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Propofol requirement for insertion of cuffed oropharyngeal airway *versus* laryngeal mask airway with and without fentanyl: a dose-finding study

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Background. The cuffed oropharyngeal airway (COPA) is a modified Guedel-type oral airway with a cuff at its distal end. The objectives of this prospective, randomized study were to compare the COPA and the laryngeal mask airway (LMA†) in terms of propofol requirement with and without fentanyl pretreatment for smooth insertions.

Methods. Seventy-five patients undergoing general anaesthesia were randomly assigned to either a COPA (n=38) or LMA (n=37) group for airway management, and each group was further randomized to a saline-propofol or fentanyl-propofol group for anaesthesia induction. The saline-propofol group received i.v. saline and the fentanyl-propofol group received i.v. fentanyl 1 μg kg^{-1} followed 30 s later by i.v. propofol. Insertion of the device was attempted 90 s after propofol administration without the use of neuromuscular blocking agents or other adjuvants, and the responses of 'movement' or 'no movement' were judged by three observers blinded to the drug dose. Each dose of propofol at which insertion was attempted was predetermined by modification of Dixon's up-and-down method with 0.5 mg kg^{-1} as the step size, and 2 mg kg^{-1} as an initial dose.

Results. Without fentanyl pretreatment, propofol requirement [mean (SD), 95% CI] for COPA placement [2.17 (0.38), 1.77–2.56 mg kg^{-1}] was significantly less than for LMA insertion [3.42 (0.26), 3.15–3.69 mg kg^{-1}, P<0.001]. In contrast, propofol requirements after fentanyl were comparable between the COPA and LMA groups [1.50 (0.42), 1.06–1.94 and 1.42 (0.26), 1.15–1.69 mg kg^{-1}, respectively], but were less than for the placebo group with both devices (P<0.05). Haemodynamic changes and duration of apnoea were similar with both devices irrespective of fentanyl pretreatment.

Conclusions. Insertion of the COPA can be accomplished with a smaller bolus dose of propofol compared with the LMA, but propofol requirements are similar with both devices after a small dose of fentanyl.

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The cuffed oropharyngeal airway (COPA), a new extratracheal device, is a modified Guedel airway with an inflatable distal cuff and a proximal 15-mm standard connector, which can be attached to the anaesthetic breathing system, thereby enabling anaesthetic gas delivery during spontaneous respiration.[1] Since the introduction of the COPA for clinical use, several studies have compared it with the laryngeal mask airway (LMA†) with respect to ease of insertion, physiological tolerance, intra- and postoperative incidence of complications, and ability to provide positive-pressure ventilation through it.[1–3] Even though insertion of the LMA is associated with a shorter time to establish an effective airway and fewer airway manipulations, reports of success rate of the COPA and the incidence

†LMA® is the property of Intavent Limited.

of early and late complications are conflicting.[1–3] In addition, successful use of these devices may be influenced by experience. Ultimately, both seem to provide a safe and effective airway for spontaneously breathing, anaesthetized patients as well as for those receiving positive-pressure ventilation.

Regarding anaesthetic requirements to insert these devices, studies have shown that the COPA may be inserted under lighter levels of sevoflurane anaesthesia than the LMA,[4 5] suggesting that upper airway stimulation is less during COPA than LMA placement. More recently, using the target-controlled infusion system, plasma concentration of propofol required to place the COPA was less than for the LMA.[6] However, insertion of these devices is most commonly accomplished by bolus injections of propofol alone or in combination with an opioid.[7 8] No clinical trial has compared propofol doses required for successful placement of these devices using a procedure which reflects clinical practice. More importantly, effects of opioid pretreatment on propofol requirements and any haemodynamic changes have not been compared during insertion of the COPA and LMA.

We hypothesized that the COPA would be less stimulating to the upper airway than the LMA during insertion. We also postulated that fentanyl pretreatment would reduce the propofol requirement because of its potent suppressive effect on upper airway reflexes.[9] Fentanyl pretreatment should therefore attenuate the adverse haemodynamic effects associated with a bolus of propofol. Accordingly, this prospective, randomized study was designed to determine: (i) propofol requirements for successful placement of the COPA and LMA; (ii) the effect of fentanyl on these propofol requirements; and (iii) any haemodynamic changes from fentanyl pretreatment during propofol induction.

Methods

The study procedure was approved by our institutional clinical investigation committee, and informed consent was obtained from each patient. Seventy-five patients aged 18–60 yr, ASA status I or II, undergoing elective gynaecological, orthopaedic, plastic or urological surgery under general anaesthesia were studied. Patients were not studied if they were pregnant; had had an allergic reaction to propofol or fentanyl; had, gastro-oesophageal, central nervous system or respiratory tract pathology; had a known or predicted difficult airway such as Mallampati classification >3;[10] or required a position other than supine or lithotomy for surgery. They were randomly assigned to either a COPA (n=38) or LMA (n=37) group for airway management, and each group was further randomized to saline-propofol or fentanyl-propofol group for their anaesthetic technique.

All patients received famotidine 20 mg orally 90 min before induction of general anaesthesia. No other opioid or sedative premedication was given. Anaesthetic management and insertion of both extratracheal devices were performed by a single anaesthetist (M. T.), who had experience of more than 100 and 300 insertions of the COPA and the LMA, respectively. The anaesthetic induction technique was standardized: monitors were applied before induction, including electrocardiogram, pulse oximeter, and non-invasive arterial pressure monitor. After preoxygenation for 5 min, saline 10 ml or fentanyl 1 μg kg^{-1} diluted in 10 ml of saline was given i.v. to the saline-propofol and fentanyl-propofol groups, respectively. Thirty seconds later, each patient received a predetermined dose of i.v. propofol, beginning with 2 mg kg^{-1} for the first patient in each group, given over 30 s through a peripheral i.v. catheter. Then, 60 s after the completion of the propofol injection, the COPA or LMA insertion was attempted by the investigator, who was blinded to both the dose of propofol and the group (saline *vs* fentanyl) assignment. If the patient response was described as 'movement', additional bolus dose of propofol 0.5 mg kg^{-1} was given and insertion was reattempted at 30-s intervals until it was successful.

The dose of propofol for each patient was predetermined by a modification of Dixon's up-and-down method.[11] For the next patient, the predetermined dose of propofol was increased by 0.5 mg kg^{-1} if the preceding patient's response was judged as 'movement', or decreased by 0.5 mg kg^{-1} if a response was described as 'no movement' during insertion of either airway device. Both devices were inserted and fixed according to the manufacturer's instructions and the literature.[12] The size of the COPA was determined by placing the distal end of the upright COPA at the angle of the mandible. When viewed from the side, the tooth/lip guard of the COPA would be ~1 cm ventral to the lip in a device of the appropriate size. After insertion, the COPA was first fastened by the rubber strap, its cuff was inflated with the maximum recommended inflation volume, and then it was connected to the anaesthetic breathing system. A size 3 LMA was selected for women who weighed <65 kg, and a size 4 was used for all other patients. After insertion of the LMA, the cuff was inflated first with the maximum recommended volume of air, and then it was connected to the anaesthetic system.[12] Both airway devices were coated with a water-soluble lubricant immediately before use. Manual inflation with an adequate tidal volume was used to confirm a plateau of the end-tidal carbon dioxide waveform on capnography and to assess the patency of the airway. Airway leak was excluded as part of successful insertion. After insertion of either device, the patients were allowed to breathe spontaneously a mixture of inspired sevoflurane 1% in oxygen for 5 min before surgery commenced. Duration of apnoea, defined as the time from propofol administration until spontaneous respiration resumed, as documented on a gas analyser (Capnomac Ultima SV; Datex, Helsinki, Finland) was noted. In addition, non-invasive systolic (SAP) and diastolic arterial pressure (DAP), and heart rate (HR) were recorded at 1-min intervals after the end of propofol administration.

Table 1 Patient characteristics and surgical data. Values are mean (SD or range) or numbers (%). No significant difference was detected among the four groups

	Saline-propofol		Fentanyl-propofol	
	COPA	**LMA**	**COPA**	**LMA**
Total randomized	22	19	16	18
Male/female	4/18	5/14	6/10	4/14
Age (yr)	35 (18–60)	38 (18–60)	36 (21–58)	38 (18–59)
Weight (kg)	58 (8)	60 (11)	59 (13)	57 (12)
Height (cm)	159 (7)	158 (7)	157 (12)	159 (10)
Smoker (*n*)	4 (18%)	3 (16%)	3 (19%)	3 (17%)
Mallampati classification				
1	11	10	10	8
2	9	7	4	6
3	2	2	2	4
Surgical procedure				
Gynaecological	10	10	10	11
Orthopaedic	8	5	6	4
Plastic	2	1	0	0
Urological	2	3	0	3

Patients' responses to the COPA or LMA were described as 'no movement' or 'movement'. 'No movement' was defined as the absence of bucking or gross purposeful movement after insertion and inflation of the cuff of the COPA or LMA until an effective airway was established. This was confirmed from the square waveform of the capnometer, synchronous thoracoabdominal movements, and the absence of stridor. 'Movement' refers to resistance to mouth opening, gross purposeful movement during instrumentation, coughing, straining or laryngospasm occurring before or after inflation of the device, or when any of the above occurred during airway manipulation before an effective airway was established. The presence or absence of movement was documented by three operating room personnel; the investigator in charge of the anaesthetic, the surgeon and the nurse in charge of the case. When at least two of the observers documented any movement, the case was described as 'movement', except that difficulty in mouth opening was judged solely by the investigator. Each patient was given a single dose of propofol before the first insertion attempt. The three observers were blinded to the dose of propofol and the group assignment, but not to the airway device.

Propofol requirement was determined by calculating the midpoint dose of all independent pairs of patients using a crossover technique, that is 'movement' to 'no movement'. The ED_{50} for the COPA and LMA groups were defined as the average of the crossover midpoints in each group. We studied consecutive patients until at least six crossover midpoints were obtained in each group. We analysed our data using a probit test (proprietary software, SAS Version 8.02, Cary, NC, USA) to obtain 95% confidence intervals (CI), and a logistic regression test to obtain the probability of 'no movement' *vs* dose of propofol, the maximum likelihood estimators of the model variables, and a goodness of fit. Other statistical analyses used were the χ^2 test and unpaired Student's *t*-test with Bonferroni's correction to compare physical characteristics and other variables among groups. Temporal haemodynamic data were first analysed using repeated-measures analysis of variance (ANOVA), and if a significant difference was detected, it was followed by paired Student's *t*-test with Bonferroni's correction. All data are expressed as mean (SD). A P-value <0.05 was considered significant.

Results

There were no significant differences among the four groups in terms of physical characteristics, history of smoking, Mallampati classification, or the surgical procedure (Table 1).

The extratracheal devices were inserted within three attempts in all patients after additional propofol. The LMA was successfully inserted in all patients in the LMA-saline-propofol and LMA-fentanyl-propofol groups without supporting the airway, whereas six and eight patients in the COPA-saline-propofol and COPA-fentanyl-propofol groups, respectively, required airway support (mostly chin-lift). Propofol requirements in the COPA-saline-propofol group [95% CI] and in the LMA-saline-propofol group were 2.17 (0.38) mg kg^{-1} [1.77–2.56] and 3.42 (0.26) mg kg^{-1} [3.15–3.69], respectively ($P<0.001$; Fig. 1). Pretreatment with fentanyl 1 μg kg^{-1} significantly reduced the propofol requirement of the COPA-fentanyl-propofol group to 1.50 (0.42) mg kg^{-1} [1.06–1.94] ($P<0.05$ *vs* the COPA-saline-propofol group). Similarly, propofol requirement in the LMA-fentanyl-propofol group (1.42 (0.26) mg kg^{-1} [1.15–1.69]) was significantly less than that of the LMA-saline-propofol group ($P<0.01$). However, no significant difference was detected between the propofol requirements of the COPA-fentanyl-propofol and LMA-fentanyl-propofol groups ($P=0.69$; Fig. 2).

Logistic regression curves of the probability of no movement upon COPA and LMA insertion without fentanyl pretreatment are shown in Figure 3. Maximum likelihood estimators of the logistic regression model variables and assessment of goodness of fit are presented in Table 2. Maximum likelihood estimators of the logistic regression model variables could not be obtained in the LMA-fentanyl-propofol group because of an inadequate number of data points between 0 and 100% probability. Thus, propofol requirements were not compared between the COPA-fentanyl-propofol and LMA-fentanyl-propofol groups using this model, and goodness of fit was not assessed in these two groups. There were no significant differences between the observed and the predicted values in the COPA-saline-propofol and LMA-saline-propofol groups.

On arrival at the operating room, arterial pressure and HR were similar among the four groups (Table 3). Administration of saline caused no haemodynamic changes, while fentanyl produced significant decreases in HR in the COPA-fentanyl-propofol and LMA-fentanyl-propofol

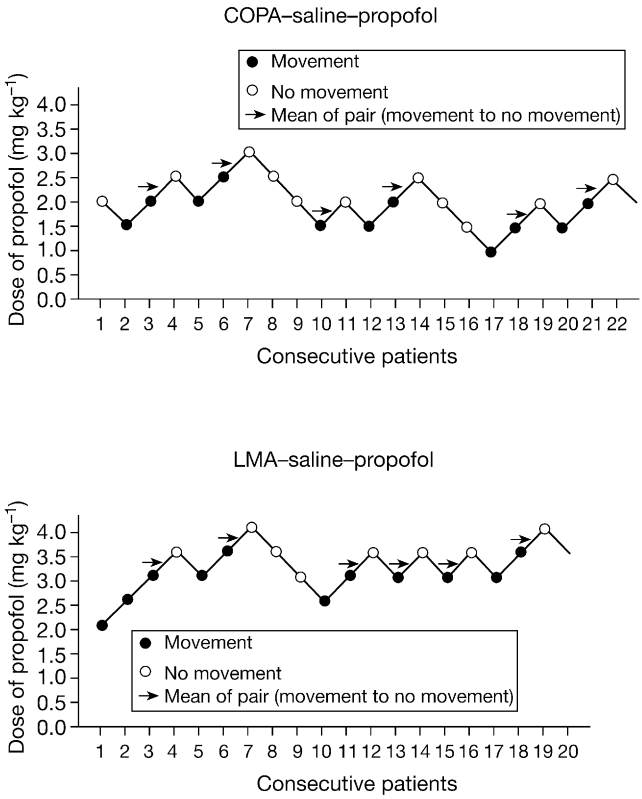

Fig 1 The responses of 22 and 19 consecutive patients in whom COPA (top panel) or LMA (bottom panel) insertion was attempted, and the dose of propofol without fentanyl pretreatment. Arrows indicate the midpoint doses of all independent pairs of patients involving a crossover (i.e. movement to no movement). The doses of propofol required for smooth insertion of the COPA and LMA were 2.17 (0.38) and 3.42 (0.26) mg kg^{-1}, respectively (P<0.001).

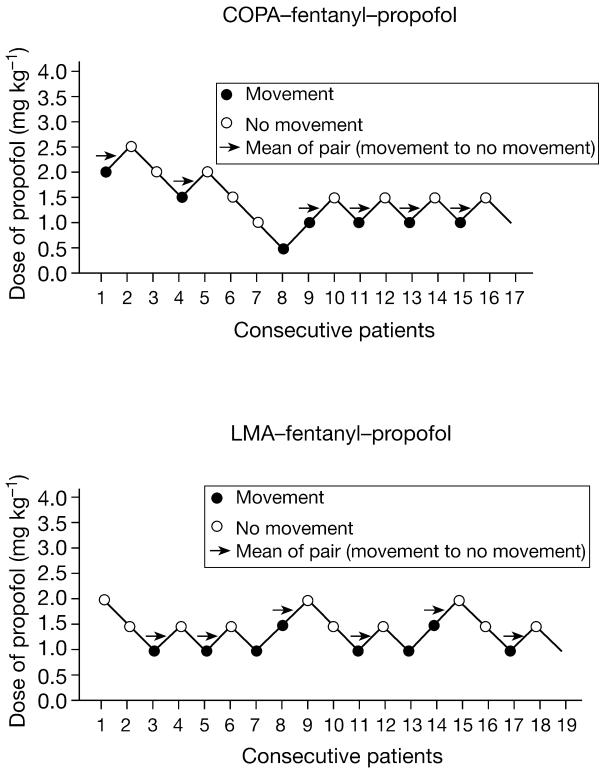

Fig 2 The responses of 16 and 18 consecutive patients in whom COPA (top panel) and LMA (bottom panel) insertion was attempted, and the dose of propofol after fentanyl 1 μg kg^{-1} pretreatment. Arrows indicate the midpoint doses of all independent pairs of patients involving a crossover (i.e. movement to no movement). The doses of propofol required for smooth insertion of the COPA and LMA were 1.50 (0.42) and 1.42 (0.26) mg kg^{-1}, respectively (P=0.69).

groups. After induction of anaesthesia with propofol, SAP and DAP decreased significantly in all groups throughout the 5 min observation period compared with preinduction values (DAP data not shown). HR increased significantly in the COPA-saline-propofol and COPA-fentanyl-propofol groups 1 min after propofol administration, and significantly decreased in the LMA-fentanyl-propofol group 5 min after induction, but remained unchanged from preinduction values at other time points. There was no significant difference in arterial pressure and HR values between the four groups at any interval (Table 3).

Responses of patients who showed 'movement' are summarized in Table 4. An oxyhaemoglobin saturation <90% was seen in one patient in each of the COPA-saline-propofol, COPA-fentanyl-propofol, and LMA-saline-propofol groups. There was no disagreement in the judgment of 'movement' or 'no movement' among the three observers. Durations of apnoea of the COPA-saline-propofol, LMA-saline-propofol, COPA-fentanyl-propofol, and LMA-fentanyl-propofol groups were 170 (91), 179 (74), 164 (64), and 152 (45) s after the start of propofol injection, respectively (P>0.05). No ventricular or supraventricular arrhythmia was noted in any patient during the study period.

Discussion

The major finding of this study was that the propofol requirement for smooth insertion of the COPA was less than that LMA insertion in adult patients without opioid pretreatment. To the best of our knowledge, no previous study has compared propofol requirements for the placement of these devices in a single clinical trial using a method that closely approximates to clinical practice. In terms of anaesthetic requirement for these devices, our results are in accordance with a previous report showing that time of sevoflurane exposure before acceptable COPA placement was shorter than that for the LMA.[4] Our previous study also demonstrated that minimum alveolar sevoflurane concentration required to place the COPA [1.33 (0.38)%] was significantly less than that for the LMA [2.00 (0.42)%].[5] More recently, the calculated plasma concentration of propofol required to place the COPA using the target-controlled infusion system was less than for the LMA.[6] These results, together with our present findings, suggest

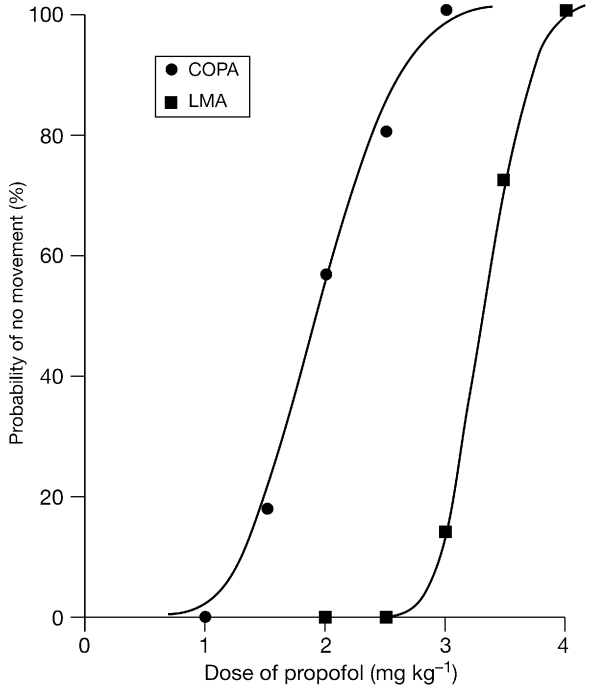

Fig 3 Dose–response curves for propofol plotted from logit analyses of individual dose of propofol (mg kg^{-1}) and the respective responses to COPA or LMA without fentanyl pretreatment.

Table 2 Estimated values of the coefficient of logit. Goodness of fit χ^2 COPA=0.9309; LMA=0.9635. (p/1–p)=B0+B1X, B0=intercept, B1=slope, X=dose of propofol (mg kg^{-1})

	Saline-propofol	
	COPA	**LMA**
Intercept	–6.359	–19.118
Slope	3.223	5.744
Propofol requirement (mg kg^{-1})	1.973	3.328
P-value	0.029	0.023

that upper airway stimulation may be less during COPA than LMA placement. This may be attributed, at least in part, to a difference in the depth of insertion and the area of the upper airway stimulated by the cuff of the two devices. The distal end of the COPA, when inserted correctly, only reaches the base of the tongue and the hypopharynx, and its cuff occupies more compliant hypopharyngeal tissue. In contrast, the cuff of the LMA occupies the narrower supraglottic region and is applied tightly to the glottis. One may argue that with the LMA inflation of the cuff with the maximum recommended volume may exert greater pressure on the narrower glottic region, and produce greater stimulation compared with the COPA, accounting for the difference in the propofol requirements between the two devices. However, if gradual, intermittent inflation of the cuff of the LMA was used to overcome this effect, multiple manual inflation may be required to confirm the establishment of the airway, which would decrease arterial carbon dioxide tension and affect the duration of apnoea, invalidating the purpose of this study.

The dose of propofol required for the placement of the LMA in our study was considerably greater than in previous reports.[13 14] Our results suggest that, without fentanyl, propofol 3.7 mg kg^{-1} is required to achieve a satisfactory level of anaesthesia in most patients, while Blake and colleagues,[13] recommended propofol 2 mg kg^{-1} for LMA insertion. The difference is partly because our patients received no sedative premedication, while in the study by Blake and colleagues, patients received oral temazepam before induction. Propofol 2.5 mg kg^{-1} alone administered in unpremedicated patients can lead to undesirable effects, such as swallowing, gagging, coughing, vigorous movement of the extremities, and laryngospasm.[8] Another possibility would be that our criterion of smooth insertion (i.e. the definition of 'no movement') may have been relatively strict compared with previous reports.

Our study also demonstrated that fentanyl pretreatment significantly reduced propofol requirements for both COPA and LMA placement. To avoid airway complications, inhibition of the upper airway reflexes, such as the cough reflex, is indispensable for smooth insertion of these devices. Tagaito and colleagues[9] studied the effects of fentanyl on upper airway reflexes in humans during propofol anaesthesia, and found dose-dependent suppression. Indeed, a previous study showed that fentanyl 1 μg kg^{-1} given before propofol induction significantly improved the conditions for LMA insertion compared with placebo.[14] Similarly, fentanyl has been reported to reduce minimum alveolar sevoflurane concentration required for tracheal intubation in a dose-dependent manner in humans.[15] In contrast to our assumption, however, reducing the dose of propofol by fentanyl pretreatment did not result in less haemodynamic change compared with propofol alone, and the degree of arterial pressure decrease was clinically acceptable in all groups. In addition, duration of apnoea was similar with or without fentanyl for both devices. Although a larger study involving more patients may be warranted, our results indicate that there is no clinical benefit of adding fentanyl to a smaller dose of propofol compared with using a larger dose of propofol alone for insertion of the COPA or LMA.

It is not clear from our results why propofol requirements were similar for both airway devices after fentanyl pretreatment, and no previous study has compared the anaesthetic requirement for COPA and LMA insertion after opioid premedication or pretreatment. Considerably different propofol requirements for COPA and LMA insertion without fentanyl, but not when a small dose of fentanyl pretreatment is used, suggest that study design may have affected the results found with these devices in terms of upper airway stimulation. We cannot exclude the possibility that a potent inhibitory effect of fentanyl on upper airway reflexes may have masked the differential

Table 3 Arterial pressure and heart rate before and after anaesthetic induction with propofol. Values are mean (SD). *$P<0.05$ *vs* corresponding values on arrival in the operating room, †$P<0.05$ *vs* preinduction values. No significant difference was detected among the four groups

	Saline-propofol		Fentanyl-propofol	
	COPA	**LMA**	**COPA**	**LMA**
On arrival at the operating room				
SAP	129 (14)	136 (16)	132 (14)	138 (18)
DAP	76 (12)	76 (10)	73 (12)	80 (10)
HR	75 (12)	80 (14)	79 (11)	78 (15)
Preinduction after fentanyl or saline				
SAP	131 (15)	136 (16)	129 (13)	135 (19)
DAP	75 (11)	76 (10)	69 (10)	77 (13)
HR	75 (13)	82 (14)	76 (10)*	72 (15)*
1 min after propofol (at insertion)				
SAP	120 (14)†	117 (21)†	119 (12)†	122 (19)†
HR	80 (15)†	89 (13)	83 (12)†	74 (11)
2 min after propofol (1 min after insertion)				
SAP	117 (17)†	111 (21)†	111 (15)†	116 (21)†
HR	76 (13)	86 (15)	80 (13)	68 (12)
3 min after propofol (2 min after insertion)				
SAP	114 (11)†	109 (11)†	102 (13)†	109 (21)†
HR	79 (14)	83 (12)	74 (10)	67 (9)
4 min after propofol (3 min after insertion)				
SAP	107 (12)†	105 (12)†	100 (13)†	100 (15)†
HR	80 (17)	83 (12)	72 (10)	66 (12)
5 min after propofol (4 min after insertion)				
SAP	103 (11)†	101 (10)†	101 (12)†	97 (13)†
HR	79 (16)	81 (9)	70 (10)	63 (9)†

SAP=systolic arterial pressure (mm Hg); DAP=diastolic arterial pressure (mm Hg); HR=heart rate (beats min^{-1}). Preinduction=after saline or fentanyl before propofol administration.

Table 4 Summary of patients' responses who were described as showing 'movement' on insertion of the COPA or the LMA after propofol induction. Data are number of patients. One patient in each of the COPA-saline-propofol, LMA-saline-propofol, and LMA-fentanyl-propofol group developed both gross extremity movement and coughing

	Saline-propofol		Fentanyl-propofol	
	COPA	**LMA**	**COPA**	**LMA**
Total randomized	22	19	16	18
Number of patients with 'movement'	11	11	7	8
Difficult mouth opening	4	1	6	5
Gross extremity movement	3	6	1	3
Straining	2	0	0	0
Coughing	2	5	0	1
Laryngospasm	1	0	0	0

stimulatory effects of the COPA and LMA on the upper airway.

Our results must be interpreted with some caution. First, we should have enrolled some patients of Mallampati class 4, as these airway devices may be especially useful when intubation fails or a difficult airway is anticipated.[16–18] Secondly, there was a chance that the responses of one observer might have biased the judgment of another. Making video recordings of the procedure and subsequent analysis by independent observers would have eliminated such a possibility. Lastly, primary outcome measures, such as the bispectral index, were not monitored, nor was the effect-site concentration of propofol estimated using a target-controlled infusion system. However, a recent report showed that time to the peak effect of propofol after bolus injection was 1.6 min using Marsh kinetics.[19 20] Indeed, the lowest bispectral index occurred within 2 min after bolus injection of propofol delivered at a speed similar to our procedure in healthy adult patients.[21]

In conclusion, our study demonstrated that the propofol requirement for smooth insertion of the COPA was less compared with the LMA when propofol was used alone, but was similar to the LMA when fentanyl 1 μg kg^{-1} was given immediately before the propofol. Even though fentanyl pretreatment reduced the propofol requirements for both devices, our data did not support the routine use of fentanyl in combination with propofol for the placement of the COPA or LMA.

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