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ORIGINAL ARTICLE

A COMPARATIVE EVALUATION OF MIDAZOLAM -THIOPENTONE WITH PROPOFOL ON LARYNGEAL MASK AIRWAY INSERTION CONDITION

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ABSTRACT: BACKGROUND AND AIMS: Laryngeal mask airway (LMA), an alternative airway device, provides and maintains a seal around the laryngeal inlet for spontaneous ventilation as well as modest level of positive pressure ventilation. But LMA requires a sufficient depth of anaesthesia& depression of airway reflexes to avoid adverse reactions like gagging, coughing, head & limb movements etc. We intended to test the efficacy of Thiopentone and Midazolam combination as an effective alternative to Propofol for insertion of LMA. **MATERIALS AND METHODS:** One hundred twenty patients (18-34 years) posted for different minor procedure (<45 min) under general anaesthesia were divided into 2 equal groups (Group TM & P) in a randomized, double-blind fashion. In group TM (n=60) Thiopentone 5mg/kg+ Midazolam 0.05 mg/kg and group P (n=60) Propofol 2.5 mg/kg was administered prior to insertion of LMA. Then the inserting condition (jaw relaxation, gagging, coughing, hiccup, laryngospasm & head and limb movement) were evaluated into 3 point scale. The response will be graded as Mild (Transient and minimal), Moderate (Response lasted not >20 sec) and Severe (Sustained >20sec or needed Propofol to allow LMA insertion). **RESULTS:** Propofol is superior to combination of thiopentone-midazolam, in terms of achieving conditions like jaw relaxation, coughing & suppression of gagging during LMA insertion but regarding other variables like laryngospasm, hiccup & patient movement, which are equally important prerequisites for successful LMA insertion, there was not much statistically significant difference found between propofol and combination of thiopentone-midazolam. **CONCLUSION:** Combination of thiopentone - midazolam effectively blunts airway reflexes and adequately facilitates laryngeal mask airway insertion which can be comparable to propofol.

KEYWORDS: Laryngeal Mask Airway (LMA), Thiopentone, Midazolam, Propofol.

INTRODUCTION: The prime responsibility of an anesthesiologist is proper maintenance of a patent airway during surgical procedures. Since the earliest days of anaesthesia, every endeavor has been made of dispelling the potential problems associated with airway management.

After significant development of endotracheal intubation in anaesthetic practice, the deleterious effect on hemodynamic response, due to sympathetic stimulation by laryngoscopy and intubation leading to sudden unexpected high accentuation of blood pressure & heart rate, compelled researchers to venture into alternative measures of airway management which were safe, effective and easier than bag mask ventilation & also induced more subtle hemodynamic response, which, of course are desirable in all clinical situations.

It was in the year 1981, A.I.G. Brain designed the prototype of modern laryngeal mask airway (LMA).[1] It is an excellent device to maintain airway in selected surgeries. It not only provides a

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better airway with respect to ventilation and oxygenation than a conventional face mask and oro pharyngeal airway but also obviates the need for endotracheal intubation.

Achieving effective ventilation using face mask requires technical skill and adequate expertise. Two key elements of this technique are good seal between the mask and patients face and an unobstructed airway providing adequate ventilation. Maintenance of airway during anaesthesia using a face mask requires support of lower jaw, which occupies both the hands of the anesthesiologist thus causing hand fatigue.

Moreover, inadequate ventilation, pressure injury to the eyes, allergy to face mask material, abdominal distension from positive pressure ventilation, ending to potential chances of aspiration & difficult mask holding in obese patients are major drawbacks of this face mask technique. To avoid all these difficulties, LMA can prove to be an effective alternative device.

Laryngoscopy & intubation, on the other hand, may result in injury to the lips, teeth, gums & soft tissue of the pharynx and laryngeal inlet as well as may lead to post-extubation sore throat. LMA insertion on the contrary does not require laryngoscopy & is devoid of such complications. Moreover, in difficult intubation cases, LMA may be life saving for the patients. In year 1996, LMA was incorporated in ASA difficult airway algorithm.[2]

Other advantages of LMA, like smoother transition from anaesthesia to emergence with LMA in situ & requirement of lesser skill for insertion, has made LMA even more popular among anesthesiologists.

Insertion of this supraglottic device to provide & maintain a seal around the laryngeal inlet for spontaneous ventilation as well for positive pressure ventilation, requires sufficient depth of anaesthesia& depression of airway reflexes to avoid adverse reactions like gagging, coughing, head & limb movements etc. Considering the advantages of LMA over face mask & endotracheal intubation, the study had been taken up with an idea of comparing the condition for LMA insertion, by two most widely used intravenous inducing agents.

Propofol (2.5 mg/kg) remains the induction agent of choice for insertion of LMA as it attenuates airway reflexes more than any other inducing agent & it has also shorter elimination half-life.[3,5] But on the other hand, it induces greater degree of hypotension & bradycardia which is not desirable in many clinical conditions.

Thiopentone, on the contrary, may not depress airway reflex adequately, as much as propofol, resulting in gagging, coughing, head & limb movement and laryngospasm, which are undesirable for LMA insertion but does not produce significant bradycardia or hypotension.**[3-5]**

To overcome these difficulties associated with thiopentone, a number of co-induction agents are introduced with thiopentone, as potential combination of agents for LMA insertion as suitable alternatives to propofol. Midazolam, particularly, when used as an adjuvant to thiopentone may decrease the incidence of adverse response to LMA insertion.[6]It is also comparatively less expensive than propofol and has been shown to have a synergistic action with thiopentone.

So, this study was conducted to compare clinically acceptable LMA inserting condition after induction with either propofol or thiopentone with midazolam.

MATERIALS AND METHODS: This single centre, prospective randomized, double blinded, parallel Group study was carried out in the Department of Anaesthesiology after obtaining permission from the Institutional Ethical Committee in the period between February 2008 and April 2010.

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After obtaining permission from ethics committee, written informed consent was taken. Total 120 adult patients were randomly allocated to two equal groups (n=60 in each group) using computer generated random number list.

ASA physical status I & II, aged between 18-34 years of both sexes undergoing different minor procedure (<45 min.) under general anaesthesia were enrolled in the study. Patients in Group P (n=60) received inj Propofol (2.5 mg/kg) & those in Group TM (n =60) received inj Midazolam (0.05mg/kg) followed by inj Thiopentone (5 mg/kg) after 3 minutes according to standard induction technique.

EXCLUSION CRITERIA: Patient refusal, any known hypersensitivity or contraindication to propofol, midazolam, thiopentone, pregnancy, lactating mothers, hepatic, renal or cardiopulmonary abnormality, hypertension, malignancy, alcoholism, diabetes, long term anxiolytic therapy. Patients having history of significant neurological, psychiatric or neuromuscular disorders were also excluded.

In preoperative assessment the patients were enquired about any history of drug allergy, previous operations or prolonged drug treatment. General examination, systemic examinations and assessment of the airway were done. Preoperative fasting of minimum 6 hours was ensured before operation.

All patients received premedication of tablet diazepam 10 mg orally the night before surgery as per preanesthetic checkup direction to allay anxiety, apprehension and for sound sleep. The patients also received tablet ranitidine 150 mg in the previous night and in the morning of operation with sips of water.

On the day of operation, the baseline hemodynamic parameters were measured again in the pre-operative room. According to the body weight of the patient calculated amount of drugs were prepared for administration in the OT. Hemodynamic parameters (HR, BP, and SpO2) were studied in pre-operative room.

After arrival of patients in the operation theatre, intravenous cannulation was done and all standard monitoring devices (ECG, NIBP, Pulse oximetry, Capnography& Temperature) was attached. In both the groups, inj fentanyl (1µg/kg) and inj glycopyrrolate (0.01mg/kg) were given as premedication prior to induction of anaesthesia. After pre oxygenation with 100 % oxygen for 3 min the patients received either of the two study drugs according to their allocated group.

Group P (n=60) received inj Propofol (2.5 mg/kg) & Group TM (n =60) received inj Midazolam (0.05mg/kg) followed by inj Thiopentone (5 mg/kg) after 3 minutes according to standard induction technique. Patients received 100% O_2 throughout the induction till insertion of LMA.

One min after induction of anaesthesia LMA were inserted (priory lubricated with methylcellulose jelly, according to the method described by Brain) by an experienced anaesthesiologist and the occurrence of the adverse reactions were noted, if any, by the same who was unaware of the groups of drugs used.

In our study, the time from loss of eyelash reflex till the completion of LMA insertion was taken as the time taken for LMA insertion. The overall ease of insertion was assessed as excellent, satisfactory or poor on a 3 point scale where:

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- Excellent (E)=> means no adverse reaction.
- Satisfactory (S) =>means mild response, not affecting the ease of insertion.
- Poor (P) =>means moderate or severe response to LMA insertion.
- The response were graded as Mild (Transient and minimal), Moderate (Response lasted not >20 sec) and Severe (Sustained >20sec or needed Propofol to allow LMA insertion).

After insertion of LMA, anaesthesia was maintained with 66% N_2O in O_2 with isoflurane. The study ended when the patient will reach adequate depth of inhalation anaesthesia.

STATISTICAL ANALYSIS OF DATA: All the data were entered into Excel Spreadsheet and analyzed using statistical software 'SPSS and Statistica.' All variables were numeric and were taken as normally distributed. Comparison between groups: the test of statistical significance applied was Student's unpaired t test. Within group comparison: The test of statistical significance applied was- repeated Measures ANOVA followed by Tukey's test for two time point comparisons if ANOVA returns p value < 0.05.Categorically variables were compared between - groups by Chi Square test. A two tailed p value less than 0.05 was considered as significant and less than 0.01 as significant and less than 0.001 as highly significant.

RESULTS AND ANALYSIS: We recruited 60 subjects per group, more than the calculated sample size. There were no dropouts or any medical complications during our study.

The age, sex distribution, body weight, height, ASA status and duration of surgery in the two groups were found to be comparable [Table-1]. There was statistically significant difference in time taken during LMA insertion as well as fixation for ventilating conditions between the groups (2-tailed unpaired t-test) [Table-2]. [Table-3] showed that there was no statistically significant difference in requirement of bolus dose of propofol between the groups ($p>0.05$).

From [Table-4] it was observed that, there were significant number of patients showing excellent jaw relaxation condition in P group ($p<0.05$) than in TM group. From [Table-4] we found that no statistically significant difference in respect to excellent & satisfactory condition achieved regarding gagging between the groups ($p>0.05$) during LMA insertion but coughing resulted in poor LMA placement condition in TM group which was statistically more significant when compared with group P. [Table-4] showed that no statistically significant difference was observed in respect to excellent, satisfactory & poor grades achieved attributed to hiccup, laryngospasm and body movement during LMA insertion between the groups ($p> 0.05$).

DISCUSSION: Since the Laryngeal mask airway (LMA) was developed by Dr. Archie Brain in 1981, it has gradually gained widespread acceptance among the anaesthesiologists worldwide for management of airway during general anaesthesia. It was even incorporated in the ASA difficult airway algorithm in 1996.[2]

The LMA is inserted under finger guidance into the hypopharynx which requires sufficient depth of anaesthesia and depression of airway reflexes. Propofol is better suited for this purpose, as it has more depressant effect on airway reflexes in contrast to thiopentone which is associated with greater incidence of undesired response whether used alone or in combination with an opioid.

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When used alone, propofol also does not provide ideal conditions for LMA insertion, as it may cause coughing, gagging and patient movement.

Different drugs including intravenous lignocaine, midazolam, and alfentanil and alfentanil-midazolam combination have therefore been used along with propofol in order to get ideal conditions for LMA insertion.

In our study, we have compared the condition for LMA insertion and the incidence of undesired responses produced by propofol with thiopentone sodium & midazolam after supplementing both with glycopyrrolate and fentanyl because of established safety and cost effectiveness of the combinations.

In our study the two groups were identical in respect to age, sex, height, ASA status, surgical time and body weight. There was no significant statistical difference between the two groups [Table 1] and therefore demographic profile for LMA insertion was same in both the groups ($p>0.05$).

Blake et al.[4] in 1992, compared dosage of propofol ranging from 1.5 mg/kg to 2.5 mg/kg for assessing conditions for successful LMA insertion and concluded that, whereas 1.5 mg/kg propofol was associated with more number of failed insertions, 2 mg/kg as well as 2.5 mg/kg of propofol was associated with similar rate of success in regards to successful LMA insertion. So in our study the induction bolus of propofol was kept at 2.5 mg/kg.

Drage MP et al.[7] in their study in 1996 showed that jaw thrust was a reliable and better method to assess the adequacy of the depth of anaesthesia for uncomplicated insertion of LMA. In our study also appropriate time for attempting LMA insertion was guided by the loss of response to jaw thrust.

In a study by Koh KF et al.[8] in 1999 comparisons between propofol + fentanyl, thiopentone + fentanyl and thiopentone + fentanyl + atracurium was done in respect to the conditions for LMA insertion produced. In that study thiopentone + fentanyl group showed worst conditions for LMA insertion whereas thiopentone + fentanyl + atracurium group and propofol + fentanyl group had similar conditions for LMA insertion. In our study fentanyl was used in both the groups but no muscle relaxant was used in any group to eliminate the bias in results obtained.

In our study, the time from loss of eye lash reflex till the completion of LMA insertion was taken as the time taken for LMA insertion. It was remarkably less in the group propofol induction (84.69±3.23secs) as compared to the group thiopentone-midazolam induction (96.33±4.61secs) (Table 4, Fig 17). Although this was found to be statistically significant (p value <0.05). Kati I et al.[9] in 2003, when comparing conditions for LMA insertion between propofol and sevoflurane, reported a similar time(50 ± 10 sees) required for LMA insertion with propofol and that, it was far lesser than time required for insertion of LMA with sevoflurane (120 ± 30 secs).

Talwar V et al.[10] in 2004, however reported much longer time for insertion of LMA with propofol (4.31± 0.27 minutes) but yet then it was significantly lesser than that with thiopentone sodium (4.62 ± 0.64 minutes). In their study, they did not mention starting and end points of recording their time for LMA insertion.

Our study shows that, whereas, the number of patients exhibiting excellent jaw relaxation during LMA insertion were more in propofol group than in thiopentone-midazolam group, but more incidence of satisfactory jaw relaxation were found in thiopentone-midazolam group than patients in propofol group [Table 4].

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Though this finding was statistically significant, as ($p<0.05$), as long as achievement of excellent & satisfactory jaw relaxation condition for LMA insertion is considered, but number of satisfactory jaw relaxation are more in thiopentone-midazolam group than propofol group because, less number of patients in the propofol group were left in satisfactory jaw relaxation group for LMA insertion (as 47 out of 60 patients already developed excellent jaw relaxation in propofol group) and it was of statistical significance($p<0.05$).

Our finding has resemblance with the findings in the study of Talwar et al. in 2004.[10] However Driver et al.[11] in their study they found better mouth opening even on reduction of propofol dose from 2.5 mg/kg to 1.25 mg/kg when combined with midazolam and alfentanil which was statistically very highly significant (p value < 0.001).These statistical differences may be attributed to the better suppression of upper airway reflexes by propofol-alfentanil combination used in their study as compared to propofol-fentanyl combination used in our study.

In our study, there was no statistically significant difference in undesired responses shown by patients in both the groups as ($p>0.05$) [Table 3] but the severity of responses as was measured by requirement of additional bolus dose of propofol, found to be greater in thiopentone-midazolam group. In our study, incremental boluses of propofol were required in 13.33% patients in thiopentone-midazolam group compared to only 8.33% patients in propofol group. Identical observation has been reported by Driver et al in their study in 1997.[12]

In their study however none of the patients required incremental boluses in propofol group. It may be attributed to the fact that, unlike in our study, they used alfentanil with the induction agents which causes much better suppression of airway reflexes than fentanyl.

In their study none of the patients required succinylcholine but in our study, 8 patients (13.33%) in thiopentone-midazolam group required rescue bolus dose of propofol to settle them, whereas, 5 (8.33%) of the patients in propofol group required additional bolus of propofol. But requirement of additional bolus dose, patient movements were significantly low in propofol group which was similar to the study of Talwar et al.[10]

In our study, though number of patients exhibiting gagging were more in thiopentone-midazolam group than in propofol group [Table 4] and statistically significant difference ($p<0.05$) were observed between propofol group and thiopentone& midazolam group in terms of excellent & satisfactory LMA inserting condition but statistically less number of patients ($p<0.05$) in propofol group develop poor LMA inserting attributed to gagging.

Similar observations were made by Scanlon P et al.[5] Talwar et al.[10] and Brown GW et al.[13] as they found statistically significant differences in incidence of gagging, which they reported, was higher with thiopentone than with propofol.

In our study, though number of patients exhibiting coughing were more in thiopentone-midazolam group than in propofol group [Table 4] and statistically significant difference ($p>0.05$) was observed between the two groups in terms of excellent, satisfactory and poor LMA inserting condition, attributed to coughing. Similar observations were made by Scanlon et al.[5] Talwar et al.,[10] and Brown et al.[13]

Incidence of hiccup during LMA insertion, in our study, was found to be higher with thiopentone-midazolam than with propofol [Table 4], though not statistically significant ($p>0.05$) in respect to excellent & satisfactory LMA inserting condition, but none of the patients in propofol group developed poor condition, attributed to hiccup, during LMA insertion, whereas only one patient in

thiopentone-midazolam group developed poor inserting condition due to hiccup, which was statistically not significant.

Occurrence of excellent, satisfactory or poor LMA inserting condition, attributed to laryngospasm, in our study, was found to be higher with thiopentone-midazolam than with propofol [Table 4], though not statistically significant (p>0.05). This finding is supported by Talwar V et al.[10]

Number of patients exhibiting moderate movements of head & limb during LMA insertion was found to be higher in thiopentone-midazolam group as compared to propofol group in our study [Table-4]. This finding was similar to that of Scanlon et al.[5] and Nishiyama et al.[14] and but in our study, this observation was not statistically significant (p> 0.05).

CONCLUSION: To summarize, propofol is found to be a superior agent in terms of achieving conditions like jaw relaxation, gagging and coughing during LMA insertion than combination of thiopentone-midazolam, but regarding other variables like laryngospasm, hiccup & patient movement, which are equally important prerequisites for successful LMA insertion, there was not much of statistically significant difference found between propofol and combination of thiopentone-midazolam.

Therefore it can be concluded that, combination of thiopentone-midazolam effectively blunts airway reflexes and adequately facilitates laryngeal mask airway insertion which can be comparable to propofol.

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Parameter	Group P (n=60) Propofol	Group TM (n=60) Thiopentone+ Midazolam	p value
Age (years)	33.20±12.19	30.93±11.66	0.46
Bodyweight (Kg)	60.77±9.36	61.23±6.32	0.82
Sex (Male/Female)	34:26	28:32	0.792
Height (cm)	165.48±6.95	166.32±7.15	0.76
ASA physical status (I/II)	46:14	44:16	0.31
Surgery time (min)	36.4±5.2	37.8±4.3	0.430

Table 1: Comparison of demographic data between the two study groups

Parameters	Group P(n=60)	Group TM (n=60)	P value
Time taken to place LMA	84.69±3.23	96.35±6.27	0.036
Time taken to fix & start ventilation by LMA	92.33±4.61	105.56±5.96	0.032

Table 2: Time taken for LMA insertion

Bolus Propofol dose	Group P(n=60)	Group TM (n=60)	P value
Required	5(8.33%)	8(13.33%)	--
Not required	55(91.66%)	52(86.66%)	0.254

Table 3: Additional bolus doses of Propofol needed during LMA insertion

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Incidences during LMA insertion	Group	Excellent (E)	Satisfactory (S)	Poor (P)	P value
Jaw Relaxation	TM	40	16	4	0.009
	P	47	8	5	
Gagging	TM	37	18	5	0.056
	P	45	12	3	
Coughing	TM	53	1	6	0.005
	P	54	4	2	
Hiccup	TM	43	16	1	0.829
	P	45	14	1	
Laryngospasm	TM	43	12	5	0.550
	P	46	9	5	
Patient Movement	TM	45	12	3	0.714
	P	46	10	4	

Table 4: Vital Parameters during (including side effects) LMA insertion

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