COMPARISON OF MIDAZOLAM AND MINI DOSE SUCCINYLCHOLINE IN AIDING LMA INSERTION IN ADULT ELECTIVE SURGERY PATIENTS - A RANDOMISED CLINICAL TRIAL IN GVMC

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ABSTRACT

BACKGROUND

The LMA¹ has gained widespread acceptance as general purpose airway and is used in up to 30% of patients undergoing general anaesthesia.^{2,3} The most popular induction agent for LMA insertion continues to be propofol as it obtunds oropharyngeal reflexes.^{4,5,6}

MATERIALS AND METHODS

1. All patients were randomly grouped under 2 groups viz., Group A propofol with midazolam, Group B propofol with succinylcholine. Group A received 0.04 mg/kg body weight of midazolam.
2. All patients are pre oxygenated with 100% O₂ for 3 min. All patients are then induced with propofol bolus until the endpoint of loss of eye lash reflex is obtained. Then, in group B alone 0.1 mg/kg succinylcholine is injected. We wait for 60 sec. for fasciculations if any and proceed with LMA. Insertion. Patients were then maintained on assisted ventilation with 100% oxygen over a period of 60 sec. After 60 sec., well-lubricated LMA was inserted by the standard techniques. During insertion of laryngeal mask airway, jaw relaxation, gagging/coughing, limb movements, presence or absence of laryngospasm, haemodynamics were noted. If jaw relaxation was found to be inadequate to permit LMA insertion, boluses of propofol were given until adequate jaw relaxation occurred.

RESULTS

In this study, the conditions of LMA insertion, patient's response to LMA insertion and the haemodynamic changes^{7,5,6} during and after LMA insertion⁸ in the following two groups of patients were observed.

Group A – Inj. Propofol 2.5 mg /kg + 0.04 mg/kg midazolam.

Group B – Inj. Propofol 2.5 mg/kg + 0.1 mg/kg succinylcholine.

Good jaw relaxation, good overall insertion conditions, first attempt insertion, no airway trauma, no increased dose of propofol, stable haemodynamics were noticed in group A patients.

CONCLUSION

To conclude, addition of Midazolam (0.04 mg/kg) to the standard dose of propofol provides better LMA insertion conditions than the addition of mini dose Succinylcholine (0.1 mg/kg).

KEYWORDS

Midazolam, Propofol, Succinylcholine.

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BACKGROUND

The LMA has gained widespread acceptance as general purpose airway^{9,10} over conventional face mask and ET tube and is used in up to 30% of patients undergoing general anaesthesia.³

The most popular induction agent for LMA insertion continues to be propofol induction agent as it obtunds oropharyngeal reflexes.⁴ Standard induction doses (2-3 mg/kg) of propofol, which allow adequate jaw relaxation

and prevent patient reaction to LMA insertion^{4,11} i.e., gagging, coughing, movements etc., commonly result in hypotension.^{12,13}

A prospective randomised controlled study was constructed to compare the usefulness of midazolam and mini dose succinylcholine^{14,15} to aid LMA insertion in propofol anaesthesia, in patients coming for elective short general surgery procedures.

The study was conducted in Department of Anaesthesiology, Government Vellore Medical College.

Aim of the Study

The aim of the study is to observe the usefulness of Midazolam and mini dose Succinylcholine to facilitate the insertion of laryngeal mask airway during propofol anaesthesia in elective general surgery patients based on the following parameters.

- Conditions during insertion of laryngeal mask airway such as jaw relaxation, ease of insertion, number of

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attempts for insertion, airway trauma and total dose of propofol.

- Patient's response to insertion of laryngeal mask airway such as gagging, coughing, head and limb movements, laryngospasm, etc.
- Haemodynamic parameters like mean arterial pressure, heart rate and oxygen saturation.

MATERIALS AND METHODS

After obtaining institutional ethical committee clearance and the patient consent, the study was carried out on 50 patients posted for elective surgical procedures lasting less than or equal to 45 min. at Government Vellore Medical College.

Patient belonging to the age group of 18–50 years of both the sexes were selected.

Inclusion Criteria

- Elective short surgical procedures lasting less than or equal to 45 min. patients of ASA physical status I and II.
- Aged between 18 – 50 years of both sexes.

Exclusion Criteria

- Patients with full stomach, pregnant patient.
- Patients posted for emergency surgery.
- Patients with oral, perioral pathology such as tumours, abscess or grossly enlarged tonsils.
- Patients with fixed reduced pulmonary compliance such as pulmonary fibrosis, severe cardiovascular, hepatic or renal disease.

Types of Surgeries

The various types of surface surgeries that were included in this study are shown in Table 1.

Types of Surgeries	Group A	Group B	Total
Fibroadenoma Excision	5	8	13
Lipoma Excision	4	3	7
Hydrocoele – Excision and Eversion	2	3	5
Herniorrhaphy	2	2	4
Ganglion Excision	2	1	3
Gynaecomastia – Webster's Procedure	1	1	2
Haemorrhoids, fissure in ano	3	3	6
Other minor surgeries	6	4	10

Table 1

Patient Preparation

All patients were advised overnight fasting.

Pre-Loading

All patients are preloaded with 10 mL/kg of balanced salt solution.

Pre-Medication

All patients were premedicated with

Inj: Glycopyrrolate 4 mcg/kg IV.

Inj: Fentanyl¹⁷ 2 mcg/kg.

Monitors Used

Noninvasive Blood pressure (NIBP), Electrocardiogram (ECG), Pulse oximetry, ETCO₂

Methodology

All patients were randomly grouped under 2 groups viz., Group A propofol with midazolam, Group B propofol with succinylcholine. Group A received 0.04 mg/kg body weight of midazolam.

All patients are preoxygenated with 100% O₂ for 3 min. All patients are then induced with propofol bolus until the endpoint of loss of eye lash reflex is obtained. Then in group B alone 0.1 mg/kg succinylcholine^{16,14,15} is injected. We wait for 60 sec. for fasciculations if any and proceed with LMA insertion. Patients were then maintained on assisted ventilation with 100% oxygen over a period of 60 sec. After 60 sec., well-lubricated LMA was inserted by the standard techniques described in the intravent manual. During insertion of laryngeal mask airway jaw relaxation, gagging/coughing, heads & limb movements, presence or absence of laryngospasm were noted. If jaw relaxation was found to be inadequate to permit LMA insertion, boluses of propofol were given until adequate jaw relaxation occurred.

Jaw Relaxation

Was graded by Young, Clark, Dundee.

Adequate – Adequate jaw relaxation and LMA insertion done without any difficulty.

Incomplete – Inadequate jaw relaxation but LMA insertion is possible with difficulty.

Poor – Inadequate jaw relaxation and LMA insertion is not possible.

Overall Insertion Conditions

Was graded by Lund and Stovner.

Excellent - (Insertion – easy, no reaction from the patient).

Good – (Insertion results in slight cough or movements).

Poor – (Insertion possible but with marked unacceptable response).

Gagging or Coughing on Insertion

Was graded as present or absent.

Head and Limb Movements

Was graded as present or absent.

After insertion of LMA, cuff was inflated with appropriate volume of air and connected to the breathing circuit. Correct positioning of the LMA was verified by bilateral chest expansion, bilateral air entry by auscultation, capnography and the absence of leak around the cuff. The ventilation was assisted with bag until resumption of spontaneous respiration. Anaesthesia was maintained with oxygen (2 L/min.), Nitrous oxide (4 L/min.) and Halothane (1%). The haemodynamics were monitored before premedication, 1 minute after LMA insertion and throughout till agents were discontinued and 100% oxygen administered. LMA was removed after the patient had gained adequate level of consciousness and after adequate return of pharyngeal reflexes. After removal of LMA, the patient was observed for any spasm, coughing, vomiting. In the postoperative period, the patients were observed in the ward for 24 hours.

Statistical Analysis Using Student T-Test

The t-test assesses whether the means of two groups are statistically different from each other. The t-value will be positive if the first mean is larger than the second and negative if it is smaller. Once we compute the t-value we look it up in a table of significance to test whether the ratio is large enough to say that the difference between the groups is not likely to be a chance finding.

RESULTS

This study was conducted and 50 patients were divided into 2 groups of 25 patients each.

Group A – Propofol with midazolam group.

Group B – Propofol with Succinylcholine.

Demographic Profile

In group B, 48% of patients are male and rest 53% are female, while in group A 52% of patients are male and rest female. The mean age of patient is 30.12 and 30.84 in groups A and B respectively. The mean weight is 53 and 53.22 in groups A and B respectively. Patients in each were statistically comparable in relation to sex, age and weight. See Fig -1.

Comparison of Conditions for LMA Insertion

One -Sample Test

	Test Value =0					
	t	Df	Sig (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Adequate	3.326	2	.080	16.333	-4.79	37.46
Incomplete	1.765	2	.220	8.667	-12.46	29.79

Table 4

Jaw relaxation was more in group A compared to group B and the results are statistically as shown in tables above.

Overall Ease of Insertion

The overall ease of insertion is graded as excellent, good, poor or unacceptable. The overall ease of insertion was excellent in 100% of group A patients, while it was 44% in group B. See Fig .3 & Table 5.

Jaw relaxation, overall insertion conditions and number of attempts for LMA insertion were observed and the results were tabulated as follows. Also see figure 2.

Jaw Relaxation	Group A	Group B
Adequate	25	16
Incomplete	0	9
Poor	0	0

Table 2

One-Sample Statistics

	N	Mean	Std. Deviation	Std. Error Mean
Adequate	3	16.33	8.505	4.910
Incomplete	3	8.67	8.505	4.910

Table 3

Ease of Insertion	Group A	Group B
Excellent	25	11
Good	0	14
Poor	0	0

Table 5

One-Sample Test

	Test Value =0					
	t	Df	Sig (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Excellent	2.800	2	.107	14.667	-7.87	37.21
Good	1.972	2	.187	10.333	-12.21	32.87

Table 7

The overall insertion conditions are excellent in Group A (Propofol with Midazolam) compared to the other groups and this is statistically significant as shown above.

Number of Attempts for Successful Insertion of LMA

In 100% of patients in group A, LMA was inserted in the first attempt, while in only 64% of patients in group B respectively. This is represented as the following data. See Fig. 4 & Table 8.

Attempt	Group A	Group B
First Attempt	25	16
Second Attempt	0	9

Table 8

One-Sample Statistics

	N	Mean	Std. Deviation	Std. Error Mean
Excellent	3	14.67	9.074	5.239
Good	3	10.33	9.074	5.239
Poor	3	.00	.000(a)	.000

Table 6

Mean cannot be computed because the standard deviation is 0.

One-Sample Statistics

	N	Mean	Std. Deviation	Std. Error Mean
First Attempt	3	17.00	7.550	4.359
Second Attempt	3	8.00	7.550	4.359

Table 9

One-Sample Test

	Test Value =0					
	t	Df	Sig (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
First Attempt	3.900	2	.060	17.000	-1.75	35.75
Second Attempt	1.835	2	.208	8.000	-10.75	26.75

Table 10

100% of LMA insertions in Group B was done in the first attempt while only 64% of LMA insertions were done in the first attempt in Group B respectively, this is statistically significant as shown above.

Comparison of Patient Response to LMA Insertion

Patient movement, gagging, coughing, laryngospasm during LMA insertion were compared between the 2 groups. See Fig. 5.

Patient Movement

Patient Moving	Group A	Group B
Yes	0	3
No	25	22

Table 11

One-Sample Statistics

	N	Mean	Std. Deviation	Std. Error Mean
Yes	3	5.00	6.245	3.606
No	3	20.00	6.245	3.606

Table 12

One-Sample Test

	t	Df	Sig (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Yes	1.387	2	.300	5.000	-10.51	20.51
No	5.547	2	.031	20.000	4.49	35.51

Table 13

There was no patient movement in all patients in group A, whereas there was movement in 12% of patients in group B, which is statistically very significant. Additional doses of Propofol was used for those patients.

Laryngospasm

	Group A	Group B
Yes	0	0
No	25	25

Table 14

In both the groups, there was no incidence of laryngospasm. Likewise there was no gagging or coughing in both 2 groups.

Total dose of Propofol (mg/kg) Required for LMA Insertion

	Group A	Group B
Total Propofol dose (mg/kg)	2.06	2.60

Table 15

One-Sample Statistics

	N	Mean	Std. Deviation	Std. Error Mean
Does	3	2.4733	.36679	.21177

Table 16

One-Sample Test

	t	Df	Sig (2-tailed)	Mean Difference	95% confidence Interval of the Difference	
					Lower	Upper
Does	11.680	2	.007	2.47333	1.5622	3.3845

Table 17

The mean total dose of propofol used are 2.06 and 2.60 respectively in group A, B which is also statistically significant.

Airway Trauma

	Group A	Group B
Yes	0	9
No	25	16

Table 18

Also see fig. 6 & Table 18.

One-Sample Statistics

Airway Trauma	N	Mean	Std. Deviation	Std. Error Mean
Yes	3	5.67	4.933	2.848
No	3	19.33	4.933	2.848

Table 19

One-Sample Test

Airway Trauma	T	Df	Sig (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Yes	1.990	2	.185	5.667	-6.59	17.92
T No	6.788	2	.021	19.333	7.08	31.59

Table 20

The incidence of airway trauma as witnessed by blood staining of LMA is 32% in group B, while none of group A had any, which is statistically significant.

Haemodynamic Changes – Pulse Rate and MAP

The mean variability in heart rate (heart rate pre-op minus heart rate 1 min. post-insertion) is least in group A which is statistically significant. The pictorial representation of the

mean variability in heart rate (pre-op heart rate minus 1 min. post-insertion heart rate) is as follows.

Also see Fig. 7 & 8.

One-Sample Test

	N	Mean	Std. Deviation	Std. Error Mean
HR	3	19.28	2.383	1.376

Table 21

One-Sample Test

	Test Value = 0					
	t	Df	Sig (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
HR	14.014	2	.005	19.280	13.36	25.20

Table 22

The mean variability in mean arterial pressure (pre-op MAP minus 1 min. post-insertion MAP) is least in case of group A patients than group B, which is statistically significant. There is no change in saturation (SpO₂) levels either preop, post-induction or post-insertion between the 2 groups.

One-Sample Statistics

	N	Mean	Std. Deviation	Std. Error Mean
MAP	3	21.28	1.698	.980

Table 23

One-Sample Test

	Test Value = 0					
	T	Df	Sig (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
MAP	21.713	2	.002	21.280	17.06	25.50

Table 24

Summary

In this study, the conditions of LMA insertion, patient's response to LMA insertion and the haemodynamic changes during and after LMA insertion in the following two groups of patients were observed.

Group A – Inj. Propofol 2.5 mg/kg + 0.04 mg/kg midazolam.

Group B – Inj. Propofol 2.5 mg/kg + 0.1 mg/kg succinylcholine.

- The jaw relaxation was adequate in 100% of group A patients compared to 64% of patients in Group B.
- Overall insertion conditions were excellent in 100% of patients in group A compared to 64% of patients in group B.
- LMA was inserted successfully in the first attempt in 100% of patients in Group A compared to 64% in group B.
- Airway trauma as evidenced by blood staining of LMA was found in 32% in group B while none of the patients in Group A had airway trauma.
- Post-op myalgia was present in 40% of patients in group B.
- Patient's movement were present in 12% of patients in Group B and 0 in Group A.
- The total dose of Propofol required for successful insertion of LMA was 2.60 mg/kg in Group B, while it is 2.06 mg/kg the least in group A which is the cause of significant haemodynamic stability in patients of group A.

DISCUSSION

Adverse response to insertion of laryngeal mask airway such as gagging, coughing and laryngospasm, may make correct positioning difficult or even impossible. So LMA insertion requires suppression of upper airway reflexes. Although propofol obtunds the upper airway reflexes, Stonham, Bree and Sneyd reported that easy insertion of the LMA was seen in only approximately 60% of patients with Propofol anaesthesia,¹⁷ which means that the sole use of Propofol does not always guarantee successful insertion of LMA, comparisons have been made between various muscles relaxants in the LMA insertion.

Cook TM, Seavel et al compared topical and intravenous lignocaine to insertion of LMA with thiopentone.¹⁸ The group who had lignocaine topical had a lower incidence of laryngospasm. In the present study, there was no incidence of laryngospasm in both the groups.

Wafaa Taha Salem, Dept. of Anaesthesiology, National Cancer Institute, Cairo University investigated the use of

Midazolam or mini dose succinylcholine as a co-induction agent with propofol to facilitate LMA insertion in 60 patients undergoing urological procedures. The patients were divided into 3 groups; Propofol group (P) receiving 2.5 mg/kg Propofol for Induction, while group PM received 0.04 mg/kg Midazolam 3 min. pre-induction and group PS received 0.1 mg/kg succinylcholine 30 sec. after propofol. The number of insertion attempts, total dose of propofol, jaw relaxation, gagging, coughing, patient movement, laryngospasm, overall insertion conditions and haemodynamic changes were recorded. Significant reduction in induction dose of propofol was noted in PM groups (40%). Success rate of first attempt was 60%, 95% and 90% in P, PM, PS groups respectively. Group PM showed less Haemodynamic change, overall insertion conditions were excellent in 20%, 75% and 50% respectively in three groups. In our study also total dose of propofol was low by 25% in group A, the ease of insertion and jaw relaxation was graded excellent in 100% of patients in group A. In our study also haemodynamics were stable in group A. Hence, it is concluded that midazolam aids LMA insertion in propofol anaesthesia.

CONCLUSION

To conclude, addition of Midazolam (0.04 mg/kg) to the standard dose of propofol provides better LMA insertion conditions than the addition of mini dose Succinylcholine (0.1 mg/kg).

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