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Abstract

Background: The manufacturer Ambu® recommends that the AuraOnce™ laryngeal mask be removed once the patient is fully awake. Studies have shown benefit in removal of the laryngeal mask airway while a patient is deeply anaesthetized. Current evidence is inconclusive, as to which approach is preferable and safer in adults.

Methods: one hundred and sixteen adult patients were randomly assigned to two groups of 58. For the deep arm; The AuraOnce™ laryngeal mask was removed after attaining an end tidal minimum alveolar concentration of Isoflurane of 1.15%. Occurrence of airway complication(s) (One or more of the following; Airway obstruction requiring airway manipulation; Laryngospasm; Desaturation to 90% or less on pulse oximetry) was noted until the subject was fully awake (appropriate response to command) in the post-anaesthesia care unit. For the awake arm; The AuraOnce™ laryngeal mask was removed on attaining an end tidal minimum alveolar concentration of Isoflurane of <0.5% and an appropriate response to command or obtaining appropriate response to command irrespective of end tidal concentration. Occurrence of airway complication(s) in theatre and post anaesthesia care unit was recorded. Time to theatre exit was recorded for both groups.

Results: Baseline demographic characteristics were similar between the groups. More airway complications were encountered in the Deep arm - 13 (22.4%) relative to the Awake arm -5 (8.6%), this was found to be statistically and clinically significant, P value P=0.040, odds ratio 3.0622; 95% CI, 1.0139 to 9.2483.

Conclusion: The removal of the AuraOnce™ laryngeal mask while the patient is still deeply anaesthetised is not as safe as or safer than awake removal.

Keywords: AuraOnce™ laryngeal mask, deep anaesthesia.

Introduction

The Laryngeal Mask Airway (LMA) is a supra-glottic airway device that was invented in 1981 by Archie Brain, an Anaesthesiologist[1]. Its invention marked a turning point in airway management in anaesthesia as it offered a convenient bridge between the use of an endotracheal tube and facemask ventilation. Several advantages have been cited for its use as compared to the endotracheal tube or the facemask, as an airway management option given the appropriate indication. A meta-analysis by J. Brimacombe et al found that the LMA had thirteen advantages over the endotracheal tube and four over the face mask as techniques of airway management[2].

Of the advantages, ease of use is a prominent feature of the LMA. This relative ease of use and safety profile has led to the utilization of an estimated 200 million LMAs globally as of 2013 3. At The Aga Khan University Hospital, Nairobi (the site of this study), records availed by the hospital showed that out of the 9138 general anaesthesia procedures carried out in the year 2015, 2032 (21.8%) were performed using the LMA. The utilization of the LMA can be anticipated to increase given the cur-

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rent use of the device in procedures previously deemed as contraindications. For instance, several publications report use in surgery performed in prone position; airway surgery such as adeno-tonsillectomy and laparoscopy

The LMA can be considered to be a relatively new invention, as such, certain aspects of its use remain unsettled and research towards clarifying and improving these aspects is ongoing. Whether to remove the LMA when patient is "awake" (appropriate response to command) or "deep" (anaesthetized) is one such area.

At our institution, the Ambu® AuraOnce™ laryngeal mask, (ALM), is the design variant most utilized. The Ambu® ALM features a special 70° curve that carefully replicates natural human anatomy. Moulded directly into the tube for additional safety, the unique shape of the mask makes correct insertion fast and easy without putting extra stress on the upper jaw. The manufacturer of the ALM, Ambu®, recommends that the ALM be removed once the patient is fully awake and protective airway reflexes are active[7]. This recommendation was also put forth by the inventor of the LMA, Archie Brain[1] in 1983. There appears to be no objective evidence in support of these recommendations, as such, use of the LMA over the past 25 years has led to several studies to substantiate this recommendation.

This gap in knowledge is summarized in the conclusion of a Cochrane systematic review by Mathew P.J. et al, that current evidence does not show superiority of either approach[8]. They also noted that the quality of currently available evidence was low.

An internet search also revealed several discussion forums/blogs on the same topic that yielded no conclusive evidence cited or consensus from proponents of either approach[9,10].

The variation in individual practice is based primarily on possible complications associated with either approach. Deep removal being associated with possibility of airway loss (soft tissue obstruction, laryngospasm) and subsequent desaturation and hypoxia. Whereas awake removal being associated with the possibility of coughing, retching , agitation on emergence ,increased incidence of gastric content regurgitation , laryngospasm, biting hence occluding LMA[11]. Why users opt for either technique is not clearly delineated, as both approaches seem to have several undesirable outcomes with unspecified frequency.

This study set out to determine the proportion of airway complications occurring in awake versus deep (anaesthetized) patients undergoing anaesthesia. The ultimate aim was to distinctly quantify the proportion of airway complications associated with either approach thus aid decision making on safe use of the ALM. Our research question was: is there a difference in proportion in the occurrence of airway complications between spontaneously breathing adults patients when the ALM is removed deep versus awake following Isoflurane general anaesthesia? We hypothesized that there is no difference in the proportion of airway complications in spontaneously breathing adult patients when the ALM is removed deep or awake following isoflurane general anaesthesia. Our primary objective was to compare the impact of having AuraOnce™ laryngeal mask removal deep versus awake on the occurrence of airway complications following general anaesthesia in spontaneously breathing adult patients. Our secondary objectives were to compare the impact of deep versus awake AuraOnce™ laryngeal mask removal on anaesthesia theatre turn- around time and the incidence of airway obstruction requiring airway manipulation; laryngospasm; desaturation to <90% on pulse oximetry among patients where the AuraOnce™ laryngeal mask is removed deep and awake.

Methods

Approval to conduct the study was sought and obtained from the Aga Khan University Research Ethics Committee prior to initiating the study. The study was carried out between February 1 2017 and May 31 2017. Participant flow diagram is shown in figure 1. It was a prospective randomized control trial conducted at the Aga Khan University Hospital, Nairobi. This is a 300 bed private not-for-profit institution that provides tertiary and secondary level health care services. We included all ASA I and II patients between 18 years- 65 years scheduled to receive general anaesthesia with a laryngeal mask airway (as the airway management device) for low to moderate risk, elective surgery lasting less than two hours as per protocol. Reasons for exclusion from the study were:

1.   Active/ongoing history of upper and or lower respiratory tract infection/disease
2.   Patients with a difficult AuraOnce™ laryngeal mask insertion (defined as greater than two attempts)
3.   Patients with severe gastroesophageal reflux disease

4.   Patients with a symptomatic hiatus hernia
5.   Patients with a BMI> 40kg/m²
6.   History of Obstructive sleep apnoea
7.   Patients in whom muscle relaxants were to used
8.   Patients with Mallampati class 3 and 4
9.   Patients who did not give consent
10.   Patients who did not understand English or Swahili
11.   Patient with psychiatric disease

No study reviewed/found in literature was similar or methodologically congruous with this study. Proportions that may have been drawn from the aforementioned systematic review are mostly from paediatric studies. Given the marked inherent anatomical and physiological differences of the adult airway vis-à-vis the paediatric airway it was deemed imprudent to draw proportions of airway complications from paediatric studies. The remaining adult studies markedly differed in methodology and primary objective thus proportions from those studies were ruled out as well. For instance the study by Nunez et al (over and above our questions about the methodology of this study) had a 3.03% incidence of airway complications in the awake arm versus 51.5% incidence in the deep arm and the study by Gataure et al showed an incidence of 54% airway complications in the awake arm versus 20% in the deep arm[9,11]

The difference in these proportions are 48.5% and 34% respectively. The study by Gataure concedes that the incidence of complications in the awake arm were unusually high and possibly caused by a methodological flaw. As for Nunez's study the remarkably high incidence of airway complications is the deep arm was due to deliberate delay in placing the Guedel airway, thus markedly exaggerating complication incidence in that arm. Lastly the observational study by Hseih et al found no airway complication in all their patients (this study only looked at removal of the LMA while patients were deep)[13].

Given evaluation of above data, the proportions drawn from those studies to calculate the sample size would have probably yielded a type II error, also bearing in mind the small sample sizes utilized in these studies. The Aga Khan University, Nairobi, Scientific committee therefore advised that we consult the anaesthesia department faculty to advice on probable proportions based on their clinical experience. A difference of 25% was thus settled upon by consensus after reviewing the above studies and local practice.

We therefore resorted to expert opinion based on lack of appropriate evidence in this field of study.

The following sample size calculation formulae were used:

$$n = \frac{\left[Z_\alpha \sqrt{(1+1/m)\bar{p}(1-\bar{p})} + Z_\beta \sqrt{p_0(1-p_0)/m + p_1(1-p_1)} \right]^2}{(p_0 - p_1)^2}$$

$$\bar{p} = \frac{p_1 + m p_0}{m + 1}$$

Where;
P0 = Probability of airway complications in the control group (Awake arm = 0.25)
P1 = Probability of airway complications in the experimental group (Deep "anaesthetized" arm = 0.50)
m = Ratio of controls to experiment subjects (=1).
Z_α = normal deviate corresponding to a type I error of 0.05 or 95% CI in a two tail test = 1.96
Z_β = normal deviate corresponding to a Type II error of 20% equivalent to power 0.8 = 0.842
n = 116 (58 in each arm)

A sample size of 116 patients was drawn to demonstrate a 25% difference in the occurrence of airway complications between patients in whom the ALM was removed awake (appropriate response to command) versus in those whom the ALM was removed deep (anaesthetized).
The study was powered to 80% with an alpha of 5%.
Patients were recruited from the day-care unit. Patients were informed of the nature of the study, screened for eligibility and recruited if eligible. Eligible patients had verbal explanations on the purpose and nature of the study. The patients who gave written informed consent were enrolled into the study. Our statistician developed a simple random allocation sequence using a computer algorithm. Each of the random numbers were sequentially assigned to either; Awake arm: Green sticker; Deep arm: Red sticker. The statistician serialized envelops to correspond to the random allocation sequence and insert the green and red stickers in them. Patients who consented for the study had the serialized envelop attached to their file. The research assistant(s) opened the envelope and

knew the group allocation and attached the sticker on the patient data collection tool. Blinding to the interventions was technically not possible for the study.

Once the patient was on the theatre table, ASA recommended14 monitoring set up (i.e. capnography, pulse oximetry, temperature, electrocardiography and non-invasive blood pressure monitoring on Mindray Wato Ex-65 monitor) applied and baseline vital signs measurement taken. Intravenous access was obtained using a gauge 18 - 20 cannula. The patient was then pre-oxygenated at 6 litres oxygen flow rate for 3 minutes.

Induction was standardized as follows; Propofol 2 milligrams per kilogram IV (this was titrated to effect as is our standard practice, to avoid inadvertent adverse effects such as hypotension and bradycardia given variable patient response) and Isoflurane initiated at 2% on the vaporizer; appropriate size ALM was inserted using the classical technique, and inflated to a maximum volume according to size as per manufacturers recommendation[7,15]. Placement confirmation was by auscultation and capnography and the ALM was then secured. Patients were manually ventilated until spontaneous breathing resumed (no mechanical ventilation was carried out as it was thought that this may confound outcome because resumption of spontaneous breathing at the end of surgery may have be delayed).

Opioid use portended to be a confounder on airway complications, as such, standardization was to be attained by administering the opioid at beginning of surgery and at recommended dosage i.e. Pethidine 1 milligrams per kilogram or Morphine 0.1mg/kg of Fentanyl 1 to 2 mcg/kg. These doses were guided by the potential pain associated with the procedure range in which the ALM is used. Routine use of traditional non-steroidal anti-inflammatory drugs as well as paracetamol was applied if there were no contraindications. Opioids dosage was adjusted as per patient requirements and deviation from the protocol noted. Suction if applied was documented in the data collection tool. All patients in the deep arm were to be suctioned on removal of the ALM.

The end of surgery was represented by the point marked by end tidal of 1 MAC (1.15 for Isoflurane) as the anaesthetist dialled down Isoflurane anticipating end of procedure. At that point (end tidal of 1.15% Isoflurane) a timer was started. The timer would be stopped once the patient existed the theatre door.

For the Deep arm of the study; Isoflurane vaporizer was turned off; Oxygen dialled to 100% at 6 litres per minute and on attaining an end tidal concentration of 1.15% Isoflurane, the ALM was removed (without deflating cuff) and an appropriate sized oropharyngeal airway placed and the patient positioned in "sniffing position"; a Hudson mask was then be placed at 6 litres oxygen flows. At the discretion of the anaesthetist, the patient exited the operating theatre in transit to the post anaesthesia care unit (PACU).

For the awake arm of the study; Isoflurane would be turned off; oxygen dialled to 100% at 6 litres flow rate; on attaining an end tidal concentration <0.5% Isoflurane and an appropriate response to command (as defined) the ALM was removed, however, if the patient was noted to be waking up prior to attaining an end tidal of < 0.5% and had an appropriate response to command then the ALM was withdrawn irrespective of end tidal concentration of Isoflurane a Hudson mask would then be placed and oxygen administered at flows 6 litres flow rate. At the discretion of the anaesthetist the patient exited the operating theatre in transit to the PACU.

Intra-operative and post-operative data was collected by trained research assistants and PACU nurses using a data collection form. This continued until the patient was fully awake and responding appropriately to command (as defined) for both groups from end of surgery (as defined). Parameters of interest were: Airway obstruction (defined as need for airway manipulation); laryngospasm; desaturation to 90% or less on pulse oximetry. The composite all the parameters was defined as airway complication(s). All the raw data in this study was filed in suitable box file and flash disk which were kept locked in the principal investigator's locker. All data sheets<="" span="" style="-font-family: "Times New Roman";">were checked for completeness prior to filing.

Categorical variables were summarized using frequency and percentages while continuous variables were summarized using descriptive statistics i.e. means. Pearson Chi Square test was carried out to test the difference in proportions between the incidence of airway complications in the deep arm and awake arm following ALM removal. The secondary outcomes yielded continuous data i.e. time it takes to exit theatre. The Mann Whitney test was used for the means of the time to exit theatre for deep and awake ALM removal as the data was non parametric in distribution. All data analysis was done at 95% level of significance using STATA version 15.

Results

A total of 135 subjects were recruited, 19 were excluded and 116 proceeded into the later part of the study, 58 subjects randomized in each arm. No drop outs during collection or analysis were encountered. There was no re-markable difference between the participants in the two arms of the study as shown in table 1. There were 5 out of 58 patients in the awake arm who developed airway complications (as per definition) and 13 out of 58 patients in the deep arm who developed airway complications (as per definition) as shown in table 2.

Table 1. Baseline characteristics of patients between awake and deep arm

	Arm		p-value
	Awake (n=58)	Deep (n=58)	
Age			
18 – 27	8	13	
28 – 37	18	23	
38 – 47	16	12	0.405□
48 – 57	14	8	
58 – 67	2	2	
Sex			
Male	19	15	
Female	39	43	0.415□
Specialty			
Gynaecology	2	11	
General Surgery	46	36	
Orthopaedics	9	9	0.051□
Urology	1	2	
Duration of surgery (mins)			
<=30	9	11	
31 – 60	36	24	
61 - 90	11	15	
91 - 120	2	6	0.74 ◊
121 - 150	0	0	
151 - 180	0	1	
181 - 210	0	1	
Mean duration	51.29 (±19.432)	60.31 (±33.307)	0.61 □
Opioid use			
Fentanyl	31	27	
Tramadol	2	1	
Morphine	14	10	
Pethidine	24	29	0.94 ◊
Remifentanyl	0	1	
Notes: □ Pearson Chi Square test was applied ◊ Yates' correction p-value □ Mann Whitney U-test was applied P values of less than 0.05 was considered statistically significant.			

Table 2: Comparison of occurrence of airway complication between awake arm and deep arm

		Airway Complication (as per definition)		Total
		Yes n (%)	**No** n (%)	
Study arms	**Awake**	5(8.6)	53(91.4)	58
	Deep	13(22.4)	45(77.6)	58
Total		**18**	**98**	**116**
		χ2 (1) = 4.209, P value 0.040☐		
Notes: ☐ Pearson Chi Square test was applied P values of less than 0.05 was considered statistically significant.				

The mean theatre exit time (as measured from the time 1 MAC of isoflurane was noted at the end of surgery) for the awake arm of the study was 12.29 minutes (± 3.637) and for the deep arm of the study was 7.72 minutes (± 5.730) as shown in table 3. There were 5(8.6%) patients out of 58 in the awake arm who developed airway obstruction requiring airway manipulation compared to 13(22.4%) patients out of 58 in the deep arm who developed airway obstruction requiring airway manipulation as shown in table 4.

None of the patients in the awake arm developed laryngospasm, compared to 2 (3.4%) patients out of 58 who developed laryngospasm in the deep arm as shown in table 5. None of the patients in the awake arm were noted to have desaturated to less than <90% on pulse oximetry after the ALM was removed, compared to 2 (3.4%) patients out of 58 in the deep arm who did developed desaturation to <90% on pulse oximetry as shown in table 6.

Table 3: Comparison of mean duration of theatre exit time between awake arm and deep arm

	Mean theatre exit time in minutes		P value
Study arms	**Awake**	**Deep**	
	12.29(± 3.637)	7.72(± 5.730)	0.0001 ☐
Notes: ☐ Mann Whitney U-test was applied (z score = 6.424452, z critical {5% two tailed} =1.959964, p value < 0.0001) P values of less than 0.05 was considered statistically significant.			

Table 4: Comparison of occurrence of airway obstruction requiring airway manipulation between awake arm and deep arm
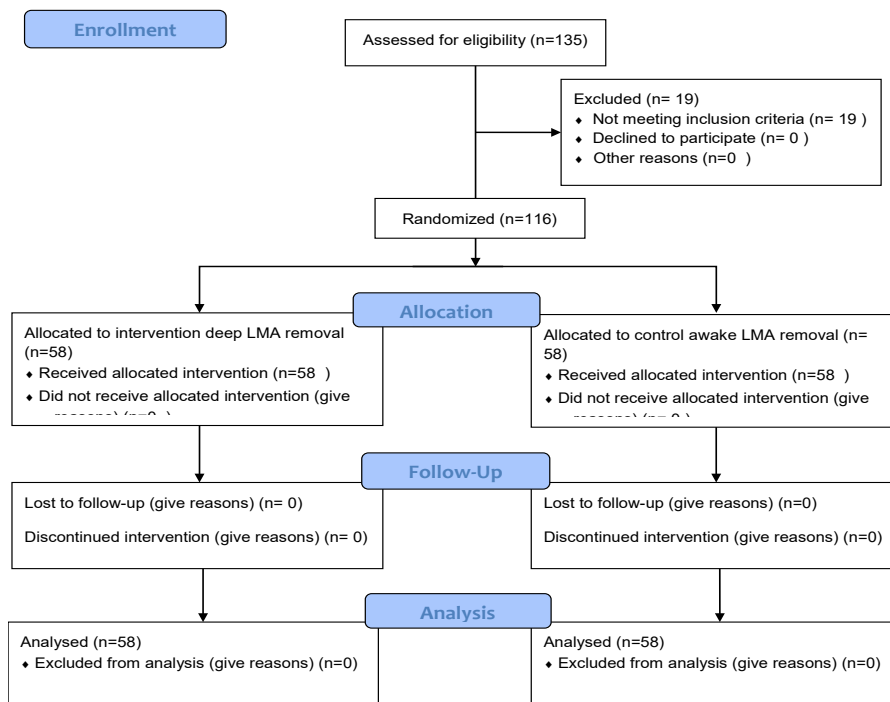
		Obstruction		Total
		Yes n (%)	**No** n (%)	
Study arms	**Awake**	5(8.6)	53(91.4)	58
	Deep	13(22.4)	45(77.6)	58
Total		**18**	**98**	**116**
		χ2 (1) = 4.209, P value 0.040☐		
Notes: ☐ Pearson Chi Square test was applied P values of less than 0.05 was considered statistically significant.				

Table 5: Comparison of occurrence of laryngospasm between awake arm and deep arm

		Laryngospasm		Total
		Yes n (%)	No n (%)	
Study arms	Awake	0(0)	58(100)	58
	Deep	2(3.4)	56(96.6)	58
Total		2	114	116
		χ2(1) = 2.035, P value 0.154☐		
Notes: ☐ Pearson Chi Square test was applied P values of less than 0.05 was considered statistically significant.				

Table 6: Comparison of occurrence of desaturation to <90% on pulse oximetry between awake arm and deep arm

		Desaturation		Total
		Yes n (%)	No n (%)	
Study arms	Awake	0(0)	58(100)	58
	Deep	2(3.4)	56(96.6)	58
Total		2	114	116
		χ2(1) = 2.035, P value 0.154☐		
Notes: ☐ Pearson Chi Square test was applied P values of less than 0.05 was considered statistically significant.				

Figure 1: CONSORT Flow Diagram

Discussion

The key finding of this study was that there was a statistically significant difference in the occurrence of airway complication (defined as - One or more of the following; airway obstruction requiring airway manipulation; laryngospasm; desaturation to 90% or less on pulse oximetry) between the awake (defined as 'MAC awake' - Alveolar concentration at which 50% concentration} for the commonly used volatile agents) arm and deep (at-least 1 MAC -Minimum alveolar concentration of Isoflurane) arm.

As regards airway obstruction requiring airway manipulation fewer patients in the awake arm developed airway obstruction requiring airway manipulation compared to those in the deep arm. This was found to be statistically significant p = 0.040. As regards laryngospasms, none of the patients in the awake arm developed laryngospasm, compared to 2/58(3.4%) patients who developed laryngospasm in the deep arm. This was found not to be statistically significant (p = 0.154). There was a similar conclusion with the latter as regards desaturation to <90% on pulse oximetry as the proportions were identical and thus p = 0.154.

This study found that there was a statistically significant difference (p < 0.0001) in the mean theatre exit time between the awake arm, 12.29 minutes (± 3.637) and the deep arm, 7.72 minutes (± 5.730).

The primary outcome results of this study thus reject the null hypothesis that there is no difference in the proportions of airway complications in spontaneously breathing adult patients when the laryngeal mask airway is removed deep or awake following isoflurane general anaesthesia. There was a significant difference in complications, with the deep arm show more adverse outcome.

The main finding of the study contrasts with the conclusion in the systematic review by Mathews and colleagues,8 that there is no superiority in either approach. The awake approached showed significantly less adverse outcomes statistically. Clinically, this study set out to have a 25% difference between the two arms be considered as clinically significant. The difference between the two arms was 13.8%, which did not surpass our set threshold. Despite this, the airway complications studied are critical events that portend adverse sequelea if unchecked. As such, it would be imprudent to disregard this finding as clinically insignificant, also considering that the calculated odds ratio was 3.0622; 95% CI, 1.0139 to 9.2483.

The study by Gataure et al11 had a contrary conclusion to this study i.e. deep (anaesthetized) LMA removal was associated with less airway complications compared to awake LMA removal. Gataure et al found a complication incidence of 20% in the deep arm and 54% in the awake arm (Total of 66 patients). The authors (Gataure et al) contend that the markedly high proportion of complications in the awake group may have been due to lack of familiarity of PACU nurses with the LMA who subsequently ended up removing the LMA before patient was actually truly awake. This is in contrast to this study, where the awake arm had complication incidence of 8.6%. This marked reduction in incidence may be due to the fact that the ALM in this study was removed in theatre by an anaesthetist (rather than PACU by a nurse). Also the seemingly more objective and standard point of assessing wakefulness i.e. on attaining an end tidal concentration <0.5% Isoflurane and an appropriate response to command (as defined) may have aided in achieving the remarkably lower incidence of complications in the awake arm of this study relative to Gataure et al's study. As regards complications in the deep arm, Gataure et al study looked at coughing, biting, retching, vomiting, excess saliva, Airway obstruction. The only comparable parameter with this study was airway obstruction of which Gataure's study had zero occurrence, this differs from our incidence of 22.4%. This is possibly because the patients in Gataure's study were recovered in the lateral position compared to this study in which participants were recovered in the supine position.

In contrast to the only other adult study that specifically sought a difference in airway complications during deep versus awake LMA removal by Nunez et al[12], this study had a far lower complication rate in the deep arm (17.2% relative to 51.5% in Nunez's study). This may have been due to a difference in methodology, whereby in this study a Guedel airway was placed immediately after removing the ALM in the deep arm as compared to the Nunez study protocol, where the Guedel airway was put only if/when airway obstruction occurred. In the author's opinion Nunez's protocol was counterintuitive, as the effects of volatile agents on muscle tone (i.e. reduction in tone) would predispose the patient to airway obstruction. This may explain the higher complication rate in the deep arm of Nunez's study. The awake arm of Nunez's study is by and large comparable to this study's results (8.6% relative to 6.1% in Nunez's study). This similarity in incidence

may lend credence to the use of a single, objective end point to define appropriate response to command, as illustrated in Nunez's study as well as this study. Both these studies utilized opening mouth to command as a marker of wakefulness/appropriate response to command.

As compared to the study by Heidari et al[16] this study showed that depth of anaesthesia may possibly affect the occurrence of airway complications contrary to what Heidari et al found.

Baird et al study had remarkably high occurrence of airway complications in both arms[17], this may be inferred to be due to lack of clear specified end points, also no exclusions may have led to recruitment of patients who were already at risk of upper airway obstruction. The results of Baird et al's study relative to this on show that patient selection is critical irrespective of whether the LMA is removed deep or awake.

As per the literature review it is worth noting that this is the only study to our knowledge where Isoflurane has been used as the sole volatile anaesthetic agent to examine the impact of deep versus awake ALM removal on airway complications. Also, the clear definition of the objective end points used to define 'deep' and 'awake' makes the study reproducible in contrast to the aforementioned studies and possibly resulted in the significantly less occurrence of airway complications in both the awake arm and the deep arm of the study. Therefore, this study adds unique knowledge with regards to the use of laryngeal mask airway as a supra-glottic airway device during general anaesthesia.

Limitations

This study was relatively small and this may affect the generalizability of the results obtained from this study. The method of randomisation chosen was progressively less random as the number of envelopes reduced, this affected the quality of the recruitment. We did not use objective monitoring like Bispectral Index Monitoring (BIS) or Entropy in our deep or awake arm since they were not readily available.

Conclusion

On the basis of the results of this study, it can be concluded that there is a difference in the proportions of airway complications in spontaneously breathing adult patients when the laryngeal mask airway is removed deep

or awake following Isoflurane general anaesthesia. Therefore, the removal of the ALM while the patient is deep (anaesthetized) is not as safe as or safer than awake removal of the ALM as recommended by the manufacturer, Ambu®, and also recommended by Archie Brain in the Intavent laryngeal mask airway manual. Therefore, in cases where it is desirable to remove the laryngeal mask airway while the patient is deep, extra vigilance is required in view of the increased potential for adverse airway complications.

Registration PACTR201705002284531.

Conflict of interest
None declared.

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