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Impact of Deep Versus Awake Laryngeal Mask Airway Removal on Airway Complications in Spontaneously Breathing Adult Patients following Isoflurane General Anesthesia.

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Postgraduate Medical Education Programme

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IMPACT OF DEEP VERSUS AWAKE LARYNGEAL MASK AIRWAY REMOVAL ON AIRWAY COMPLICATIONS IN SPONTANEOUSLY BREATHING ADULT PATIENTS FOLLOWING ISOFLURANE GENERAL ANESTHESIA.

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A dissertation submitted in part fulfilment of the requirements for the degree of

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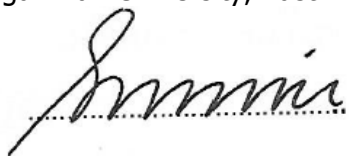

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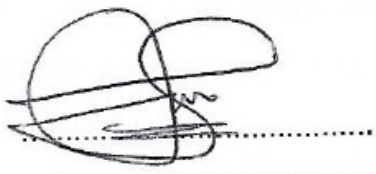

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DEDICATION

I dedicate this work to my wife Karimi Kinyua, my "agathos daimon", whose support through this journey has been beyond measure, and to my father, Professor James H. Ombaka who has constantly illuminated my path, in my pursuit of knowledge.

ABSTRACT

Background: The Laryngeal Mask Airway (LMA) is one of several supra-glottic airway management devices used in anaesthesia. The scope of use of the LMA is progressively expanding to areas previously contraindicated, for instance laparoscopy and prone position surgery. Certain aspects of LMA use remain unsettled. Whether to remove the LMA when a patient is "awake" vs "deep" following anaesthesia is one such area. The manufacturer Ambu® recommends that the AuraOnce™ LMA be removed once the patient is fully awake and protective airway reflexes are active. Despite this, several studies have shown benefit in removal of the LMA while a patient is "deep" (anaesthetized). Current evidence is inconclusive as to which approach is preferable and safer in adults.

Objectives

Primary Objective: To compare the impact of having LMA removal deep versus awake on the occurrence of airway complications following general anaesthesia in spontaneously breathing adult patients using Isoflurane as the sole volatile agent.

Secondary Objective: To compare the impact of deep versus awake LMA removal on anaesthesia theatre turn-around time.

Primary outcome measure(s): Airway complication(s), defined as; one or more of the following; Airway obstruction requiring airway manipulation; Laryngospasm; Desaturation to 90% or less on pulse oximetry.

Secondary outcome measure(s): Time to theatre exit

Study Setting: The Aga Khan University Hospital, Nairobi, Kenya.

Study Design: A prospective randomized control trial (open).

Sample size: A sample size of 116 participants, 58 in each arm.

Study population: ASA I and II patients aged 18-65 years scheduled for theatre for low to moderate risk, non-emergent surgery.

Procedure: 116 adult patients were randomly assigned to one of two groups. A standard anaesthesia protocol was used for induction and maintenance of anaesthesia.

For the deep arm; The LMA was removed at the end of surgery 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 LMA 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) (One or more of the following; Airway obstruction requiring airway manipulation; Laryngospasm; Desaturation to 90% or less on pulse oximetry) was in theatre and post anaesthesia care unit.

Time to theatre exit was recorded for both groups from the point of attaining an end tidal minimum alveolar concentration of Isoflurane of 1.15% to the point of theatre exit, in both groups. These processes were in addition to standard care.

Data collection: Parameters of interest being; Airway obstruction requiring airway manipulation, laryngospasm, desaturation to 90% or less on pulse oximetry, all of which were composited to define 'airway complication'. Time to theatre exit after attaining an end tidal of 1.15% Isoflurane.

Results: 116 ASA I & II patients scheduled to undergo elective surgery were included in this study, 58 (50%) subjects in the **awake arm** and 58 (50%) subjects in the **deep arm**. 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 study concludes that there is a significant difference in the occurrence of airway complications when the laryngeal mask airway is removed deep (anaesthetized) compared to awake (appropriate response to command). In this regard, the removal of the LMA while the patient is still deeply anaesthetised is *not* as safe as or safer than awake laryngeal mask airway removal.

LIST OF ABBREVIATIONS

LMA – Laryngeal mask airway

PACU – Post anaesthesia care unit

JCIA – Joint Commission International Accreditation

ASC – Anaesthesia and surgical care

MAC – Minimum alveolar concentration

YRS - Years

M – Male

F – Female

KG – Kilogram

ASA – American Society of Anaesthesiology

SBP – Systolic blood pressure

DBP – Diastolic blood pressure

MAP – Mean arterial pressure

G – Gauge

MG – Milligrams

FiISO – Fraction of inspired Isoflurane

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Finally, my sincere gratitude to the hospital management, theatre staff and my fellow residents for their support throughout the process of this study.

Thank you all

DECLARATION

I declare, this dissertation does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any university and that to the best of my knowledge it does not contain any material previously published or written by another person except where due reference have been made in the text.

The editorial assistance provided to me has in no way added to the substance of my proposal which is the product of my own research endeavours.

(Signature of Candidate)

30th May, 2017

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DEFINITIONS

1. **Deep** – at least 1 MAC (Minimum alveolar concentration) which is 1.15% for Isoflurane(1).

2. **Awake** - 'MAC awake', Alveolar concentration at which 50% of subjects respond appropriately when recovering from anaesthesia, MAC of 0.3–0.5 (end tidal concentration) for the commonly used volatile agents(2).

3. **Safety** - Patient safety is the absence of preventable harm to a patient during the process of health care(3).

4. **End of surgery** - Point marked by end tidal of 1 MAC (1.15% Isoflurane) as anaesthetist dials down Isoflurane anticipating end of procedure.

5. **Airway manipulation** – Jaw thrust; positive pressure ventilation.

6. **Airway complication** – One or more of the following; airway obstruction requiring airway manipulation; laryngospasm; desaturation to 90% or less on pulse oximetry(4).

7. **Minimum Alveolar Concentration** - Minimum alveolar concentration or MAC is the concentration of the vapour in the lungs at 1 atmosphere, that is needed to prevent movement (motor response) in 50% of subjects in response to surgical (pain) stimulus(2).

8. **Appropriate response to command** – for this study appropriate response was for the patient to open their mouth to command.

1.0 INTRODUCTION

The Laryngeal Mask Airway (LMA) is a supra-glottic airway management device (Fig 1). It was invented in 1981 by Archie Brain, an anaesthesiologist (5). 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(6). They also noted that the LMA had two disadvantages over the endotracheal tube and one over the facemask(6). 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(7). 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 current 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; laparoscopy(8–10). The expanding scope of use can be viewed as an attempt to reap the advantages of the device cited in other areas of application.

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" (anesthetized), is one such area.

At the Aga Khan University hospital, Nairobi, the AuraOnce™ LMA is the design variant most utilized. The manufacturer of the AuraOnce™ LMA (Ambu®) recommends that the LMA be removed once the patient is fully awake and protective airway reflexes are active(11). This recommendation was also put forth by the inventor Archie Brain(5) 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(12). They also noted that the quality of currently available evidence was low.

A pilot survey of anaesthesia providers at the Aga Khan University hospital, Nairobi, on routine practice of deep vs awake LMA removal (carried out in July, 2016) revealed a preference for deep LMA removal. Of the 18 respondents surveyed, 15 (83.33%) reported to favour deep LMA removal (not published work).

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(13,14).

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)(15). Why users opt for either technique is not clearly delineated as both approaches seem to have several undesirable outcomes with unspecified frequency.

Some paediatric studies have concluded that fewer complications occur with removal of the LMA in the deep (anaesthetized) state(16) and there seems to be some degree of consensus on the deep removal approach. No study(s) on an adult population has shown similar distinct benefit of either approach.

This study set out to determine the proportion of airway complications occurring in awake versus deep (anaesthetized) patients undergoing anaesthesia at the Aga Khan University Hospital, Nairobi. 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 LMA. Moreover, increased knowledge on safe practice has implications on efficiency and healthcare costs both direct and indirect as regards formulation and use of guidelines, resource allocation (i.e. cadre of human resource required to safely deploy, use & remove the device) and time management (i.e. theatre turnaround time)(17).

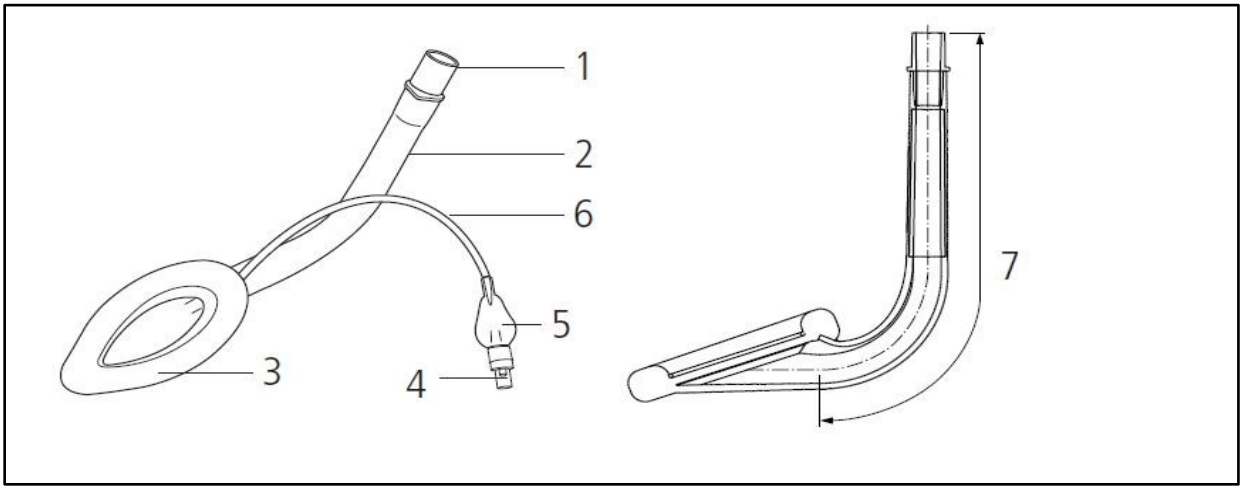


Figure 1: The Laryngeal Mask Airway(12)

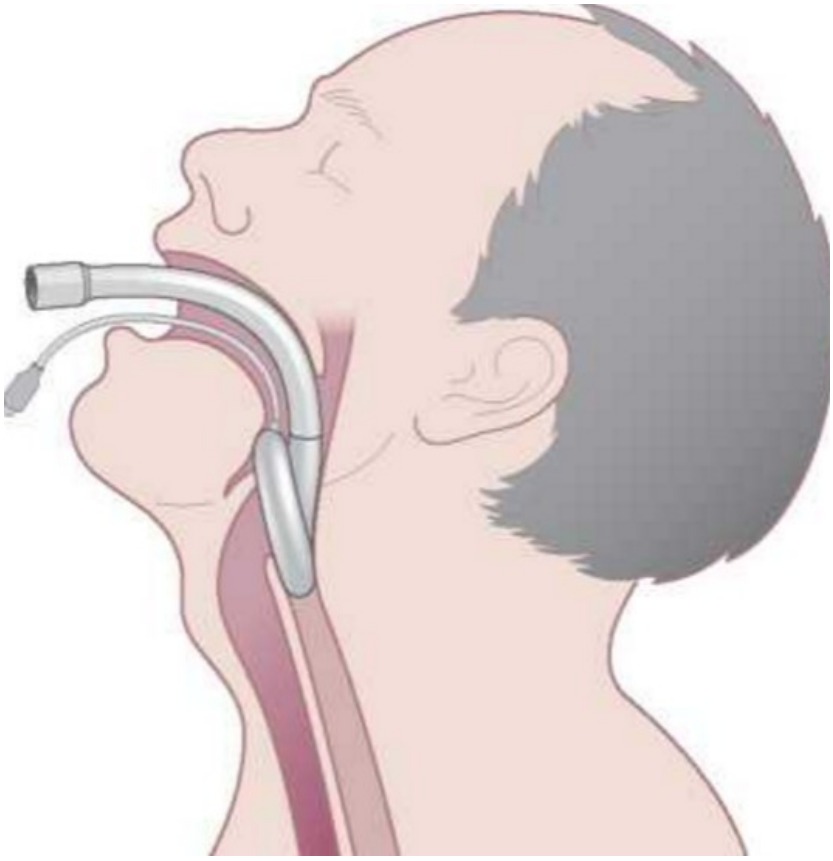


Figure 2: LMA appropriately positioned(18)

2.0 LITERATURE REVIEW

There are several studies on deep versus awake LMA removal. Most of these are randomized control trials. The bulk of which are in the paediatric population(s)(16,19,20). A total of four studies on adult population have been done that interrogate complications associated with LMA removal specifically. All are randomized control trials. Methodology is varied, as is outcome. Other studies reviewed yielded data that may be extrapolated to aid analysis and discussion.

A Cochrane systematic review by Mathew et al.(12), done in 2015 summarized all this data i.e. the adult and paediatric results. This is the only systematic review on the subject. No meta-analysis was found on the subject.

No published study from the African continent on the subject was found.

This literature review focused on adult population studies as results from paediatric studies are not necessarily generalizable to adult populations given the inherent physiological and anatomic differences.

The review is structured as a chronologically annotated analysis of literature on this topic.

In Archie Brain's introductory paper on the concept of the LMA(5) in 1983, a cohort of 23 adult patients had the LMA removed with the only prerequisite for doing so being spontaneous ventilation resumption (some patients had been paralyzed and required reversal of neuromuscular blocking agents). No remarks on the anaesthetic depth are noted in the paper. The study reported no complications associated with LMA removal specific to the airway. The primary data points of interest in his questionnaire were: coughing, retching, vomiting and laryngospasm. The author conceded that the study sample size was small and no generalizations could be made from the data. The author subsequently made the recommendation to remove the LMA when the patient was awake in the Intavent Laryngeal Mask Instruction Manual in 1992(21). No conclusive data was presented in the manual.

In 1995, a study by Gataure et al (15) compared the incidence of several airway complications (coughing, biting, retching, vomiting, excessive salivation and airway obstruction) in adults randomized into two groups of 50 each. The study also assessed the incidence of gastric regurgitation by measuring the pH of the LMA tip following withdrawal. They concluded that

airway complications were significantly more in the awake group ($p < 0.01$). As regards the gastric regurgitation, this was also found to be more in the awake group ($p<0.05$).The difference between this study and ours was the use of multiple anaesthetic agents i.e. Enflurane and Nitrous oxide. Nitrous oxide use in particular poses several challenges as regards the outcomes under investigation, for instance, it causes expansion of the laryngeal mask cuff which is associated with increased occurrence of sore throat, it also predisposes patients to have postoperative nausea and vomiting and lastly, there is potential for diffusion hypoxia at emergence. These factors markedly alter patient characteristics (as regards airway complications) in the postoperative period. The LMA in Gataure et al's study was withdrawn at end of anaesthesia with possible varied depths of anaesthesia .The authors did not articulate a standard depth of anaesthesia or standard response to command to mark the point of withdrawal of the LMA and may have exposed patients to varied periods of blunted airway reflexes and thus varied risk profiles for the occurrence of airway complications. The author concedes to this fact by noting in his discussion that in the awake arm it was difficult to ascertain whether the patient was fully awake at the point of LMA removal. This may explains why this study had a remarkably higher incidence in airway complications in the awake arm contrary to conventional practice (54% complication in the awake arm vs 20% in the deep arm). The population chosen for this study i.e. Urology patients with an average age of 66 years and predominantly male, limits the generalizability of the data obtained. The authors concluded that it was safer to remove the LMA while patients were deeply anaesthetized in the operating theatre.

In 1998, a study by Nunez et al randomized 66 adult patients into two groups(22). The LMA was removed while patient was deeply anaesthetized in one arm and once patients had regained consciousness (marked by appropriate response to open mouth) in the other group. It was found that no regurgitation occurred in either group. They also concluded with a marked significance ($p<<0.001$) that complications occurred more in the anaesthetized group (51.5% of the deep group relative 3% in the awake group). Parameters of interest were apnoea, laryngospasm, bronchospasm and regurgitation. The difference in this study and ours, was the use of two inhalational agents i.e. Isoflurane and nitrous (bearing in mind the aforementioned implications of nitrous oxide use with the LMA), the lack of utilization of a Guedel airway in all deeply anaesthetized patients until when an adverse event occurred may explain the study's high incidence of airway obstruction. This study concluded that it was safer to leave the LMA in place until the patient had fully regained consciousness.

In 1999, a study by M. B. Baird et al randomized 300 children and adults into two groups(23). They removed the LMA while patient was either deeply anaesthetized (depth not specified) in one arm or once patients had regained consciousness (marked by opening mouth and eyes) in the other group. The adverse respiratory events of interest were, coughing, oxygen desaturation and airway obstruction. This study utilized Isoflurane with 67% Nitrous oxide and oxygen. For the deep arm a Guedel airway was placed and the patient put in lateral position and then taken to PACU on oxygen via Hudson mask at 5 litres per minute, while for the awake arm the patient was turned to lateral position and a T-piece attached and oxygen administered at 10 litres per min then the patient transferred to PACU. Focusing on the adult patients results (specifically those similar to this study), the awake arm had a complication rate of 38.1% compared to 45.7% in the deep arm. They concluded that in adults, it was safer to remove the LMA when the patient had regained consciousness and protective airway reflexes.

The latter three studies directly compared deep versus awake LMA removal with appropriate controls. Several other studies addressed the same issue but the primary motive was to compare the effect of different agents on airway complication incidence when the LMA was remove deep. Other studies set out to describe specific end points (i.e. minimum alveolar concentration of inhalational agents) at which the LMA could be removed without complication when the patient was deep (anaesthetized). Four such studies were identified.

In 2005, Heidari et al carried out (24) a double blind randomized study of 156 adult patients (the demographic characteristics were not clear in the available literature). They sought to find out the influence of the depth of anaesthesia and choice of anaesthetic agent (Halothane versus Propofol) on the incidence and severity of airway hyper reactivity on LMA removal. Salient points from this study were that choice of agent and depth of anaesthesia do indeed alter airway hyper reactivity when the LMA was removed in the deep anaesthetized state. Propofol is known to effectively blunt airway reflexes, as such the "propofol group" had remarkably less airway complications relative to the "Halothane group". Moreover propofol reduces incidence of postoperative nausea and vomiting whereas halothane increases its occurrence. Thus pitting the two agents against each other has some inherent confounders.

Also in 2005, a study by Yon Hee Shim et al studied 35 adults (aged 22 to 64 years) undergoing perianal surgery(25). Prior to this study no literature on specific depth of anaesthesia appropriate for LMA removal is available. They determined that at an end tidal concentration of

1.18% MAC of Sevoflurane there was minimal occurrence of breath holding, laryngospasm or desaturation to a SPO 2 < 90% in 95% of patients.

In 2008, Ming Hui Hseih et al carried out an observational study where they observed the occurrence of airway complications in 300 patients in whom minor plastic and urologic procedures had been done in spontaneously breathing patients using an LMA and maintained on Isoflurane(26). In all the patients the LMA was removed at a varied depths of anaesthesia (deliberately) and an oral airway with a T- connector put in place. The T-connector allowed serial monitoring of capnography to assess the integrity of respiration/ventilation. They reported that no airway complication was observed in all 300 patients in whom this technique was applied.

In 2011, Hui et al conducted a study (27) that had similar methodology to the aforementioned study by Yon Hee Shim(25) with a population of 38 adults aged between 18 – 44 years. They concluded that the classic LMA could successfully be removed in 95% of anaesthetized adults without airway complications (coughing, gagging, clenched teeth, head or body movement during or within 1 min after removal, or breath holding, laryngospasm or desaturation to SpO2 < 90% during or immediately after removal.) at an end-tidal Desflurane concentration of 5.55%, equivalent to an MAC of approximately 0.93.

The aforementioned studies thus prompted interest to evaluate the occurrence of airway complications (as defined) following LMA removal either in deep (anaesthetized) versus awake (responsive to command) in adults while utilizing Isoflurane as the sole inhalational anaesthetic agent.

3.0 JUSTIFICATION

The Laryngeal Mask Airway (LMA) is the most used supra-glottic airway management device at the Aga Khan University Hospital, Nairobi, Kenya. Use globally stands at 200 million units as of 2013(7). 2032 units (which represents 21.8% of all cases done under general anaesthesia) were used at the Aga Khan University Hospital, Nairobi in the year 2015. This remarkable utilization of the device and an anticipated increase in usage requires that patient safety and system efficiency be considered in all aspects of LMA utilization in order to accrue worthwhile benefit from its use.

A pilot survey of anaesthetic practice at the Aga Khan University Hospital, Nairobi, carried out in July of 2016, showed a preference for deep LMA removal (83.33%) contrary to the recommendation by the manufacturer and several other studies(11,22).(This survey only sought preference, no reasons for individual preference were sought). As noted in the literature review, no data was available to conclusively corroborate local practice and advance best practice (28).

One of the unique aspects of practice at Aga Khan University Hospital, Nairobi, was the predominant use of Isoflurane as the primary volatile inhalational anaesthetic without nitrous oxide. This is in comparison to the aforementioned studies where Enflurane, Desflurane, Sevoflurane, Halothane and varied mixtures with Nitrous oxide were used in the studies mentioned in the literature review. All these agents elicit distinctly different (though comparable) pharmacokinetic (i.e. effects of body on drugs) and pharmacodynamic (effect of the drugs on the body, including the airway) characteristics. Of particular interest are the studies by Gataure et al and Nunez et al that used Enflurane and Isoflurane (respectively) but in combination with Nitrous oxide. These combinations (halogenated volatile agent with Nitrous oxide) significantly alter emergence pharmacokinetics of halogenated volatile agents by the second gas effect, as illustrated by Peyton et al and Einarsson S. et al (29,30).Therefore this study may add to the gap in knowledge with respect to LMA use where Isoflurane is the sole volatile inhalational agent used for general anaesthesia.

Airway complications are critical adverse events as the sequelea may be debilitating or even fatal if unchecked. Therefore, best practice mandates use of techniques that mitigate this risk and yield best (relatively) outcomes(28).

With patient safety as the driving principle, this study provided data that may lead to practice changing information as well as addition to the current state of knowledge both institutionally and globally on the subject.

The Helsinki Declaration on Patient Safety in Anaesthesiology(31) recommends that evidence-based practice and quality improvement be at the core of anaesthetic practice as does Joint Commission International(32). This study aspired to aid attainment of these goals in the field of anaesthesia.

A possible secondary gain from the study may be improved system efficiency, accrued from process standardization attained by formulation of evidence based guidelines on LMA use and thus predictable – anaesthetic - theatre turn around time. Such knowledge may have an impact on healthcare costs.

4.0 RESEARCH QUESTION

Is there a difference in proportion in the occurrence of airway complications between spontaneously breathing adults patients when the laryngeal mask airway is removed deep versus awake following Isoflurane general anaesthesia?

4.1 Null hypothesis

There is no difference in the proportion of airway complications in spontaneously breathing adult patients when the laryngeal mask airway is removed deep or awake following isoflurane general anaesthesia.

4.2 Alternate hypothesis

There is a difference in the proportions between the occurrences of airway complications in spontaneously breathing adult patients when the laryngeal mask airway is removed deep versus awake following Isoflurane general anaesthesia.

5.0 STUDY OBJECTIVES

5.1 Primary objective

- To compare the impact of having LMA removal deep versus awake on the occurrence of airway complications following general anaesthesia in spontaneously breathing adults patients.

5.2 Secondary objective

- To compare the impact of deep versus awake LMA removal on anaesthesia theatre turn- around time (process optimization).
- To compare the incidence of each of the following; airway obstruction requiring airway manipulation; laryngospasm; desaturation to <90% on pulse oximetry among patients where the LMA is removed deep and awake.

6.0 METHODOLOGY

6.1 Study design

Prospective randomized control trial

6.2 Study site

The study was conducted at Aga Khan University Hospital, Nairobi. The Aga Khan University Hospital, Nairobi is a 300 bed private not-for-profit institution that provides tertiary and secondary level health care services.

Operating theatre records of 2015, showed that a total of 2032 operations carried out at the hospital utilized the LMA.

6.3 Study population

All patients scheduled to receive general anaesthesia with a laryngeal mask airway (as the airway management device) for elective, low to moderate risk surgery in supine or lithotomy positions.

NB: At the Aga Khan University Hospital Nairobi, no oral/airway surgeries are performed using the LMA.

6.4 Eligibility criteria

6.4.1 Inclusion criteria

- 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.
- Surgeries less than two hours as per protocol

6.4.2 Exclusion criteria

- Active/ongoing history of upper and or lower respiratory tract infection/disease
- Patients with a difficult LMA insertion (defined as greater than two attempts)
- Patients with severe gastroesophageal reflux disease
- Patients with a symptomatic hiatus hernia
- Patients with a BMI> 40kg/m^2
- History of Obstructive sleep apnoea
- Patients in whom muscle relaxants is to be/ is used
- Patients with Mallampati class 3 and 4
- Patients who did not give consent
- Patients who did not understand English or Swahili
- Patient with psychiatric disease

7.0 SAMPLING

7.1 Sample size determination

A sample size of 116 patients was drawn to demonstrate a 25% difference in the occurrence of airway complications between patients in whom the LMA was removed awake (appropriate response to command) versus in those whom the LMA was removed deep (anaesthetized).

The study was powered to 80% with an alpha of 5%.

The rationale used to arrive at this sample size is elaborated below.

There are no studies looking at the occurrence of airway complications following removal of the LMA in deep versus awake spontaneously breathing patients while utilizing Isoflurane as the *sole* volatile inhalational anaesthetic agent.

Isoflurane is the most utilized volatile inhalational agent in use at the Aga Khan University Hospital, Nairobi and the LMA is the most widely used supra-glottic airway management device at the institution.

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. 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).

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;

P_0 = Probability of airway complications in the control group (Awake arm = 0.25)

P_1 = 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)

8.0 RECRUITMENT PROCEDURE

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 oral explanations on the purpose and nature of the study. The patients who gave written Informed Consent were enrolled into the study.

8.1 Randomization

The 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 consent 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.

9.0 STUDY PROCESS

At the commencement of the study, all consultant anaesthetists, anaesthesia residents, anaesthetic assistants and nurses that would be in contact with study participants were familiarized with the study and the data collection tool.

A standard anaesthesia protocol was followed:

Once the patient was on the theatre table, ASA recommended (33) 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(s) was then pre-oxygenation 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 standard practice at Aga Khan University Hospital Nairobi, to avoid inadvertent adverse effects such as hypotension and bradycardia given variable patient response) and Isoflurane initiated at 2% on the vaporizer; appropriate size LMA was inserted using the classical technique(11,34);placement confirmation by auscultation and capnography and the LMA 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 LMA is used at the Aga Khan University Hospital Nairobi. 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 LMA.

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.

NB: the study did not intend to reduce the variation at that point of the study but to investigate the impact of this intervention on theatre exit in spite of those variations. Also end tidal measurement offered an objective end point with less variation vis a vis other end points not determined by the surgeon, especially for procedures without definite end points such as hysteroscopies. 1 MAC represented a point that all patients under general anaesthesia would encounter (irrespective of alterations made to the FiISO during the procedure) after switching off the vapourizer at the end of surgery. Egress of the volatile agent there after being driven by the patient's respiratory drive.

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 LMA 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 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 LMA 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 LMA was withdrawn irrespective of end tidal concentration of Isoflurane (This approach took into consideration that MAC awake only holds true for 50% of patients as per the definition), 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.

NB: Theatre exit at the discretion of the may have varied depending of various anaesthetist factors. We did not seek to reduce this variability as theatre turn around time was a secondary objective and we only sought to see the impact of our primary objective on turn around time

despite the variability (hopefully setting the stage for subsequent study where all variables could be controlled).

9.1 Data collection procedure and tools

Intraoperative and postoperative data was collected by trained research assistants and PACU nurses using a data collection form (APPENDIX III).

Data collection continued until the patient was fully awake and responding appropriately to com mand (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).

9.2 Data storage

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 were checked for completeness prior to filing.

9.3 Statistical analysis

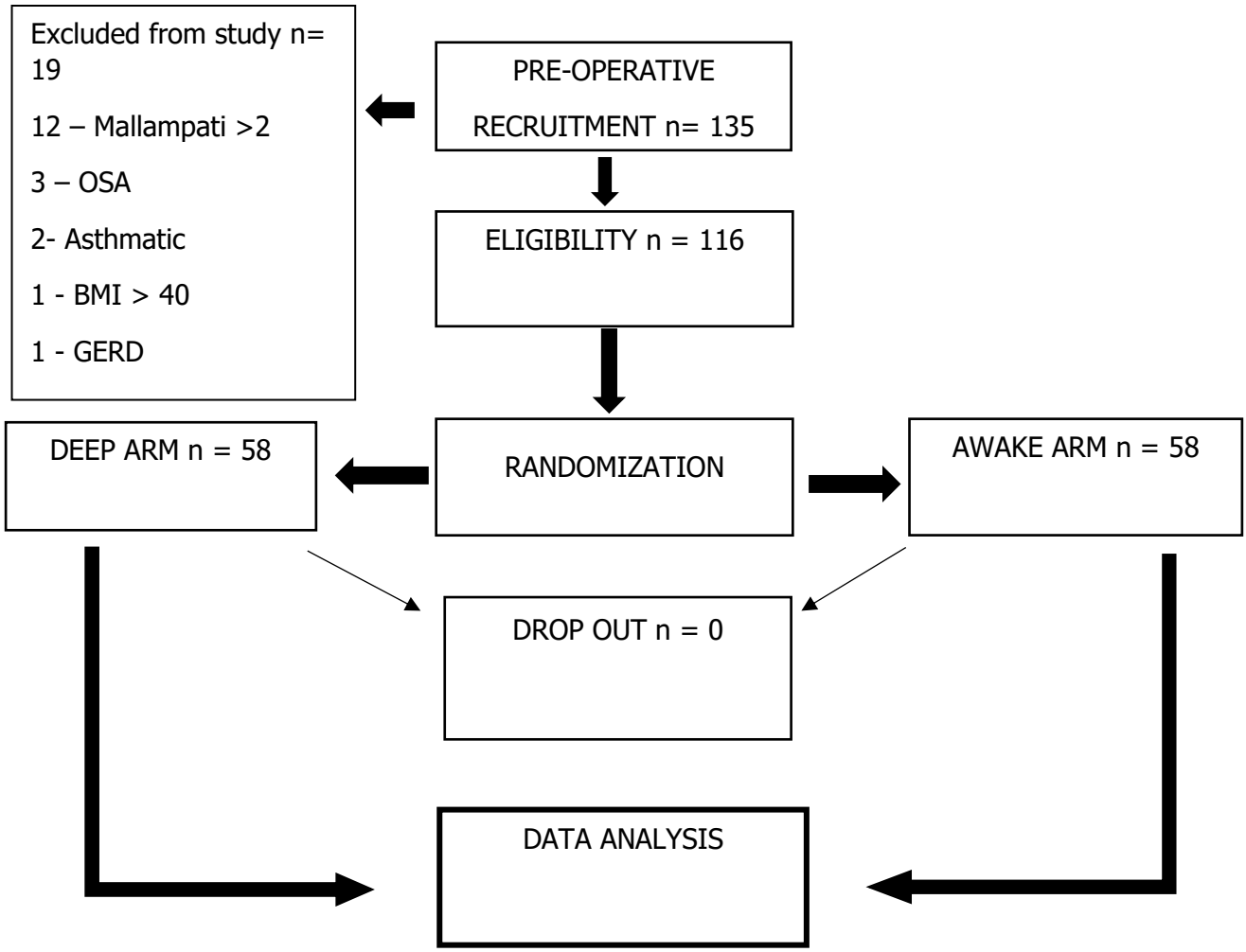
Data yielded by the study were quantitative.

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 LMA 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 LMA removal as the data was non parametric in distribution

All data analysis was done at 95% level of significance using STATA version 15.

9.4 Study flow process



10.0 ETHICAL CONSIDERATIONS

10.1 Institutional Ethics Committee approval

Approval to conduct the study was sought and obtained from the Aga Khan University Research Ethics Committee prior to initiating the study.

10.2 ADHERENCE TO THE TENETS OF MEDICAL ETHICS

10.2.1 Non-maleficence

This was safeguarded at all stages of the study. The eligibility criteria was clearly defined so that any patient at risk of overt adverse effects was excluded. All those involved in the study e.g. anesthetists, anesthesia residents, anesthetic assistants were appropriately appraised about the study. Complications arising from the study were addressed objectively via protocols in current use by the Aga Khan University Hospital, Nairobi anaesthesia department (refer to Appendix V).

10.2.2 Autonomy

Recruitment into this study was voluntary and participants could withdraw their consent to the study at any time prior to initiating the actual study process. Withdrawal would have no implications on their routine care. Eligible patients received a consent-seeking explanation form. Thereafter, patients who agreed to participate in the study signed the informed consent form.

10.2.3 Beneficence

The fact that this study would not benefit the study participants directly was explained to the patient before recruitment.

10.3 Confidentiality and privacy

Every precaution was taken to respect the privacy of recruited patients. All data forms in this study contained only the patient randomization numbers. All used data forms were filed and kept in a locked filing drawer. Only the principal investigator had access to these records.

10.4 Social Justice

The findings from this study were disclosed to the Aga Khan University Hospital faculty; board of examiners; participants and disseminated to health providers via the Aga Khan University, Nairobi, Faculty of Health Sciences Academic Rounds plenary; Aga Khan University Library. The results will also be submitted for peer review and possible publishing in a respectable journal of anaesthesia. The study was registered by the Pan African Clinical Trial Registry (**PACTR201705002284531**).

It was anticipated that the findings of this study would aid attainment of best practice and patient safety in anaesthesia provision at the Aga Khan University Hospital and beyond.

10.5 Safety monitoring and evaluation

In the event of adverse outcomes, the Aga Khan University Hospital, Nairobi policy on critical/sentinel events was to be referred to and implemented (this was not necessary/required throughout the study duration). Due process i.e. a Clinical incidence reporting was to be undertaken and the incident logged and an appropriate root cause analysis undertaken. This would have also been communicated to the Research Ethics Committee.

Appropriate management of the affected patient(s) was to be at the discretion of the anaesthesiologist/ principle investigator and other medical specialties as deemed appropriate. In the event of overt/explicit untoward outcome(s) affecting a large proportion of patients in either group, an interim analysis was to be carried out and the study terminated (after consulting appropriate faculty/ethical committee) to mitigate further occurrences (this was not necessary/required).

11.0 RESULTS

11.1 Recruitment

Data collection was carried out between February 2017 and May 2017. 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.

11.2 Baseline characteristics of randomized participants

There was no remarkable difference between the participants in the two arms of the study (Table 1).

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	0.405♣
28 – 37	18	23	
38 – 47	16	12	
48 – 57	14	8	
58 – 67	2	2	
Sex			
Male	19	15	0.415♣
Female	39	43	
Specialty			
Gynaecology	2	11	0.051♣
General Surgery	46	36	
Orthopaedics	9	9	

Urology	1	2	
Duration of surgery (mins)			
<=30	9	11	0.74 ◇
31 – 60	36	24	
61 - 90	11	15	
91 - 120	2	6	
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	0.94 ◇
Tramadol	2	1	
Morphine	14	10	
Pethidine	24	29	
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.

11.3 Outcomes

11.3.1 Primary outcome

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) (Table 2, Figure 3).

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**
		$\chi 2$ (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.

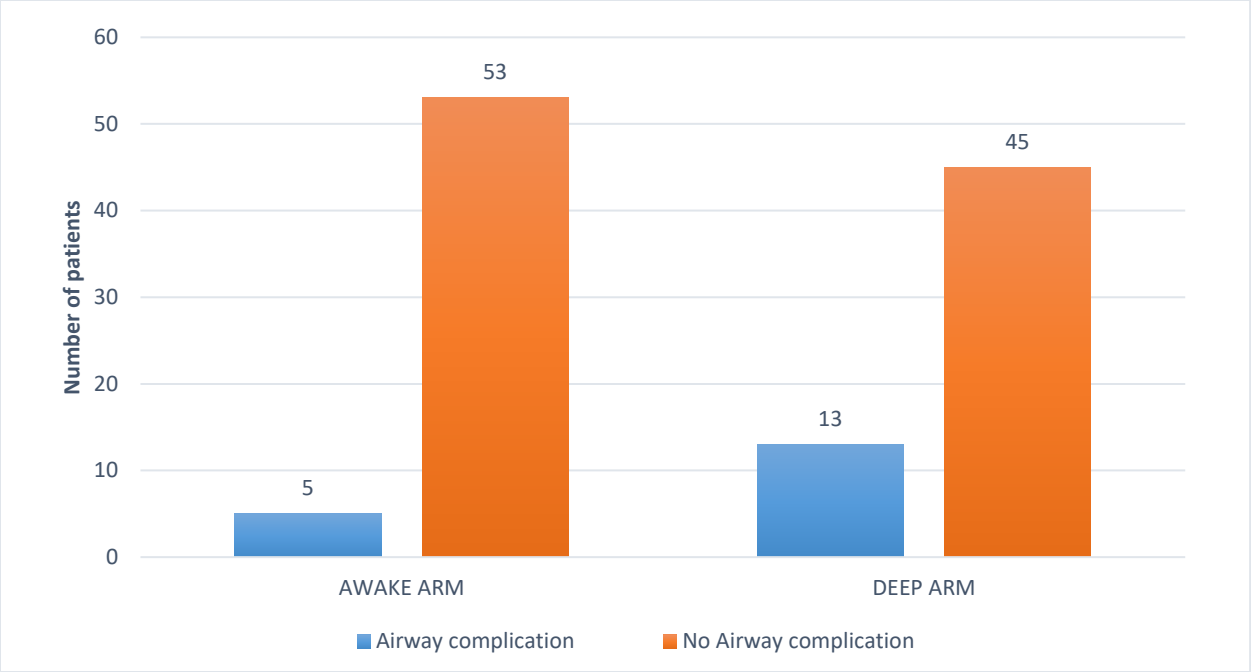


Figure 3: Comparison of occurrence of airway complication between awake arm and deep arm

11.3.2 Secondary outcomes

Impact of deep versus awake LMA removal on anaesthesia theatre turn- around time (process optimization).

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)(Table 3, Figure 4).

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.

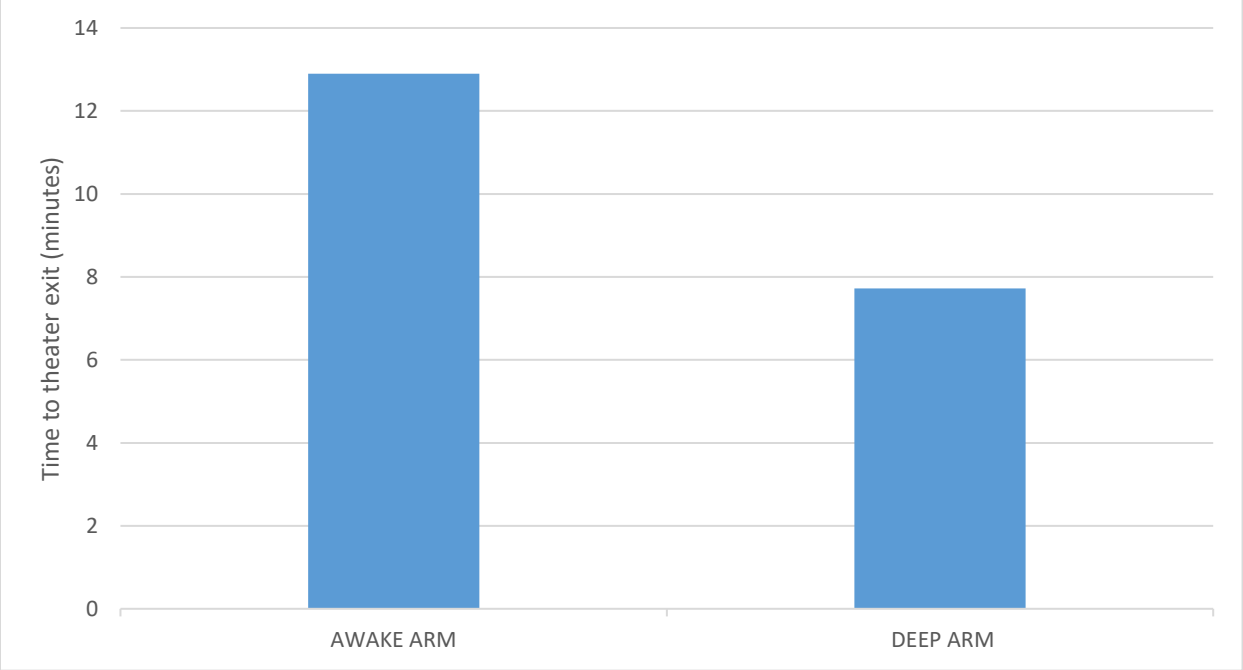


Figure 4: Comparison of mean duration of theatre exit time between awake arm and deep arm

Frequency of airway obstruction requiring airway manipulation

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 (Table 4, Figure 5).

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**
		$\chi 2$ (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.

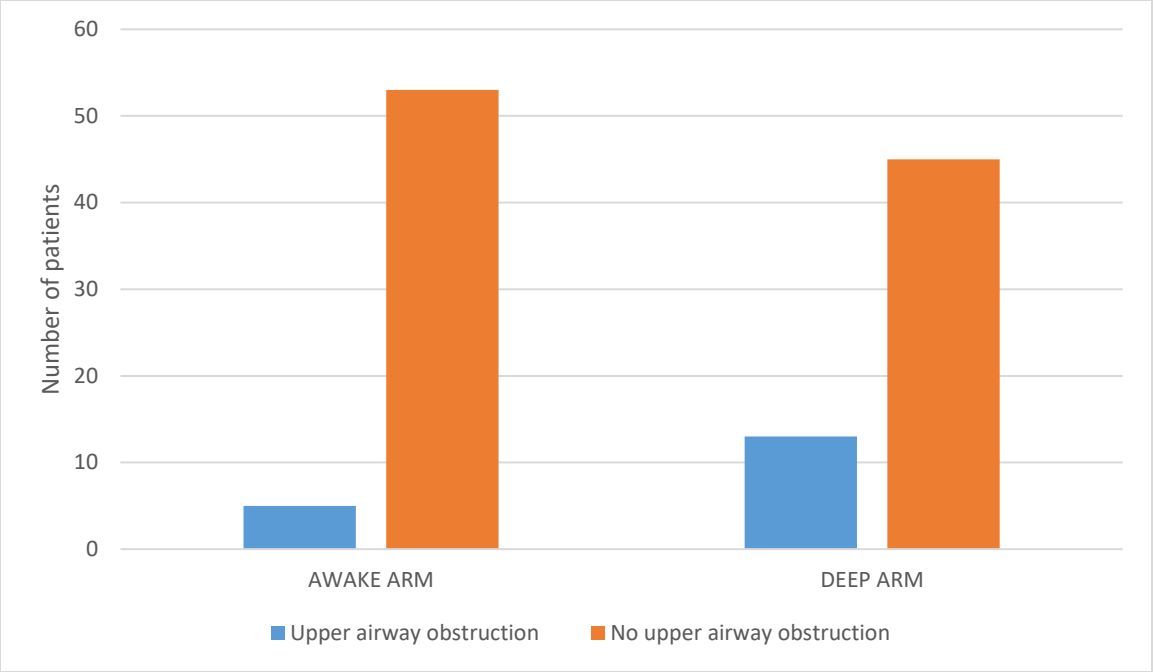


Figure 5: Comparison of occurrence of airway obstruction requiring airway manipulation between awake arm and deep arm

Frequency of Laryngospasm

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 (Table 5, Figure 6).

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.

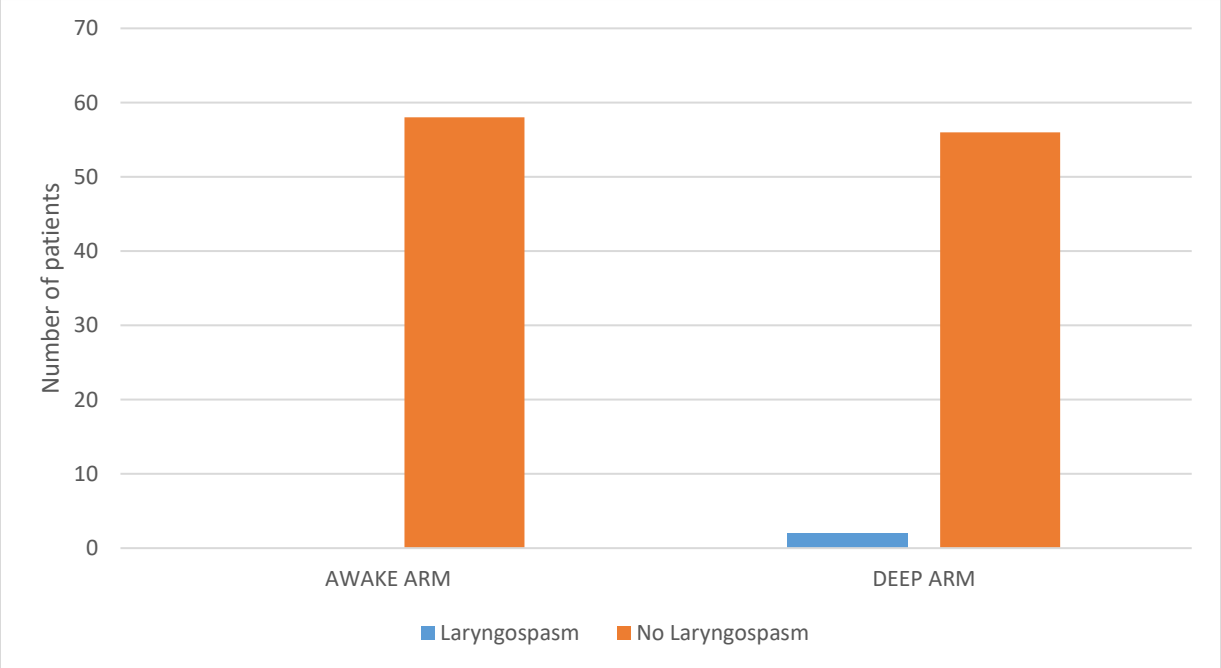


Figure 6: Comparison of occurrence of laryngospasm between awake arm and deep arm

Frequency of desaturation to <90% on pulse oximetry

None of the patients in the awake arm were noted to have desaturated to less than <90% on pulse oximetry after the LMA was removed, compared to 2 (3.4%) patients out of 58 in the deep arm who did developed desaturation to <90% on pulse oximetry (Table 6, Figure 7).

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.

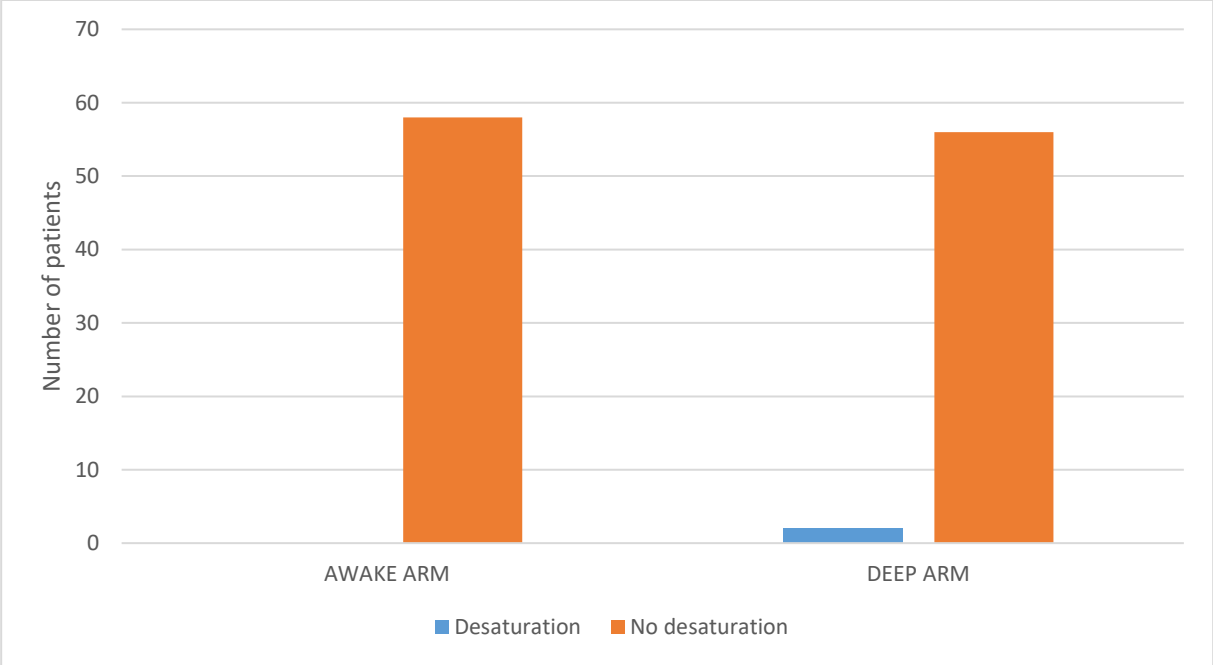


Figure 7: Comparison of occurrence of desaturation to <90% on pulse oximetry between the awake arm and the deep arm

12.0 DISCUSSION

The primary aim of this dissertation was to investigate whether there was a difference in proportion in the occurrence of airway complications between spontaneously breathing adults patients when the laryngeal mask airway is removed deep versus awake following general anaesthesia while using Isoflurane as the sole volatile anaesthetic agent.

The secondary aims were; to compare the impact of deep versus awake LMA removal on anaesthesia theatre turn-around time and to compare the incidence of each primary parameter of interest i.e. airway obstruction requiring airway manipulation, laryngospasm, desaturation to <90% on pulse oximetry among patients in whom the LMA is removed deep compared to awake.

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. With airway complication occurring in 5 (8.6%) of the awake arm subjects compared to 13 (22.4%) in the deep arm out of a total of 116 patients (58 in each arm) **P=0.040**, odds ratio **3.0622**; **95%** CI, **1.0139** to **9.2483**.

As regards airway obstruction requiring airway manipulation 5/58(8.6%) patients in the awake arm developed airway obstruction requiring airway manipulation compared to 13/58(22.4%) patients in the deep arm developed airway obstruction requiring airway manipulation (These proportions are similar to the aggregate airway complications because of the aforementioned definition of airway complication in this study). 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).

Of note is that the study was not specifically powered to ascertain differences in the secondary outcomes (i.e. airway obstruction requiring airway manipulation; laryngospasm; desaturation to 90% or less on pulse oximetry, theatre turn around time), as such, no further analysis or conclusion was drawn from the secondary outcomes.

It is important to note that of the two patients that experienced laryngospasm and desaturation to less than 90%, none required more advance airway management e.g. endotracheal intubation or reinsertion of the LMA. Positive pressure ventilation and jaw thrust sufficed to reverse the events. The lowest saturation point of these two patients was unfortunately not noted but none of the affected patients suffered overt adverse outcome. It is also note-worthy that all airway complications occurred in theatre and none were noted in the PACU, as such, all airway interventions were promptly carried out by the anaesthetist in theatre.

Opioid use was thought to be a potential significant confounder to airway complications by causing respiratory depression and sedation, we therefore assessed its impact on outcome in these groups of patients. Given that some patients required more opioids than others because of the varied pain intensity elicited by different procedures and inter-individual variation in sensitivity to opioids and pain perception, opioids were titrated to effect and patients who required more or less opioids than the recommended doses were noted (26 of the 116 patients received an additional opioid). Of the 26 patients who received additional opioid dose(s), 4 experienced airway complications (as per definition). A Chi square test was carried out to measure association between receiving multiple opioid doses (beyond recommend dose of one opioid or a different opioid) versus a single dose of opioid, this and found no statistical significance $p = 0.98$, alpha =0.05, odds ratio 0.987, 95% CI 0.2948 to 3.3043. There was also no significant difference in the opioid usage between both groups (awake vs deep arms) Yates' $p = 0.94$, alpha =0.05. There was also no significant difference in the usage of long acting opioids (i.e. Morphine) between the two groups (patients with airway complications in the deep arm vs awake arm) Chi square test $p = 0.36$, alpha =0.05.

No patients were noted to have had bronchospasm.

Duration of surgery was also analysed to evaluate its impact on airway complications. This was found not to be statistically significant, with $Z = 1.48$, $p = 0.14$, alpha =0.05 (Mann Whitney U test). Also none of the patients whose surgery went beyond two hours experienced any airway complications.

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 et al. (12) 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 absolute number of airway complications, especially laryngospasm (2/116) may indeed seem small, but in our opinion the benefits of deep LMA removal are outweighed by this avoidable risk.

The study by Gataure et al. (15) 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 LMA 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 (22), 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 LMA 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(24) 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's study had remarkably high occurrence of airway complications in both arms(23), 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 alluded to earlier, a survey of anaesthesia practitioners (both faculty and residents) at the Aga Khan University Hospital, Nairobi, showed a marked preference (83.33% of the 18 respondents surveyed) for removal of the laryngeal mask airway while patient(s) were deep (anaesthetized). This study's outcome does not corroborate this preference of 'deep' LMA removal by anaesthesia practitioners at the Aga Khan University Hospital, Nairobi. This warrants further investigation of the practice by anaesthesia faculty and residents to establish why they prefer deep LMA removal vis-à-vis awake LMA removal as the deep arm has a higher risk of airway complication as shown by this study. A more comprehensive survey and discussion is

thus required to interrogate whether the benefits of deep LMA removal truly outweighs the risks.

On a global scale, as regards the practice of anaesthesia, the results of this study alongside other similar studies will aid the anaesthesia practitioner in decision making on matters regarding the laryngeal mask airway. Knowledge of the possible complications and patient demographics that would favour awake versus deep laryngeal mask airway removal will add to the anaesthetist's repertoire thus aiding appropriate patient care and guideline formulation.

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 laryngeal mask airway 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.

The incremental knowledge about the laryngeal mask airway garnered from this form of study (and others on the same subject) is the hallmark of the scientific method (i.e. acquiring new knowledge, correcting and integrating prior knowledge).This is the driving principle behind achieving best practice and patient safety in anaesthesia, which was the broad goal that underpinned this study.

12.1 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.

12.2 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 laryngeal mask airway while the patient is deep (anaesthetized) is not as safe as or safer than awake removal of the LMA as recommended by the manufacturer of the AuraOnce™ LMA (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.

12.3 Recommendations

A similar study powered to detect the difference in occurrence of airway obstruction requiring airway manipulation; laryngospasm; desaturation to 90% or less on pulse oximetry as individual parameters would be a worthwhile endeavour that would help discern more specific risk factors for their occurrence.

Large, blinded, appropriately randomized, case controlled study of this nature is required given the limitations of this study.

Future work should consider obtaining larger sample size and note risks of bias (particularly selection, performance & detection) which has been evident in this, and all previous studies, bearing in mind the conclusions from the Cochrane review by Mathew P.J. et al (12).

12.4 Dissemination of results

The findings will be disseminated at an appropriate forum such as a meeting of the anaesthesia department and the Aga Khan University Hospital, Nairobi , Kenya – Faculty of health sciences, Academic rounds. The final results of this study will be submitted to a peer reviewed international journal for publication.

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ndertype=abstract

14.0 APPENDIX I: EXPLANATION FORM

EXPLANATION FORM

(For study on the impact of deep versus awake laryngeal mask airway removal on airway complications in spontaneously breathing adult patients following isoflurane general anaesthesia.)

Name of principal investigator: Dr. Ronald Ombaka

Name of the institution: Aga Khan University Hospital, Nairobi

Introduction

I am a medical doctor training for a postgraduate degree in Anaesthesiology at the Aga Khan University, Nairobi.

I am conducting a study to compare the effect of removing a laryngeal mask airway (LMA) when a patient in deep ("asleep" following recovery from anaesthesia) versus awake (able to appropriately respond to command following recovery from anaesthesia). The laryngeal mask airway is a device used to maintain the airway (the passage through which one breathes) while anaesthesia is being administered for an operation. It ensures that a patient is breathing for one's self or assisted by the anaesthesiologist appropriately (without difficulty) while under anaesthesia. (See below image Figure; Figure 2: LMA appropriately positioned; Figure 8: (A) Patent airway; (B) Obstructed/closed airway. (The Laryngeal mask airway maintains patency (open) of the airway allowing ventilation/breathing during anaesthesia)*.(18)*. It is thus part of providing safe anaesthesia.

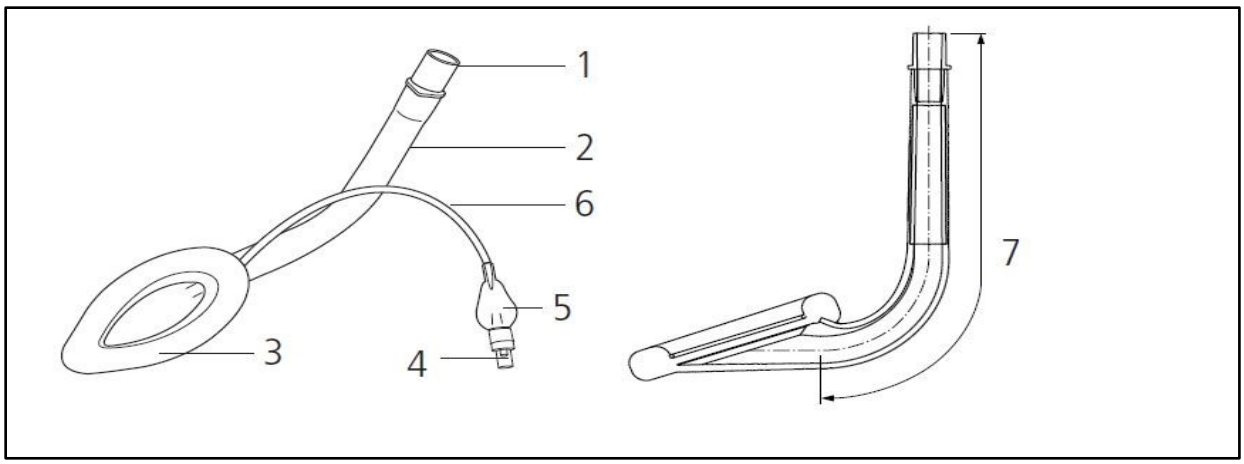


Figure 1: The Laryngeal Mask Airway(18)

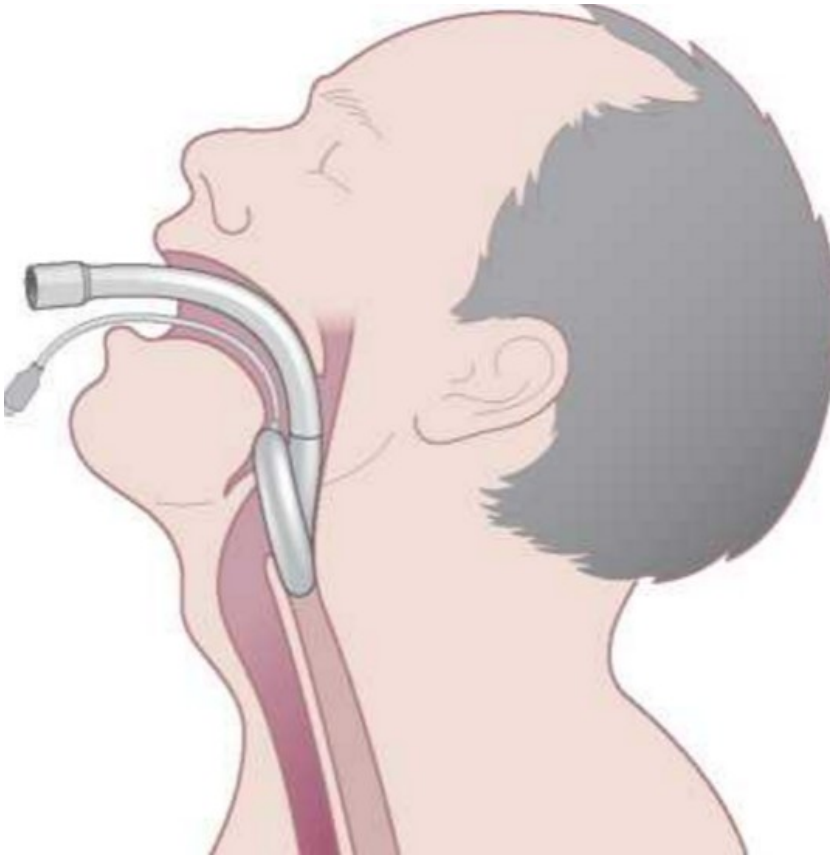


Figure 2: LMA appropriately positioned(18)

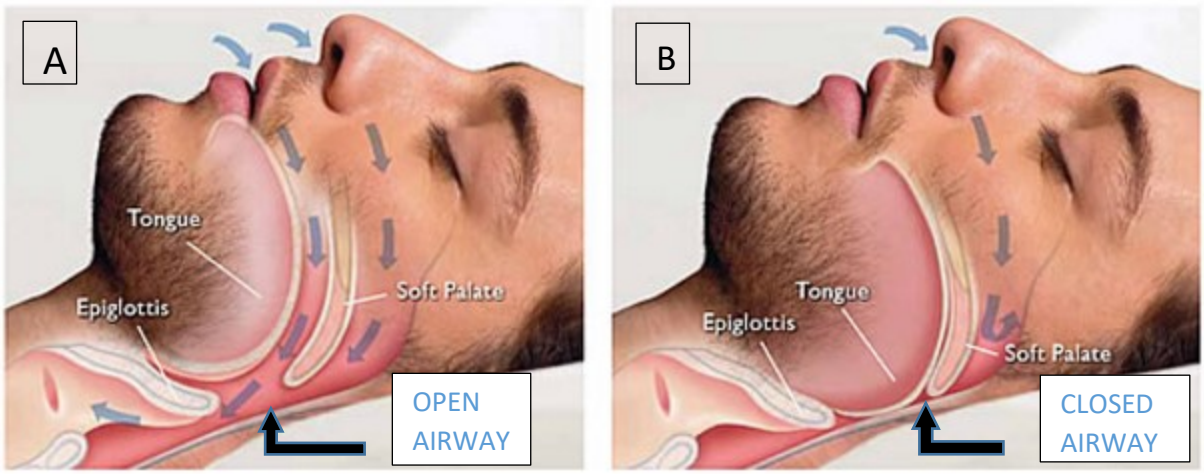


Figure 8: (A) Patent airway; (B) Obstructed/closed airway. (The Laryngeal mask airway maintains patency (open) of the airway allowing ventilation/breathing during anaesthesia).(18)

As you read this form, there may be some words that you do not understand. Please do not hesitate to ask me to clarify as we go through the information and I will take time to explain.

The purpose of this study is to improve the safety of using the LMA by comparing which approach (i.e. removal when deep or awake) is associated with less complications when a patient is recovering from anaesthesia.

Your care during this study will not be affected in any negative way if you agree to participate either approach (i.e. removal deep/ awake) may be implemented as part of current routine care at this institution with the current practice.

Participant selection

You are being asked to participate as part of a group of patients who will need planned surgery under general anaesthesia.

Research intervention and procedures

If you agree to participate, we shall (following anaesthesia at the end of your surgery) remove the laryngeal mask airway either when you are awake and appropriately responding to command or when you are deep ("asleep") this is in addition to routine standard procedure and using the standard equipment and standard monitoring. The only difference will be which approach shall

be used. The approach applied to any patient shall be random. Both approaches are currently applied at random. Which approach is better shall be revealed by the outcome of this study.

Risks and discomforts

Both approaches have inherent risks, these include; coughing, retching, agitation on emergence(confusion and delirium), increased incidence of gastric content regurgitation(stomach content coming up the food pipe) , laryngospasm(wind pipe/vocal cord closure), biting (the LMA) for awake removal and airway loss (soft tissue obstruction- similar to what causes certain people to snore-, laryngospasm –airway closure due to vocal cord closure) and subsequent desaturation and hypoxia (oxygen reduction in the blood- similar to what occurs in suffocation-) for deep removal.

The occurrence of these events is not a must and most times none of these responses occur at all. This study intends to find out which approach has less of these complications and thus make LMA use safer.

As regards discomfort, the above responses are indeed quite stressful to the human body but adequate analgesia and wearing off of anaesthetic medication from the body renders the patient amnestic (unable to recall) thus even after the event (if any) most patients have vague or no recollection of any complication having occurred. Therefore patients are by and large comfortable after anaesthesia.

Patient safety is paramount in anaesthesia, as such, the patient will be attended to by competent staff throughout the procedure and after. Any complications that may arise will therefore be attended to promptly as part of routine care of patients.

Benefits

There is be no direct benefit to patients in the study.

The knowledge obtained from this project will improve our understanding of the prevention airway complications following use of the laryngeal mask airway. This will result in safer use of the device in patients in the future.

Study outcome

If you are interested, we can communicate the results of this study to you through telephone, electronic mail or post office mail. Should you agree to participate in the study, any information pertaining to the study, will be communicated to you via the contact information you provide.

Compensation

There will be no compensation for participating in this study. In case any commercial products such as new device(s) are developed as a result of this study, you will not receive monetary or other benefit from the development of such products.

Confidentiality

Any information you provide during the study will be kept strictly confidential. Your full name will not appear on any study document and only staff participating in this study will have access to the information you provide.

Right to refuse or withdraw

Your participation in this research is entirely voluntary. You are free to choose whether or not you wish to participate. Your decision whether or not to participate will not affect your current or future relations with Aga Khan University Hospital, Nairobi.

There will be no penalties or loss of any benefit should you decide to withdraw from the study. If for any reason, you are not eligible for the study, or decide not to participate, you will receive normal care and standard treatment and medications. You are also free to withdraw from the study at any time and for any reason should you wish to do so.

Your co-operation is highly appreciated.

Should you have any questions feel free to communicate with me concerning the study on the following address:

Dr. Ronald Ombaka

Cell-phone number 0711-410-932

RSU Office: 0711 09 2148

Or 0732 10 2148

Or 366 2148

P.O. Box 30270-00100

Aga Khan University Hospital, Nairobi, Kenya.

14.1 APPENDIX II: CONSENT FORM

CONSENT FORM

(For study on the impact of deep versus awake laryngeal mask airway removal on airway complications in spontaneously breathing adult patients following isoflurane general anaesthesia.)

I ……..hereby consent to participate in this study, having been fully informed of the nature of the study by Dr. Ronald Ombaka.

Date……. Signature……..

I ……..... (Spouse/Guardian) hereby give consent for.....to participate in this study, having been fully informed of the nature of the study by Dr. Ronald Ombaka.

Date……. Signature……..

E-mail address ……..

Telephone number: ……..

I, Dr. Ronald Ombaka, confirm that I have fully explained to my patient what this research involves and hereby undersign.

Date……Signature…….

Should you have any questions feel free to communicate with me concerning the study on the following address: **Dr. Ronald Ombaka** Cell-phone number 0711-410-932

14.2 APPENDIX III: TRANSLATED CONSENT FORM

FOMU YA IDHINI

Fomu hii itatiwa sahihi na mgonjwa anayetayarishwa kufanyiwa upasuaji usio wa dharura kwenye chumba cha upasuaji, kabla ya kushirikishwa kwenye utafiti huu.

Ikiwa kwa sababu moja au nyingine hataweza kutia sahihi, basi mtu wa ukoo wake wa kwanza anayetambuliwa na hospitali hii anaweza kutia sahihi kwa niaba yake.

Mimi.....nakubali kwa hiari yangu kushiriki kwenye utafiti huu baada ya kuelezwa kwa kina kuhusu utafiti huu na Daktari Ronald Ombaka.

Tarehe .....sahihi (mgonjwa).....

Ama

Mimi.....natoa idhini kwa niaba ya..... (Jina la mgonjwa) ili ashiriki kwenye utafiti huu baada ya kuelezwa kwa kina kuhusu utafiti huu na Daktari Ronald Ombaka.

Tarehe.....sahihi (mtu wa ukoo).....

Mimi Daktari Ronald Ombaka nimehakikisha ya kwamba nimemuelezea mgonjwa pamoja na mtu wa ukoo wake kuhusu utafiti huu kwa kina.

Tarehe……. Sahihi…….

Kwa maswali yoyote utakayo kuwa nayo kuhusu utafiti huu unaweza kuwasiliana nami kwa njia ya rununu wakati wowote: **Dr Ronald Ombaka** Nambari ya rununu: **0711410932**

14.3 APPENDIX IV: STUDY PROTOCOL & DATA COLLECTION TOOL

CHECKLIST

(Tick " √ " where response is " YES " and cross " X " where response is " NO ")

CODE/IDENTIFIER: ……

AGE (YRS): ……..

SEX (M/F): ……..

WEIGHT (KG): ……..

ASA STATUS (I/II) ……..

BASELINE BLOOD PRESSURE (SBP/DBP [MAP]): ___/____ ( )

BASELINE HEART RATE

IV CANNULATION: G___

PRE-OYGENATION WITH 100% OXYGEN FOR 3 MINUTES ( )

PROPOFOL 2MG/KG: ( )

LARYNGEAL MASK AIRWAY SECURED WITH BITE BLOCK ( )

ISOFLURANE (FiISO) 1.5- 2% IN OXYGEN/AIR MIXTURE VIA MAGILL CIRCUIT; END -TIDAL > 1.15%: ( )

DATA COLLECTION TOOL

Data collection tool:

Type of surgery ……Duration (in minutes)…….

Opioid used ……..Dosage……..…….

Time from end of surgery to theatre exit (In minutes)… ……

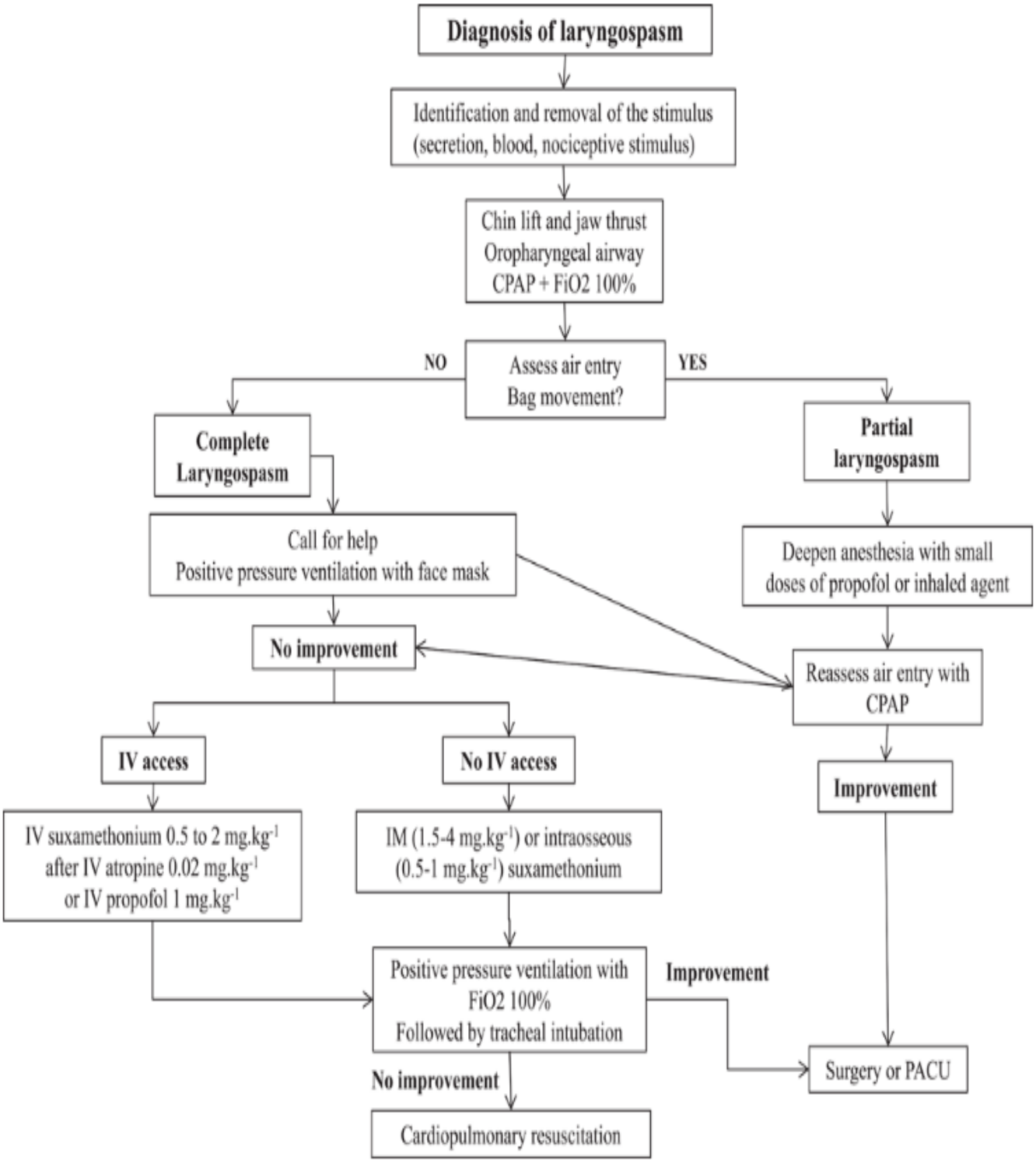
Use of suction Yes ☐ No ☐

PRIMARY PARAMETERS	Yes	No
Airway obstruction and need for airway manipulation	☐	☐
Laryngospasm	☐	☐
Desaturation <90% on pulse oximetry	☐	☐

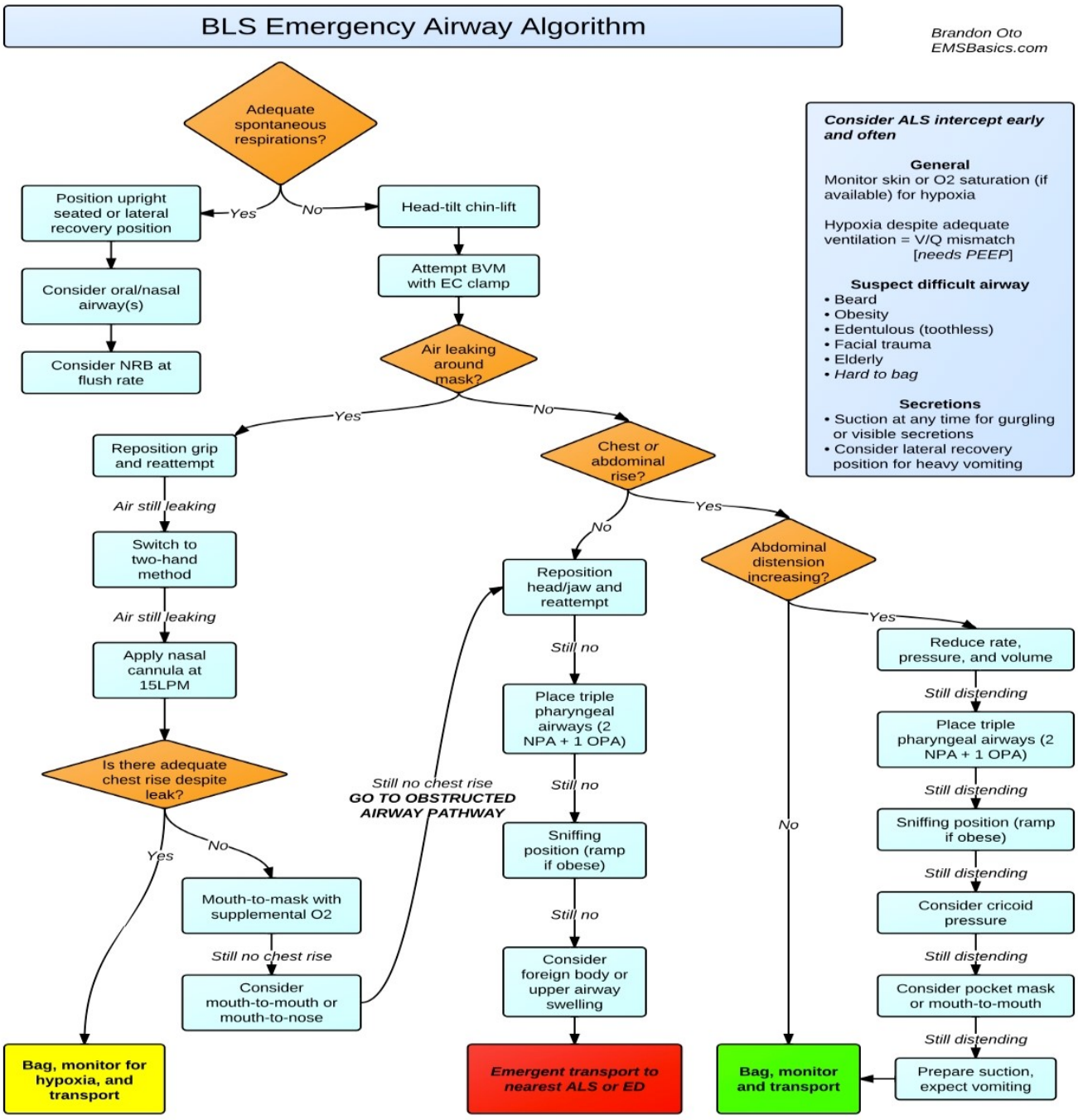
Airway complication (as per definition) Yes ☐ No ☐

14.4 APPENDIX V

LARYNGOSPASM MANAGEMENT ALGORITHM (35)



AIRWAY OBSTRUCTION MANAGEMENT ALGORITHM(36)



NB: Above algorithm applies to non-anaesthesia staff. Anaesthesia professionals at discretion to apply advanced airway management techniques as deemed appropriate.

REGURGITATION/VOMITING

MANAGEMENT
Inform the surgeon
Head down, lateral posture, if feasible
Apply cricoid pressure
Try to clear and suction the airway
Give 100% oxygen
Consider deepening anaesthesia **(1)*** to visualise and clear the pharynx/airway
Try gentle mask CPAP/IPPV with cricoid pressure **(2)***
Ventilate the lungs with cricoid pressure
IF YOU CANNOT VENTILATE **page 14****
Give suxamethonium and atropine.
Intubate with cricoid pressure, expedite surgery.

ASPIRATION
SIGNS (3)
Laryngospasm/airway obstruction
Bronchospasm/wheeze/crackles
Hypoventilation/dyspnoea/apnoea
Reduced compliance (ARDS)
Desaturation/bradycardia/arrest.

FURTHER CARE
Sedation, analgesia, IPPV via ETT
Suction airway, optimise FIO_2 and PEEP
Bronchoscopy and lavage if necessary
Bronchodilators as necessary **(4)**
Chest X ray. If normal, and
If saturation is adequate, extubate **(5)**
If stable after 2 hours in recovery, send to the ward and arrange for follow up **(5)**
If unstable or saturation is inadequate **(5)**
- Maintain intubation and IPPV
- Admit to a high dependency area **(6)**

Explain what happened to relations/friends
Repeat chest X ray and blood gases
Consider PEEP, bronchodilators, inotropes
Culture sputum
Antibiotics; not routine
Consider other causes **(7)**
Reassess daily **(8)**.
Explain what happened to the patient
Arrange follow up as necessary.

DESATURATION MANAGEMENT ALGORITHM(38)

DESATURATION

EMERGENCY MANAGEMENT

Complete COVER ABCD–A SWIFT CHECK **(1)***

Hand ventilate with 100% oxygen

Confirm the FIO_2 is appropriate

Confirm the $ETCO_2$ is appropriate, if it is low consider:

- Anaphylaxis → page 48**
- Pneumothorax → page 46**
- Air (or other) embolism → page 44**

Auscultate again, specifically exclude endobronchial intubation **(2)**

REVIEW AND TREAT OTHER POSSIBLE CAUSES

Underlying cardiopulmonary problems

If bronchial secretions or plugs are suspected **(3)**

- Posture and suction ETT/bronchi
- Give a "long slow blow" especially in children
- If cardiovascularly stable consider PEEP/CPAP

If acute shunt is suspected **(4)**

- Ensure the patient is supine and level

If a pneumoperitoneum is present, deflate the abdomen

Consider gas embolism **(5)**

Pulse oximeter malfunction (6)

Consider: polycythaemia, methaemoglobinaemia, acute tricuspid incompetence, probe sited distal to an AV fistula.

Table 1 Crisis management algorithm – memorise and practise: an explanation of each cue in the mnemonic "COVER ABCD"

C1	Circulation	Establish adequacy of peripheral circulation (rate, rhythm and character of pulse). If pulseless, institute cardiopulmonary resuscitation (CPR). The core algorithm must still be completed as soon as possible.
C2	Colour	Note saturation. Examine for evidence of central cyanosis. Pulse oximetry is superior to clinical detection and is recommended. Test probe on own finger, if necessary, whilst proceeding with O1 and O2.
O1	Oxygen	Check rotameter settings, ensure inspired mixture is not hypoxic.
O2	Oxygen analyser	Adjust inspired oxygen concentration to 100% and note that only the oxygen flowmeter is operating. Check that the oxygen analyser shows a rising oxygen concentration distal to the common gas outlet.
V1	Ventilation	Ventilate the lungs by hand to assess breathing circuit integrity, airway patency, chest compliance and air entry by "feel" and careful observation and auscultation. Also inspect capnography trace.
V2	Vaporiser	Note settings and levels of agents. Check all vaporiser filler ports, seatings and connections for liquid or gas leaks during pressurisation of the system. Consider the possibility of the wrong agent being in the vaporiser.
E1	Endotracheal tube	Systematically check the endotracheal tube (if in use). Ensure that it is patent with no leaks or kinks or obstructions (see suggested protocol in *Anaesth Intensive Care* 1993;21:615). Check capnograph for tracheal placement and oximeter for possible endobronchial position. If necessary, adjust, deflate cuff, pass a catheter, or remove and replace.
E2	Elimination	Eliminate the anaesthetic machine and ventilate with self-inflating (e.g. Air Viva) bag with 100% oxygen (from alternative source if necessary). Retain gas monitor sampling port (but be aware of possible problems).
R1	Review monitors	Review all monitors in use (preferably oxygen analyser, capnograph, oximeter, blood pressure, electrocardiograph (ECG), temperature and neuromuscular junction monitor). For proper use, the algorithm requires all monitors to have been correctly sited, checked and calibrated.
R2	Review equipment	Review all other equipment in contact with or relevant to the patient (e.g. diathermy, humidifiers, heating blankets, endoscopes, probes, prostheses, retractors and other appliances).
A	Airway	Check patency of the unintubated airway. Consider laryngospasm or presence of foreign body, blood, gastric contents, nasopharyngeal or bronchial secretions.
B	Breathing	Assess pattern, adequacy and distribution of ventilation. Consider, examine and auscultate for bronchospasm, pulmonary oedema, lobar collapse and pneumo- or haemothorax.
C	Circulation	Repeat evaluation of peripheral perfusion, pulse, blood pressure, ECG and filling pressures (where possible) and any possible obstruction to venous return, raised intrathoracic pressure (e.g. inadvertent PEEP) or direct interference to (e.g. stimulation by central line) or tamponade of the heart. Note any trends on records.
D	Drugs	Review intended (and consider possible unintended) drug or substance administration. Consider whether the problem may be due to unexpected effect, a failure of administration or wrong dose, route or manner of administration of an intended or

14.5 APPENDIX VI

JUSTICFICATION OF EXCLUSIONS:

Upper or lower respiratory tract infection / disease - this referred to any patients with respiratory symptoms that would confound the outcome e.g. predispose to laryngospasm or desaturation. Given the numerous respiratory diseases with varied presentation, we did not define active criteria for any particular disease. The decision was left to the discretion of the anaesthetist recruiting the patient.

History of obstructive sleep apnoea - Given the predisposition to airway collapse and hypoventilation that may be seen in this subset of patients, this group of patients was excluded as it was inferred that their airway dynamics would predispose them to the complications sought out by this study. Bearing in mind the effect of volatile agents on muscle tone, we agreed to exclude these patients who experience airway obstruction caused by reduction in muscle tone in regular sleep (i.e. without inhaled volatile agents) as they would have confounded outcome (especially in the deep arm).

Patients in whom muscle relaxants used - the reason for this exclusion was that our centre does not routinely perform neuromuscular monitoring and therefore patients in whom such agents are used are at a risk of residual neuromuscular blockade thus subsequently putting the airway at risk at the point of emergence from anaesthesia and reversal of neuromuscular blockade therefore predisposing those patients to adverse airway events. This would also have affected turnaround time without having direct association with isoflurane emergence kinetics.

Patients with Mallampati class 3 or 4 - Patients with high Mallampati score may elicit upper airway obstruction due to association of these scores with obstructive sleep apnoea.