

Study of Effect of Midazolam on the Dose of Propofol for Laryngeal Mask Airway Insertion in Children

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Introduction

The major responsibility of an anesthesiologist is to provide adequate respiration for the patient and the most vital element is providing respiration is the airway. No anesthetic is safe unless diligent efforts are devoted to maintain an intact function airway. In studies it has been found that adverse respiratory episodes were mainly due to inadequate ventilation, esophageal intubation and insufficient tracheal intubation.

With the induction of anesthesia and onset of apnea, ventilation and oxygenation are supported by traditional methods; facemasks and end tracheal tubes. Recent supralaryngeal airway support devices are Laryngeal Mask Airway (LMA) and Combined Or pharyngeal Airway (COPA)

LMA was designed by Dr. Archie Brain as a novel concept in airway management by establishing end to end circumferential seal around laryngeal inlet with inflatable cuff. It is a till for managing emergency airway as an aid to intubation and as a bridge filling the niche between facemask and tracheal tubes in terms of both anatomical position and degree of invasiveness. The device does not, however, provide a water tight seal around the larynx, and should not be used in patients at risk of regurgitation. There is a risk of gastric inflation during positive pressure ventilation.

LMA in children is becoming increasingly common and it has been noticed that placement may be more difficult may be more difficult in children. It has been suggested that the standard insertion technique recommended by Brain may be sub-optimal infants and children may be due to their different anatomy (large tongue in relation to mandible; glottis lies higher and anterior than adult; vocal cords are angled more forwards and downwards and large and floppy epiglottis)

Insertion of LMA is accompanied by smaller cardiovascular responses than those after laryngoscopy and intubation an its use may be indicated in those patients in whom a marked pressor response would be deleterious. Insertion of LMA soon after induction is facilitated by propofol, which depresses pharyngeal and laryngeal reflexes. The larger

central compartment volume is consistent with higher induction dose requirement in children. Propofol has been shown to be superior to thiopental when these agents are used along for facilitating insertion of LMA and has been recommended as induction agent of choice for its insertion. However, bolus intravenous propofol may cause prolonged apnoea, is more expensive than thiopental and often causes pain on injection.

Midazolam is an effective sedative premedicant in children which is synergistic with propofol and may reduced dose required for LMA insertion.

Midazolam is less expensive than propofol and has a relatively short elimination half-life (1-4 hrs). In this study we will determine the dose of propofol for LMA insertion in children with and without premedication with intravenous midazolam and also observe the haemodynamic and respiratory changes.

Aims and Objective

1. To determine the optimum dose of propofol in children premedicated with midazolam or unpremedicated for insertion of laryngeal mask airway.
2. To observe haemodynamic and respiratory changes before induction, during and after insertion of laryngeal mask airway till 10 minutes.

Review of Literature

The laryngeal mask airway (LMA) was designed as a new concept in airway management and has been gaining a firm positioning a firm positioning in anaesthetic practice. It is an innovative airway management device intended as an alternative to face mask. It forms an airtight seal by enclosing the larynx rather than plugging the pharynx and avoids airway obstruction in the oropharynx.

The LMA was originally designed by Dr Archie Brain in 1981 Royal London Hospital based on the cast model of hypopharynx. He examined the shape of pharynx by making plaster of Paris casts from cadaver. Device was made available to clinicians in 1988.

Advantages of LMA over facemasks and endotracheal tubes has been studies in a review article by Asai & Morris in 1944.

Advantages of LMA over facemasks

- Skill is required to obtain an airtight seal with a facemask whereas with LMA it is easy when airway pressures are between 17 to 20 cm of water. Even it is better in adentulous patient.
- Oropharyngeal airway obstruction occurs frequently with facemask. Laryngeal mask avoids complication by bypassing tongue and soft palate.
- Waste anaesthetic gases can be effectively scavenged with LMA i.e. nitrous oxide concentration near anaesthetists breathing zone is well below 25 ppm during spontaneous and controlled ventilation (Lambert-Jensen et al., 1990; Sarma and Leman, 1990)
- Hypoxemia and interruption of surgery to reestablish a clear airway are less likely to occur i.e. allows safer anaesthetic management from a distance (Williams and Bailey, 1993; Smith and White, 1992; Johnston et al., 1990)
- Lack of need for manipulation at patient's head and neck may be advantageous with patient of unstable cervical spine.
- LMA frees the anaesthesiologists' hands for recordkeeping, monitoring and drug administration. Fatigue from maintain the airway with face mask is eliminated.
- End tidal gas concentration can also be monitored.

Advantages of LMA over ETT

- LMA insertion technique is easily learned (Davies et al, 1990) and success rate by unskilled personnel is 94 to 100% (Davies et al., 1990; Pennant and Walker, 1992; Bodrick et al., 1989)
- Incidence of sore throat is less when LMA is used (Smith and White, 1992; Alexander and Leach, 1989; Swann et al., 1993; Johnston et al., 1990; Akhtar et al 1992)
- Emergence and recovery times are shorter when LMA is used (Smith and White, 1992). Recovery of ciliary function is also rapid.
- Avoidance of a facemask reduces injury to the eyes and facial nerves.
- Muscle relaxants and laryngoscopy are not necessary and laryngeal mask can be placed within 30 seconds from induction with propofol. Time taken is usually less than that for tracheal intubation (Davis et al., Pennant and Walker, 1992)
- Patients tolerate the LMA at a lighter level of anaesthesia than they do ETT (Wilkins et al., 1992)

- Avoidance of succinylcholine may minimize post-operative myalgia and contributes to financial saving.
- Avoidance of laryngoscope also reduces the risk of trauma to lips, gums and teeth.
- There is minimal cardiovascular response to insertion of the LMA compared to ETT and time taken is also less.
- There is no risk of esophageal and endobronchial intubation.
- Dead space is less than facemask but more than ETT.
- LMA produces minimal stimulation if left in place until protective airway reflexes have returned.
- Insertion and removal of LMA has minimal effects on intraocular pressure (IOP) unlike ETT
- Incidence of coughing (Mason and Bingham, 1990; Akhtar et al., 1992; Sarma, 1990; Mcrirnick, 1991) and interruption of spontaneous breathing are much less during removal of LMA.
- Injury to airway is uncommon, because the LMA has a soft blunt edge and should not touch vocal cords or trachea.

Disadvantages of LMA compared to Oropharyngeal

Airway and ETT

- LMA should not be used in situations associated with increased risk of aspiration like full stomach, previous gastric surgery, gastroesophageal reflux, obesity, diabetic gastroparesis, dementia, trauma, opiate medication, increased intestinal pressure (Dorsch and Dorsch, 1988)
- Patient with glottis and subglottic airway obstruction such as tracheomalacia or external compression of trachea, should not be maintained with a LMA as it cannot prevent collapse of trachea (Asai and Morris, 1994; Maltby, 1994)
- Supraglottic pathology (cyst, abscess, hematoma, tissue disruption) can make proper positioning difficult or impossible (Evans, 1995), although LMA is useful in supraglottic edema or thyroglossal tumor (King et al., Dalrymple and Lloyd, 1992)
- LMA should not be used in obstetrical patients except when intubation and manual ventilation with a face mask are not possible (Dorsch and Dorsch, 1998)
- Presence of bleeding disorder is a relative contraindication to use of LMA (Brimacombe, 1992; Thompsett and Cundy, 1992)
- LMA is not suitable for patients who require high inflation pressures i.e. those with low compliance or high resistance like obesity, bronchospasm,

thoracic trauma, pulmonary edema or fibrosis (Dorsch and Dorsch, 1988)

- LMA may be difficult or impossible to insert in those with an angle between oral and pharyngeal axis of less than 90 at back of tongue, limited mouth opening, palatal clefts, oropharyngeal masses, sharp edges of moth (Ishimura et al., 1995; Brimacombe and Brain, 1997).

Historical Background

Brain (1983) described that when viewed mechanically tracheal intubation is a procedure in which two tubes, one manmade and other anatomical are connected together by inserting one into the other, a cuff being inflated on the inner tube to produce gas tight seal. In engineering terms, this gas tight junction between two tubes is unsatisfactory, since it involves a degree of constriction at point of junction unless outer tube is itself expanded to compensate. Ideally both should be connected end to end, since the option of expanding anatomical tube is not practical. Examination of post-mortem specimens of adult females and males was made to assess how such a joint might be achieved. It was noted that airtight seal could be effected against perimeter of larynx posteriorly by an ETT and standar anaesthesia mask. It can be inserted blindly without laryngoscopy.

Blake et al. (1992) conducted a study on fifty adult patients ASA I and II for dosage, haemodynamic and respiratory effects of proposal for laryngeal mass (LMA) insertion, one of four induction doses 1.5 to 2.6 mg/kg was delivered over 30 seconds and the first attempt at LMA insertion was made at 90 seconds. The LMA was inserted at 90 seconds in 35 patients and by 300 seconds in 13 other (mean plasma concentration at 90 seconds was 7.7 mcg/ml (no delay) versus ug/ml (insertion delayed) ($p < 0.01$). Insertion was less successful after 1.5 mg/kg (failed at 90 seconds in 6 of 12 patients). But did not vary with other doses. Additional doses 0.5 mg/kg/30 seconds was required in 22 patients of LMA insertion or to prevent movement, resulting in propofol concentration at 120-180 seconds above 7 mcg/ml. Respiratory effects were minor but mean arterial pressure decreased by 18 ± 1.4 mm Hg at 90 seconds. Cardiovascular effects did not differ significantly between dosage groups or with the use of additional propofol.

Wilson et al. (1992) described cardiovascular changes during insertion of LMA and compared with cardiovascular responses induced by laryngoscopy and endotracheal intubation in 40 elective cases for gynaecological operations. Anaesthesia was induced by thiopentone (4-5 mg/kg) and maintained using manual ventilation of lung to normocapnia, via a Bain system with 67% N₂o and 1% Enflurane in oxygen; vecuronium was used for muscle relaxation. The mean maximum increased in systolic arterial

pressure after laryngoscopy and tracheal intubation was 51.3 % compared with 22.9% of LMA insertion ($p < 0.01$). Increased in Heart rate was similar (26.6 % vs 25.7 %) but heart rate remained elevated for long after tracheal intubation. They concluded that LMA insertion was associated with smaller cardiovascular changes and may be indicated in patients in whom marked pressor response would be deleterious.

Fassoulaki et al. (1990) studied ventilatory adequacy and respiratory mechanics with LMA vs endotracheal tube (ETT). They concluded that in patienrs with normal airway pressure and compliance, PPV (positive pressure ventilation) using LMA is comparatively effective than ETT.

Pediatric LMA are scaled down version of adult forms (**Mason & Bingham, 1990**) LMA can be used in children in whom unusual anatomy makes tracheal intubation difficult (**Borsch & Dorsch, 1990**).

Allsop et at. (1995) assessed the case of insertion of Brain LMA in children between 4 and 9 years after induction of anaesthesia with propofol. Patients were randomized into three groups - Group A - 2.5 mg/kg, Group B - 3.0 mg/kg, Group C- 3.5 mg/kg. Insertion conditions were studied as good, acceptable, unacceptable or impossible. Good and acceptable conditions were obtained in 35%, 70%, 95% in Group A, B and C respectively ($p < 0.0001$). There was no statistically significant intergroup variation in systolic and diastolic arterial pressure of un heart rate for 5 minutes after induction. All measured cardiovascular changes were considered to be clinically insignificant in healthy children. They concluded that it is safe and effective to insert a LMA immediately after induction of anaesthesia with propofol 3.5 mg/kg.

Mason and Bingham (1990) conducted a survey on the LMA in pediatric patients (6 months to about 12 years). Due to various differences between airway of infant and young children they performed a clinical evaluation in pediatric anaesthesia and since the use of the LMA in children is becoming increasingly common. LMA was used in 200 children in different surgical procedures. Some problem with the use of the device was encountered in 47 cases (23%), but in only five cases (2.5%) problem was serious enough in 191 children. Downfolding of epiglottis over laryngeal inlet was indentified in 8/24 patients where flexible laryngoscopy wad performed. A questionnaire was completed if device was used with this information - age, weight, any preexisting airway problems; operation and duration of insertion; ease of insertion, number of attempts and any associated problems; quality of the airway and manoeuvres necessary to achieve perfect airway, presence of a leak on compression of reservoir bag; the ease of removal and any associated problems. It was concluded that

size 2 LMA can be successfully used within the weight range 6-30 kg.

Lopez-Gil et al. (1996) conducted a prospective survey of 1400 children safety and efficacy of LMA by ten trainee anaesthetists. It provided information about insertion and complication rates using the standard insertion technique and a limited range of standardized anaesthetic techniques. LMA was not used in patients at risk of aspiration or for intra-abdominal, thoracic, major head and neck or vascular surgery or patient who were ASA grade 4 or 5. Placement was successful in 90% at first attempt, 8% at second attempt and 2% required an alternative technique of insertion. Induction was defined as the start of injection of propofol until beginning of surgery. All patients were unpremedicated and anaesthesia was induced with propofol 3 mg/kg given over 1 minute. Additional boluses of propofol were given as required and maintained at 10 mg/kg/hr reducing after 15 minutes to 5 mg/kg/hr or 0.5-1% Isoflurane. One patient vomited during insertion and procedure was abandoned, but aspiration did not occur. Overall problem rate was 11.5% and with p value <0.02, more problems were during induction of anaesthesia. Oxygen saturation decreased below 90% on 23 occasions (1.7%). Problems were unrelated to mode of ventilation, or whether isoflurane or TIVA with propofol was used for maintenance. Most problems came with use of size 1 LMA (<0.001). There was no major morbidity associated with use of device. They concluded that LMA provides safe and effective form of airway management for infants and children in the hands of supervised anaesthesia.

Jhonston et al. (1990) found that there were significantly fewer episodes of hypoxemia and interruption of surgery with use of LMA as compared to face mask. Unlike facemask LMA frees the hand of anaesthesiologist and does not require jaw support. This study was done in 48 children (2-10 years).

Lot of studies were done on the induction agent and various additives to aid ease of insertion of LMA.

Marthlew et al. (1996) determined the dose-response curves and effective doses of propofol for insertion of LMA in 60 unpremedicated and 60 premedicated with midazolam patients (3-12 years). Propofol depresses pharyngeal and laryngeal reflexes and oral midazolam is an effective sedative premedicant in children (**McClusky and Meakin, 1994**) which is synergistic with propofol (**Short and Chiu, 1991**) and may reduce dose required for LMA insertion. One of several doses of propofol was administered i.v. over 15 sec to groups of 10 children and conditions of LMA insertion were assessed at 60 sec. Conditions were considered satisfactory if jaw relaxed, there was no coughing, gagging, swallowing of laryngeal spasm and minimal or no levels movement. If found unsatisfactory

anaesthesia was deepened with further increments of propofol or an inhalational agent or both until LMA was tolerated. Dose-response curves were parallel ($p=0.64$), but curve shifted left of that of unpremedicated children and propofol requirements were reduced by one-third ($p<0.0001$). ED50 and ED90 of premedicated patients were 2.6 (2.2-2.8) mg/kg and 3.6 (3.2-4.3) mg/kg and unpremedicated patients were 3.8 (3.4-4.2) mg/kg and 5.4 (5.4-6.8). During the study they did not observe any differences in the incidence of cardio-respiratory side effects between low and high dose propofol groups.

Molloy et al. (1999) conducted a study in 44 patients between 18-65 years and found that duration of apnoea was in a range of 10-60 seconds (mean 35 seconds) if propofol was used as induction agent.

Acalovschi et al. (1995) studied the effect of propofol on laryngeal reactivity and the haemodynamic response to LMA insertion. Ease of insertion and haemodynamic effects were assessed 2 minutes after induction of anaesthesia with propofol 2.5 mg/kg or thiopentone 4.5 mg/kg in 3 of ASA-I premedicated patients. Inserting conditions were significantly better with propofol than with thiopentone ($p<0.001$). Transient increase in systolic and diastolic blood pressure was not significant following insertion of LMA. Heart rate varied little from baseline.

Short and Chiu (1991) concluded that propofol and midazolam act synergistically in combination. Using end points of "Hypnosis" (loss of response to verbal command) and "anaesthesia" (loss of response to a 5 sec, transcutaneous tetanic stimulation) determined dose-response curves for propofol and midazolam alone and in combination. $p<0.01$ was found for hypnosis and the combination having 1.44 times the potency and dose of propofol reduced by 52% anaesthesia. Addition of Midazolam shifted the curve to left ($p<0.01$). The dose of propofol required to anaesthetize 50% of patients was reduced from 1.93 mg/kg to 0.93 mg/kg with the addition of midazolam 0.13 mg/kg at this point. Arterial pressure measurements were analyzed upto the time of assessment of hypnosis and anaesthesia because of the change in arterial blood pressure caused by these assessments and variable stimuli applied depending on degree of sedation. A decrease in systolic, diastolic and mean arterial pressure occurred in all three treatment categories ($p<0.01$), but there was no correlation between increasing dose and magnitude of change in arterial pressure of Midazolam, Propofol or combination. This may be due to interaction of CNS GABA receptors. This study was conducted in 200 unpremedicated female patients undergoing elective gynaecological surgery.

Maurice et al. (1989) studied pharmacokinetic profile of propofol in young children 4-7 years after a single bolus dose 2.5 mg/kg. They concluded that due to large central

compartment volume, higher induction doses are required in children. Propofol was distributed rapidly and extensively and cleared rapidly from body.

In terms of respiratory depression, propofol and fentanyl appear to produce synergistic effect preinduction. Amongst the haemodynamic changes SBP, DBP and HR are significantly reduced from preinduction value after propofol injection in control group. After 1 minute of LMA insertion values increased significantly from preinduction. Values except DBP but significant decrease with $p < 0.05$ was seen in all values after 5 minutes of LMA insertion.

Taylor et al (1986) concluded that induction of anaesthesia with propofol is accompanied by a greater degree of ventilatory depression than follow thiopentone.

Bapat and Yound (1996) found in his study that propofol when used as an induction agent showed a much lower incidence of poor insertion (8%) and none of the patient (mean age 43.1 years) had airway obstruction.

McKealing et al. (1988) proposed that propofol is well suited for insertion of LMA because of its greater depressant effect on airway reflexes than that of thiopentone.

Godsiff et al. (1995) proposed that adding midazolam to propofol allowed a reduced dose of propofol to be used without adverse effects, while reducing anaesthetic costs.

Gill et al. (2001) concluded that midazolam reduces the dose of propofol required for induction of anaesthesia and successful insertion of LMA. Propofol when used as a sole induction agent relatively large doses are required to achieve successful LMA insertion and may produce unwanted cardiorespiratory depression. 142 patients were randomized in different groups and found that patient receiving midazolam required significantly less propofol and reported less pain on injection of propofol.

Scanlow et al. (1993) used propofol 2.5 mg/kg or thiopentone 5 mg/kg i.v. and concluded that propofol is superior to thiopentone as an induction agent for insertion of LMA. Following induction, ventilation was assisted with 50% O₂ and nitrous oxide and 2% isoflurane before insertion of LMA. Adverse response was seen in 76% with propofol. There were less head movement (11%), gagging (20%) and laryngospasm (9%) in propofol and patients in propofol group required treatment for laryngospasm. No patient was judged to be inadequately relaxed in propofol group.

Material and Method

With the approval of ethical committee of the University, the study was conducted in Darbhanga Medical College and Hospital, Laheriasarai. Informed written consent was taken

by parents of each patient between age group of 3 to 12 years of both sexes with ASA grading I and II.

The surgeries included paediatric surgeries, orthopaedic surgeries and general surgeries.

Patients suffering from cardiac abnormalities, neuromuscular disease, pulmonary abnormalities (e/g Asthma), abnormal airway anatomy, any condition with increased risk of regurgitation of gastric contents and prolonged surgeries (>3 hr) were excluded.

Anaesthetic Technique

Informed consent was taken before induction of anaesthesia. Before surgery all patients were randomly assigned in one of the two groups:

- (a) **Group A** - 3 groups (20 patients each) of unpremedicated patients received 3, 4 and 5 mg/kg propofol designated as A1, A2 and A3 respectively.
- (b) **Group B** - 3 groups (20 patients each) of premedicated patients (0.05 mg/kg midazolam) received 3, 4 and 5 mg/kg propofol designated as B1, B2 and B3 respectively.

A pulse oximeter, electrocardiogram and non-invasive blood pressure monitor was attached. 0.05 mg/kg Midazolam i.v. 10 mm before propofol induction was given. Injection lignocaine 10 mg was added to each 100 mg propofol. Propofol was administered over a period of 15 sec via and i.v. cannula following which lungs were ventilated with 100% oxygen for 60 sec before attempting insertion of LMA. Haemodynamic (Mean arterial pressure and heart rate) and respiratory changes were observed.

Condition was considered satisfactory if jaw relaxed, there was no coughing, gagging, swallowing of laryngospasm, and minimal or no limb movements.

The observations and results were subjected to statistical analysis.

STATISTICAL ANALYSIS

For analysis of data chi-square test for proportions has been used. To see the differences between the two groups student's test has been used.

Observation

The study was conducted on 120 patients of ASA grade I and II of either sex between 3-12 years scheduled for various pediatric surgery and orthopaedic surgery undergoing general anaesthesia admitted to concerning wards of Darbhanga Medical College & Hospital, Laheriasarai. Patients were randomly allocated in different subgroups undergoing surgery. The following study was made:

Table I: Comparison Baseline Characteristics in Different Groups

	Group A			Group B		
	A1	A2	A3	B1	B2	B3
Age (in Years)	4.5±1.2	4.6±1.34	4.5±1.33	4.5±1.46	4.5±1.36	4.5±1.36
Sex	10 M 10 F	9 M 11 F	10 M 10 F	12 M 8 F	11 M 9 F	10 M 10 F
Weight (in Kg)	18.4±3.30	18.0±3.34	18.3±2.95	19.1±3.62	19.1±3.03	19.1±3.11
Height (in cm)	80.1±3.55	81.1±3.51	81.2±3.05	82.0±3.48	81.1±3.09	81.0±3.05

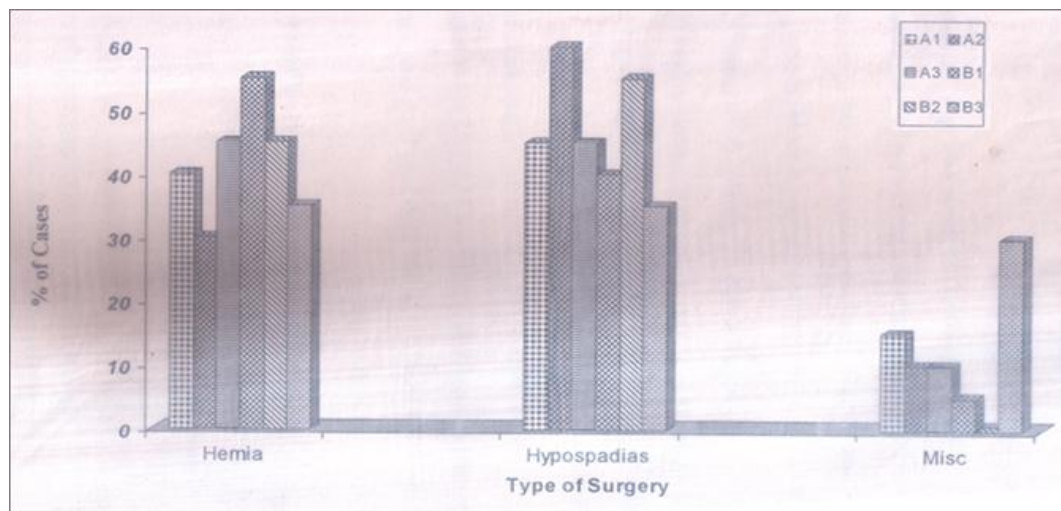
The ages (mean + SD) of patients in subgroup A1, A2 and A3 were 4.2+1.2, 4.5+1.34 and 4.5+1.33 years; in subgroup B1, B2 and B3 were 4.5+1.46, 4.5+1.36. Thus, there is no significant difference in age in different groups.

The number of male and female were same in Subgroup A1, A3 and B3 i.e 10 each. The number of males and females in A2 were 9 and 11 while in group B2 were 11 and 9 respectively. Subgroup B1 had 12 male and 8 female patients. Thus, there is no significant difference in sex in different groups.

Mean weight (+SD) of patients in subgroup A1, A2 and A3 were 18.4+3.30, 18.0+3.34 and 18.3+2.95 kilograms; and in subgroups B1, B2 and B3 were 19.1+3.62, 19.1+3.03 and 19.1+3.11 kilograms respectively. There is no significant difference in weight in different subgroups.

Height (mean+SD) in centimeters of patients in subgroups A1, A2 and A3 were 80.1+3.55, 81.1+3.51 and 81.2+3.05 and in subgroup B1, B2 and B3 were 82.0+3.48, 82.0+3.09 and 81.0+3.05. There is no significant difference in height in different subgroups.

Thus we find that there is no significant difference in age, sex, weight and height in different groups.

**Table 2: Operative Procedure**

Type of Surgery	Group A						Group B					
	A1		A2		A3		B1		B2		B3	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Hernia	8	40	6	30	9	45	11	55	9	45	7	35
Hypospadias	9	45	12	60	9	45	8	40	11	55	7	35
Miscellaneous Surgeries*	3	15	2	10	2	10	1	5	-	0	6	30
Total	20	100	20	100	20	100	20	100	20	100	20	100

*Miscellaneous surgeries included ureteric stone, phimosis, orthopaedic limb surgeries etc.

The type of surgeries which were maximally conducted in all the subgroups were hernia and hypospadias. Maximum number of cases of hernia were conducted in subgroup B1

(11) followed by A3 (9), B2 (9), A1 (8), B3 (7) and least in A2 (6)

12 cases of hypospadias were conducted in subgroup A2 followed by 11 cases in subgroup B2. 9 cases were

conducted in both subgroups A1 and A1. Number of cases conducted in subgroup B1 and B3 were 8 and 7. Amongst the miscellaneous surgeries maximum cases were conducted in subgroup B3, while no surgery could be conducted in B2. 3, 2, 2 and 1 cases were conducted in subgroup. A1, A3, A3 and B1. The duration of surgery in minutes (mean+SD)

(minutes) in subgroup A1, A2 and A3 were 57.40+8.40, 58.60+7.40 and 58.40+6.40 and in subgroup B1, B2 and B3 were 57.40+6.60, 58.47+8.42 and 57.90+7.40. There is no significant difference in duration of surgery in different age groups ($p < 0.005$).

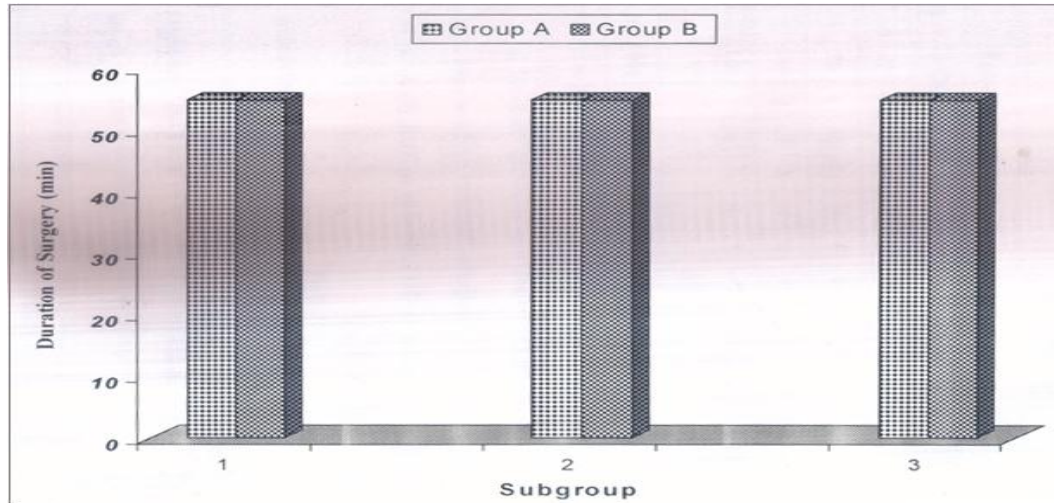


Table 3: Occurrence of Adverse events during attempted LMA placement

Groups	Inadequate jaw relaxations		Coughing		Gagging		Limb Movements		Laryngospasm	
	No.	%	No.	%	No.	%	No.	%	No.	%
A ₁	10	50	18	90	17	85	18	90	0	0
A ₂	6	30	10	50	11	55	4	20	0	0
A ₃	4	20	2	10	1	5	2	10	0	0
B ₁	4	20	10	50	8	40	10	50	0	0
B ₂	1	5	3	15	3	15	6	30	0	0
B ₃	0	0	1	5	0	0	2	10	0	0
Comparison between groups	χ^2	p	χ^2	p	χ^2	p	χ^2	p	χ^2	p
A ₁ vs B ₁	3.96	0.05	7.61	<0.001	8.64	<0.01	7.61	<0.01	0	1
A ₂ vs B ₂	4.33	0.03	5.44	<0.02	7.03	<0.008	0.52	0.48	0	1
A ₃ vs B ₃	4.33	0.03	0.35	0.55	1.00	0.32	0	1	0	1

The incidence of **inadequate jaw relaxation** was maximum in subgroup A1 (50%), while no incidence was seen in subgroup B3. Incidence in subgroup A1 and A3 were 30% and 20%, while in subgroup A1 vs B1, A2 vs B2 and B2 and A3 vs B3 we found that incidence of inadequate jaw relaxation is significantly decreased with $p < 0.05$ in midazolam-propofol group (Group B)

The incidence of **coughing** was found to be 90%, 50% and 10% in subgroup A1, A2 and A3 respectively, while the incidence in subgroup B1, B2 and B3 were 50%, 15% and 5%. Comparing the subgroup A1 vs B1 and A2 vs B2 were found that the incidence of coughing was significantly high with p value < 0.05 , though the incidence of coughing was higher than subgroup B3 (not significant ($p = 0.55$)).

The incidence of **gagging** was 85%, 55% and 5% in subgroup A1 A2 and A3 while 40%, 15% and 0% in subgroup B1, B2 and B3. The incidence of gagging in subgroup A1 and A1 were significantly high ($p < 0.05$) when compared with subgroup B1 and B2 was not significant ($p = 0.32$)

The incidence of **limb movement** seen in subgroup A1, A2 and A3 were 90%, 20% and 10% respectively, while in subgroup B1, B2 and B3 were 50%, 30% and 10%. When compared subgroup A1 with B1 and A1 with B2, the incidence of limb movement was found to be significantly high ($p < 0.05$). The incidence was same in subgroup A3 and B3 and thus was non-significant ($p = 1.0$)

No incidence of **laryngospasm** was seen in any of the groups.

Table 4: Successful Placement of LMA in different groups

	Group A			Group B		
	A1	A2	A3	B1	B2	B3
No.	2	6	12	5	16	20
%	10	30	60	25	80	100

Table 4a: Comparison of successful placement of LMA in different groups

Comparison	χ^2	p
A ₁ vs B ₁	1.558	0.212
A ₂ vs B ₂	10.101	0.001
A ₃ vs B ₃	10.00	0.002

Amongst Group A, the success rate was highest in subgroup A3 with 60%, while least in A1 with only 10%. 30% patients could be successfully inserted with LMA in subgroup A1. Amongst the Group B, almost all patients were successfully inserted with LMA in subgroup B3 while 80% and 25% was the success rate in subgroup B2 and b1.

Comparing subgroup A1 vs B1 statistically significant difference was not found. However, for comparisons between A2 vs B2 and A2 and B3 success rate was significantly statistically.

Table 5: Mean Arterial Pressure (MAP) (mm Hg) at different time intervals

Group	Baseline (BL)	Before Insertion (BI)	After Insertion (AI)	5 Min After Insertion (5M)	10 Min After Insertion (10M)
A1	60.0±3.52	55.1±3.56	65.0±3.52	57.1±3.37	55.9±3.43
A2	62.0±2.85	58.1±2.77	66.1±2.90	58.2±2.93	57.7±2.55
A3	62.1±2.68	56.0±2.77	65.0±2.75	57.2±2.02	57.0±2.59
B1	60.0±3.31	55.9±3.29	62.0±3.23	60.0±3.25	58.9±3.27
B2	60.0±2.54	55.0±2.48	61.0±2.43	55.0±2.47	54.9±2.46
B3	61.0±3.05	50.8±2.86	63.8±2.86	61.7±2.98	57.8±2.92

Table 5a: Comparison of MAP between baseline and at different time intervals within group.

Comparison	A1		A2		A3		B1		B2		B3	
	't'	'p'	't'	'p'	't'	'p'	't'	'p'	't'	'p'	't'	'p'
1. BL/BI	4.27	<0.001	4.28	<0.001	6.92	<0.001	3.83	<0.001	6.13	<0.001	10.63	<0.001
2. BL/AI	4.38	<0.001	4.40	<0.001	3.29	<0.001	1.89	>0.05	1.24	>0.05	2.92	<0.01
3. BL/5M	2.59	<0.01	4.05	<0.001	5.70	<0.001	0.0	>0.05	6.15	<0.001	0.72	>0.05
4. BL/10M	3.64	<0.001	4.90	<0.001	5.96	<0.001	1.03	>0.05	6.29	<0.001	3.30	<0.001

Table 5b: Comparison of MAP between two groups

Group	Baseline (BL)		Before Insertion (BI)		After Insertion (AI)		5 Min After Insertion (5M)		10 Min After Insertion (10M)	
	't'	'p'	't'	'p'	't'	'p'	't'	'p'	't'	'p'
A1/B1	0.0	>0.05	0.72	>0.05	2.73	<0.01	2.70	<0.01	2.76	<0.01
A2/B2	2.8	<0.05	3.63	<0.001	5.65	<0.001	3.64	<0.001	3.44	<0.001
A3/B3	1.18	>0.05	5.71	<0.001	1.32	>0.05	4.94	<0.001	0.89	>0.05

Tables 5, 5a show the changes in MAP (mm Hg) at various time intervals in various subgroups. Baseline MAP was comparable in all subgroups with MAP (mm Hg) being 60±3.52 mm Hg, 62.0±2.85 mm Hg, 62.1±2.68 mm Hg, 60.0±3.31 mm Hg, 60.0±2.45 mm Hg and 61.0±3.05 mm Hg in subgroups A1, A2, A3, B1, B2 and B3 respectively.

After induction with propofol (before insertion) in Group A we found a significant fall in all the subgroups from its baseline i.e 55.1±3.56 in subgroup A1, 58.1±2.77 in subgroup A2, 56.0±2.77 in subgroup A3. Similarly, there

was also a significant decrease in MAP before insertion in subgroup B1, B2 and B3 from its baseline (BL) and found to be 59.9±3.29, 50.8±2.86 mm Hg. Maximum decreased was seen in Group B3. When we measure MAP after insertion there was increase in MAP in all the subgroups of group A (A1 65±3.52, A2 66.1±2.90, A3 65.0±2.75). This increased was highly significant when we compared from its baseline in MAP in all the subgroups of Group B (B1 62.0±3.23; B2 61.0±2.43, and B3 63.8±2.86) and it significant with p value <0.01 in B3 but not significant with p value >0.05 in B1, B2.

After 5 minutes and 10 minutes we found a gradual decrease in MAP in all the subgroups of A1, A2 and A3. When compared with baseline (BL), it was significant ($p < 0.05$). Similarly, we found a decrease in MAP in Group B. At 5 minutes the decrease was not significant from the baseline in subgroup B1 and B3.

At 10 minutes the decrease in MAP in subgroup B1 was not significant from the baseline. While significant decrease in MAP in subgroup B2 and B3.

When we compared the MAP between the group i.e. group A vs group B (Table 5b), when we compare MAP before

insertion (BI) we found it was significant between A1 vs B2 but not significant between A1 vs B1 and A3 vs B3.

When we compare MAP after insertion it was significant between A1 vs B1 and A1 vs B2 but not significant between A3 vs B3.

The fall in MAP at 5 minutes also significant between A1 vs B1, A2 vs B2 and A3 vs B3.

The fall in MAP at 10 minutes was significant between A1 vs B2 and A2 vs B2 but not significant A3 vs B3.

Table 6: Heart Rate (HR) at different time intervals in all groups

Group	Baseline (BL)	Before Insertion (BI)	After Insertion (AI)	5 Min After Insertion (5M)	10 Min After Insertion (10M)
A1	120.0±3.89	115.4±3.56	134.9±3.52	122.0±3.61	119.7±3.70
A2	122.0±3.26	117.1±3.29	136.6±3.30	122.9±4.03	123.1±4.15
A3	118.0±3.05	112.9±2.85	132.9±2.85	119.9±2.88	118.2±2.77
B1	120.0±3.31	112.1±3.25	123.0±3.22	121.6±3.19	120.3±3.15
B2	120.1±3.23	112.1±3.23	123.0±3.27	121.3±3.16	114.4±3.15
B3	120.0±3.05	105.0±3.05	123.0±3.05	121.9±2.73	114.0±2.76

Tab 6a: comparison of Heart Rate/min. between baseline and different time intervals within groups.

Group	A1		A2		A3		B1		B2		B3	
	't'	'p'	't'	'p'	't'	'p'	't'	'p'	't'	'p'	't'	'p'
1. BL/BI	3.80	<0.001	4.61	<0.001	5.33	<0.001	7.42	<0.001	7.63	<0.001	15.16	<0.001
2. BL/AI	12.38	<0.001	13.72	<0.001	15.56	<0.001	2.83	<0.01	2.93	<0.01	3.03	<0.003
3. BL/5M	1.64	>0.05	0.76	>0.05	1.97	>0.05	1.52	>0.05	1.25	>0.05	2.02	<0.05
4. BL/10M	0.24	>0.05	0.90	>0.05	0.21	>0.05	0.29	>0.05	5.53	<0.001	6.35	<0.001

Table 6b: Comparison of HR/min. between groups.

Group	Baseline (BL)		Before Insertion (BI)		After Insertion (AI)		5 Min After Insertion (5M)		10 Min After Insertion (10M)	
	't'	'p'	't'	'p'	't'	'p'	't'	'p'	't'	'p'
A1/B1	0.0	>0.05	2.98	<0.001	10.87	<0.001	0.36	>0.05	0.54	>0.05
A2/B2	1.80	>0.05	4.73	<0.001	12.67	<0.001	1.36	>0.05	7.28	<0.001
A3/B3	2.02	<0.05	8.25	<0.001	10.34	<0.001	2.20	<0.05	4.68	<0.001

Table 6 and 6a show the changes in HR at various time intervals in all subgroups. We found that mean baseline (BL) heart rate is compatible in all groups. A1, A2, A3, B1, B2 and B3 i.e. 122.0±3.26 beats/min, 118.0±3.05 beats/min, 120.0±3.31 beats/min, 120.1±3.23 beats/min and 120.1±3.09 beats/min

After induction with propofol (before insertion) in Group A we found significant decrease in all the subgroups – A1 (115.4±3.56), A2 (117.1±3.29) and A3 (112.9±2.85) beats/min from the baseline (BL) with $p < 0.001$.

Similarly, there was also significant decrease in HR before insertion to 112.1±3.25, 112.1±3.23 and 105.0±3.05 beats/min in subgroup B1, B2 and B3 respectively. The fall in HR was maximum in subgroup B3.

Rise in HR was found to be significant after LMA insertion in Group A – A1 (134.9±3.52), A2 (136.6±3.30) and A3 (132.9±2.85) beats/min.

Rise in HR also significant after insertion in Group B – B1 (123.0±3.22), B2 (123.0±3.27) and B3 (123.0±3.05) beats/min from the baseline.

After 5 minutes HR changes were not significant ($P < 0.05$) in various subgroups. 122.0±3.61, 122.9±4.03, 119.9±2.88, 121.6±3.19, 121.3±3.16 and 121.9±2.73 ins subgroup A1, A2, A3, B1, B2 and B3 respectively from baseline.

After 10 minutes the fall in heart rate was found to be not significant from the baseline in subgroups A1, A2 and A3 (119.7±3.70; 123.1±4.15 and 118.2±2.77 beats/min

respectively) with $p > 0.05$. In subgroup B1, it was also not significant but in subgroup B2 and B3 there was significant ($p < 0.001$) fall in HR being 114.4 ± 3.15 and 114.0 ± 2.76 beats/min.

We compare the HR/min between the group i.e group A vs group B when we compare HR before insertion (BI), we found fall in HR was significant between A1 vs B1; A2 vs B2 and A3 vs B3 with $p < 0.001$.

When we compare HR after insertion it was significant between A1 vs B1; A2 vs B2 and A3 vs B3 with $p < 0.001$.

The changes HR at 5 minutes not significant $P > 0.05$ between A1 vs B1 and A2 vs B2 but significant $P < 0.05$ in A3 and B3.

The fall in HR at 10 minutes was significant $p < 0.001$ between A2 vs B2 and A3 vs B3 but not significant A1 vs B1.

Table 7: Oxygen saturation (SPO₂%) at different time interval

Group	Baseline (BL)	Before Insertion (BI)	After Insertion (AI)	5 Min After Insertion (5M)	10 Min After Insertion (10M)
A1	98.0±1.04	99.0±0.65	99.1±0.62	99.1±0.77	99.1±0.67
A2	98.5±0.92	99.1±0.70	99.2±0.65	99.1±0.70	99.3±0.64
A3	98.4±0.92	99.0±0.71	99.1±0.74	99.0±0.71	99.1±0.74
B1	98.5±0.98	98.9±0.77	99.1±0.62	99.0±0.55	99.2±0.65
B2	98.4±0.92	99.0±0.81	99.0±0.84	99.0±0.74	99.0±0.74
B3	98.5±0.98	98.9±0.86	99.1±0.70	99.1±0.70	99.1±0.70

Tables 7a: Comparison of SpO₂% between baseline and at different time intervals within group.

Group	A1		A2		A3		B1		B2		B3	
	't'	'p'	't'	'p'	't'	'p'	't'	'p'	't'	'p'	't'	'p'
1. BL/BI	3.55	<0.001	2.26	<0.01	2.25	<0.05	1.40	>0.05	2.22	<0.05	1.33	>0.05
2. BL/AI	3.96	<0.001	2.71	<0.01	2.58	<0.01	2.25	<0.05	2.10	<0.05	2.17	<0.05
3. BL/5M	3.70	<0.001	2.26	<0.05	2.25	<0.05	1.94	>0.05	2.22	<0.05	2.17	<0.05
4. BL/10M	3.88	<0.001	3.11	<0.001	2.58	<0.01	2.59	<0.01	2.22	<0.05	2.17	<0.05

Table 7b: Comparison of SpO₂% between the groups

Group	Baseline (BL)		Before Insertion (BI)		After Insertion (AI)		5 Min After Insertion (5M)		10 Min After Insertion (10M)	
	't'	'p'	't'	'p'	't'	'p'	't'	'p'	't'	'p'
A1/B1	1.27	>0.05	0.43	>0.05	0.0	>0.05	0.46	>0.05	0.47	>0.05
A2/B2	0.34	>0.05	0.41	>0.05	0.82	>0.05	0.43	>0.05	1.34	>0.05
A3/B3	0.32	>0.05	0.39	>0.05	0.0	>0.05	0.44	>0.05	0.0	>0.05

The baseline SPO₂ in various groups were 98.0±1.04 in A1, 98.5±0.92 in A2, 98.4±0.92 in A3, 98.5±0.98 in B1, 98.4±0.92 in B2 and 98.5±0.98 in B3.

We found that there was not significant difference in SPO₂ at before insertion, after insertion, at 5 minutes and at 10 minutes from base line in A1, A2, A3, B1, B2 and B3.

DISCUSSION

In the present study of "Effect of Midazolam and Premedication on the Dose of Propofol of Laryngeal Mask Airway Insertion in Children" with aim of determining the optimum dose of propofol in children premedicated with midazolam or unpremedicated for insertion of laryngeal mask airway and to observe haemodynamic and respiratory changes before induction, during and after insertion of laryngeal mask airway till 10 minutes, we observed that the

age, sex, weight and height were almost similar in all the subgroups (A1, A2, A3, B1, B2, B3). Table 1 shows the corresponding 'p' values of all groups for age, sex, weight and height. From the above study it can be inferred that the demographic profile of 6 subgroups regarding age, sex, weight and height are almost similar.

The type of surgeries which were maximally conducted in all the subgroups were hernia and hypospadias. Miscellaneous surgeries included ureteric stones, phimosis, orthopedic limb surgeries etc., which were less in number. Also, there was no significant difference in duration of surgery in different subgroups.

Also, there was no significant difference in time from administration of Midazolam to induction of anaesthesia in the group which received premedication (Group B). It is similar to study conducted by Martlew et al. in 1996 where

he used oral midazolam for premedication (0.5 mg/kg) 30-60 min before anaesthesia.

Occurrence of adverse effects during LMA insertion

In our present study we observed the occurrence of adverse events during LMA placement and found that the incidence of inadequate jaw relaxation was higher in group A with 50%, 30% and 20% in subgroups A1, A2 and A3 respectively. Thus we observe that as the dose of propofol is increasing the incidence of inadequate jaw relaxation is decreasing.

In group B, the incidence was 20%, 5% and 0% in subgroup B1, B2 and B3 respectively. Thus we also observed here a decreasing trend with increasing dose of propofol.

Comparing subgroup A1 vs B1, A2 vs B2 and A3 vs B3, we found that the incidence of inadequate jaw relaxation is significantly decreased with $p < 0.05$ in midazolam premedicated group (Group B).

The incidence of limb movements was found to be 90%, 20% and 10% in subgroup A1, A2 and A3. We observed a decrease in incidence of limb movement as the dose of propofol increased.

In subgroup B1, B2 and B3 incidence was found to be 50%, 30% and 10%. Here also we observed a decrease in limb movement when induced with increased dose of propofol.

Comparing subgroups A1 vs B1, A2 vs B2 and A3 vs B3 we found the incidence of limb movement was significantly higher in subgroup B1 and B2 ($p < 0.05$). Interestingly, the incidence was same in subgroup A3 and B3.

Martlew et al. (1996) also considered adequate jaw relaxation and limb movement as the condition for satisfactory LMA placement in paediatric age group. They proposed that effective dose of propofol in midazolam premedicated group was significantly less than propofol alone group. They found that, at propofol 3.8 mg/kg 50% patients had adverse events whereas in our study at propofol 4 mg/kg 30% had inadequate jaw relaxation and 20% showed limb movement. They found that at a dose of 5.4 mg/kg propofol, only 10% had adverse events during insertion of LMA, whereas in our study we found that at a dose of 5 mg/kg 20% had inadequate jaw relaxation and 10% showed limb movements. When midazolam was used as premedication, **Martlew et al.** observed that, at a dose of 2.6 mg/kg of propofol 50% children had adverse events during LMA insertion, whereas in our study at 3 mg/kg of propofol (Group B1) 20% had inadequate jaw relaxation and 50% showed limb movement. **Martlew et al.** also observed that at 3.6 mg/kg, only 10% showed adverse events, whereas in our study at 4 mg/kg we found inadequate jaw relaxation in 5% and limb movement in 30% children.

Increased induction requirements for propofol in children may be due to large central volume of distribution of drug (**Saint Maurice et al. 1989; Marsch et al. 1991**) and a greater cardiac output per kilogram body weight, which should result in lower peak concentration of propofol in blood perfusing the brain after bolus injection.

Scanlow et al. in 1993 found 0% and 20% incidence of inadequate jaw relaxation and limb movement using propofol at a dose of 2.5 mg/kg in adults. In our study, we found 50% and 90% incidence of inadequate jaw relaxation and limb movements at 3 mg/kg propofol. They proposed that propofol was better choice in facilitating LMA insertion due to adequate jaw relaxation.

Bapat and Yound (1996) observed the incidence of inadequate jaw relaxation and limb movement of 24% and 16% at a dose of propofol 2.5 mg/kg in adults, while in our study we found 50% and 90% respectively at dose of 3 mg/kg.

In our present study findings with propofol are consistent with literature. Among group A and B, the incidence of inadequate jaw relaxation was less in Group B (propofol-midazolam group)

So we can infer that propofol-midazolam combination facilitates LMA insertion better than propofol alone in children.

Coughing, Gagging and Laryngospasm.

The incidence of coughing was found to be 90%, 50% and 10% in subgroup A, A2 and A3 respectively, while the incidence in subgroup B1, B2 and B3 we found that the incidence of coughing was significantly high with p value < 0.0001 and < 0.02 respectively. Though the incidence of coughing was higher than subgroup B3 but not significant ($p = 0.55$).

The incidence of gagging was 85%, 55% and 5% in subgroup A1, A2 and A3 while 40%, 15% and 0% in subgroup B1, B2 and B3. The incidence of gagging in subgroup A1 and A2 were significantly high ($p < 0.05$) when compared with subgroup B1 and B2 respectively, while the comparison between A3 and B3 was not significant ($p = 0.32$).

No incidence of laryngospasm was seen in any case under study.

Marlew et al. (1996) considered coughing, gagging, laryngospasm as the confounding factors for successful insertion of LMA in age 3-12 years at 3.8 mg/kg of propofol 50% patients had adverse events, while in our study, 50%, 55% and 0% patients had coughing, gagging and laryngospasm respectively. When midazolam was used as premedication at a dose of 2.6 mg/kg of propofol, 20% had

adverse events, while in our study at 3 mg/kg 50%, 40% and 0% was the incidence of coughing, gagging and laryngospasm respectively. Only 10% had adverse events at a dose of 3.6 mg/kg, while in our study, 15%, 15% and 0% had coughing, gagging and laryngospasm respectively at 4 mg/kg of propofol.

Lopez Gil et al. (1996) conducted a prospective study in 1400 infants and children and found 14 children had upper airway reflex stimulation at 3 mg/kg propofol alone, while we observe coughing, gagging and laryngospasm in 17, 17 and 0 out of 20 patients at 3 mg/kg. However, they also considered retching and bronchospasm.

Bapat and Young (1996) observed 8%, 2% and 0% incidence of coughing, gagging and laryngospasm respectively at 2.5 mg/kg of propofol in adult patients, while in our study incidences are 90%, 80% and 0% respectively.

Molloy et al. (1999) found 20%, 14% and 11% incidence of coughing, gagging and laryngospasm respectively at 2.5 mg/kg propofol while we observed 90%, 85% and 0% respectively at 3 mg/kg propofol.

The reason for increased incidence may be due to abnormal anatomy: relatively large tongue in relation to the mandible, the glottis lies higher end more anteriorly than adult while the vocal cords are angled more towards and downwards, epiglottis is large and floppy and may lie against the posterior wall the pharynx which can cause upper airway obstruction.

Increased induction requirements for propofol in children may be due to large central volume of distribution of drug (**Saint Maurice et al. 1989; Marsch et al. 1991**) and a greater cardiac output per kilogram body weight, which should result in lower peak concentration of propofol in blood perfusing the brain after bolus injection.

Our present study findings are consistent with the literature. The result can be drawn that coughing, gagging and laryngospasm may occur when depth of anesthesia is to light i.e. of lower doses of propofol in sued (**Asai and Morris, 1994**) Since the incidence of adverse events is found to be lower in propofol and midazolam group than propofol along, it can be inferred that premedicated children with midazolam have lesser chance of adverse effects during insertion of LMA.

Successful Placement of LMA in Different Groups

Amongst Group A, the success rate was highest in subgroup A3 with 60%, while least in A1 with only 10%. 30% patients could be successfully inserted with LMA in subgroup A2. Amongst the Group B, almost all patients were successfully inserted with LMA in subgroup B3 while 80% and 25% was the success rate in subgroup B1 and B2.

Comparing subgroup A1 vs B1 statistically significant difference was not found. However, for comparisons between A2 vs B2 and A3 and B3 success rate was significantly high in subgroup B which was also significant statistically.

Martlew et al. (1996) concluded from his study in paediatric patients, that the effective dose of propofol for insertion of LMA in 90% of unpremedicated children exceeded 5mg/kg (5.4 mg/kg), but it was reduced to 3.6 mg/kg when midazolam was used as premedicament whereas in our study 60% of patients could be inserted with LMA at dose of 5 mg/kg propofol alone, and in propofol-midazolam group at 4 mg/kg 80% were successfully placed with LMA at a dose of 3.8 mg/kg with propofol alone and at 2.6 mg/kg with propofol-midazolam group while in our study about 30% were successful with 4 mg/kg propofol alone group and 25% and 3 mg/kg propofol-midazolam group.

McKeating et al. (1988) in their study concluded that propofol depressed pharyngeal and laryngeal reactivity more than thiopentone. The synergistic action of midazolam with propofol was observed by Short and Chiu (1991). Patients were assessed 2 min after propofol and 4 min after midazolam, this time being the approximate time to peak effect of each drug when given as in i.e. bolus. For, hypnosis, synergistic action was found significant ($p < 0.001$), the combination having 1.44 times the potency of the individual agents. The dose of propofol required to produce anaesthesia was reduced by 52% in presence of midazolam ($p < 0.01$) and the co-efficient of synergism being 0.78 ED50 of propofol was reduced from 1.93 mg/kg to 0.93 mg/kg with the addition of midazolam 0.13 mg/kg. They postulated a role of CNS GABA_A receptors in medicating sedation caused by propofol and midazolam.

Dose of propofol in children may be relatively higher than that in adults, because dose of propofol require to tolerate facemask is high in children (estimated ED90 was 4 to 5 mg/kg) this was proposed by Patel et al. in 1988

Midazolam was used as it does not enhance airway reactivity and has a shorter elimination half lie (1-4 m) (Reves et al., 1985; Short and Chiu, 1991). So our present study findings are consistent with the literature. The result which can be inferred that the effective dose of successful LMA placement in paediatric age group (3-12 years) is lesser with propofol and midazolam as compared to propofol alone.

Haemodynamic Changes

Mean Arterial Pressure (MAP)

In present study baseline MAP was comparable in all the groups with MAP being 60.0±3.52, 62.1±2.85, 62.1±2.68,

60.0±3.31, 60.0±2.54 and 61.0±3.05 mm Hg in subgroups A1, A2, A3, B1, B2 and B3 respectively.

After induction with propofol (before insertion) in Group A we found a significant fall in all the subgroups from its baseline i.e. 55.1±3.56 in A1, 58.1±2.77 in A2 and 56.0±2.77 in A3. Similarly, there was also a significant decrease in MAP before insertion in subgroup B1, B2 and B3 from its baseline (BL) and found to be 55.9±3.29, 55.0±2.48 and 50.8±2.86 mm Hg. Maximum decrease was seen in Group B3. When we measure MAP after insertion there was increase in MAP in all subgroups of group A (A1 65.0±3.52, A2 66.1±2.90, and A3 65.0±2.75). This increase was significant when we compared from its baseline (BL) with p value <0.001. Similarly, there was increase in MAP in all subgroups of Group B (B1 62.0±3.23; B2 61.0±2.43 and B3 63.8±2.86) and it is significant with p value <0.001 in B3 but not significant with p value >0.05 in B1 and B2.

After 5 minutes and 10 minutes we found a gradual decrease in MAP in all the subgroups of A1, A2 and A3. When compared these changes with baseline (BL) it was significant (p<0.05). Similarly, we found a decrease in MAP in Group B, At 5 minutes the decrease was not significant from the baseline in subgroup B1 and B3.

At 10 minutes the decrease in MAP in subgroup B1 was not significant from the baseline, while significant decrease in MAP in subgroup B1 and A3 vs B3.

When we compare change of MAP after insertion it was significant (p<0.01) between A1 vs B1 and A2 vs B2 but not significant (p>0.05) between A1 vs B3.

The fall in MAP at 5 minutes also significant (p<0.001) between A1 vs B1, A2 vs B2 and A3 vs B3.

The fall in MAP at 10 minutes was significant (p<0.01 and P<0.001) between A1 vs B1 and A2 vs B2 but not significant (p>0.05) between A3 vs B3.

Several investigations have commented on minimal haemodynamic changes. Interestingly, **Martlew et al. (1996)** did not observe any difference in cardiorespiratory side effects between low and high dose of propofol, unlike our present study **Short and Chui (1991)** observed in their study that there was a decrease in systolic, diastolic and mean arterial pressure in propofol and propofol-midazolam group (p<0.01), but there was no correlation between increasing dose and magnitude of change in arterial pressure. When they compared the changes in arterial pressure produced by propofol with propofol-medazolam combination for anaesthesia, there was no difference between the two treatments. We also found no significant change in MAP after induction between two groups except in propofol-midazolam group in 5 mg/kg dose group where

there was significant decrease in MAP than propofol alone group.

Goyagi et al. (2003) found significant decrease before anesthesia (after propofol induction with 1.95-2.6 mg/kg) in diastolic blood pressure (DBP) and systolic blood pressure (SBP) from preinduction values. After insertion increase was seen in SBP with p<0.05, but increase in DBP was not statistically significant. At 5 minutes, may be due to deepening of anesthesia all the values (SBP and DBP) decreased significant from preinduction values after 5 minutes. In our study we also found a significant decrease in MAP after induction, significant increase after insertion in propofol group and significant decrease from preinduction values at 5 min due to further deepening of anesthesia.

Asai and Morris (1994) in their review article on LMA said that BP increases after placement of LMA and the increase is similar to those of insertion of Guedel's airway but less than tracheal intubation. So, our study findings are consistent with the literature. The inference that can be drawn from the present data is that midazolam pretreatment provides more stability than propofol alone group haemodynamically during LMA placement. Both 5 mg/kg and 4 mg/kg propofol are effective in propofol-midazolam group for LMA insertion. Since the fall in MAP is found to be significantly more after induction within the group and between the group, we can infer that 4 mg/kg with midazolam is optimum dose of propofol for LMA insertion.

Heart Rate (HR)

We found that mean baseline (BL) heart rate is compatible in all group A1, A2, A3, B1, B2 and B3 i.e. 120.0± 3.89, 122.0± 3.26, 118.0± 3.05, 120.0± 3.31, 120.1± 3.23 and 120.0± 3.05 beats/min respectively.

After induction with propofol (before insertion) in Group A we found significant (p<0.001) decrease in all subgroups – A1 (115.4± 3.56), A2 (117.1± 3.29) and A3 (112.9± 2.85) from baseline (BL)

Similarly, there was also significant decrease in HR before insertion to 112.1±2.25, 112.1±3.023 and 105.0±3.05 beats/min in subgroup B1, B2 and B3 respectively. The fall in HR was maximum in subgroup B3.

Rise in HR was found to be significant after LMA insertion in Group A- A1 (134.9±3.52), A2 (136.6±3.30) and A3 (132.9±2.85) beats/min.

Rise in HR also significant after insertion in Group B- B1 (123.0±3.22), B2 (123±3.27) and B3 (123.0±3.05) beats/min from baseline.

After 5 minutes HR changes were not significant (p>0.05) in various subgroups – 122.0±3.61, 122.9±4.03, 119.9±2.88,

121.6+3.19, 121.3+2.16 and 121.3+2.73 in subgroup A1, A2, A3, B1, B2 and B3 respectively from baseline.

After 10 minutes, the fall in heart rate was found to be not significant from baseline in subgroups A1, A2 and A3 (119.7+3.70; 123.1+4.15 and 118.2+2.77 beats/min respectively) with p value (>0.05). In subgroup B1, it was non-significant but in subgroup B2 and B3 there was significant ($p > 0.001$) fall in HR being 114.4+3.15 and 114.0+2.76 beats/min

When we compare in HR before insertion (BI) we found fall in HR was significant between A1 vs B1, A2 vs B2 and A3 vs B3 with $p < 0.001$.

When we compare in HR after insertion it was significant between A1 vs B1, A2 vs B2 and A3 vs B3 with $p < 0.001$.

The change HR at 5 minutes not significant $p > 0.05$ between A1 vs B1 and A1 vs B2 but significant with $p < 0.05$ in A3 and B3.

The fall in HR at 10 minutes was significant $p < 0.001$ between A2 vs B2 and A3 vs B3 but not significant between A1 and B1.

Martlew et al. (1996) did not observe any difference in cardiorespiratory side effects between low and high doses of propofol unlike our present day.

Goyagi et al. (2003) observed a significant decrease in heart rate after induction with propofol (ED₉₅ 2.6 mg/kg). A significant increase in HR was seen after insertion and at 5 min there was significant decrease from preinduction values. Similar changes were found in our study in propofol along group at any dose.

Asai and Morris (1994) in their review article on LMA said that HR increases after placement of LMA and the increase is similar to those of insertion of Guedel's airway but less than tracheal intubation.

Our present study findings are consistent with the literature. The inference that can be drawn from the present data is that midazolam pretreatment provides more haemodynamic stability during LMA placement. Both 5 mg/kg and 4 mg/kg propofol are effective in propofol-midazolam group for LMA placement. Since, the fall in MAP and HR is found to be more before insertion of LMA with 5 mg/kg of propofol. We can infer that 4 mg/kg with midazolam is optimum dose of propofol of LMA insertion.

Percentage Oxygen Saturation

The baseline SpO₂ in various groups were 98.0 +1.04 in A1, 98.5+0.92 in A2, 98.4+0.92 in A3, 98.5+0.98 in B1, 98.4+0.92 in B2 and 98.5+0.98 in B3.

We found that there was not significant difference in SpO₂ at before insertion, after insertion at 5 minutes and at 10 minutes from baseline in A1, A2, A3, B1, B2 and B3.

Lopez Gil et al. (1996) in a prospective study observed SpO₂ <90> in 11 children during insertion out of 1400 total at a dose of 3 mg/kg, unlike our study where SpO₂ did not fall below 98+1.80 at any stage of insertion.

The inference that can be drawn from the present data is that there is no effect in SpO₂ due to dose of propofol if midazolam is added as premedication to it.

Thus addition of midazolam improves the cost efficiency and provides a better condition for placement of LMA in children.

SUMMARY AND CONCLUSION

The present study of "Effect of Midazolam as Premedication on the Dose of Propofol of Laryngeal Mask Airway Insertion in Children" with aim of determining the optimum dose of propofol in children premedicated with midazolam or unpremedicated for insertion of laryngeal mask airway and to observe haemodynamic and respiratory changes before induction, during and after insertion of laryngeal mask airway till 10 minutes was conducted on 120 pediatric patients of ASA Grade I and II of either sex aged 3 to 12 years scheduled of paediatric surgeries and orthopaedic surgeries undergoing general anaesthesia admitted to concerning wards of Darbhanga Medical College and Hospital, Laheriasarai.

- All patients were randomly divided into two groups: Group A and Group B. Group A was further divided into 3 subgroups of unpremedicated patients who received 3, 4 and 5 mg/kg propofol designated as A1, A2 and A3 respectively. Group B was further divided into subgroups of premedicated patients (0.05 mg/kg midazolam) who received 3, 4 and 5 mg/kg propofol designated as B1, B2 and B3 respectively.
- Regarding the adverse effects during LMA placement we found that the incidence of inadequate jaw relaxation and limb movements is higher in Group A than in Group B. Among Group A, incidence is lesser in Subgroup A3 than Subgroup A1 and A2. Among Group B, incidence is lesser in Subgroup B3 than in Subgroup B1 and B2. Thus we observe a decreasing trend of inadequate jaw relaxation and limb movement with increasing dose of protocol and adding midazolam as premedication further decreased its incidence.
- Incidence of coughing, gagging and laryngospasm is higher in Group A than in Group B. Among Group A, incidence is lesser in Subgroup A3 than

Subgroups A1 and A2. Among Group B, incidence is lesser in Subgroup B3 than Subgroups B1 and B2. Thus, we observed a decreased trend of coughing, gagging and laryngospasm with increasing dose of propofol and adding midazolam as premedicant further decreased its incidence.

- Regarding mean arterial pressure we found decreased before insertion of laryngeal mask airway in both Group A and Group B but this decrease is significantly high in subgroup B3 when compared to subgroup A3. The increase in mean arterial pressure is significant in all the subgroups of Group A as compared to its respective subgroups in Group B after LMA placement. The fall in MAP at 5 minutes is also significant from baseline in Group A as compared to its respective subgroup in Group B. The fall in MAP at 10 minutes is significant from baseline in Subgroup A1 and A2 compared to Subgroup B1 and B2 whereas A3 vs B3 was no-significant.
- Heart rate is significantly decreased in Subgroup B1, B2 and B3 vs Subgroup A1, A2 and A3 respectively before insertion with maximum decrease in B3. After insertion of laryngeal mask airway heart rate significantly increased from baseline in subgroups of Group A in comparison to its respective subgroup of Group B. At 5 minutes decrease in heart rate is not significant in Group A compared to its respective subgroups of Group B. At 10 minutes we find that decrease in heart rate from baseline is significant when compared between Subgroup B2 vs. A2 and B3 vs A3 whereas it is not significant in Subgroup A1 vs B1.
- Immediate conclusion after this study is that LMA is a useful airway drill in paediatric patients which is easy and atraumatic to insert with minimum stimulation of cardiovascular system than endotracheal intubation. Insertion of LMA soon after induction is facilitated by propofol which depresses pharyngeal and laryngeal reflexes. Midazolam is an effective sedative premedicant in children which is synergistic with propofol and reduced effective dose required for LMA insertion.
- Increasing dose of propofol decreases the adverse events like inadequate jaw relaxation, limb movements, coughing, gagging and laryngospasm. Midazolam when added to propofol further reduces the incidence of adverse events and provides more favourable environment for insertion of LMA.
- At higher doses of propofol (5mg/kg), hypotension is a major problem due to its cardiovascular depressant action. Therefore, 4 mg/kg propofol along with midazolam is the optimum dose where

there is more hemodynamic stability and we get better conditions for LMA insertion.

- Thus addition of midazolam improves the cost efficiency and provides a better condition for placement of LMA in children.

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Master-Chart

MASTER CHART GROUP A1 (PROPOFOL-3mg/Kg)																													
Sl.No.	Name	Age (Yrs)	Sex	Height (cm)	Body wt. (kg)	Diagnosis	Operation Done	LMA Size	Mean Arterial Blood Pressure (MAP)mmHg				Heart Rate per minute				Oxygen saturation (SPO2)%				Inadequate jaw relaxation	Coughing	Gagging	Limb Movement	Laryngospasm				
									Baseline (BL)	Before Insection (BI)	After Insection (AI)	5mn after Insection (5M)	10 mn after Insection (10M)	Baseline (BL)	Before Insection (AI)	After Insection (AI)	5mn after Insection (5M)	10 mn after Insection (10M)	Baseline (BL)	Before Insection (BI)						After Insection (AI)	5mn after Insection (5M)	10 mn after Insection (10M)	
1	AK	4.5	M	80	18	Hypospadias	Repair	2	60	55	65	57	56	120	115	135	122	120	98	99	99	99	99	99	99	+	+	+	+
2	PK	3.5	M	77	16	Hypospadias	Repair	2	57	52	62	54	52	124	118	138	125	122	97	98	99	99	99	99	99	+	+	+	+
3	SK	5.5	F	83	20	Inguinal Hernia	Herniotomy	2	63	58	68	59	58	116	119	130	117	115	99	100	99	99	99	99	99	+	+	+	+
4	DK	4	M	78	17	Rt Inguinal Hernia	Herniotomy	2	58	53	63	56	54	122	117	137	125	122	98	99	99	99	98	98	98	+	+	+	+
5	TK	5	F	82	19	Rt Inguinal Hernia	Herniotomy	2	65	58	67	60	58	118	113	133	120	118	98	99	99	100	100	100	100	+	+	+	+
6	LK	3	F	76	15	Rt Supracondylar fracture	Repair	2	56	51	61	53	52	124	119	139	126	124	96	98	98	98	98	98	98	+	+	+	+
7	PR	6	M	84	21	Hypospadias	Repair	2.5	64	59	69	61	60	116	111	131	118	116	100	99	100	100	100	100	100	+	+	+	+
8	SR	2.5	F	75	14	Inguinal Hernia	Herniotomy	2	55	50	60	53	52	125	120	140	127	125	98	99	99	99	99	99	99	+	+	+	+
9	MK	6.5	M	85	22	Hypospadias	Repair	2.5	65	60	70	62	61	115	110	130	117	115	97	99	100	99	99	99	99	+	+	+	+
10	NK	4.5	F	80	18	Inguinal Hernia	Herniotomy	2	60	55	65	57	56	120	115	135	122	120	97	98	99	99	99	99	99	+	+	+	+
11	SG	4	M	78	16	Hypospadias	Repair	2	58	53	63	56	54	122	117	137	125	122	99	100	100	100	100	100	100	+	+	+	+
12	RK	5	M	82	22	Hypospadias	Repair	2.5	62	57	67	59	58	118	113	133	120	118	98	99	98	98	98	98	98	+	+	+	+
13	SK	3.5	M	77	16	Hypospadias	Repair	2	57	52	68	54	53	123	118	138	125	122	98	100	100	100	100	100	100	+	+	+	+
14	OP	5.5	F	83	25	Clavicle fracture	Reduction	2.5	63	58	68	59	58	117	112	132	118	117	97	98	99	98	98	98	98	+	+	+	+
15	BK	3	M	76	15	Hypospadias	Repair	2	56	51	61	53	52	124	119	139	126	124	98	99	99	99	99	99	99	+	+	+	+
16	VK	6	M	84	21	Hypospadias	Repair	2.5	64	59	69	61	60	176	111	132	120	116	98	99	99	100	99	99	99	+	+	+	+
17	YK	2.5	F	75	13	Inguinal Hernia	Herniotomy	2	55	50	60	52	51	125	120	139	126	124	99	100	100	98	100	100	100	+	+	+	+
18	GK	6.5	F	86	23	Inguinal Hernia	Herniotomy	2.5	65	60	70	62	61	115	110	130	117	115	96	98	98	100	98	100	98	+	+	+	+
19	JR	3.5	M	77	15	Phimosis	Circumcision	2	56	51	61	53	52	126	119	139	126	125	100	99	99	100	100	100	100	+	+	+	+
20	JR	5.5	F	84	21	Umbilical Hernia	Reduction	2.5	64	59	69	61	60	114	111	131	118	114	98	99	99	99	99	99	99	+	+	+	+

GROUP A2 (PROPOFOL-4 mg/Kg)
 Mean Arterial Blood Pressure

Sl.No.	Name	Age (yrs)	Sex	Height (cm)	Body wt. (kg)	Diagnosis	Operation Done	LMA Size	Pressure (MAP)mmHg						Heart Rate per minute						Oxygen saturation (SPO2)%						Inadequate jaw relaxation	Coughing	Gagging	Limb Movement	Laryngospasm
									Baseline (BL)	Before Insection (BI)	After Insection (AI)	5min after Insection (5M)	10 min after Insection (10M)	Baseline (BL)	Before Insection (AI)	After Insection (AI)	5min after Insection (5M)	10 min after Insection (10M)	Baseline (BL)	Before Insection (BI)	After Insection (AI)	5min after Insection (5M)	10 min after Insection (10M)								
1	RK	4.5	M	81	18	Hypospadias	Repair	2	62	58	66	58	58	122	117	137	124	124	124	98	99	99	99	99	99	99					
2	SK	3.5	M	79	16	Hypospadias	Repair	2	60	56	64	56	56	125	120	140	127	127	127	98	99	99	99	99	99	99	+	+	+	+	
3	MP	5.5	M	83	20	Hypospadias	Repair	2	64	60	68	60	59	119	114	134	121	120	99	100	100	98	99	99	99						
4	MR	4	M	78	15	Hypospadias	Repair	3	61	57	64	56	56	124	120	138	126	126	97	98	98	99	98	99	98						
5	JR	5	F	84	21	Inguinal Hernia	Herniotomy	3	63	59	67	60	58	120	115	135	122	121	100	99	99	100	100	100	100	+	+	+	+	+	
6	SG	4	F	79	16	Inguinal Hernia	Herniotomy	2	60	56	64	56	56	125	120	140	128	127	98	100	99	99	99	100	99						
7	SK	5	M	83	20	Hypospadias	Repair	2	64	60	68	61	60	119	114	134	120	120	99	99	99	99	100	99	99						
8	PK	2.5	F	76	13	Hypospadias	Repair	2	58	54	62	54	54	126	122	142	130	130	99	99	99	99	100	99	99						
9	VK	6.5	F	87	23	Ureteric Stone	Pycloolithotomy	3	66	62	70	63	62	118	113	133	120	120	99	98	98	98	98	100	99	+	+	+	+	+	
10	BK	3	F	77	14	Hypospadias	Repair	2	59	55	63	55	55	125	120	140	127	127	100	100	99	99	100	99	99						
11	UK	7	F	85	22	Inguinal Hernia	Herniotomy	3	65	61	70	62	61	119	115	134	122	122	97	98	100	99	100	100	100						
12	SP	4.5	M	81	18	Hypospadias	Repair	2	62	58	66	58	58	122	117	137	124	124	98	100	100	98	99	99	99	+	+	+	+	+	
13	SK	3.5	F	78	15	Umbilical Hernia	Reduction	2	60	56	64	56	56	125	120	140	127	127	98	99	99	100	99	99	99	+	+	+	+	+	
14	TK	5.5	F	84	21	Clavicle Fracture	Reduction	3	64	60	69	60	60	119	115	135	122	122	98	99	99	100	98	99	99						
15	CK	3	M	77	14	Hypospadias	Repair	2	59	55	63	55	54	126	120	140	128	128	99	99	99	99	99	99	99	+	+	+	+	+	
16	DK	6	F	85	22	Inguinal Hernia	Herniotomy	3	65	61	69	61	60	118	113	133	120	120	97	100	100	98	99	99	99						
17	LK	2.5	F	76	13	Hypospadias	Repair	2	57	52	62	54	54	127	122	142	121	121	100	98	98	99	100	99	99	+	+	+	+	+	
18	RK	6.5	M	87	23	Hypospadias	Repair	3	67	63	71	62	61	117	112	132	112	112	98	99	99	99	99	99	99						
19	NK	3.5	M	79	16	Hypospadias	Repair	2	59	55	63	55	55	125	120	133	125	125	99	99	99	100	99	99	99	+	+	+	+	+	
20	GK	5.5	F	83	20	Inguinal Hernia	Herniotomy	2	65	61	69	69	60	119	113	133	118	118	98	100	100	100	100	100	100	+	+	+	+	+	

GROUP A3 (PROPOFOL-5mg/Kg)																													
Sl.No.	Name	Age (yrs)	Sex	Height (cm)	Body wt. (Kg)	Diagnosis	Operation Done	LMA Size	Mean Arterial				Heart Rate per minute				Oxygen saturation (SPO2)%				Coughing	Gagging	Limb Movement	Laryngospasm					
									Baseline (BL)	After Injection (BI)	After Injection (AI)	5min after Injection (5M)	10 min after Injection (10M)	Baseline (BL)	Before Injection (AI)	After Injection (AI)	5min after Injection (5M)	10 min after Injection (10M)	Baseline (BL)	Before Injection (BI)					After Injection (AI)	5min after Injection (5M)	10 min after Injection (10M)		
1	UK	4.5	M	81	18	Inguinal Hernia	Herniotomy	2	62	56	65	57	57	118	113	133	120	118	98	99	99	99	99						
2	SP	4	M	79	16	Hypospadias	Repair	2	60	54	63	55	55	120	115	135	122	120	98	98	98	99	98						
3	SK	5	F	83	20	Hypospadias	Repair	2	64	58	67	59	58	116	111	131	119	117	99	100	100	99	100						
4	TK	3	M	78	15	Supra condylar fracture	Reduction Fixation	2	59	52	61	53	53	121	115	135	122	120	97	99	99	98	99						
5	CK	6	M	84	21	Hypospadias	Repair	2.5	65	59	68	60	60	115	110	130	117	115	100	99	99	100	99						
6	DK	2.5	M	77	14	Hypospadias	Repair	2	58	52	61	53	53	122	117	137	124	121	98	99	98	98	98	+					
7	LK	6.5	F	85	22	Inguinal Hernia	Herniotomy	2.5	66	60	69	61	61	114	109	129	116	115	98	99	100	100	100						
8	RK	2	M	76	14	Hypospadias	Repair	2	58	52	61	53	53	123	118	138	125	123	99	100	100	99	99						
9	NK	7	M	86	23	Hypospadias	Repair	2.5	66	60	69	61	61	113	108	128	115	113	97	98	98	99	99	+					
10	GK	4	M	79	17	Hypospadias	Repair	2	60	54	63	55	55	120	115	135	122	120	100	99	99	99	99						
11	CK	5	M	83	20	Hypospadias	Repair	2.5	64	58	67	59	55	116	111	131	118	116	98	99	99	99	100						
12	TK	4.5	F	81	19	Inguinal Hernia	Herniotomy	2	62	56	65	57	57	118	113	133	120	118	99	100	99	98	98						
13	MK	3	F	78	15	Hypospadias	Repair	2	59	53	68	54	54	121	116	136	123	122	98	98	99	100	99						
14	LK	6	F	85	22	Inguinal Hernia	Herniotomy	2.5	65	59	68	60	59	115	110	130	116	116	99	99	100	100	99	+					
15	GK	4	F	79	16	Inguinal Hernia	Herniotomy	2	61	55	64	57	56	119	114	134	121	119	97	99	98	98	99						
16	YK	5	F	83	20	Inguinal Hernia	Herniotomy	2	63	57	66	58	58	117	112	132	119	117	100	100	100	99	100						
17	SK	3.5	F	78	15	Inguinal Hernia	Herniotomy	2	59	53	62	57	57	121	115	135	122	121	98	98	98	99	98						
18	DK	5.5	F	84	21	Inguinal Hernia	Herniotomy	2.5	65	59	68	60	60	115	110	130	117	116	99	99	99	99	100						
19	BK	3.5	F	79	16	Congenital dislocation hip	Reduction	2	60	54	63	56	55	122	116	136	123	122	98	98	99	98	98						
20	AK	5.5	F	85	22	Inguinal Hernia	Herniotomy	2.5	64	58	67	59	59	114	110	130	117	115	98	100	100	100	100	+					

GROUP B1 (PROPOFOL-3 mg/Kg + MIDAZOLAM- 0.05 mg/Kg)																																	
Sl.No.	Name	Age (yrs)	Sex	Height (cm)	Body wt. (Kg)	Diagnosis	Operation Done	LMA Size	Blood Pressure (MAP)mmHg			Heart Rate per minute			Oxygen saturation (SPO2)			Coughing	Gagging	Limb Movement	Laryngospasm												
									Baseline (BL)	After Injection (AI)	5min after Injection (5M)	10 min after Injection (10M)	Baseline (BL)	After Injection (AI)	5min after Injection (5M)	10 min after Injection (10M)	Baseline (BL)					Before Injection (BI)	After Injection (AI)	5min after Injection (5M)	10 min after Injection (10M)								
1	RK	4.5	M	82	19	supracondylar Fractur	Reduction	2	60	56	62	60	60	120	112	123	122	120	98	99	99	99	99	99	+	+	+	+	+	+			
2	SK	4	M	80	17	Hypospadias	Repair	2	58	54	60	58	57	122	114	125	124	122	98	99	99	99	99	99	+	+	+	+	+	+			
3	MP	5	F	84	21	Rt Inguinal Hernia	Hemiotomy	2.5	62	58	64	62	62	118	110	121	120	120	99	99	99	99	99	99	+	+	+	+	+	+			
4	MR	3	M	79	16	Hypospadias	Repair	2	57	52	58	56	56	123	115	126	125	123	97	98	98	99	98	99	98								
5	JR	6	M	85	22	Hypospadias	Repair	2.5	63	59	65	63	63	117	110	120	118	117	100	100	100	100	100	100	100	+	+	+	+	+	+		
6	SG	2.5	F	78	15	Umbilical Hernia	Reduction	2	56	52	58	56	56	124	116	126	124	123	99	98	98	99	99	99	99	+	+	+	+	+	+		
7	SK	6.5	M	86	24	Hypospadias	Repair	2.5	64	60	66	64	64	116	108	119	118	116	99	100	100	9	99	99	98								
8	PK	3.5	F	78	15	Lt Inguinal Hernia	Hemiotomy	2	58	54	60	58	58	122	114	126	124	123	98	99	99	99	99	99	98								
9	VK	5.5	M	89	23	Hypospadias	Repair	2.5	62	58	64	62	62	118	110	121	119	117	98	99	99	100	100	100	100								
10	BK	2	M	77	14	Hypospadias	Repair	2	55	51	57	55	55	125	117	127	126	125	99	98	99	99	99	99	100	+	+	+	+	+	+		
11	AK	7	F	87	24	Inguinal Hernia	Hemiotomy	2.5	65	60	66	64	63	115	107	118	116	116	97	99	99	99	99	99	99								
12	PK	4.5	M	82	19	Hypospadias	Repair	2	60	56	62	60	60	120	112	123	121	120	100	100	100	100	100	100	99	+	+	+	+	+	+	+	
13	SK	4	M	81	17	Hypospadias	Repair	2	59	55	61	59	58	121	113	124	123	121	98	99	99	99	99	99	99	+	+	+	+	+	+	+	
14	DK	5	M	83	22	Inguinal Hernia	Hemiotomy	2.5	61	57	63	61	61	119	111	122	121	119	100	99	99	99	99	98	98								
15	TK	3.5	M	79	16	Inguinal Hernia	Hemiotomy	2	56	52	59	57	57	124	116	127	126	124	99	97	100	100	100	100	100	+	+	+	+	+	+	+	
16	LK	5.5	F	85	22	Inguinal Hernia	Hemiotomy	2.5	64	60	66	64	63	116	108	118	117	117	98	98	99	99	99	99	100	+	+	+	+	+	+	+	+
17	PR	3	M	78	15	Umbilical Hernia	Reduction	2	57	53	59	57	57	123	115	126	124	124	98	100	98	99	99	99	99	+	+	+	+	+	+	+	
18	SR	6	F	86	23	Inguinal Hernia	Hemiotomy	2.5	63	59	65	63	63	117	108	120	119	117	97	99	99	99	98	99	99	+	+	+	+	+	+	+	
19	MK	2.5	F	77	14	Umbilical Hernia	Reduction	2	55	51	57	56	55	125	117	128	126	125	100	99	99	99	99	100	100	+	+	+	+	+	+	+	
20	NK	6.5	F	87	24	Inguinal Hernia	Hemiotomy	2.5	65	61	67	66	65	115	108	119	118	116	98	99	100	99	99	99	99	+	+	+	+	+	+	+	

Sl.No.	Name	Age (yrs)	Sex	Height (cm)	Body wt. (Kg)	Diagnosis	Operation Done	LMA Size	GROUP B2 (PROPOFOL - 4mg/Kg + MIDAZOLAM - 0.05 mg/Kg.)										Inadequate jaw relaxation	Coughing	Gagging	Limb Movement	Laryngospasm
									Mean Arterial Blood Pressure (MAP)mmHg		Heart Rate per minute				Oxygen saturation (SPO2)%								
								Baseline (BL)	Before Insection (BI)	After Insection (AI)	5min after Insection (5M)	10 min after Insection (10M)	Baseline (BL)	Before Insection (BI)	After Insection (AI)	5min after Insection (5M)	10 min after Insection (10M)	Baseline (BL)	Before Insection (BI)	After Insection (AI)	5min after Insection (5M)	10 min after Insection (10M)	
1	CK	4.5	M	81	19	Hypospadias	Repair	2	60	55	61	55	55	120	112	123	122	115	98	99	99	99	99
2	TK	4	M	79	17	Inguinal Hernia	Hemiotomy	2	59	54	60	54	54	122	114	125	124	117	98	99	99	99	99
3	MK	5	M	83	21	Hypospadias	Repair	2.5	61	56	62	55	54	118	110	120	118	112	99	99	99	99	99
4	LK	3.5	F	78	16	Hypospadias	Repair	2	58	53	60	54	53	123	115	126	124	117	97	98	97	98	99
5	GK	5.5	M	84	22	Hypospadias	Repair	2.5	62	57	63	58	58	117	109	120	118	111	100	100	100	100	100
6	YK	3	M	78	15	Hypospadias	Repair	2	57	52	58	52	52	124	116	127	125	118	98	99	99	99	99
7	SK	6	M	84	23	Inguinal Hernia	Hemiotomy	2.5	63	58	64	58	58	116	108	119	117	110	98	99	99	99	99
8	DK	2.5	F	77	16	Umbilical Hernia	Reduction	2	56	51	57	51	51	125	117	128	126	119	99	99	99	98	98
9	BK	6.5	M	85	23	Hypospadias	Repair	2.5	64	59	64	58	58	115	107	118	117	110	98	98	98	100	100
10	AK	3.5	M	77	16	Hypospadias	Repair	2	58	53	59	53	53	123	115	126	124	117	99	100	100	99	99
11	SG	5.5	M	84	22	Hypospadias	Repair	2.5	62	57	63	57	57	117	109	120	118	111	97	97	97	97	99
12	MK	2	M	76	14	Hypospadias	Repair	2	56	51	57	51	51	125	117	128	126	119	100	100	100	100	100
13	GK	7	F	86	24	Umbilical Hernia	Reduction	2.5	64	59	65	59	59	115	107	118	117	110	98	99	99	99	97
14	JK	4	M	80	18	Hypospadias	Repair	2	59	54	60	54	54	122	114	125	123	117	98	99	99	99	99
15	JR	5	F	82	20	Inguinal Hernia	Hemiotomy	2	61	56	62	56	56	119	111	122	120	113	99	99	99	99	99
16	GK	4.5	F	81	19	Inguinal Hernia	Hemiotomy	2	60	55	61	55	55	121	113	124	122	115	97	98	100	99	99
17	PG	3	F	78	16	Umbilical Hernia	Reduction	2	57	52	58	52	52	123	115	126	124	117	100	100	99	100	100
18	PL	6	F	85	22	Inguinal Hernia	Hemiotomy	2.5	63	57	64	58	57	117	109	120	118	111	98	98	99	99	99
19	DK	3.5	F	79	17	Hypospadias	Repair	2	58	53	59	53	53	122	114	125	123	116	98	100	100	98	98
20	CK	5.5	F	84	22	Inguinal Hernia	Hemiotomy	2.5	62	57	63	57	57	118	110	121	119	112	99	99	99	99	99

GROUP B3 (PROPOFOL - 5 mg/Kg + MIDAZOLAM-0.05 mg/Kg)

Sl.No.	Name	Age (yrs)	Sex	Height (cm)	Body wt. (kg)	Diagnosis	Operation Done	LMA Size	Mean Arterial Blood Pressure				Heart Rate per minute						Oxygen saturation (SPO2) ^Y	Inadequate jaw relaxation	Coughing	Gagging	Limb Movement	Laryngospasm										
									Baseline (BL)	Before Injection (BI)	After Injection (AI)	5min after Injection (5M)	10 min after Injection (10M)	Baseline (BL)	Before Injection (BI)	After Injection (AI)	5min after Injection (5M)	10 min after Injection (10M)							Baseline (BL)	Before Injection (BI)	After Injection (AI)	5min after Injection (5M)	10 min after Injection (10M)					
1	AK	4.5	F	81	19	Umbilical Hernia	Reduction	2	61	50	63	61	57	120	105	123	122	114	98	99	99	99	99	99	99									
2	BK	4	M	79	17	Hypospadias	Repair	2	59	40	62	60	56	122	107	125	125	116	98	99	100	99	99	99	99	99								
3	DK	5	F	83	21	Inguinal Hernia	Herniotomy	2.5	63	53	66	64	60	118	103	121	120	114	100	99	99	100	100	100	100	100								
4	CK	3.5	F	78	16	Inguinal Hernia	Herniotomy	2	58	48	61	58	54	123	108	126	124	118	99	98	98	98	98	98	98	98								
5	TK	5.5	M	84	22	Hypospadias	Repair	2.5	64	54	67	65	61	117	102	120	119	110	99	100	100	100	100	100	100	100								
6	RK	3	F	77	15	Ureteric stone	Pyelolithotomy	2	57	47	60	58	64	124	109	127	125	117	98	97	99	99	99	99	99	99								
7	MK	6	M	85	23	Hypospadias	Repair	2.5	65	54	67	65	61	116	101	119	118	110	97	98	99	99	99	99	99	99								
8	NK	2.5	F	77	15	Inguinal Hernia	Herniotomy	2	57	47	60	57	54	124	109	127	125	117	100	100	100	99	99	99	99	99								
9	LK	6.5	F	85	23	Inguinal Hernia	Herniotomy	2.5	65	54	67	65	61	116	101	119	118	111	98	99	99	100	100	100	100	100								
10	PK	2	F	76	14	Polydactyly	Excision	2	56	46	59	57	53	125	110	128	126	119	98	99	98	99	98	98	98	98								
11	VK	7	M	86	24	Hypospadias	Repair	2.5	66	55	68	66	62	115	100	118	118	110	97	99	100	98	99	98	99	99								
12	BK	4.5	F	81	19	Inguinal Hernia	Herniotomy	2	61	51	64	62	58	120	105	123	122	114	100	99	99	100	99	99	99	99								
13	SK	3.5	F	78	16	Inguinal Hernia	Herniotomy	2	59	49	62	60	56	122	107	125	124	116	99	99	99	99	99	99	99	99								
14	GK	5.5	M	84	22	Hypospadias	Repair	2.5	63	53	66	64	60	118	103	121	120	112	98	98	99	99	100	100	100	100								
15	JK	3	F	78	16	Clavicle Fracture	Reduction	2	58	48	61	59	55	123	108	126	124	116	98	100	100	98	98	98	98	98								
16	UK	6	M	84	23	Hypospadias	Repair	2.5	64	54	67	65	61	117	102	120	119	111	99	99	98	100	100	100	100	100								
17	TK	4	M	80	18	Hypospadias	Repair	2	60	50	63	61	57	121	106	124	123	115	100	99	99	99	99	98	98	98								
18	CK	5	M	82	20	Phimosis	Circumcision	2	62	52	65	63	59	119	104	122	121	113	98	99	99	99	99	99	99	99								
19	LK	3.5	M	79	17	Congenital dislocation	Reduction	2	58	48	61	59	55	123	108	126	125	117	98	100	100	100	100	100	100	100								
20	DK	5.5	M	83	21	Supracondylar Fracture	Reduction	2.5	64	54	67	65	61	117	102	120	119	111	97	97	97	98	98	98	98	98								