Performance of first and second generation supraglottic airway devices in patients with simulated difficult airway: a randomised controlled trial

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Abstract

Background: Guidelines for management of unanticipated difficult intubation recommend the use of supraglottic airway devices (SADs) in cases of failed intubation. However, there is a lack of comparative studies for different type of devices. In this randomised controlled trial, the performance of 1st and 2nd generation supraglottic airway devices was compared in patients with a simulated difficult airway.

Material and methods: We enrolled 90 patients, scheduled for elective surgery and suitable for supraglottic airway device insertion. Laryngeal mask airway (LMA)-classic (LMAC), LMA-proseal (LMAP) and LMA-flexible (LMAF) were evaluated. The modified Mallampati test was used for the preoperative airway assessment. Maximal mouth opening, body mass index, thyromental and sternomental distances, and neck circumference were measured, and patients with predicted difficulty were excluded. Insertion time, ease of insertion, oropharyngeal leak pressure, and Brimacombe and Berry Bronchoscopy Scores were evaluated. Peak airway pressure was measured at 1, 15 and 60 min following the insertion of SADs. Complications were recorded.

Results: Oropharyngeal leak pressures were 35.2 ± 8.1, 31.7 ± 7.7 and 31.3 ± 6.0 mm Hg for LMAP, LMAC and LMAF respectively ($P = 0.079$). First min peak airway pressure values were 14.0 ± 4.2, 15.0 ± 3.9, 14.9 ± 4.4 mm Hg respectively ($P = 0.403$). There was a significant positive correlation between oropharyngeal leak pressure and first min peak airway pressure ($r = 0.264$, $P = 0.013$). Mean number of attempts was 1.1 ± 0.3 times ($P = 0.840$). Insertion time was 20.0 ± 10.4, 17.0 ± 5.7 and 16.4 ± 10.2 s respectively ($P = 0.440$). Ease of insertion score was 2.0 ± 0.9, 2.1 ± 0.9 and 2.1 ± 1.3 respectively ($P = 0.837$). There was no significant difference for optimization manoeuvre requirement or fibreoptic scope grades ($P = 0.265$, $P = 0.651$, respectively).

Conclusions: First and second generation of supraglottic airway devices provided similar clinical performance for patients with difficult airway and trauma due to limited cervical motion.

Key words: difficult airway, cervical collar, supraglottic airway devices.

Clinical Trial Registration: NCT02979171 at Clinical Trials.gov.

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The incidence of difficult laryngoscopy has been indicated to be 5.8% in patients undergoing general anaesthesia [1], whereas the incidence of difficult intubation is 1/2000 in elective patients and ranges between 1/50 and 1/100 in emergency medicine patients [2]. Supraglottic airway devices (SADs) have nowadays a clear role in this setting, with many studies and reports and recommendations [3–5] supporting the recommendation of SAD's rescue role in case of difficult ventilation/intubation in all international guidelines [6, 7].

Various types of SADs have been developed and are now available on the market, with different and specific features [8] and obeying a kind of evolutional pathway [9]. Most of the masks are suitable for emergency situations, but there are only a limited number of studies comparing SADs on patients with difficult airway in general anaesthesia. Simulation of a difficult airway scenario (such as cervical trauma, cervical fracture, cervical radiotherapy or treatment of burn injuries) is a method commonly used for analysing different rescue intubation tools in both

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paediatric and adult patients and, specifically, application of a cervical collar might easily reproduce a difficult airway condition reducing inter-incisors distance and limiting cervical excursion [10–12].

First and second generation SADs differ in the capability to access the stomach with a dedicated port and with increased sealing capability due to differently designed cuff and pressure-release effect due to gastric emptying opportunity [13]. While LMAC and LMAF are first generation SADs, LMAP is a second generation device allowing higher oro-tracheal leak pressure and aspiration of gastric contents [14]. The Proseal LMA has been successfully used in paediatric and adult patients with simulated difficult airway; many data are available for rescue use LMAC, while there are only case reports in the literature regarding the use of reinforced LMA [15–17].

We conducted this prospective randomized clinical trial comparing LMAP, LMAF and LMAC in patients undergoing general anaesthesia in a simulated difficult airway scenario with a cervical collar. The aim of this study was to provide evidence for a recommendation regarding the use of first and second generation SADs in difficult airway management.

METHODS

It was an observational study. Ethical approval was obtained from the regional ethics review board of Bilim University Medical School (no: 44140529/2015-48). Informed written consent was obtained from all patients. This study followed the Ethical Principles for Medical Research Involving Human Subjects as outlined in the Declaration of Helsinki. This trial was registered at ClinicalTrials.gov: NCT02979171.

Recruitment and setting

The study included a total of 90 elective patients who did not have a history of difficult intubation in their medical history. A consort diagram is provided as supplementary material (Figure 1). Exclusion criteria included fullness and/or massive gastroesophageal reflux, a body mass index (BMI) > 30 kg m^{-2}, any disease related to cervical spine, a mouth opening < 20 mm, a history of upper respiratory tract infection within 10 days prior to the operation, sore throat before the operation, risk of dental injury, a history of cervical radiotherapy, a known acquired or congenital disease, tracheal intubation requirement and emergency surgery, and the infeasibility of mask ventilation due to the presence of a cervical collar. Patients aged 18–80 years, American Society of Anaesthesiology (ASA) status 1–3, scheduled for elective surgery and suitable for SAD insertion were included. Patients were randomized to three groups to receive LMAP (1st Group), LMAF (2nd Group) and LMAC (3rd Group). Randomization was performed using opaque envelopes.

The modified Mallampati test was used for the preoperative airway assessment. Maximal mouth opening, body mass index, thyromental and sternomental distances, and neck circumference were measured and patients with predicted difficulty were excluded. Insertion time, ease of insertion, oropharyngeal leak pressure and Brimacombe and Berry Bronchoscopy Scores were determined by a fibreoptic scope. Peak airway pressure was measured at the 1st, 15th and 60th min following SADs' insertion. Complications were also recorded, including desaturation (SpO_2 < 92%), laryngospasm, bronchospasm, inadequate ventilation (obstructive chest movements, abnormal capnographic waves, increased $etCO_2$, tidal volume < 6 mL kg^{-1}), suspected aspiration or regurgitation, airway obstruction and cough, tooth, tongue or lip trauma, post-operative nausea and vomiting, sore throat, dysphonia and dysphagia (mild/moderate/severe) at 24 hours after surgery were also recorded.

Patients were monitored using electrocardiography (ECG), peripheral oxygen saturation (SpO_2) and non-invasive blood pressure (NIBP). Before surgery, the maximum mouth opening, thyromental distance, sternomental distance and neck circumference at the level of the thyroid cartilage were measured in supine position. For the induction of anaesthesia, patients were given intravenous propofol 2-3 mg kg^{-1}, rocuronium 0.6 mg kg^{-1}, and fentanyl 2 µg kg^{-1}. Anaesthesia was maintained using sevoflurane 2% and air/O_2 mixture 60–40%. After the loss of eyelash reflex, face mask ventilation was performed with SpO_2 > 95% and $EtCO_2$ 30 to 35 mm Hg

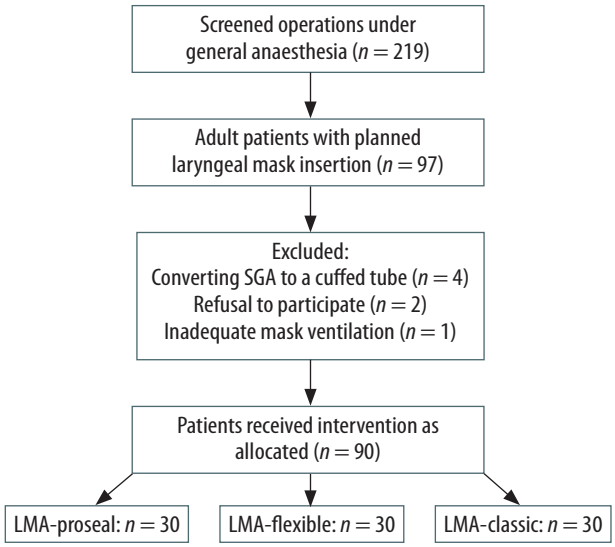

FIGURE 1. Consort diagram of the study

in capnography. Subsequently, a cervical collar was placed. According to the manufacturer's recommendations, the appropriate type of LMA was placed after the cuff was completely deflated and a water-based lubricant gel was applied to the upper surface of the LMA. LMA cuff pressure was set to 60 cm H_2O using a manometer [18]. Afterwards, patients were mechanically ventilated keeping tidal volume at 6–8 mL kg^{-1}. Ventilation was considered effective if a tidal volume ≥ 6 mL kg^{-1} was obtained with normal capnography waves and adequate chest wall expansion for at least three subsequent mechanical breaths. For the measurement of airway leak, the expiratory valve was closed and gas flow was set to 6 L min^{-1}, and the pressure level at which air leak became audible was recorded. A total of three airway interventions were allowed to adjust the head and/or neck position for appropriate ventilation after the LMA was placed. The difficulty of intubation was rated on a 5-point visual analogue scale from 1 (easiest) to 5 (most difficult). Successful LMA insertion was defined as visual observation of rise of the chest with ventilation and normal end-tidal carbon dioxide waveform [19]. In the event of three failed attempts and insufficient ventilation despite airway interventions, the cervical collar was removed and LMA placement was attempted. In cases when LMA could not be placed despite these manoeuvres, patients were intubated and excluded from the study.

A flexible fibreoptic bronchoscope was employed to determine the Brimacombe and Berry Bronchoscopy Score [20]:

1 – vocal cords not visible,
2 – vocal cords and anterior epiglottis visible,
3 – vocal cords and posterior epiglottis visible,
4 – only vocal cords visible.

Patients were mechanically ventilated in the volume-controlled ventilation mode keeping $EtCO_2$ between 30 and 40 mm Hg. After all measurements were completed, the cervical collar was removed. The mean arterial pressure (MAP), heart rate, peak airway pressure (PAP), oxygen saturation and $EtCO_2$ levels were recorded at 1, 15 and 60 min after LMA placement.

Statistical analysis

SPSS 22.0 Armonk, NY: IBM Corp. was used for statistical analysis. Descriptive statistics of study data were expressed with the median, standard deviation, median, minimum, maximum, frequency and ratio values. Distribution of variables was analysed using the Kolmogorov-Smirnov test. Quantitative data were evaluated with the ANOVA (Tukey test), Kruskal-Wallis, Mann-Whitney *U* test and independent sample *t* test. The paired sample *t*-test and Wilcoxon test were used for the analysis of repeated measurements. Qualitative data were normally analysed using the χ^2 test, but when the χ^2 test conditions were not met, Fisher's test was employed instead. Pearson and Spearman correlation analysis were used to identify correlations.

Sample size generated a 90% power and 95% confidence interval. To ensure a standard effect of 0.85, 30 patients were included in each group.

RESULTS

Ninety-seven patients scheduled for an elective surgical procedure under general anaesthesia were enrolled in the study. Three patients were excluded from the study due to various reasons including the extension of the surgical duration over 4 hours after the placement of the LMA, the alteration of the surgical method and air leak during the operation and the failure of ventilation. The other reasons for exclusion were converting LMA to a cuffed tube ($n = 4$), refusal to participate ($n = 2$) and inadequate mask ventilation ($n = 1$). Ninety patients were randomly distributed into three groups. Patient demographics and the findings on physical and airway examination were not statistically different in groups ($P > 0.05$, Table 1). Inter-incisor gap, thyromental distance, sternomental distance and neck circumference did not differ between groups ($P > 0.05$, Table 1). The fibreoptic grade score was not different between groups ($P > 0.05$, Table 1).

Oropharyngeal leak pressure, the time and ease of LMA insertion, the duration of anaesthesia and surgery were not different between groups ($P > 0.05$, Table 2).

The heart rate and mean arterial pressure values were not significantly different between groups before induction, at the 1st min, 15th min and 60th min (Figures 2 and 3). The minimum SpO_2 values were 98.8 ± 1.6%, 99.1 ± 1.1% and 98.8 ± 1.3% for groups I, II and III, respectively. The maximum end-tidal CO_2 levels were reached at the 1st minute after the placement of the LMA in all three groups, being 33.1 ± 4.2 mm Hg, 32.7 ± 3.4 mm Hg and 32.5 ± 3.7 mm Hg respectively in groups I, II and III ($P = 0.695$). The peak airway pressure was achieved at the 60th minute after LMA placement in all groups and measured to be 16.2 ± 4.2 mm Hg, 16.7 ± 3.7 mm Hg and 16.4 ± 3.9 mm Hg in groups I, II and III, respectively ($P = 0.876$). The required airway manipulations and complication rates were not different between groups (Table 3). The results of correlation between oropharyngeal cuff leak pressure and peak airway pressure are presented in Table 4.

DISCUSSION

In this prospective randomized trial, we compared first and second generation laryngeal mask

TABLE 1. Patient demographics and findings on physical examination that indicate difficult intubation

	Group I (mean ± SD)	Group II (mean ± SD)	Group III (mean ± SD)	*P*
Age (years)	46.7 ± 14.3	56.1 ± 16.5	54.0 ± 16.8	0.062
Gender (*n*,%)				
Female	14 (50.0)	18 (60.0)	11 (36.7)	0.237
Male	14 (50.0)	12 (40.0)	18 (60.0)	
BMI	26.3 ± 4.0	25.7 ± 3.6	26.0 ± 4.2	0.908
ASA (*n*, %)				
I	14 (50.0)	11 (36.7)	10 (33.3)	0.535
II	10 (35.7)	16 (53.3)	13 (43.3)	
III	4 (14.3)	3 (10.0)	6 (20.0)	
Inter-incisor gap (cm)	4.5 ± 0.7	4.3 ± 0.7	4.8 ± 0.8	0.086
Thyromental distance (cm)	9.0 ± 1.1	8.9 ± 1.2	8.9 ± 1.2	0.841
Sternomental distance (cm)	13.6 ± 1.4	13.4 ± 1.2	13.6 ± 1.3	0.702
Neck circumference (cm)	36.1 ± 3.0	34.7 ± 4.0	34.6 ± 5.5	0.428
Mallampati score (*n*, %)				
I	8 (28.6)	7 (23.3)	5 (16.7)	0,900
II	18 (64.3)	20 (66.7)	21 (70.0)	
III	1 (3.6)	3 (10.0)	3 (10.0)	
IV	1 (3.6)	0 (0.0)	0 (0.0)	
Brimacombe and Berry Bronchoscopy Scores (*n*, %)				
I	2 (7.1)	5 (16.7)	4 (13.3)	0.651
II	10 (35.7)	11 (36.7)	13 (43.3)	
III	13 (46.4)	11 (36.7)	7 (23.3)	
IV	3 (10.7)	3 (10.0)	5 (16.7)	

TABLE 2. Comparison of oropharyngeal leak pressure, time for laryngeal mask insertion, ease of insertion, duration of anaesthesia and surgery between groups

	Group I (mean ± SD)	Group II (mean ± SD)	Group III (mean ± SD)	*P*
Oropharyngeal leak pressure (mm Hg)	35.2 ± 8.1	31.7 ± 7.7	31.3 ± 6.0	0.079
Time for insertion (s)	20.0 ± 10.4	17.0 ± 5.7	16.4 ± 10.2	0.440
Number of attempts	1.1 ± 0.3	1.1 ± 0.3	1.1 ± 0.3	0.840
Ease of insertion	2.0 ± 0.9	2.1 ± 0.9	2.1 ± 1.3	0.837
Duration of anaesthesia (min)	97.4 ± 38.5	110.4 ± 44.9	101.7 ± 34.3	0.237
Duration of surgery (min)	71.7 ± 36.4	87.1 ± 41.7	79.8 ± 32.5	0.051

airways in a simulated difficult airway with a cervical collar. No significant difference was detected between the groups regarding the oropharyngeal cuff leak pressure, Berry fibreoptic scoring systems, the duration of placement and success rate.

The DAS guidelines recommend the use of SADs at the second step of intervention for difficult airway algorithms and the use of second generation SADs is particularly recommended for the aspiration of gastric contents through the aspiration port [6]. We used the LMAP as the second generation device in this study, but our results might suggest that both LMAC and LMAF – both being first generation devices – could be effectively and safely used, also taking into account that first generation LMAs might still be the most common SADs available.

LMAF may prevent the obstruction and kinking observed when using the classical LMA, which could be of some importance for the use in maxillofacial trauma patients with difficult airway [21]. A meta-analysis including ten RCTs showed that the LMAF had advantages over ETT in terms of lower incidences of hoarseness, coughing and oxygen desaturation [22]. Also, the incidence of aspiration was similar between the reinforced LMA and tracheal in-

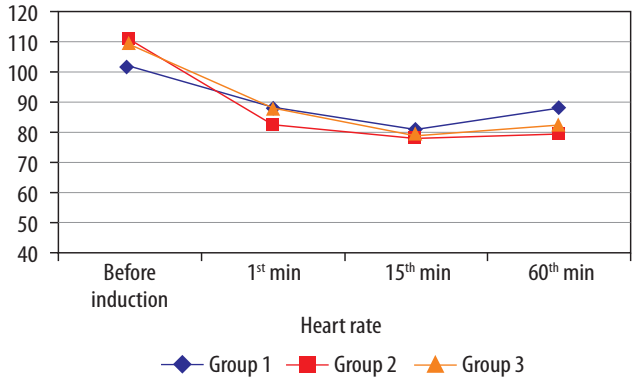

FIGURE 2. Comparison of heart rate (beat/min) values of patients

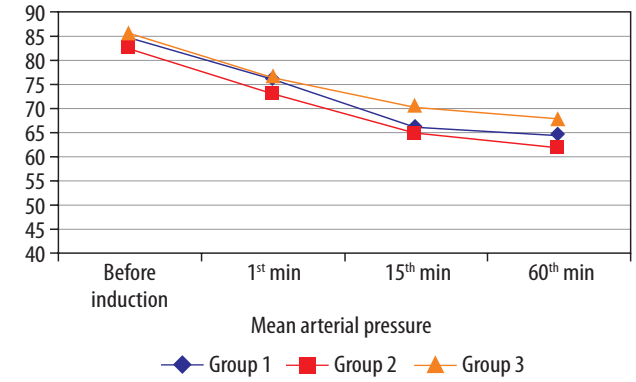

FIGURE 3. Comparison of mean arterial pressure (mm Hg) values of patients

tubation groups. Nevertheless, we do not support the use of reinforced LMA in patients with a high risk of aspiration because patients with the LMA are vulnerable to different degrees of aspiration compared to tracheal intubation [23].

Since we applied the Berry fibreoptic grading, we showed that our patients' mean score was 2 and that LMA created a sufficiently deep cavity, minimizing the risk for aspiration. A potential implication of our results might be that LMAF could be safely used for theout-of-hospital setting and for short time procedures or during transfer to hospital, but in experienced hands, including use of positive pressure ventilation as confirmed also from a 15-year single centre retrospective study [24].

Theiler *et al*. [10] compared LMA supreme and I-gel in 60 patients with difficult airway under anaesthesia and obtained a similar success rate, tidal volume and airway leak pressure for the two methods. Even though I-gel generated less epiglottic downfolding and a better epiglottic view, a longer time of placement was observed. In our study, however, there was no significant difference between the devices regarding fibreoptic evaluation results or the duration of insertion.

There was no difference between the groups in terms of postoperative major complications. A sore throat lasting less than 24 hours after surgery and blood staining on the device were minor complications encountered in our study (not more than 6.7% in group 2).

In a meta-analysis including a total of 1436 patients, the rate of successful LMAP placement at

TABLE 3. Incidence of required airway manipulations and complications

Factor	Group I	Group II	Group III	*P*
Airway manipulations required (*n*, %)				
Yes	6 (21.4)	2 (6.7)	4 (13.3)	0.265
No	22 (78.6)	28 (93.3)	25 (83.3)	
Head extension	0 (0.0%)	1 (3.3%)	0 (0.0%)	
Pulling	0 (0.0%)	0 (0.0%)	1 (3.3%)	
Pulling, pushing backwards	0 (0.0%)	0 (0.0%)	1 (3.3%)	
Pulling, pushing backwards, re-insertion	1 (3.6%)	0 (0.0%)	0 (0.0%)	
Pushing backwards	4 (14.3%)	1 (3.3%)	2 (6,7%)	
Re-insertion	1 (3.6%)	0 (0.0%)	0 (0.0%)	
Complication				
Complication after removal of LMA				
Yes	7 (25.0%)	3 (10.0%)	2 (6.7%)	0.106
No	21 (75.0%)	27 (90.0%)	27 (90.0%)	
Complication in recovery unit				
Yes	4 (14.3%)	4 (13.3%)	1 (3.3%)	0.325
No	24 (85.7%)	26 (86.7%)	28 (93.3%)	
Complication on the first postoperative day				
Yes	1 (3.6%)	2 (6.7%)	0 (0.0%)	> 0.05
No	27 (96.4%)	28 (93.3%)	29 (96.7%)	

χ^2-square test (Fischer test)

the first attempt was reported to be 85% and that of LMAC to be 93% ($P > 0.0001$; $\chi^2 = 20.66$) [25]. According to this study, the success rate of LMAC at the first attempt was higher as compared to LMAP. In the present study, nevertheless, the success rate at the first attempt was high for all three devices and there was no significant difference between the devices. Results from our study should anyway be interpreted in light of long training and experience with SADs use of all performing investigators.

Keller *et al*. [26] compared LMAP and LMAC in relation to oropharyngeal cuff leak pressure in 32 paralysed patients under anaesthesia, finding higher values for LMAP. In our study, the mean oropharyngeal cuff leak pressure was found to be 36 mm Hg, 32 mm Hg and 31 mm Hg for LMAP, LMAF and LMAC, respectively. Furthermore, all three devices were found to be similar in terms of clinical performance including oropharyngeal cuff leak pressure ($P = 0.07$).

Considering the fact that there is a positive correlation between the peak airway pressure at the 1st min and the oropharyngeal cuff leak pressure, we believe that the risk for airway leak and insufficient ventilation is very low even if the airway pressure increases during light anaesthesia. Brimacombe *et al*. [27] performed a randomized comparison between LMAF and LMAC in 40 paralysed patients, finding that the two devices were similar regarding the ease of placement, fibreoptic view and clinical performance. No haemodynamic change was observed during the use of the three devices, with global haemodynamic stability, which could be of some importance hypothesizing the use of these SADs in cervical trauma or other difficult intubation conditions, where haemodynamic effects could be detrimental for the patients.

LIMITATIONS

The most significant limitation of this study is that it was based solely on a difficult intubation simulation. Although patients' mouth opening and neck movements were limited, practitioners did not feel any pressure that they normally experience related to crisis management during a real difficult intubation case. In the event of a real difficult intubation scenario, the outcomes of the procedure may be affected by practitioners' stress and environment [28]. The second most important limitation was the limited sample size. There should be large case series for further evaluation, possibly including different difficult airway scenarios to reinforce the results and their possible translation into clinical use.

CONCLUSIONS

This prospective randomized clinical trial compared the performances of the LMAC, LMAP and LMAF in patients with difficult airway simulated by using cervical collars. All devices had similar clinical performance under difficult intubation conditions. The LMAC probably still remains the most commonly used rescue device for difficult airway scenarios, due to its long-standing presence in airway carts and in anaesthesiologists' experience. Our study demonstrated that there is no significant difference between first and second generation LMAs in terms of the duration of placement, the ease of use and the efficacy of ventilation, no major side effects being recorded. This study also revealed that second generation LMAs can be preferred and easily used in emergency trauma patients with a full stomach due to better oropharyngeal leak pressure performance.

In conclusion, as no significant difference was observed between first and second generation LMAs regarding the ease of placement and success rate in difficult intubation and/or cervical trauma conditions, each of these devices in experts' hands can be safely used in operating rooms and under emergency conditions such as trauma units.

TABLE 4. Correlation between oropharyngeal cuff leak pressure and peak airway pressure

		1st min PAP	15th min PAP	60th min PAP
OPCLP	*r*	0.262	0.178	0.097
	P	0.013	0.099	0.370

PAP – peak airway pressure, OPCLP – oropharyngeal cuff leak pressure Spearman correlation

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