All patients were premedicated with intravenous (IV) midazolam 1 mg, IV xylocaine 2% 1 mg/kg and IV fentanyl 2 µg/kg. Induction was done with IV propofol 2 mg/kg. After assessing the adequacy of bag and mask ventilation, IV atracurium 0.5 mg/kg was given. All patients were oxygenated with 100% oxygen for 3 min prior to I-gel™ insertion. An appropriate size I-gel™ was selected, in accordance with the patient's weight, as per manufacturer's recommendation and inserted using midline approach with the patient in the sniffing position. In group A, I-gel™ was glided downwards and backwards along the hard palate using index finger with a continuous but gentle push until a definitive resistance was felt. In group B, Macintosh laryngoscope blade was inserted up to the vallecula, tongue was displaced laterally and epiglottis lifted anteriorly under vision without necessarily visualising the vocal cords or the tracheal opening. The lubricated I-gel™ was then advanced till the proximal bowl of the I-gel™ got positioned just below the epiglottis. In all patients, I-gel™ was inserted by an anaesthesiologist having experience of at least 100 insertions or five years of experience in airway management.

After placement of I-gel™, OPLP was measured by closing the expiratory valve of the circle system at a fixed gas flow of 3L/min at manual mode of ventilation. OPLP was measured at the point at which airway pressure reached the equilibrium, detectable by audible air leak or noise, using a stethoscope placed just lateral to the thyroid cartilage. To ensure safety, maximum allowable OPLP was fixed at 40 cm of H<sub>2</sub>O.<sup>[6,8,9]</sup> The FOB (Olympus Porta View LF-TP flexible tracheal intubation fibrescope with outer diameter of 5.2 mm; working length of 600 mm) was then passed through the airway tube of I-gel™ with its tip resting over the tip of I-gel™ and the glottic view was recorded and graded using Brimacombe score; Grade 0: Functional failure with the vocal cord invisible, Grade 1:Vocal cords not seen, but function adequate, Grade 2:Vocal cords and anterior epiglottis seen, Grade 3: Vocal cords

and posterior epiglottis seen, Grade 4: Only vocal cords visible.<sup>[10]</sup> A FOB score of ≤2 was considered suboptimal and a score of 3 and 4 was considered optimal for the anatomical fit of I-gel™.

Successful placement of the device and effective ventilation was confirmed by square wave capnography, presence of bilateral equal chest rise and delivery of adequate tidal volumes. The leak volume and peak inspiratory airway pressures were monitored continuously. Throughout the surgery, anaesthesia was maintained with sevoflurane 1.2-2%, patients being ventilated on controlled mode with fractional inspired oxygen concentration (FiO<sub>2</sub>) of 50%, using a mixture of oxygen and air. OPLP, FOB score, haemodynamic parameters and insertion characteristics (time taken for I-gel™ insertion, ease of insertion and number of attempts at insertion) were recorded by an independent observer who was blinded to the insertion technique. A maximum of three attempts were allowed for I-gel™ insertion using either of the techniques in all the patients. Patients in whom successful placement of I-gel™ was not possible after three attempts were intubated with endotracheal tube and were excluded from the study. At the end of surgery, neuromuscular blockade was reversed and I-gel™ was removed after the patient had spontaneous rhythmic respiration and was able to open his/her mouth on command. The I-gel™ was observed for any blood staining by an independent researcher blinded to group allocation. Patients were observed in the post-anaesthesia care unit for any episodes of desaturation, nausea and vomiting, sore throat or hoarseness of voice.

With reference to a previous study, the total participants studied in blind group and laryngoscopic-guided insertion group were different, proportion of patients with optimal positioning of the airway device being 45% and 67%, respectively.<sup>[9]</sup> Using these proportions, as reference for estimating the sample size, the sample size was calculated with a two-sided alpha of 0.05 and a power of 80% along with a confidence level of 95%. Considering contingency as mentioned in the reference article, sample size calculated was 76 patients in each group. Since we had randomised the study participants using block randomisation method with blocks of size 6, a minimum of 78 participants were studied in each group.

All statistical analyses were performed using MedCalc for Windows, (MedCalc Software, and version 19.3 Ostend, Belgium). Categorical data/results were

presented as ratio or percentage, continuous data were presented as mean ± standard deviation or median (95% confidence interval). Chi-square test was used to analyse the categorical variables while intragroup comparison of mean changes in outcomes was evaluated by unpaired t test. The strength of association between insertion technique and the anatomical fit of the device was calculated in terms of relative risk ratio. The statistical significance was represented as confidence interval (CI) and the level of significance was set at *P* < 0.05.

## RESULTS

Out of the 180 participants enrolled for the study; 24 patients were excluded, 20 patients had reactive airway symptoms and 4 denied to participate in the trial. A total of 156 patients were included in the final analysis [Figure 1]. The demographic profile, ASA status and anaesthesia time was comparable in both the groups [Table 1].

When visualised through the FOB, it was noticed that optimal position of I-gel™ was achieved in 96.15% patients in group B when compared to 60.26% patients in group A (*P* < 0.0001). The relative risk of suboptimal positioning in the Macintosh laryngoscope-guided insertion group was 0.0968 when compared with the standard blind insertion technique, which accounts for a 86.98% relative risk reduction (RRR) for suboptimal positioning when I-gel™ was inserted under laryngoscope-guided vision (0.0968 with 95% CI [0.0309-0.3034], *P* value = 0.0001) [Figure 2]. The OPLP was higher in the laryngoscope-guided insertion group in comparison to the blind insertion group (26.89 ± 3.37 with 95% CI [26.13-27.66] versus 24.42 ± 3.00 with 95% CI [22.74-25.10], respectively; *P* < 0.0001). The time taken for insertion of I-gel™ was significantly longer in Group B than in Group A (17.70 ± 3.26 seconds and

Table 1: Demographic profile

Variables	Group A (mean±SD)	Group B (mean±SD)	<i>P</i>
Age	33.38±8.84	35.83±8.80	0.085
Weight	65.76±7.22	65.96±7.23	0.868
Gender (Male/Female, <i>n</i> )	36/42	14/64	0.0002
ASA PS (I/II, <i>n</i> )	48/30	50/28	0.740
MPG (1/2, <i>n</i> )	24/54	22/56	0.725
Anaesthesia time	42.61±7.29	42.02±5.58	0.571

Values are presented as mean±standard deviation (SD) or numbers. Group A: Blind insertion group; Group B: Macintosh laryngoscope-guided insertion group. ASA PS: American Society of Anesthesiologists physical status; MPG: Mallampati grading

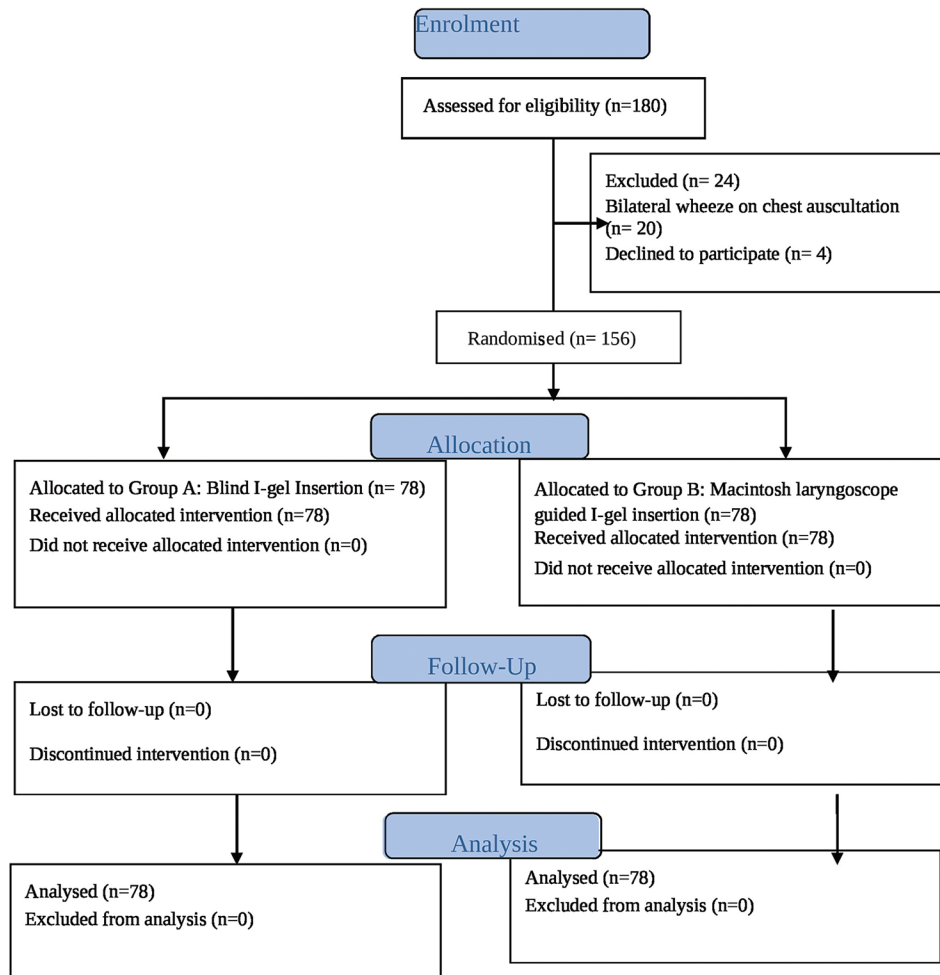


Figure 1: Consolidated Standards of Reporting Trials (CONSORT) Flow Diagram

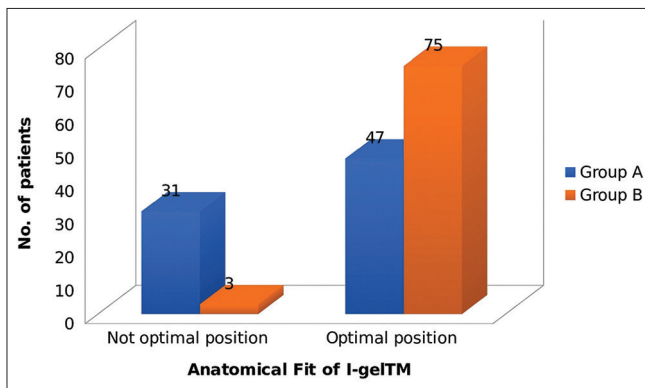


Figure 2: Incidence of malposition. No.: Number

12.91 ± 2.95 seconds, respectively), but the difference was not clinically relevant. The rate of successful insertion at the first attempt was 92.31% in Group A versus 97.44% in Group B ( $P = 0.106$ ). Postoperatively, incidence of blood staining of I-gel™ was higher in Group B but was statistically not significant when compared with Group A (7.69% in Group B versus 16.67% in Group A,  $P = 0.086$ ) [Table 2]. There were

no incidences of clinically significant alterations in the haemodynamic profile and stable vital parameters were observed throughout the procedure in both the study groups [Table 3 and Figure 3].

## DISCUSSION

Our study findings demonstrate that there is a 39.74% risk of suboptimal positioning of I-gel™ when I-gel™ is inserted using the standard blind insertion technique, compared to only 3.85%, when the same is inserted under vision using Macintosh laryngoscope, implying a relative risk of less than 1, that is, the risk of suboptimal positioning decreases by 86.98%, when I-gel™ is inserted under vision. The laryngoscope-guided technique also achieves higher OPLP values, suggesting significant improvement in the anatomic fit and a better airway seal of the device.

Conventionally, I-gel™ is inserted blindly, however, it can be unreliable due to various reasons such as, the

**Table 2: Comparative data of I-gel™ insertion techniques**

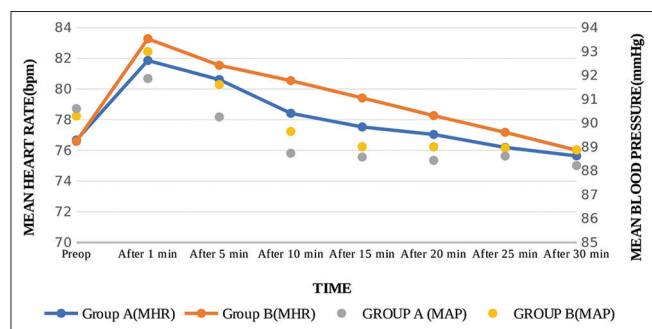
Parameter	Group A (mean±SD)	Group B (mean±SD)	P
Incidence of malposition			<0.0001
Not optimal position (FOB score ≤2)	39.74%	3.85%	RR: 0.0968
Optimal position (FOB score 3 and 4)	60.26%	96.15%	RRR: 1- RR i.e., 0.868 (86.8%)
Oropharyngeal leak pressure value	24.42±3.00	26.13±27.66	<0.0001
Ease of device insertion			0.080
Very easy	33.33%	19.23%	
Easy	60.26%	76.92%	
Difficult	6.41%	3.85%	
Total insertion time	12.91±2.95	17.70±3.26	<0.0001
Number of attempts at insertion			0.106
First attempt	92.31%	97.44%	
Second attempt	7.69%	2.56%	
Blood staining on the I-gel™	16.67%	7.69%	0.086

Values are presented as mean±SD or proportions. Group A: Blind insertion group; Group B: Macintosh laryngoscope-guided insertion group. FOB: Fiberoptic bronchoscope; RR: Relative risk; RRR: Relative risk reduction; SD: Standard deviation. P <0.05 is considered statistically significant

**Table 3: Haemodynamic parameters**

Parameter	Group A (mean±SD)	Group B (mean±SD)	P
HR			
Pre-op	76.68±8.85	76.59±6.81	0.942
At 1 minute	81.86±8.57	83.28±7.97	0.284
At 5 minutes	80.62±7.96	81.55±7.7	0.813
At 10 minutes	78.42±7.21	80.55±7.77	0.319
At 15 minutes	77.53±6.8	79.42±7.56	0.101
At 20 minutes	77.04±6.32	78.27±6.82	0.244
At 25 minutes	76.19±5.73	77.18±6.27	0.306
At 30 minutes	75.64±5.27	76.01±5.21	0.658
MAP			
Pre-op	90.61±7.36	90.3±6.86	0.753
At 1 minute	91.87±7.01	93±6.23	0.285
At 5 minutes	90.26±5.1	91.62±4.97	0.093
At 10 minutes	88.74±4	89.65±4.33	0.164
At 15 minutes	88.58±3.72	89.01±4.16	0.504
At 20 minutes	88.44±3.51	89.01±3.61	0.289
At 25 minutes	88.62±3.47	88.96±3.26	0.489
At 30 minutes	88.22±3.2	88.88±2.92	0.175

Values are presented as mean±SD. Group A: Blind insertion group; Group B: Macintosh laryngoscope-guided insertion group. HR: Heart rate; MAP: Mean arterial pressure; Pre-op: Pre-operative; SD: Standard deviation. P <0.05 is considered statistically significant



**Figure 3:** Mean Arterial Pressure (MAP) and mean Heart Rate Variation

tip of device folding over/backward, tip of distal cuff positioned between the vocal cords, epiglottis lying in the bowl of I-gel™ with downfolding, distal cuff of the device lying in the laryngopharynx or glottic compression.<sup>[4,5]</sup> The advancement in anaesthesia practice is towards securing airway devices under vision rather than inserting them blindly, for which several techniques and devices such as laryngoscopes, lightwand, C-MAC videolaryngoscope and other videolaryngoscopes have been used.<sup>[6,9,11-15]</sup>

A multicentre prospective observational study on insertion characteristics of Laryngeal Mask Airway (LMA) Protector™ has shown that additional in situ manoeuvres were required in 63% subjects; 23% subjects had inadequate ventilation and 28% subjects had difficult/impossible gastric tube

insertion when LMA Protector™ was inserted by the conventional blind insertion technique with only 66% subjects achieving suitable placement of the SGA.<sup>[16]</sup> Another study conducted by Zundert *et al.*,<sup>[17]</sup> on “insert-detect-correct-as-you-go” insertion technique has also concluded that under-vision insertion has more than 94% chances of optimal positioning of LMA-Supreme and LMA-Protector. Similar studies conducted using lightwand as a guide for LMA insertion have shown better fiberoptic laryngeal view when compared with standard blind insertion techniques.<sup>[12,13]</sup> Campbell *et al.*<sup>[15]</sup> reported the ideal FOB scores in 91.5% patients when LMA was inserted under direct laryngoscope guidance compared to only 42% when it was inserted blindly.

If FOB is not available, OPLP could be used as a surrogate measure of correct alignment and airway seal for SGAs.<sup>[18]</sup> Several studies have reported the effectiveness of under-vision-guided insertion techniques of SGA devices in terms of attaining higher OPLPs.<sup>[6,9,11-12]</sup> Kim *et al.*<sup>[9]</sup> in their study, reported higher OPLPs when LMA (LarySeal™) was inserted under laryngoscope guidance (21 ± 8.6 cm of H<sub>2</sub>O) when compared to blind insertion technique (18.1 ± 6.1 cm of H<sub>2</sub>O). Similar study conducted by Ozgul *et al.*,<sup>[6]</sup> also obtained higher OPLP values of ProSeal™ LMA in videolaryngoscope-guided insertion group in comparison to the blind insertion technique. Under vision insertions of SGAs using lightwand, video-styler,

etc. result in OPLP values within a range of 26-30 cm of H<sub>2</sub>O.<sup>[12,13]</sup> The OPLP values that we obtained in our study, in the Macintosh laryngoscope-guided insertion group (26.89 ± 3.37 cm H<sub>2</sub>O) were comparable with these OPLP values.

Videolaryngoscope does offer added advantages over conventional or direct laryngoscopy in terms of technical benefit by providing a larger, brighter and higher resolution image as the customary viewing angle of 15° is extended to 60°-80°, however, it may not be readily available in all clinical settings.<sup>[19,20]</sup> However, the Macintosh laryngoscope is readily available in all OTs, providing a cost-effective alternative and safe tool in these situations, to maximise the chances of successful placement of SGAs.

In our study, we also did not observe any significant increase in adverse events due to sympathetic stimulation caused by direct laryngoscopy, which may probably be due to the laryngoscopy technique, applied, that is, just gently lifting the epiglottis and not necessarily visualising the tracheal opening or the vocal cords. Though the mean insertion time was longer in laryngoscope-guided I-gel™ insertion group due to obvious reasons, the difference was not clinically relevant.

Implementing the idea of assisted under vision placement of I-gel™ will not only improve the quality of airway care but will also increase the proficiency of the device insertion and handling by naïve users.<sup>[21]</sup> As we have evolved from the conventional blind techniques to vision-guided techniques for central venous catheters insertion and peripheral nerve blocks, the need of the hour is to practise the under-vision-guided techniques to ensure effective placement and function of SGA devices and in many settings, the unavailability of videolaryngoscope may be one of the main hurdles for it. As Macintosh laryngoscope-guided insertion of I-gel™ achieved similar OPLP values and insertion characteristics and also resulted in comparable FOB scores to that obtained with the advanced assisted devices, this cost-effective and simple tool could be used as a substitute to guide 'under vision' insertion of SGA devices.

This study has certain limitations. First, the leak volume and peak inspiratory pressures were not documented, although monitoring of these parameters was not neglected throughout the procedure. Second, all patients selected for the study had no anticipated

difficult airway, so our results may not translate to patients with a potentially difficult airway. Third, there was no documentation or monitoring of the duration and severity score of airway trauma, and follow-up after 24 hours in the postoperative period for any possible nerve injuries. Lastly, neuromuscular blocking agent was used in the study and there is evidence suggesting that the use of neuromuscular blocking agent can alter the OPLP.<sup>[22]</sup>

## CONCLUSION

We conclude that, compared to the conventionally used blind insertion technique, the readily available Macintosh laryngoscope could be used as a clinically useful and cost effective tool to ensure proper alignment and function of I-gel™, when used to secure the airway in patients under general anaesthesia.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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