"A RANDOMIZED CLINICAL TRAIL TO COMPARE THE CONDITIONS FOR LARYNGEAL MASK AIRWAY INSERTION FOLLOWING INDUCTION WITH SEVOFLURANE AND PROPOFOL IN ADULTS"

By

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Under the Guidance of

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DECLARATION

I hereby declare that this dissertation entitled **"A RANDOMIZED CLINICAL TRIAL TO COMPARE THE CONDITIONS FOR LARYNGEAL MASK AIRWAY INSERTION FOLLOWING INDUCTION WITH SEVOFLURANE AND PROPOFOL IN ADULTS."** is a bonafide and genuine research work carried out by me under the guidance of **Dr. RAJESH MANE** MD, DNB Associate Professor, Department of Anaesthesiology, Jawaharlal Nehru Medical College, Nehru Nagar, Belgaum-590010.

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LIST OF ABBREVATIONS

µgm	– Microgram
ASA	– American Society of Anaesthesiologists
BP	– Blood Pressure
ECG	- Electrocardiograph
EtCO2	– End tidal carbon dioxide
ETT	- Endotracheal tube
Group P	– Propofol group
Group S	– Sevoflurane group
i.v.	– Intra venous
Inj	– Injection
kg	– Kilogram
LMA	- Laryngeal mask airway
MAC	- minimum alveolar concentration
mg	– Milligram
min	- Minutes
ml	– milliliter
mm	- millimeter
NIBP	– Noninvasive Blood Pressure
NS	– Non significant
ppm	- parts per million
S	- Significant
S.D	– Standard Deviation
SpO2	- Oxygen saturation
via	- namely, that is
wt	- weight

ABSTRACT

Background

Sevoflurane is a volatile anaesthetic agent, which combines rapid smooth inhalational induction of anaesthesia with rapid recovery, making ideal for day care anaesthesia. The laryngeal mask airway is often used in ambulatory anaesthesia, with intravenous propofol being the agent of choice for its insertion.

Objective

To compare conditions for LMA insertion following induction with propofol and sevoflurane viz, jaw opening, ease of insertion, patient responses and number of attempts for insertion of Laryngeal Mask Airway.

Study design: A randomized double blind clinical trial.

Methods

After obtaining approval from the institutional ethical committee, 100 adults were allocated by computer generated randomization into two groups of 50 each; group P (Propofol group) and group S (Sevoflurane group). Patients in group P were induced with 2.5mg/kg intravenous Propofol and group S with 8% Sevoflurane in 50%$O_{2\&}N_2O$ 50% through inhalational route using the primed Bain's circuit with vital capacity breath technique. After loss of eye lash reflex LMA was inserted after 1 minute and the grading of conditions for LMA insertion and number of attempts were noted. All the data collected was processed statistically.

Results

We observed excellent conditions for LMA insertion in group P (86%) and in group S (84%) with p value (0.786) which is statistically not significant.

Conclusion

Sevoflurane compares favorably to i.v. Propofol for insertion of LMA using vital capacity inhalational technique.

Keywords – Sevoflurane, Propofol, Laryngeal Mask Airway.

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INTRODUCTION

The Laryngeal Mask Airway is the most significant advance in airway management. It has been gaining a firm position in anaesthetic practice as it fills the large gap between the variably effective, nonsealed, easy to insert oropharyngeal airway, and the almost invariably effective, sealed, but relatively difficult to insert invasive tracheal tube.

The increasing emphasis on day care anaesthesia has led to the greater use of LMA as an alternative to the face mask and in some cases to tracheal intubation. Satisfactory insertion of LMA requires sufficient depth of anaesthesia for suppression of airway reflexes and to avoid untoward effects due to airway instrumentation. Since its creation, various induction agents namely thiopentone, propofol, etomidate have been used for induction of anaesthesia before laryngeal mask airway placement.

Propofol with or without an opioid has been the induction agent of choice for LMA insertion as it provides better pharyngeal and laryngeal relaxation and also has a favorable recovery profile with low incidence of side effects. However it is by no means ideal, as it is associated with significant adverse effects like pain on injection, cardiovascular and respiratory depression.

Sevoflurane, a halogenated, volatile anaesthetic agent with pleasant odour and nonirritating to the airways, is suitable for inhalation induction for both children and adults. It is also associated with a very low incidence of breath holding, coughing, and laryngospasm.

In addition, its low lipid solubility (blood/gas partition coefficient at 37^0c is 0.63-0.69) allows a rapid and smooth induction, quick adjustments of anaesthetic depth, rapid elimination, and a predictably short recovery suitable for day care anaesthesia.

Thus with the availability of a non-pungent and rapidly acting volatile anaesthetic, it would seem logical to use a inhalational technique to induce anaesthesia, thereby avoiding many of the problems associated with intravenous induction. Induction using a high inspired concentration of sevoflurane and vital capacity breath technique may provide good conditions for the insertion of LMA.

Hence, in the present study an attempt is being made to compare the conditions for LMA insertion following induction of anaesthesia with inhalation of sevoflurane or intravenous induction with propofol.

AIM OF THE STUDY

The aim of the study was to compare conditions for LMA insertion following induction with propofol and sevoflurane, namely,

1. Jaw opening
2. Ease of insertion.
3. Patient responses.

and number of attempts needed for insertion of LMA.

REVIEW OF LITERATURE

The LMA has a well–established role in the modern anaesthesia practice. Initially, the LMA was recommended as a better alternative to the face mask for airway management in anaesthetised patients. Now the device with unique design, benefits every subspecialty of anaesthesia. The design of LMA is that it forms an airtight seal by enclosing the larynx than plugging the pharynx and avoids airway obstruction in the oropharynx.

HISTORY AND DEVELOPMENT OF LARYNGEAL MASK AIRWAY (LMA)

In 1980 Dr Archie Brain, a British anaesthesiologist working at the Royal London hospital under Professor Payne, began to search for a less invasive way of connecting the artificial and anatomical airways together that would also offer greater convenience and reliability than the face mask. The rationale was that if one of the principal aims of anaesthesia was to counter surgically induced stress, it seemed logical not to use a method of delivering an anaesthetic that was itself stress inducing.[1]

The original purpose was to reduce the need for more invasive methods of airway management while offering a more reliable alternative to the face mask. Examination of similar historical attempts showed that in attempting to form a junction with the airway outside the trachea, they had focused closer to or further away from glottis.

The LMA was designed between 1981-1988 by Dr Archie Brain Consultant Anaesthesiologist at the Royal London and Newham General Hospitals.

Brain's goal was to develop a device that could rapidly overcome an obstructed airway, simple and atraumatic to insert. The solution chosen was to make use of the space available posterior to and around larynx. An examination of the anatomy using specimens confirmed the presence of an elliptical space posterior to the larynx and he predicted that filling or even stretching this partly potential space would be possible to create a seal against the laryngeal inlet.

He invented the LMA in 1981 based on plaster of paris cast models of the hypo pharynx. A prototype was constructed by forming a shallow mask with an inflatable rubber cuff joined to a tube communicating with the lumen of the mask at right angles.

The LMA represents an intermediate position with the advantage that while the artificial and anatomical airways are effectively joined, the stimulus provoked is principally alimentary rather than respiratory, permitting good airway control without provoking undesirable reflex responses.

When Dr Archie Brain invented the LMA, he never intended it to replace the other forms of airway management, namely the endotracheal tube (ETT) and the face mask, but to rather enrich the armamentarium of airway tools available to the modern anaesthesia practitioner. Two of the major reasons for LMA development were to match progress in several techniques and diagnostic procedures and to provide an airway that is more effective and reliable than face mask yet less invasive than the ETT. However, the LMA is not just a new airway gadget, but also rather a part of a new concept of delivering anaesthesia.

The increasing emphasis on day care anaesthesia has led to greater use of LMA and muscle relaxants are not necessary for LMA insertion which is of particular benefit when early ambulation is necessary.

The conditions for insertion of LMA following induction of anaesthesia with either propofol 2.5 mg/kg or thiopentone 4mg/kg in 80 patients premedicated with diazepam 10 mg was assessed by Brown et al. and found that insertion following induction with thiopentone resulted in greater incidence of cough, laryngospasm, gagging. The use of additional induction agent was necessary, but resulted in no ultimate significant difference between the groups for the provision of satisfactory conditions.[2]

In a similar study the responses to LMA insertion following induction in patients with either propofol 2.5 mg/kg or thiopentone 5mg/kg were assessed by Patrick Scanlon et al. The presence of gagging, coughing, laryngospasm and movement were noted and graded. Patients in thiopentone group were associated with more adverse responses. They concluded that propofol is superior to thiopentone as an induction agent for insertion of the LMA.[3]

Comparing the conditions for LMA insertion in 90 unpremedicated patients, who received either thiopentone 5 mg/kg preceded by 40 mg/kg of topical lignocaine spray to the posterior pharyngeal wall or propofol 2.5 mg/kg alone, Seavell et al concluded that thiopentone preceded by topical lignocaine spray provides comparable conditions for insertion of laryngeal mask to propofol, with more hemodynamic stability and a shorter period of apnea.[4]

Conditions for LMA insertion were studied by Pramod et al in 150 patients following induction with 1µg/kg of fentanyl i.v followed by either 2.5mg/kg propofol, or a sequence of 1.5 mg/kg lignocaine and 5mg/kg of thiopentone, or midazolam 0.1mg/kg and, three minutes later, 5 mg/kg thiopentone and found that fentanyl (1µg/kg) – midazolam (0.1mgkg) – thiopentone (5mg/kg) combination, which is about 35% less expensive than fentanyl(1µg/kg)- propofol (2.5mg/kg),provides equally good conditions for the insertion of LMA with less adverse effects.[5]

Driver et al in a study in 70 unpremedicated patients, assessed the conditions for insertion of LMA following co-induction with midazolam alfentanil-thiopentone and midazolam-alfentanil-propofol. Following preinduction doses of midazolam 0.04mg/kg and alfentanil 10µg/kg, patients received equipotent doses of either thiopentone or propofol. They concluded that propofol was superior to thiopentone for LMA insertion.[6]

Yeo et al ,studied the conditions for insertion of LMA in 81 patients who were premedicated with 7.5 mg midazolam orally and randomly assigned to receive either propofol 1% or an admixture of thiopentone and propofol (1.25% and 0.5% respectively), both at a dose of 0.25 ml/kg. They found that an admixture of thiopentone and propofol (1.25 and 0.5% respectively) can produce suitable conditions compared to propofol 1%, for LMA insertion. In addition to cost containment, the admixture also produces less hypotension.[7]

In a randomized double –blind study Thawaites et al compared 8% sevoflurane and propofol as induction agents for day care cystoscopy in 102 unpremedicated patients. The results suggest that sevoflurane is an ideal induction agent for adult patients.

Although induction times with sevoflurane were slower compared with propofol, they found higher incidence of apnea with propofol and regular spontaneous ventilation being achieved significantly earlier with sevoflurane.[8]

Three different anaesthetic techniques in 146 healthy outpatients undergoing ambulatory surgery were studied by Brain and Fredman. In groups I and II, anaesthesia was induced with propofol (1.5-2.0mg/kg) intravenously and maintained with nitrous oxide 60% in oxygen and either a propofol infusion, 75-160µg/kg/min or sevoflurane, 1%-2% end tidal, respectively. In group III, anaesthesia was induced and maintained with sevoflurane, 1%- 4% end tidal and nitrous oxide 60% in oxygen. All patients received fentanyl, 2-3µg/kg IV and vecuronium, 0.1mg/kg IV. They found that i.v. induction of anaesthesia with propofol was significantly faster than inhalation induction with sevoflurane and no significant differences were apparent in the incidence of coughing, airway irritation, or laryngospasm during induction of anaesthesia in both the groups.[9]

In another study, Blake et al compared inhalation induction of sevoflurane and propofol alone and sevoflurane-propofol combination in 60 unpremedicated adults. Target concentration for the 3 groups (with 60%nitrous oxide) were 3% end tidal sevoflurane , 12mg/L propofol and 1.5% sevoflurane -6mg/L propofol respectively prior to insertion of LMA at 10 minutes. Induction of anaesthesia was satisfactory in each group but movement response to LMA insertion was observed in 20 patients (least in sevoflurane group). Cardiovascular responses were similar except for a lower heart rate in the sevoflurane group. EEG, bispectral index showed a greater depth of anaesthesia in the inhalation induction group. They concluded that 3% sevoflurane with 66% nitrous oxide provided the most reliable induction of anaesthesia for LMA insertion.[10]

The induction characteristics of sevoflurane was compared in nitrous oxide and oxygen with sevoflurane in oxygen alone and a propofol infusion in 75 healthy unpremedicated patients by J.E.Hall et al and recorded four endpoints of anaesthesia: time to cessation of finger tapping, time to loss of eyelash reflex, time to jaw relaxation and time to regular settled breathing after LMA insertion. Sequential blood pressure and pulse rate and the incidence of adverse airway events were also noted. They found that sevoflurane was slightly slower for induction of anaesthesia than propofol. The different induction times were statistically, though probably not clinically significant when sevoflurane was used in a vital capacity technique with comparable cardio vascular stability.[11]

Comparing patient acceptability and cost of total intravenous anaesthesia using target control infusion with propofol and volatile induction/maintenance anaesthesia with sevoflurane in 40 patients, Watson K.R. and Shah M V found propofol had significantly faster mean induction time than sevoflurane, but was associated with double the incidence of involuntary movements. [12]

In a randomized controlled trial comparing the quality and ease of LMA insertion in 76 unpremedicated adult patients after induction of anaesthesia with either sevoflurane vital capacity breath technique or propofol 3mg/kg i.v. Lian Kah et al concluded that sevoflurane compares favorably with propofol, although prolonged jaw tightness delayed LMA insertion.[13]

In a prospective single-blind study in 88 adult patients randomized into two groups by Mary E. Molley et al, patients in group P received 2.5 mg/kg propofol i.v. and

patients in group S received sevoflurane 8% in 50% nitrous oxide and oxygen. They concluded that modified vital capacity breath inhalation induction with sevoflurane 8% is efficient for LMA insertion in most cases, but takes slightly longer time than propofol.[14]

Comparing two different inhalation induction techniques in 60 unpremedicated patients, Baker et al randomly assigned them to receive either vital capacity or tidal breathing technique. They assessed loss of eyelash reflex, time to jaw relaxation and time to the end of LMA insertion. Baker CE et al concluded that there is no statistical or clinical difference between the two induction techniques.[15]

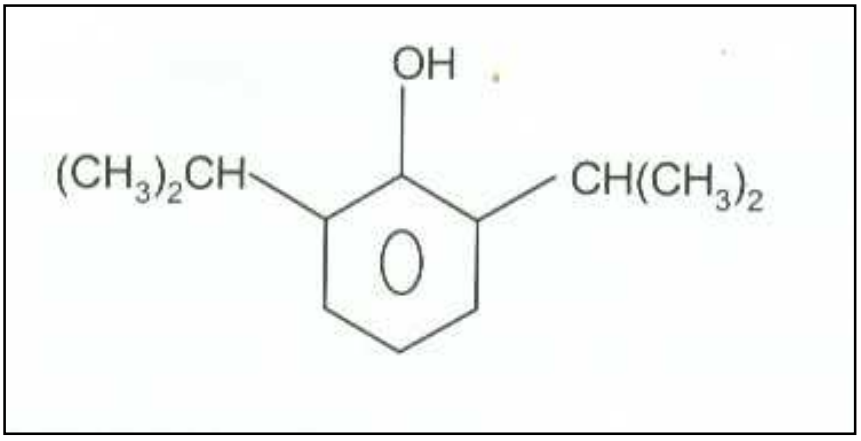
In a study by Sivalingam et al, the conditions for LMA insertion were assessed in 100 unpremedicated patients who were induced with propofol 2.5 mg/kg or vital capacity breath induction with sevoflurane (7% in the inspiratory gas) in 65% nitrous oxide and oxygen, or gaseous induction with sevoflurane plus alfentanil 5µg/kg or propofol 2.5 mg/kg and alfentanil 5µg/kg. Excellent or sastificatory conditions were observed in 100%patients in sevoflurane –alfentanil group, and 88% in the propofol-alfentanil group. They concluded that sevoflurane –alfentanil combination provides better conditions for LMA insertion when compared with sevoflurane alone, or a propofol-alfentanil combination.[16]

In a randomized double blind clinical study in 50 patients induced either with i.v. propofol or sevoflurane, Dasgupta et al assessed the conditions for LMA insertion and concluded that propofol is superior to sevoflurane probably due to better jaw relaxation and sevoflurane may provide an alternative to i.v.propofol.[17]

Marie T.Aouad, samar K.Taha et al conducted a study in 83 patients comparing Sevoflurane-Propofol Versus Sevoflurane or Propofol for Laryngeal Mask Airway insertion in adults anaesthetized with a single vital capacity breath (VCB) of 8% sevoflurane supplemented with IV propofol 1.5 mg/kg, a single VCB of 8% sevoflurane, or IV propofol 3 mg/kg and concluded that induction of anaesthesia using the combination of sevoflurane and propofol resulted in the most frequent successful LMA insertion at first attempt as compared with induction of anaesthesia with either sevoflurane or propofol alone. The sevoflurane-propofol combination was also associated with a significant decrease incidence in apnea as compared with the propofol group.[18]

PROPOFOL

Structure



Chemical name: 2-6, di-isopropyl phenol

History:

Propofol[19] was first introduced clinically by Ray and Rolly in 1977.A lot of work in the early 1970's on substituted derivatives of phenol with hypnotic properties, resulted in the development of 2-6, di-isopropyl phenol.

Propofol is insoluble in water and therefore was initially prepared in cremophor EL. The drug was reformulated using soya been oil emulsion because of anaphylactic reactions associated with cremophor EL.

Propofol was first marketed in UK in 1986 and since then, has been accepted world wide as a general anaesthetic agent both in developed and developing countries.

Physiochemical Properties:

Chemical formula:	$C_{12}H_{18}0$.	Milky white liquid
Molecular weight:	**178.27,**	**Oil at room temperature**
Melting point:	19^0C	Highly lipid soluble
Boiling point:	242^0 C	
pH range:	7-8.5	

Formulations:

Each ml. of propofol 1 % (w/v) formulation contains

Propofol : 10 mg (Active ingredient)

Soya bean oil : 10 % Lipid base.

Egg lecithin : 1.2 % Emulsifier

Glycerol : 2.25 % to maintain iso-tonicity.

Distilled water for injection: q.s.

Sodium hydroxide to maintain pH

In USA: Metabisulfite or disodium EDTA added as an anti microbial agent

In Europe: 2% propofol available is compatible with 5% dextrose if dilution is required.

Mechanism of action:

Propofol is primarily a hypnotic. The exact mechanism of action is not known. However evidence suggests that hypnotic actions are mediated by potentiating the Gama-amino butyric acid (GABA) induced chloride current through binding to β-subunit of $GABA_{A.}$ Receptor sites on β_1, β_2 and β_3 sub-units of transmembrane domains have been shown to be critical for the hypnotic action of propofol.

The α_2 - adrenoceptor system plays an indirect role in the sedative effects of propofol. Propofol also causes widespread inhibition of N-methyl D-aspartate (NMDA) subtype of glutamate receptor through modulation of sodium channel gating, an action which may also contribute to the CNS effects of the drug.

Studies have demonstrated that propofol also has a direct depressant effect on neurons of the spinal cord. The pharmacokinetics of propofol has been evaluated by numerous investigations and it has been described by both two and three compartment models.

After a single injection whole blood propofol levels decrease rapidly as a result of both redistribution and elimination. In studies using two compartments the initial distribution half life of propofol is 2-8 minutes and elimination half life varies from 1.0 to 3 hours.

An open three compartment model, describes distribution of propofol as:-

i. Rapid initial distribution from the blood to highly perfused tissues (Viz., brain, heart, lung, liver) $t_{½}$ α - 1.8 –4.1minutes
ii. Redistribution and metabolic clearance, $t_{½}$ β - 21 – 69 minutes.
iii. Slow return from poorly perfused tissues to blood $t_{½}$ 184 - 834 minutes

The context sensitive half life of propofol is less than 40 minutes. More than 98 % of propofol is plasma protein bound and so it has a large central distribution of 20 - 40L. Clearance of propofol is extremely high 1.5 to 2.2 L minute^{-1}. The time of peak effect is 90-100 seconds. The pharmacokinetics of propofol may be altered by a variety of factors viz,. gender, weight, pre-existing diseases, age and concomitant medications.

Propofol is rapidly metabolized in the liver by conjugation with glucuronide sulphate to produce soluble compounds, which are excreted by kidneys.

Less than 1 % of propofol is excreted unchanged in urine and only 2 % is excreted in faeces. The metabolites of propofol are not thought to be active.

Since clearance of propofol (1.5 to 2.2 l/minute) exceeds hepatic blood flow, extra hepatic metabolism or extra renal elimination has been suggested. This explains the faster and clear headed recovery of its use.

Propofol itself results in concentration dependent inhibition of cytochrome P_{450} enzyme system complex and thus may alter the metabolism of other drugs.

Pharmacodynamics:

1) Central Nervous system:

Propofol is primarily a hypnotic. The onset of hypnosis after doses of 2.5 mg kg^{-1} is rapid (one arm brain circulation), with a peak effect seen at 90-100 seconds. The median effective dose (ED50) of propofol for loss of consciousness is 1-1.5 mg kg-1 after a bolus. The duration of hypnosis being dose dependant, propofol provides sedation and amnesia. It alters the mood to a lesser extent than thiopentone after short surgical

procedures. Propofol also tends to produce a general state of well being. Hallucinations, sexual fantasies and opisthotonus have been reported after propofol administration.

Effects of propofol on EEG are dose dependant. Infusion of propofol demonstrates an initial increase in alpha rhythm, followed by a shift to gamma and theta frequency. High infusion rates produce burst suppression.

Propofol causes a concentration dependant decrease in the bispectral index with 50 % and 90 % patients unable to respond to verbal commands at BIS values of 63 and 51 respectively

Effect of propofol on epileptogenic EEG activity is controversial. Some report dose dependant anticonvulsant effect of propofol. But propofol is also associated with grandmal seizures and has been used for cortical mapping of epileptogenic foci.

2) Cardiovascular system:

The most prominent effect of propofol is a decrease in arterial blood pressure during induction of anesthesia independent of the presence of cardiovascular disease. An induction dose of 2 to 2.5 mg kg^{-1} produces a 25-40 % reduction in systolic blood pressure with similar changes seen in mean and diastolic blood pressure.

This is associated with a decrease in Cardiac Index (15 %), systemic vascular resistance (15-25 %), left ventricular stroke work index (30 %), mean PAP and PAOP.
The effect is maximal at 2 minutes after induction due to -

i. Direct myocardial depression and

ii. Decreased peripheral resistance and preload.

The hypotensive effect of propofol is potentiated by -

1. Hypovolaemia or cardiovascular decompensation.
2. Advanced age
3. Large doses of propofol
4. Pre medication with opioids
5. Pre- existing cardiovascular disease

An infusion of propofol result in significant reduction in both myocardial blood flow and myocardial 0_2 consumption, a finding that suggest preservation of the global myocardial oxygen supply demand ratio

3. Respiratory system:

Propofol acts as a moderate respiratory depressant and can cause apnea in upto 25-30 % population after an induction dose.

The incidence and duration of apnea is dependent on dose, speed of injection and concomitant pre-medication. The onset of apnea is usually preceded by marked tidal volume reduction and tachypnea.

Propofol is mild bronchodilator and causes bronchodilatation in patients with chronic obstructive pulmonary disease.

In animal models propofol significantly reduced free radical mediated and cyclo-oxygenase catalyzed lipid peroxidation so it is proposed that propofol may have an impact on adult respiratory distress syndrome (ARDS)

4. **Effect on liver and kidney function:**

Post-operative hepatic function tests are not altered following propofol anaesthesia. No evidence of any altered renal function has been reported following use of propofol.

5. Effect on uterus:

Propofol has little or no effect on pregnant uterus, it readily crosses the placenta but usual induction does not appear to depress neonates, and has no adverse effects on the uterine contraction or intra-operative blood loss.

6. Effect on adrenocortical function:

Propofol is not an analgesic but, does not cause ant-analgesia. Propofol causes minimal inhibition of cortisol production unlike other anaesthetic agents. It tends to decrease cortisol levels during infusion period and shows no impairment of adrenal-steroidogenesis

Other miscellaneous effects

a) Anti-Emetic effect:

At low (sub – hypnotic) doses, propofol possesses a significant anti – emetic effect. The exact cause is not known. Studies suggest that it may occur as a result of direct depression of chemoreceptor trigger zone (CTZ), and may also be due to anti – serotonergic ($5HT3_)$ properties of propofol.

b) Anti-pruritic effect:

At sub – hypnotic doses, propofol has been reported to relieve cholestatic pruritis and is found to be as effective as naloxone in treating pruritis induced by spinal opioids.

c) Anti-oxidant activity:

Propofol has been found to possess anti oxidant effects and thus acts as free radical scavenger. This suggests that propofol can be useful in conditions such as multi – organ failure and acute respiratory distress syndrome.

d) Anxiolysis:

Sub – hypnotic doses of propofol possess anxiolytic properties strengthening the cause for its use during sedation and as an adjuvant to local or regional anaesthesia.

e) Other effects:

1 Does not interfere with coagulation

2 Does not trigger malignant hyperthermia

3 Can be used in patients with porphyrias

4 Decreases polymorphonuclear leukocyte chemotaxis, but not adherence, phagocytosis and killing.

5 Also inhibits the ability of cancer cells to invade by modulating Rho-A

Side effects:

- Pain on injection
- Pro-convulsant activity via., myoclonus
- Thrombophlebitis
- Hypotension and apnea
- Supports growth of E-Coli, hence unused infusions should be discarded within 12 hours
- Propofol infusion syndrome
- Rarely anaphylactic reaction.

Presentation:

Propofol is available as 1% i.e. 10 mg/ml emulsion in 10ml and 20 ml vials for induction and 50ml, 100 ml vials for infusion. In Europe, 2 % formulation is also available, as well as a formulation in which emulsion contains medium and long chain triglycerides.

Dosage: Induction of anesthesia – Child: 2.5- 3.5 mg/kg

Adult: 1.0 –2.5 mg/kg

Sedation: 25 to 75 $\mu g\ kg^{-1}$ min

Maintenance of anaesthesia: 50 to 150 $\mu g\ kg^{-1}\ min^{-1}$

Uses:

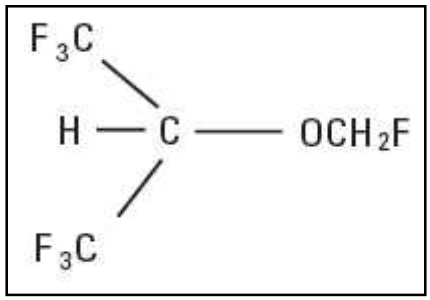
1. For induction and maintenance of general anaesthesia
2. In ICU for IV sedation and total intra-venous anaesthesia (TIVA)
3. For day care surgery as it has rapid recovery
4. In patients with bronchial asthma, porphyria and in those patients where thiopentone is contraindicated
5. In patients with malignant hyperthermia
6. As an anticonvulsant
7. As an antiemetic

Contraindication:

- Patient hypersensitive to propofol formulation
- Hypovolemia
- Epilepsy and dyslipidemia.

SEVOFLURANE

Structure



Chemical name:

Fluoromethyl 2,2,2,-trifluoro-1-(trifluoromethyl) ethyl ether

HISTORY

Sevoflurane[20] was first synthesized in the late 1960s at Baxter-Travenol laborateries by R F Wallin and coworkers.

Sevoflurane, volatile liquid for inhalation, a nonflammable and nonexplosive liquid administered by vaporization, is a halogenated general inhalation anaesthetic agent.

Sevoflurane is a clear, colorless, nonpunget, liquid containing no additives. Sevoflurane is stable when stored under normal room lighting conditions.

Physiochemical properties:

Molecular weight: 200.05

Boiling point at 760 mm Hg: 58.6°C

Specific gravity at 20°C: 1.520 - 1.525

Vapor pressure in mm Hg: 157 mm Hg at 20°C

197 mm Hg at 25°C

317 mm Hg at 36°C

Distribution Partition Coefficients at 37°C:

Blood/Gas:	0.63-0.69
Water/Gas:	0.36
Olive Oil/Gas:	47-54
Brain/Gas:	1.15

Mean Component/Gas Partition Coefficients at 25°C for Polymers Used Commonly in Medical Applications:

Conductive rubber	14.0
Butyl rubber	7.7
Polyvinylchloride	17.4
Polyethylene	1.3

FORMULATION:

Sevoflurane Volatile Liquid for Inhalation, is packaged in amber colored bottles containing 250 mL

SAFETY AND HANDLING:

Occupational Caution

There is no specific work exposure limit established for sevoflurane. However, the National Institute for Occupational Safety and Health has recommended an 8 hour time-weighted average limit of 2 ppm for halogenated anesthetic agents in general (0.5 ppm when coupled with exposure to N2O).

Storage

Store at controlled room temperature, 15° - 30°C (59° - 86°F).

CLINICAL PHARMACOLOGY

INDICATIONS

Sevoflurane is indicated for induction and maintenance of general anaesthesia in adult and pediatric patients for inpatient and outpatient surgery.

DOSAGE AND ADMINISTRATION:

The concentration of sevoflurane is delivered by using a vaporizer calibrated specifically for sevoflurane.

INDUCTION:

Sevoflurane has a nonpungent odor and does not cause respiratory irritability; it is suitable for mask induction in pediatrics and adults.

MAINTENANCE:

Surgical levels of anaesthesia can usually be achieved with concentrations of 0.5 - 3% sevoflurane with or without the concomitant use of nitrous oxide. Sevoflurane can be administered with any type of anaesthesia circuit.

Table No. 1 : MAC Values for Adults and Pediatric Patients According to Age

Age of Patient (years)	Sevoflurane in Oxygen	Sevoflurane in 65% N2O/35% O2
0 - 1 months #	3.3%	
1 - < 6 months	3.0%	
6 months - < 3 years	2.8%	2.0%@
3 - 12	2.5%	
25	2.6%	1.4%
40	2.1%	1.1%
60	1.7%	0.9%
80	1.4%	0.7%

Neonates is full-term gestational age. MAC in premature infants has not been determined.

@ In 1 - < 3 year old pediatric patients, 60% N2O/40% O2 was used.

PHARMACOKINETICS

UPTAKE AND DISTRIBUTION.

SOLUBILITY

Because of the low solubility of sevoflurane in blood (blood/gas partition coefficient @ 37°C = 0.63-0.69), a minimal amount of sevoflurane is required to be dissolved in the blood before the alveolar partial pressure is in equilibrium with the arterial partial pressure. Therefore there is a rapid rate of increase in the alveolar (end-tidal) concentration (FA) towards the inspired concentration (FI) during induction.

INDUCTION OF ANAESTHESIA

The time for the concentration in the alveoli to reach 50% of the inspired concentration is 1 minute for sevoflurane.

RECOVERY FROM ANAESTHESIA

The low solubility of sevoflurane facilitates rapid elimination via the lungs. The rate of elimination is quantified as the rate of change of the alveolar (end-tidal) concentration(FA) following termination of anaesthesia, relative to the last alveolar concentration measured immediately before discontinuance of the anaesthetic.

METABOLISM

Sevoflurane is metabolized by cytochrome P450 2E1, to hexafluoroisopropanol (HFIP) with release of inorganic fluoride and Co_2. Once formed HFIP is rapidly conjugated with glucuronic acid and eliminated as a urinary metabolite. In vivo metabolism studies suggest that approximately 5% of the sevoflurane dose may be

metabolized. The rapid and extensive pulmonary elimination of sevoflurane minimizes the amount of anaesthetic available for metabolism.

ELIMINATION

HFIP appears in the urine as inorganic fluoride. There is no evidence of toxicity associated with HFIP.

PHARMACOKINETICS OF FLUORIDE ION

Fluoride ion concentrations are influenced by the duration of anaesthesia, the concentration of sevoflurane administered, and the composition of the anaesthetic gas mixture. Peak fluoride concentrations ranged between 12 μM and 90 Mm when anaesthesia is maintained purely with sevoflurane for periods ranging from 1 to 6 hours. The half-life is in the range of 15-23 hours.

PHARMACODYNAMICS

RESPIRATORY SYSTEM

It is quite pleasant to inhale and has virtually no irritant effects on the airway. It produces dose dependent ventilatory depression, reduces respiratory drive in response to hypoxia and increases Co_2 partial pressure.

The ventilatory depression associated with sevoflurane may result from a combination of central depression of medullary respiratory neurons and depression of diaphragmatic function and contractility. It is also effective as a bronchodilator.

CARDIOVASCULAR SYSTEM

It has minimal effect on the heart rate. It causes a dose dependent depression of cardiac output and a reduction in systemic vascular resistance which results in fall in systemic blood pressure. It also causes a reduction in pulmonary arterial pressure which is not dose dependent. Hepatic and renal blood flows are preserved with concentrations upto 1 MAC.

Sevoflurane doesnot sensitize the myocardium to epinephrine although it is coronary vasodilator; it is not associated with coronary steal.

It protects against some of the metabolic changes associated with myocardial ischemia.

CENTRAL NERVOUS SYSTEM

Cerebral perfusion pressure is well maintained, the cerebrovascular response to carbondioxide and cerebro vascular auto regulation are both preserved under sevoflurane anaesthesia upto 1 MAC. It causes a slight increase in intracranial pressure in normocapnic patients.

It decreases cerebral vascular resistance and cerebral metabolic rate. It does not cause excitatory effects on the EEG.

RENAL SYSTEM

Renal blood flow is well preserved, though serum fluoride levels greater than 50µ/ml have been reported, the apparent lack of renal toxicity with sevoflurane may be related to its rapid elimination from the body. This reduces the total amount of drug available for *in vivo* metabolism.

NEUROMUSCULAR SYSTEM

Sevoflurane potentiates the action of non-depolarsing muscle relaxants. It triggers a skeletal muscle hyper metabolic state leading to high oxygen demand and the clinical syndrome known as malignant hyperthermia in susceptible individuals.

INTERACTION WITH CARBONDIOXIDE ABSORBERS

Sevoflurane alkaline degradation occurs by two pathways. The first results from the loss of hydrogen fluoride with the formation of pentafluoroisopropenyl fluoromethyl ether, (PIFE, C4H2F6O), also known as Compound A, and trace amounts of pentafluoromethoxy isopropyl fluoromethyl ether, (PMFE, C5H6F6O), also known as Compound B. Compound A concentration in a circle absorber system increases during

- Increasing Co_2 absorbent temperature
- Increasing composition (Baralyme producing higher levels than soda lime),
- Increased body temperature
- Increased minute ventilation
- Decreasing fresh gas flow rates(2L/min)

These products are thought to be toxic in rats, primarily involving renal, hepatic and cerebral damage.

SIDE EFFECTS

1. CARDIOVASCULAR: Bradycardia, Hypotension.

2. RESPIRATORY SYSTEM: Laryngospasm, Airway obstruction, Breath holding.

3. NERVOUS SYSTEM: Agitation.

4. GASTROINTESTINAL: Nausea and Vomiting.

LARYNGEAL MASK AIRWAY

The laryngeal mask[21] is designed to form a seal around the larynx with the distal part of the mask conforming to the hypo pharynx and the walls of the long axis of the mask facing towards the pyriform fossae.

A tube is attached to the back of the mask at an angle of about 30^0. This angle was chosen because it was found to be optimal angle for tracheal intubation through the laryngeal mask. This mask consists of a bowl circumscribed by a cuff, which is inflatable through a pilot tube and balloon through which the cuff pressure can be monitored. When the cuff is correctly deflated, it should form "wafer thin leading edge" facing away from the mask aperture. The pilot tube is provided with a non-return valve. Shaft opens into the concavity of the mask via a fenestrated aperture with three orifices to prevent the epiglottis from falling back and obstructing the lumen. A black line runs longitudinally along the posterior curvature of the shaft to aid in orienting the position of the tube in situ. The device is made entirely of silicone to withstand repeated autoclaving; the valve is made with polypropylene and the connector with polysulfone. The device is currently available in eight sizes and many modifications have been devised. The smaller sizes are scaled down versions of the adult sizes.

The modified versions:

1. **The Flexible LMA (Reinforced):** It consists of a flexometallic tube connected to a standard LMA. It is used in head and neck surgery. It is available in sizes 2, 2.5, 3, 4, and 5.[22]

2. **Split LMA:** used for endotracheal intubation following fibreoptic bronchoscopy through the LMA.[23]

3. **LMA C Trach /Intubating LMA:** used for endotracheal intubation, which has a rigid tube with an integral guiding handle and an epiglottis elevator bar, a guiding ramp built into the floor of the mask aperture and a modified silicone tracheal tube for use with the device.[24]

4. **Proseal LMA:** It was designed by Archie Brain in the late 1990s and released in 2000. The primary design was to construct a laryngeal mask with improved ventilatory characteristics that also offered protection against regurgitation and gastric insufflation. The principal new features are a modified cuff and a drain tube. The ProSeal LMA is a double mask, forming two end-to end junctions: one with the respiratory tract and the other with the gastrointestinal tract.[25]

5. **LMA Supreme.** Is a new supraglottic device featuring anatomically shaped airway tube into which separate drain tube has been incorporated and a modified inflatable cuff, designed to offer higher airway seal pressures around the laryngeal opening than the classic LMA. The drain tube and improved airway seal are designed to provide functional separation of the respiration and digestive tracts, especially to prevent gastric inflation during ventilation, allow venting of gastric contents and enable the passage of a gastric tube. It also incorporates integral bite block .[26]

Table 2 : Description of different sizes of LMA[27]

Patient size	Mask size	Maximum cuff	Maximum ET
Neonates/Infants up to 5 kg	1	Up to 4 ml	3.5 mm
Infants up to 5 kg	1.5	Up to 7 ml	4 mm
Infants/children 10-20 kg	2	Up to 10 ml	4.5 mm
Children20-30 kg	2.5	Up to 14 ml	5 mm
Children30-50kg	3	Up to 20 ml	6 mm cuffed
Adults 50-70 kg	4	Up to 30 ml	6 mm cuffed
Adults 70-100 kg	5	Up to 40 ml	7 mm cuffed
Large adults over 100 kg	6	Up to 50 ml	7 mm cuffed

Advantages and Disadvantages of LMA over ETT:

ADVANTAGES:

1. Placement easier and quicker.
2. Pulse rate and blood pressure changes less during insertion and emergence.
3. Muscle relaxants and laryngoscopy not necessary.
4. Incidence of sore throat is less.
5. Intraocular pressure changes less during placement and removal of LMA.

DISADVANTAGES:

1. Gastric insufflation.
2. More air leak.
3. Dislodgement.
4. One lung anaesthesia is not possible with LMA.

INDICATIONS:

1. General indications

The LMA is probably best suited for short procedures. It may be particularly useful for outpatient anaesthesia. It may also be useful in cases where the user would choose to administer anaesthesia by face mask but elects not to because of the length of the procedure. It is also useful in situations where the use of a face mask may not provide a proper seal. It is routinely used for operations on extremities, minor urological and gynecological procedures.

2. Ocular surgery

LMA may be useful in elective eye surgery since changes in intraocular pressure are less than with endotracheal tube insertion.

3. Anaesthesia at a distance

Use of LMA is indicated in patients undergoing daily radiotherapy under general anaesthesia to avoid repeated endotracheal intubation. It is also advocated in place of endotracheal intubation in anaesthesia for magnetic resonance imaging.

4. Tracheal stenosis

The LMA has been used safely in patients with tracheal stenosis. Tracheal intubation can worsen the stenosis by causing airway odema and increase in airway resistance. The LMA does not cause airway odema, as it does not enter the trachea. Airway resistance is less because the diameter of the tube of LMA is much larger than that of the endotracheal tube.

5. Fibreoptic Bronchoscopy

The LMA has been used to aid diagnostic fibreoptic bronchoscopy in adults and children and also for aiding tracheal suctioning in intensive care units.

6. Cardiopulmonary Resuscitation

The LMA has been proposed as initial method of airway control during cardiopulmonary resuscitation because of its ease to master the technique and high success rate. It may cause less damage to the unstable cervical spine than a face mask.

7. Difficult airway

The low risk/benefit ratio associated with inserting an LMA it a suitable first choice before transtracheal jet ventilation.

The LMA has two major uses during general anaesthesia.

- As a routine airway.
- As a conduit for tracheal intubation.

When the LMA is used as a conduit for tracheal intubation, blind passage of the endotracheal tube through the LMA and into the trachea is more successful in adults than in children. In general, when the LMA is used as a conduit for tracheal intubation, it is best to use a fibreoptic bronchoscope to guide an endotracheal tube into the trachea, a technique with a success rate approaching 100%.

Cricoid pressure causes conformational changes in the cuff of LMA and reduces ease of LMA insertion. It also makes passage of endotracheal tube through it more difficult.

LMA IN THE DIFFICULT AIRWAY ALGORITHM

The ASA difficult algorithm that has been presented to and used by the anaesthesia community seems to be well accepted, as documented by minimum critism. With multiple uses and multiple places of use, LMA is an important option within the ASA difficult airway algorithm. More importantly the clinical record of LMA use in "cannot ventilate ,cannot intubate" situations has been excellent, and in patients whose lungs cannot be ventilated because of supra glottic obstruction and whose trachea cannot be intubated due to unfavorable anatomy, provided they do not have obvious periglottic pathology (massive cancer, hematoma, abscess, anaphylactic laryngeal odema) the LMA should be immediately available and considered as the first choice of treatment.

The LMA as a ventilatory device and/ or intubating device is used in five circumstances and the ASA difficult airway algorithm.

1. The use of the LMA in the awake patient as a conduit for fibreoptic tracheal intubation ("awake limb" of the ASA difficult airway algorithm)
2. The use of LMA as an airway (ventilatory device) in the anaesthetised patient who cannot be tracheal intubated. (Anaesthetised non emergency limb).
3. The use of the LMA as a conduit for fibreoptic tracheal intubation in the anaesthetized patient whose lungs can be ventilated but in whom the trachea cannot be conventionally intubated ("anaesthetised nonemergency limb")
4. The use of LMA as an emergency airway in the patient whose lungs cannot be conventionally ventilated and whose trachea cannot be intubated ("anaesthetised emergency limb").

5. The use of LMA as a conduit for tracheal intubation in the patient whose trachea cannot be intubated ("anaesthetised emergency limb"). If the gas exchange is obtained by insertion of LMA in "cannot ventilate, cannot intubate" situation, precious time can be obtained to subsequently use the LMA as a conduit for tracheal intubation. If adequate ventilation is possible through the LMA it is probable that the bowl of the LMA surrounds the larynx and fibreoptic guided tracheal intubation will be successful. However, if a fibreoptic bronchoscope is not available, an attempt to do a blind orotracheal intubation via the LMA is another possibility.

Contraindications:

1. Patient factors increasing the risk of pulmonary aspiration

- ❖ Full stomach
- ❖ Upper gastrointestinal pathology
- ❖ Morbid obesity
- ❖ More than 14 weeks of pregnancy
- ❖ Trauma
- ❖ Autonomic neuropathy
- ❖ Gastrointestinal obstruction

2. Operative factors increasing risk of pulmonary aspiration

- ❖ Upper abdominal surgery
- ❖ Increased intra abdominal pressure
- ❖ Steep trendlenberg tilt

3. Patient factors with high inflation pressure

- ❖ Low compliance of lungs or chest wall
- ❖ High airway resistance
- ❖ Glottic pathology

4. Operative factors with need for high inflation pressures

- ❖ Intrathoracic surgery
- ❖ Intra abdominal procedures leading to diaphragmatic splinting

5. Diseases of mouth and pharynx

6. Bleeding diathesis (relative)

Complications:

Classification of problems and complications with LMA:

1. Insertion failure
2. Aspiration
3. Vomiting
4. Regurgitation
5. Leak
6. Breath holding
7. Pharynolaryngeal reflexes
    - ❖ Bronchospasm
    - ❖ Coughing
    - ❖ Gagging
    - ❖ Laryngeal spasm
    - ❖ Hiccup

8. Trauma involving

- Epiglottis
- Larynx
- Posterior pharyngeal wall
- Tonsils
- Uvula

9. Neurovascular

- Lingual nerve paralysis
- Hypoglossal nerve paralysis
- Vocal cord paralysis

10. Postoperative

- Sore throat
- Dysphagia
- Hoarseness

METHODOLOGY

The present study titled "**A Randomized clinical trial to compare the conditions for Laryngeal Mask Airway insertion following induction with Sevoflurane and Propofol in adults."** was conducted in KLES Prabhakar Kore Hospital and MRC & Jawaharlal Nehru Medical College Charitable Hospital between December 2007 to December 2008.

After obtaining the Institutional Ethical committee clearance and informed consent the study was undertaken on 100 ASA grade I and II patients aged between 20-65 years undergoing short general anaesthesia procedures.

INCLUSION CRITERIA

1. Patients undergoing short general anaesthesia procedures where LMA was indicated.
2. ASA I or ASA II aged 20- 65 years.

EXCLUSION CRITERIA

1. ASA III/IV.
2. Difficult airway :Mallampati Grade III/IV.
3. History of gastro intestinal reflux.
4. History of cardio vascular disease, hypertension. .
5. History of renal disease.
6. Pregnancy.
7. Patients receiving anti-epileptic medication.
8. Known allergies to any anaesthetic agent.

SAMPLE SIZE CALCULATION

Using the results of a previously conducted study and substituting the values in the below stated formula, we arrived at a sample size of 50 in each group.

$$n = \frac{2(Z\alpha+Z\beta)^2 (p\times q)}{(P_1-P_2)^2}$$

Zα=1.65, Zβ=0.84, power=80%

P1 is propofol group and

P_2 is sevoflurane group, q =(100-p).

DESIGN: - Randomized Clinical Trial.

METHOD

All the patients were interviewed on the evening prior to the operation and detailed history about any previous illness and any treatment received was elicited.

A detailed physical examination including weight in kilogram and age in years was noted.

Investigations like complete haemogram and routine urine analysis were done. All patients/ guardians were informed regarding the procedure of anaesthesia and study intervention, its benefits and disadvantages in their vernacular language. A written consent of the same from the patients /guardians was obtained.

The patients were kept nil by mouth from midnight for both solids and liquids. The patients were then allocated into group P (Propofol group) or group S (Sevoflurane group) according to a computer generated randomized table.

3 observers took part in the study.

Observer 1: An Anaesthesiologist having at least 2 years experience who did the pre-anesthetic check up including airway assessment and also induced anaesthesia in all the patients.

Observer 2: An Anaesthesiologist with more than two years experience.

Observer 3: An Anaesthesia resident in charge of the case.

Intra venous access was secured and slow infusion of crystalloids was commenced. All the patients were monitored for ECG, Non-invasive blood pressure, SpO_2 and $ETCo_2$.

Prior to induction, all patients were preoxygenated with 100% O_2 at 8L/minute using Bain's circuit (mapelson-D) with a 2L reservoir bag for 3 minutes and premedicated with Glycopyrrolate 0.005mg/kg i.v. and Fentanyl 2mcg/kg i.v in both the groups.

GROUP -P:

Patients were induced with 2.5mg/kg Propofol i.v. over 30 seconds. 2 ml of 1% Lignocaine was mixed with 20ml of Propofol to reduce the pain on injection.

GROUP-S:

The Bain's circuit reservoir bag was emptied, adjustable pressure limiting valve closed and the patient end of system sealed by pressing the outlet firmly against the pillow. The circuit was primed with 8% sevoflurane in N_2O 50%& O_2 50% at 8Litre/minute for 30 seconds.

All patients belonging to Group S was asked to exhale maximally and the facemask, connected to primed circuit was placed over mouth and nose. Patients were then advised to take vital capacity breaths.

Loss of eyelash reflex was considered as induction of anaesthesia in both the groups.

Observer 1 assessed jaw relaxation after loss of eye lash reflex.

Observer 2 was called in. He/she stayed outside the operation theatre during the induction period. Observer 1 further blinded observer 2 to the technique of induction by concealing the injection site, the vaporizer and the agent monitors with the help of a screen.

A standard LMA (LMA size #3 was used for women and size #4 for men) lubricated with lignocaine jelly on posterior surface was inserted using the method described by Brain.

In group P LMA was attempted at 1 minute following induction for 15 seconds.

If unsuccessful, spontaneous /assisted ventilation of N_2O 50%& $O_2$50% was given and repeat attempts were made every 1 minute up to maximum of 3 attempts, each time preceded by boluses of 1mg/kg i.v propofol.

In group S LMA was attempted at 1 minute following induction for 15 seconds.

If unsuccessful patients were allowed to continue spontaneous/ assisted ventilation on sevoflurane 8% in N_2O 50%& $O_2$50% and received increments of 1ml saline every 15seconds. The second attempt was made at 2 minute 15 sec and third attempt at 3 minute 30 sec after commencement of induction.

Any failures of insertion, in either of the groups, defined as failure to insert the LMA after 3 times, were rescued with succinylcholine 25mg. i.v.

Anaesthesia was maintained with O_2:N_2O 50:50% and halothane on spontaneous ventilation.

The following data were recorded by observer 3:

- The ease of insertion and jaw relaxation.
- The response of the patient to LMA insertion including the presence or absence of gagging, coughing, patient movements and laryngospasm.
- The number of attempts for LMA insertion.

The grading of conditions for LMA insertion was done by observer 2.

Table 3: Grading of conditions for LMA insertion

Introduction of LMA	**3**	**2**	**1**
Jaw opening	FULL	PARTIAL	NILL
Ease of insertion	EASY	DIFFICULT	IMPOSSIBLE
Patient response	3	2	1
Coughing	NIL	MINOR	SEVERE
Gagging	NIL	MINOR	SEVERE
Patient movements	NIL	PARTIAL	TOTAL
Laryngospasm	NIL	MODERATE	VIGOROUS
Total score			

The overall conditions for insertion of LMA were assessed as excellent, satisfactory, or poor based on the total score obtained by summing up the individual scores of each component.

Maximum total score -18

18 Excellent

16-17 Satisfactory

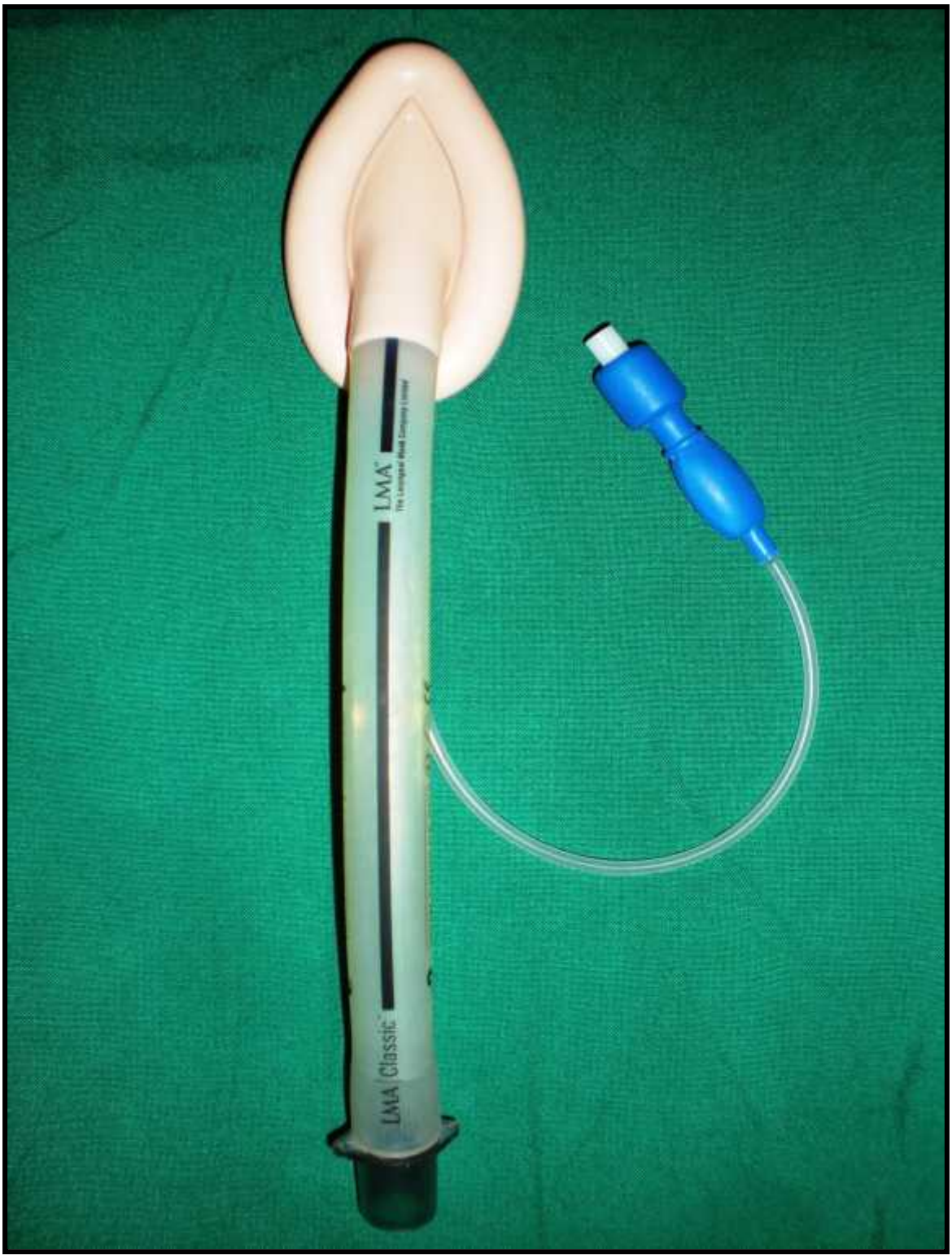
16 Poor.

After insertion of LMA, anaesthesia was continued with 50%nitrous &oxygen and halothane. The study ended when the patient was considered to reach an adequate depth of anaesthesia and was well settled after insertion of LMA.

Photo No. 1 : Propofol

Photo No. 2 : Sevoflurane

Photo No. 3 : Laryngeal Mask Airway



RESULTS

The objective of the present study was to compare the conditions for laryngeal mask airway insertion following induction with sevoflurane and propofol in adults. The study was carried out in KLES Prabhakar Kore Hospital & MRC, & Jawaharlal Nehru Medical College Charitable Hospital. Department of Anaesthesiology, Belgaum, in between the period December 2007 to December 2008.

The study included 100 ASA grade I and II patients aged between 20-65 years undergoing short general anaesthesia procedures where LMA was indicated. The patients were divided into two groups of 50 each as group P (n=50) and group S (n=50) by a computer generated randomization table.

Data was collected in both groups and observations of the analysed data are presented in the tabular form as follows.

All the qualitative data were analyzed using χ^2 test and the quantitative data using Students unpaired 't' test.

Table No. 4 : Demographic Profile

Character	Propofol group Mean ± SD	Sevoflurane group Mean ± SD	P Value
Age (years)	33.50 ± 11.50	31.70 ± 10.60	0.423(NS)
Weight (kg)	52.50±6.93	53.60±6.34	0.410(NS)
Male : Female	09/41	12/38	0.461(NS)

Students' unpaired 't' test. (P < 0.05 significant, NS = not significant, SD=Standard deviation).

Demographic data:

Table shows gender distribution, the mean and standard deviation of age and weight in the 2 groups. There was no statistical difference between the 2 groups with regard to age and weight. The data were compared using students unpaired 't' test. There were 9 males and 41 females in group P and 12 males and 38 females in group S.

Table No. 5 : Grading of conditions for LMA insertion

Parameter	Grade	Description	Group S n =50	Group P n =50
Jaw relaxation	3	Full	45	47
	2	Partial	05	03
	1	Difficult	0	0
Ease of	3	Easy	48	48
insertion	2	Difficult	02	02
	1	Impossible	0	0
Coughing	3	Nil	50	50
	2	Minor	0	0
	1	Severe	0	0
Gagging	3	Nil	50	50
	2	Minor	0	0
	1	Severe	0	0
Laryngospasm	3	Nil	50	50
	2	Moderate	0	0
	1	Vigorous	0	0
Patient	3	Nil	47	47
movements	2	Partial	03	03
	1	Total	0	0

Group S: Sevoflurane Group P: Propofol.

The above table shows the grading of conditions for LMA insertion in both groups.

47 patients had full jaw relaxation and 3 patients had partial relaxation in group P.

45 patients had full jaw relaxation and 5 patients had partial relaxation in group S.

The LMA was easy to insert in 48 patients and difficult in 2 patients of each group.

There were no patient movements in 47 patients and 3 patients had partial movements while inserting the LMA in both the groups.

None of the patients had cough, gagging and laryngospasm while inserting the LMA in either group. The different grades of all six parameters were almost the same in patients of both the groups hence no statistical test was performed.

Table No. 6: Number of attempts for LMA insertion

	Attempt	
	First	**Second**
Group P (n=50)	49	1
Group S (n=50)	50	0

Group P: PROPOFOL Group S: SEVOFLURANE

Insertion of the LMA was achieved in the first attempt in 49 patients and in the second attempt in one patient in group P, and at the first attempt in all patients in group S. No statistical test was performed, as it was not necessary.

Table No. 7: Overall conditions for LMA insertion

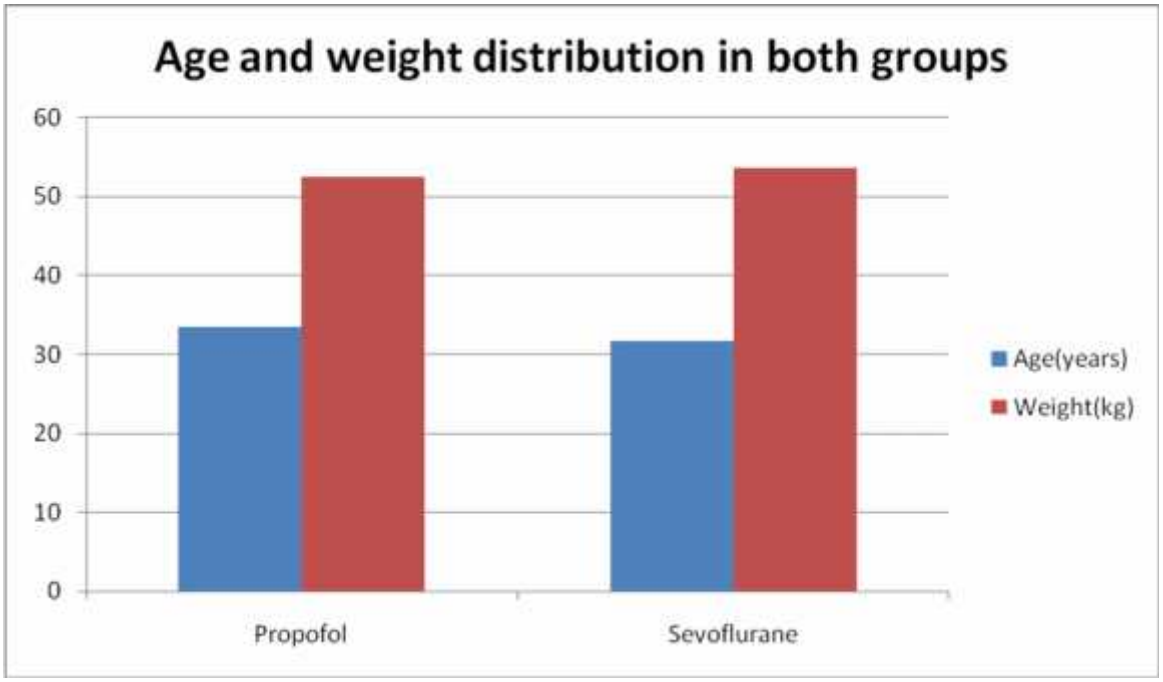
Condition (Total Score)	Excellent	Satisfactory	Poor	P value
Group P n =50	43	07	0	0.786*
Group S n =50	42	08	0	

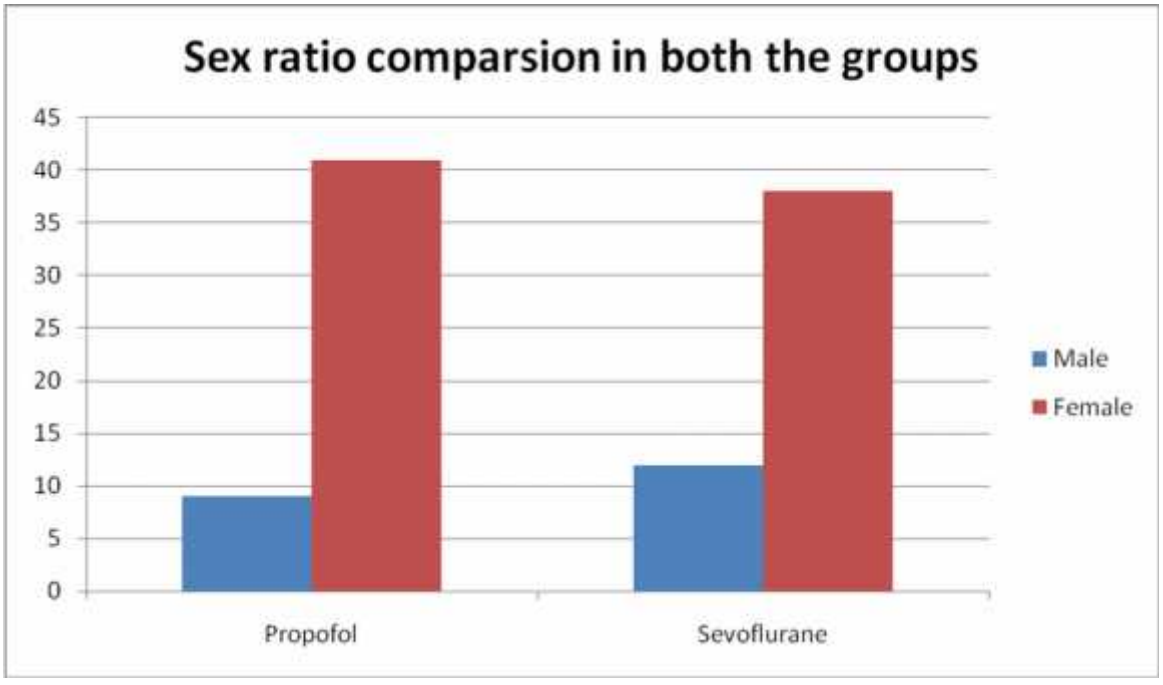
Group P: PROPOFOL Group S: SEVOFLURANE

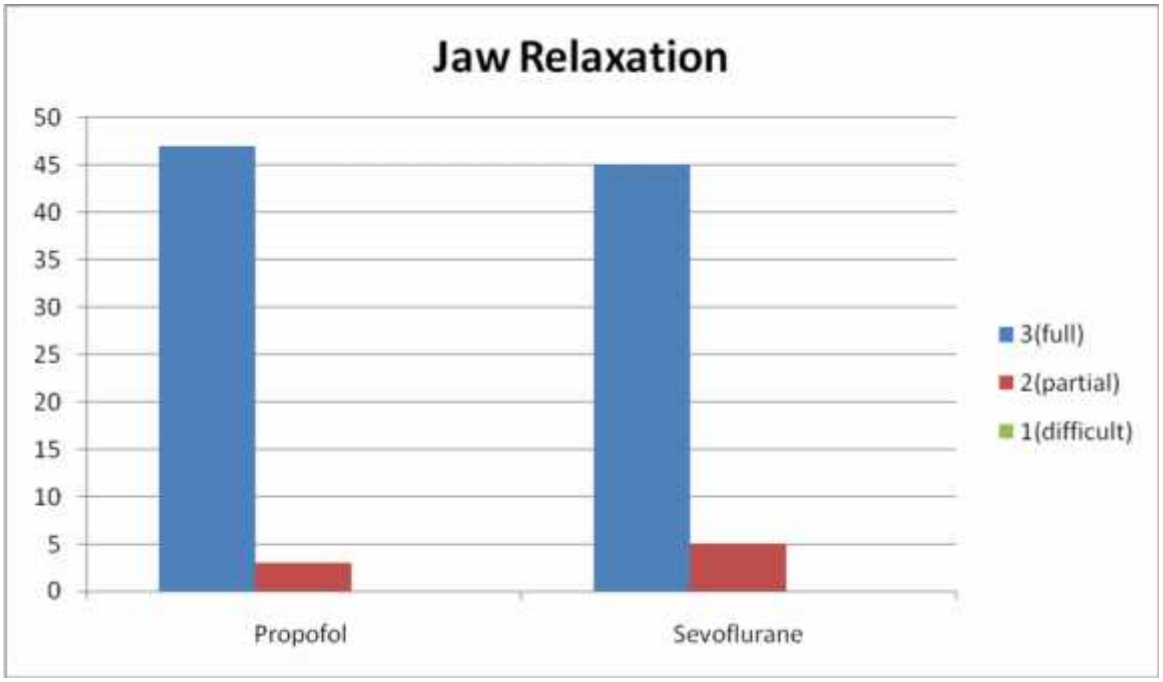
*Chi square test with Yates correction.

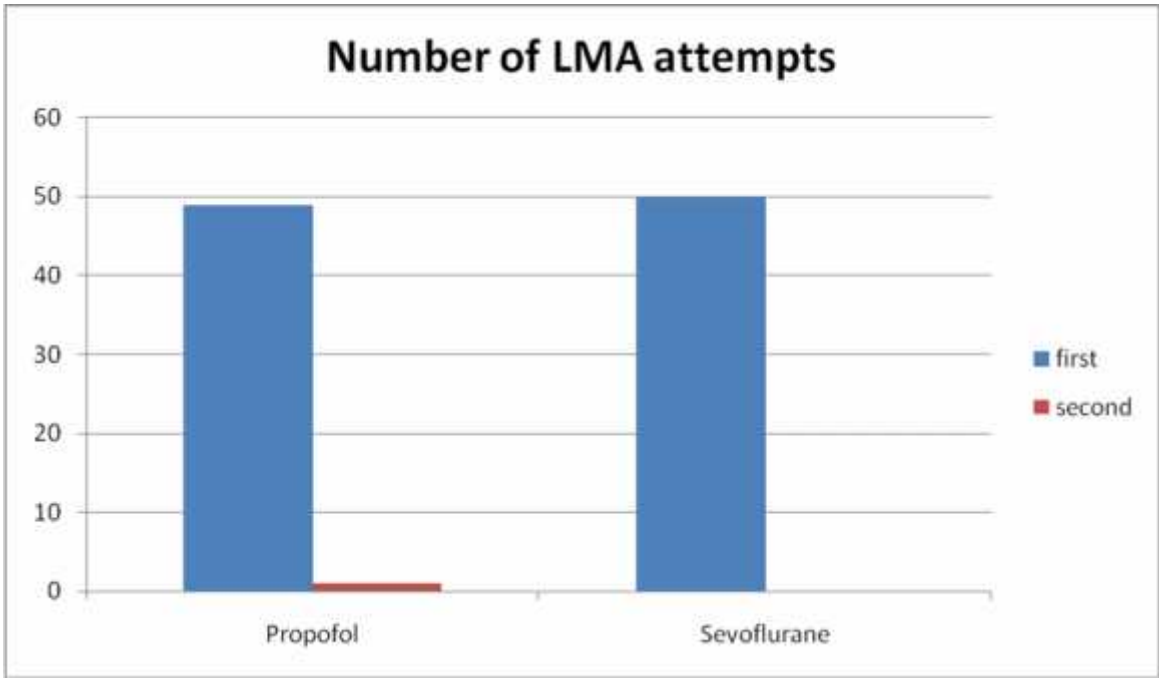
The table shows the overall conditions for LMA insertion.

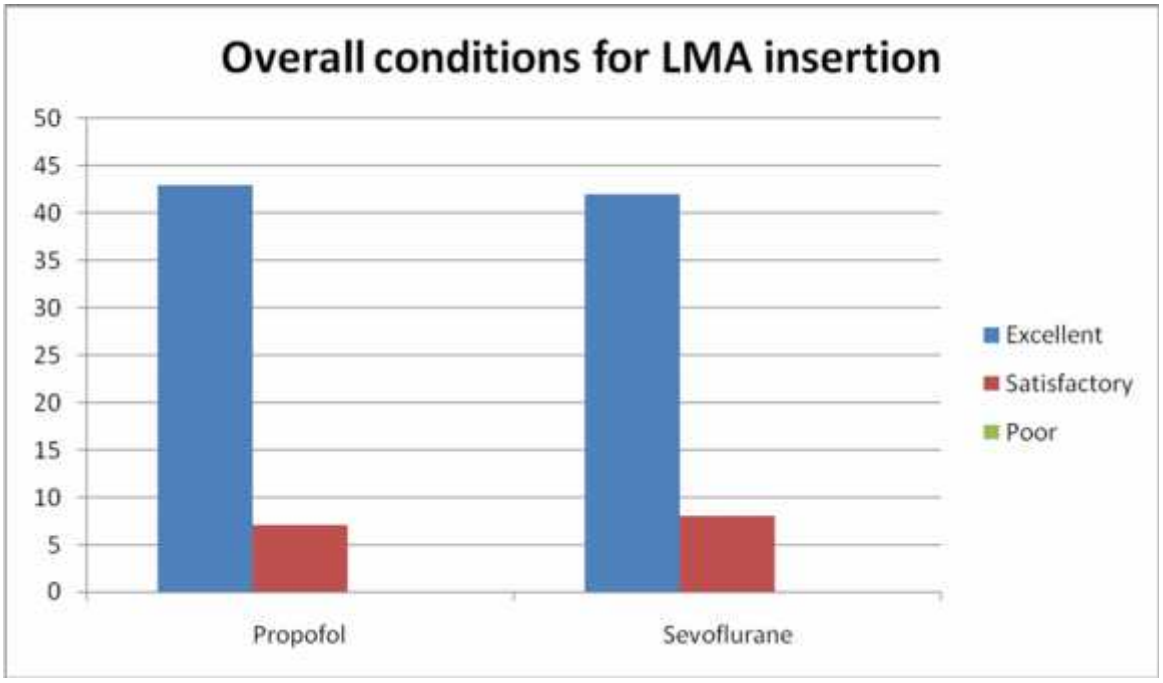
The conditions were excellent in 43 patients in group P and 42 patients in group S. Satisfactory conditions were seen in 7 patients in group P and 8 patients in group S. None of the patients in both groups had poor conditions for insertion. Chi square test was performed with Yates correction to find difference between the groups. The p value was 0.786 and was not statistically significant.


Age and weight distribution in both groups
60
50
40
30
20
10
0
Propofol
Sevoflurane
Age(years)
Weight(kg)


Sex ratio comparsion in both the groups
45
40
35
30
25
20
15
10
5
0
Propofol
Sevoflurane
Male
Female


Jaw Relaxation
50
45
40
35
30
25
20
15
10
5
0
Propofol
Sevoflurane
3(full)
2(partial)
1(difficult)


Number of LMA attempts
60
50
40
30
20
10
0
Propofol
Sevoflurane
first
second


Overall conditions for LMA insertion
50
45
40
35
30
25
20
15
10
5
0
Propofol
Sevoflurane
Excellent
Satisfactory
Poor

DISCUSSION

Insertion of the laryngeal mask airway (LMA) under deep inhaled anaesthesia alone is not commonly performed in adult patients. A popular method of providing anaesthesia for LMA insertion is with the use of i.v. propofol, which has the advantages of inducing anaesthesia rapidly and depressing upper airway reflexes. However, propofol is by no means ideal, as it has been associated with several adverse effects including hypotension, apnea, and pain on injection. Recently, vital capacity breath (VCB) inhaled induction of anaesthesia with sevoflurane has been used as an alternative to i.v. induction in adults. This method is rapid, with little excitatory phenomena, high patient acceptance, and good hemodynamic stability. Rapid insertion of the LMA after VCB induction may allow the use of sevoflurane as a single drug for the induction and maintenance of anaesthesia, which would ease the transition period and lead to cost-savings.

100 patients were included in our study (50 in each group). The patients in both the groups were comparable with respect to age, weight and gender distribution.

In this study we found that vital capacity breath induction with sevoflurane was convenient. We used Bain's circuit which was primed with sevoflurane 8% in N_2O 50% and 50% O_2 at 8litre/minute for 30 seconds by pressing the outlet against the pillow. Each patient was asked to exhale maximally and the face mask, connected to primed circuit was placed over mouth and nose. Patient was then advised to take vital capacity breaths.

The vital capacity has advantages over i.v induction of anaesthesia. The risk of anaphylaxis with i.v. agents, although small is avoided.

We graded the conditions for LMA insertion and found that 90% in sevoflurane group had full jaw relaxation as compared to 94% in propofol group.

In a related study, Muzi et al[28] reported jaw tightness after sevoflurane anaesthetic induction, which resulted in failure to insert the LMA in several patients. Similarly, Hall et al[29] reported longer time to jaw relaxation with sevoflurane compared with propofol, although they did not postulate any reasons for it.

The likely explanation for the poor mouth opening in our patients is the lag time during which the alveolar concentration of sevoflurane equilibrates with the brain, which results in inadequate anaesthesia during the initial attempt at insertion.

Furthermore, relaxation of the jaw muscles sufficient for a jaw thrust may be a reflection of adequate depth of anaesthesia. However, Inomata and Nishikawa et al[30] dispute the importance of this lag time. They argue that this is unlikely to be important with sevoflurane because of its low blood gas partition coefficient.

Another possible explanation for the difference in jaw relaxation between propofol and sevoflurane may be that the propofol group received more anaesthetic, as equipotent doses of both drugs could not be determined. A third possibility is related to the anaesthetics themselves. Propofol is known to have a relaxant effect on jaw muscles, whereas inhaled anaesthetics may cause increased muscle tone and spasticity. Therefore, for a similar depth of anaesthesia, there may be greater jaw relaxation with propofol.

Other conditions like ease of insertion, coughing, gagging, laryngospasm and patient movements were similar in either group.

This is probably due to excellent attenuation of laryngeal reflexes with both sevoflurane and propofol.

This resulted in less traumatic LMA insertions in our patients. Although LMA placement is more closely associated with deglutition and may only require suppression of the less sensitive hypo pharynx for successful placement, stimulation of the anterior laryngeal structures may occur during insertion. Therefore, successful attenuation of the laryngeal reflexes was essential to reduce the incidence of respiratory complications during LMA insertions. This is not surprising for propofol, as it is known to depress laryngeal reflexes and facilitate LMA insertion. However, sevoflurane preserves laryngeal reflexes at values up to 1.8 MAC. Its effect on laryngeal reflexes above this value is unknown, but this study suggests that sevoflurane may depress laryngeal reflexes at the higher MAC values achieved in our patients.

One patient in propofol group required a second attempt for insertion of LMA whereas none of the patients in sevoflurane group required second attempt, which was not significant.

Overall conditions for LMA insertion were excellent in 86% of patients in propofol group comparable to 84% in sevoflurane group which was statistically insignificant.

In conclusion, we found that using the high inspired concentration vital capacity breath inhalational induction, sevoflurane is comparable to propofol for induction and insertion of LMA in adults.

CONCLUSION

- Using the high inspired concentration (8%) vital capacity breath inhalational induction, sevoflurane is comparable to 2.5mg/kg of i.v. propofol for induction and insertion of LMA in adults.

- Jaw relaxation and ease of insertion, patient movements and number of attempts for LMA insertion were comparable in both the groups.

- Overall conditions for LMA insertion were comparable in both the groups.

SUMMARY

The present study titled "A Randomized clinical trial to compare the conditions for Laryngeal Mask Airway insertion following induction with Sevoflurane and Propofol in adults." was conducted in KLES Prabhakar Kore Hospital and MRC & Jawaharlal Nehru Medical College Charitable Hospital between December 2007 to December 2008.

The study included 100 ASA grade I and II patients aged between 20-65 years undergoing short general anaesthesia procedures where LMA was indicated in procedures lasting 30-60 minutes.

Group P: Propofol

Group S: Sevoflurane

All patients were premedicated with Glycopyrrolate 0.005mg/kg i.v. and Fentanyl 2mcg/kg i.v in both the groups and preoxygenated with 100% O_2 at 8L/min using Bain's circuit (Mapelson-D) with a 2Litre reservoir bag for 3 minutes. In group P, patients were induced with 2.5mg/kg Propofol i.v. over 30 seconds. 2 ml of 1%Lignocaine was mixed with each 20ml of Propofol to reduce the pain on injection. In group S the Bain's circuit reservoir bag was emptied, adjustable pressure limiting valve closed and the patient end of system sealed by pressing the outlet firmly against the pillow. The circuit was primed with sevoflurane 8%, in N_2O 50%& O_2 50% at 8Litre/minute for 30 seconds. Each patient was asked to exhale maximally and the facemask, connected to primed circuit was placed over mouth and nose. Patient was then advised to take vital capacity breaths.

Loss of eyelash reflex is considered for induction of anaesthesia in both the groups.

The following data were recorded:

- The ease of insertion and jaw relaxation.
- The response of the patient to LMA insertion including the presence or absence of gagging, coughing, patient movements and laryngospasm.

The grading of conditions for LMA insertion was done and the number of attempts for LMA insertion was noted.

Our study revealed that sevoflurane is equally comparable to i.v. propofol for insertion of LMA in adults undergoing short general anaesthesia procedures using the vital capacity inhalation technique.

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ANNEXURE - I : INFORMED CONSENT

YOUR PARTICIPATION

You Mr/Mrs/Ms. _____I.P. No. _____ are being asked to be a participant in the research study titled "**A Randomized clinical trial to compare the conditions for Laryngeal Mask Airway insertion following induction with Sevoflurane and Propofol in adults."**

onducted by **Dr. Vijay Gunturi** Postgraduate Student, Department of Anaesthesiology, Jawaharlal Nehru Medical College, Belgaum. You are eligible after looking into inclusion criteria. You read this form and ask any questions you may have before agreeing to participate.

RESEARCH BEING DONE

To compare conditions for LMA insertion following induction with propofol and sevoflurane.

Purpose of the research

To compare ease of insertion, patient response and number of attempts taken for LMA insertion following induction with propofol and sevoflurane.

Procedures involved

You will be randomly allocated either into propofol group or sevoflurane group, if you are in propofol group then you will be given IV propofol 2.5 mg/kg for induction and if you are in sevoflurane group then you will be induced with sevoflurane 8% through an inhalation route.

Ease of insertion, patient response and number of attempts taken for LMA insertion will be observed during insertion of LMA.

Potential risks and discomforts:

- No serious side effects.

Benefits of taking part in this research:

- Smooth induction.
- Prevention of hypotension, apnea and pain on injection.

Decline from participation

You have the option to decline from participation in the study without any discrimination and you will be treated as per the existing protocol for your condition.

New information

All information collected during the study from participant will be told as and when required.

Privacy and confidentiality

Privacy of individual will be respected and any information about you or provided by you during the study will be kept strictly confidential.

Injury as a result of participation

There will neither be any compensation to or for the patient and his or her relatives nor there any monetary benefits for the damage incurred.

Costs of participation in this research

Participation is free of cost.

Reimbursement for any expenses for participation in research

No reimbursement for any of your expenditures

Withdrawal or be removed

To start with as the participation was voluntary so is the decision to withdraw. Such a step will not alter the participant's management by any staff in hospital. Researcher can remove you from the study if circumstances arise.

Whom to contact

For any information about the study during the study or after that may be collected from:

- DR. V. D. PATIL. Principal, Jawaharlal Nehru Medical College, Belgaum.
- DR. RAJESH MANE Associate Professor,

  Department of Anaesthesiology, Jawaharlal Nehru Medical College, Belgaum.
- Dr. VIJAY GUNTURI. Postgraduate student in Anaesthesiology,

  Jawaharlal Nehru Medical College, Belgaum. Ph. No. 9964518218

Signature of the participant or legally authorized person:

Participant's name

Signature:

Witness name

Signature:

Date:

Place:

ANNEXURE – II : PROFORMA

Title: "**A Randomized clinical trial to compare the conditions for Laryngeal Mask Airway insertion following induction with Sevoflurane and Propofol in adults."**

Patients Name : I.P. No.:

Age : Weight: Sex:

Occupation : Date of operation:

Address :

Anaesthesiologist:

PRE-ANAESTHETIC EVALUATION:

Chief Complaints:

Past History:

a) Hypertension/Diabetes mellitus/Asthma/Epilepsy/Drug allergy.

b) Drug therapy.

c) Previous exposure to anaesthesia.

Family History:

General Physical Examination

Pallor / Icterus / Clubbing / Lymphadenopathy / Odema

Pulse: Blood pressure:

Resipiratory rate:

Musculoskeletal System Examination:

Jaw movements: Teeth:

Airway assessment: Spine:

Systemic Examination:

a. Respiratory system b. Central nervous system

c. Cardiovascular system d. Gastrointestinal system

Investigations:

Haemoglobin%

Urine routine

Any others

Pre operative physical status: ASA grade I II

Inclusion criteria

1. Patients undergoing short general anaesthesia procedures.

2. ASA I or ASA II aged 20- 65 years.

Exclusion criteria

1. ASA III/IV.

2. Difficult airway :Mallampati grade III/IV.

3. History suggestive of gastro intestinal reflux.

4. History suggestive of cardio vascular disease, hypertension .

5. History suggestive of renal disease.

6. Pregnancy.

7. Patients receiving anti-epileptic medication.

8. Known allergies to any anaesthetic agent.

Diagnosis

Proposed surgery:

Patients will be allocated by computer generated randomization into group A and group B. On the day of surgery, Intravenous line secured with 18g branula for males, 20g branula for females in a peripheral vein.

Preoperative baseline

Heart rate

Blood pressure

Monitors attached:

Pulse oximeter	Non invasive blood pressure
ECG	$ETCo_2$

Group P and group S patients will be premedicated with I.V Glycopyrrolate 0.005mg/kg and Fentanyl 2 $\mu g.kg^{-1}$ i.v. will be given.

Induction of Anaesthesia will be with IV propofol 2.5 $mg.kg^{-1}$ in group P and sevoflurane 8% in group S through inhalational route.

After loss of eye lash reflex LMA will be inserted and the following will be observed during insertion.

1. Ease of insertion.
2. Jaw relaxation
3. Patient response.

and number of attempts for insertion of LMA.

Grading of conditions for Laryngeal Mask Airway insertion were noted			
Introduction of the LMA	3	2	1
Jaw opening	Full	Partial	Nil
Ease of insertion	Easy	Difficult	Impossible
Patient response	3	2	1
Coughing	Nil	Minor	Severe
Gagging	Nil	Minor	Severe
Laryngospasm	Nil	Partial	Total
Patient movements	Nil	Moderate	Vigorous
Total score			
18	Excellent		
16-17	Satisfactory		
<16	Poor		

Number of attempts for LMA insertion:

Signature of the Staff in charge:

PROPOFOL GROUP

SL no	IP no	AGE / SEX	WEIGHT (kg)	GRADING OF CONDITIONS FOR LMA INSERTION						OVERALL CONDITIONS FOR LMA INSERTION	NO: OF ATTEMPTS FOR LMA INSERTION
				Introduction of LMA		Patient Responses					
				Jaw opening	Ease of insertion	Coughing	Gagging	Laryngospasm	Patient movements		
1	259833	44/M	65	3	3	3	3	3	3	18	1
2	261231	25/M	40	2	3	3	3	3	3	17	1
3	262373	45/M	60	3	3	3	3	3	3	18	1
4	262031	45/F	52	3	3	3	3	3	3	18	1
5	262641	30/F	48	3	3	3	3	3	3	18	1
6	263129	45/F	48	3	3	3	3	3	3	18	1
7	262610	60/M	72	3	3	3	3	3	3	18	1
8	262690	60/M	64	3	2	3	3	3	3	17	1
9	262950	35/F	54	3	3	3	3	3	3	18	1
10	265857	30/M	60	3	3	3	3	3	3	18	1
11	269270	35/F	48	2	3	3	3	3	3	17	1
12	269160	58/F	39	3	3	3	3	3	3	18	1
13	270359	25/F	52	3	3	3	3	3	3	18	1
14	269168	55/F	48	3	3	3	3	3	3	18	1
15	270654	45/F	50	3	3	3	3	3	3	18	1
16	272412	22/F	49	3	3	3	3	3	3	18	1
17	272410	28/F	48	3	3	3	3	3	3	18	1
18	272446	27/F	52	3	3	3	3	3	3	18	1
19	274157	24/F	46	3	3	3	3	3	3	18	1
20	274975	28/F	54	3	3	3	3	3	3	18	1
21	274808	29/F	59	3	3	3	3	3	2	17	2
22	275343	34/F	54	3	3	3	3	3	3	18	1
23	275953	25/F	52	3	3	3	3	3	3	18	1
24	275278	22/F	48	3	3	3	3	3	3	18	1
25	275952	24/F	57	3	3	3	3	3	3	18	1

PROPOFOL GROUP

SL No	IP no	AGE / SEX	WEIGHT (kg)	GRADING OF CONDITIONS FOR LMA INSERTION						OVERALL CONDITIONS FOR LMA INSERTION	NO: OF ATTEMPTS FOR LMA INSERTION
				Introduction of LMA		Patient Responses					
				Jaw opening	Ease of insertion	Coughing	Gagging	Laryngospasm	Patient movements		
26	277708	24/F	40	3	3	3	3	3	3	18	1
27	277702	29/F	47	2	3	3	3	3	2	16	1
28	277710	30/F	64	3	3	3	3	3	3	18	1
29	277704	25/F	37	3	3	3	3	3	3	18	1
30	280521	32/F	48	3	3	3	3	3	3	18	1
31	280523	24/F	54	3	3	3	3	3	3	18	1
32	286450	24/F	49	3	3	3	3	3	3	18	1
33	286620	22/F	54	3	3	3	3	3	3	18	1
34	287164	27/F	54	3	3	3	3	3	3	18	1
35	287544	22/F	52	3	3	3	3	3	3	18	1
36	296062	58/F	52	3	3	3	3	3	3	18	1
37	296340	22/F	51	3	3	3	3	3	3	18	1
38	297379	25/F	55	3	3	3	3	3	3	18	1
39	297371	25/F	52	3	3	3	3	3	3	18	1
40	297450	40/F	48	3	3	3	3	3	3	18	1
41	298307	27/F	54	3	2	3	3	3	3	17	1
42	298695	46/M	60	3	3	3	3	3	2	17	1
43	297855	38/M	60	3	3	3	3	3	3	18	1
44	297806	45/F	54	3	3	3	3	3	3	18	1
45	297087	27/F	52	3	3	3	3	3	3	18	1
46	298542	51/M	66	3	3	3	3	3	3	18	1
47	299940	38/F	56	3	3	3	3	3	3	18	1
48	299942	25/F	48	3	3	3	3	3	3	18	1
49	300063	22/F	48	3	3	3	3	3	3	18	1
50	300286	28/F	54	3	3	3	3	3	3	18	1

SEVOFLURANE GROUP

SL no	IP no	AGE/SEX	WEIGHT (kg)	GRADING OF CONDITIONS FOR LMA INSERTION						OVERALL CONDITIONS FOR LMA INSERTION	NO: OF ATTEMPTS FOR LMA INSERTION
				Introduction of LMA		Patient Responses					
				Jaw opening	Ease of insertion	Coughing	Gagging	Laryngospasm	Patient movements		
1	242087	30/F	48	3	3	3	3	3	3	18	1
2	251062	25/F	42	2	2	3	3	3	3	16	1
3	260838	59/M	48	3	3	3	3	3	3	18	1
4	260593	33/M	50	3	3	3	3	3	3	18	1
5	261376	24/M	65	2	2	3	3	3	3	16	1
6	259055	50/M	52	3	3	3	3	3	3	18	1
7	262678	45/M	62	3	3	3	3	3	3	18	1
8	251815	49/M	64	3	3	3	3	3	3	18	1
9	261494	30/F	48	3	3	3	3	3	3	18	1
10	262663	55/M	70	3	3	3	3	3	3	18	1
11	265799	28/F	49	3	3	3	3	3	3	18	1
12	265800	25/F	60	3	3	3	3	3	3	18	1
13	265802	30/F	52	3	3	3	3	3	3	18	1
14	269109	50/M	60	3	3	3	3	3	3	18	1
15	269281	28/F	43	3	3	3	3	3	3	18	1
16	269560	25/M	60	3	3	3	3	3	3	18	1
17	269958	34/F	56	3	3	3	3	3	3	18	1
18	270716	27/F	42	3	3	3	3	3	3	18	1
19	267602	22/F	46	3	3	3	3	3	3	18	1
20	275202	25/F	49	3	3	3	3	3	3	18	1
21	275339	22/M	60	3	3	3	3	3	3	18	1
22	275443	23/F	56	3	3	3	3	3	3	18	1
23	275950	25/F	55	3	3	3	3	3	3	18	1
24	275949	25/F	57	3	3	3	3	3	3	18	1
25	275948	25/F	49	3	3	3	3	3	3	18	1

SEVOFLURANE GROUP

SL no	IP no	AGE/SEX	WEIGHT (kg)	GRADING OF CONDITIONS FOR LMA INSERTION						OVERALL CONDITIONS FOR LMA INSERTION	NO: OF ATTEMPTS FOR LMA INSERTION
				Introduction of LMA		Patient Responses					
				Jaw opening	Ease of insertion	Coughing	Gagging	Laryngospasm	Patient movements		
26	277301	33/F	42	3	3	3	3	3	3	18	1
27	277703	26/F	42	3	3	3	3	3	3	18	1
28	280524	22/F	56	2	3	3	3	3	3	17	1
29	280522	23/F	49	2	3	3	3	3	3	17	1
30	287547	22/F	56	3	3	3	3	3	3	18	1
31	287434	33/F	48	2	3	3	3	3	2	16	1
32	287435	30/F	57	3	3	3	3	3	3	17	1
33	287548	27/F	57	3	3	3	3	3	3	18	1
34	287630	30/F	53	3	3	3	3	3	3	18	1
35	287607	54/F	58	3	3	3	3	3	3	18	1
36	296239	48/F	55	3	3	3	3	3	3	18	1
37	296688	28/F	49	3	3	3	3	3	3	18	1
38	296511	45/F	52	3	3	3	3	3	3	18	1
39	298675	50/M	66	3	3	3	3	3	2	17	1
40	297269	22/F	54	3	3	3	3	3	3	18	1
41	297074	23/F	48	3	3	3	3	3	3	18	1
42	297372	25/F	54	3	3	3	3	3	3	18	1
43	297370	25/F	48	3	3	3	3	3	3	18	1
44	297375	33/F	54	3	3	3	3	3	3	18	1
45	297542	24/F	52	3	3	3	3	3	2	17	1
46	297490	24/F	54	3	3	3	3	3	3	18	1
47	297645	22/M	56	3	3	3	3	3	3	18	1
48	296391	32/F	62	3	3	3	3	3	3	18	1
49	298691	47/F	55	3	3	3	3	3	3	18	1
50	299941	25/F	52	3	3	3	3	3	3	18	1