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Randomized double blind comparison of ketamine – propofol and fentanyl – propofol for the insertion of laryngeal mask airway in children

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***Abstract*---**The ideal combination that provides smooth insertion conditions with minimal side effects has not been identified, particularly in children. In this study, 70 children of age 3-12 years are divided randomly into 2 groups: Group 1-Group-F-Fentanyl (n=35) received Fentanyl 2µg/kg and Group 2-Group –K- Ketamine (n=35) received Ketamine 0.5mg/kg before induction of anaesthesia. Baseline heart rate and arterial blood pressure were measured. Vital parameters (Heart rate and Arterial Blood Pressure) were measured before induction, before LMA insertion and thereafter at 1, 3 and 5 minutes after LMA insertion. Ideal LMA insertion conditions were evaluated with six variables by blinded observer: mouth opening, gagging, head and limb movements, laryngospasm and resistance to insertion. Also the apnoea time was noted. The incidence of head/limb movements was statistically significant and Group Propofol – Ketamine showed 22% compared to Fentanyl-Propofol group (2.8%) Coughing/gagging was seen in 2.86% of both the groups**.** Resistance to insertion was statistically significant with p value of 0.0268 showing more in Propofol + Ketamine. There was no statistical significance in the occurrence of restricted mouth opening, restriction to LMA insertion and occurrence of swallowing between the two groups. Laryngospasm was absent in either groups. Fentanyl group showed the incidence of more apnoea (34.28) compared to Ketamine group (14.2). The heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP) were statistically more with Ketamine group than Fentanyl group. Co-induction with Fentanyl (2µ/kg) prior to Propofol (2.5mg/kg)

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induction for insertion of Laryngeal Mask Airway in children provided better insertion condition with minimal increase in heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure than admixture of Ketamine (0.5mg/kg) with Propofol.

***Keywords*---** children, propofol and fentanyl, ketamine.

Introduction

To master in anaesthesia profession, airway management is one of the most important skills. For securing patients airway under anaesthesia and providing adequate oxygenation and ventilation, various airway devices have become available. Undoubtedly, the endotracheal intubation is the definitive way of securing the airway. But this needs the usage of neuromuscular blocking agents and has its own side effects. Bag and mask ventilation may be used for providing anaesthesia for short surgical procedures.

Since the introduction of Laryngeal Mask Airway (LMA) by Dr. ARCHIE BRAIN, LMA has gained popularity among anaesthetist in securing and maintaining spontaneous ventilation in short surgical procedures bridging the gap between the endotracheal tubes and facemask. It frees the anaesthesiologist's hands for performing other important tasks, lesser incidence of airway injury and minimal cardiovascular and haemodynamic response.

Commonly, Propofol is used as induction agent for LMA insertion. The LMA insertion requires adequate depth of anaesthesia for obtundation of airway reflexes and also it has to be tolerated without undue coughing, bucking or laryngospasm. Many combinations of drugs have been tried for ideal LMA insertion conditions. Here, we have done a comparative evaluation of the conditions for LMA insertion with Ketamine versus Fentanyl adding Propofol in spontaneously breathing children undergoing day care procedures.

Aim of the study

To compare and estimate ideal insertion conditions for Laryngeal- Mask Airway with Ketamine versus Fentanyl adding Propofol in spontaneously breathing children undergoing day care procedures. To observe haemodynamic and other response to both drugs. The main objectives are:

1. Laryngeal Mask Airway ideal insertion conditions
2. Number of attempts at LMA insertion
3. Haemodynamic changes

Materials and Methods

This Prospective, randomized, double blinded, comparative study was conducted in the day care surgery theatre, Jawaharlal Nehru Medical College and Hospital, Bhagalpur, Bihar over a period of three months from January 2022 to March 2022.

In this study the incidence of apnoea with respect to success of LMA insertion in first attempt was published to be higher in the Fentanyl group (80%) compared to patients of Ketamine group(50%) with difference- 30%. Therefore 62 is the lowest sample size, possibly required for the study (n=31 in intervention arm and n=31 in control arm) So a sample size of 70 is taken in this study. A prospective, randomized, double -blinded controlled study was conducted on 70 ASA I & II children of both the sex, aging 3 -12 years undergoing elective surgery under general anaesthesia with spontaneous breathing using LMA.

Inclusion Criteria

- Age 3-12 years
- ASA :I& II
- Elective Surgeries
- Informed consent by the parents or guardians of the patients.

Exclusion Criteria

- ASA III & I V
- Patients not satisfying inclusion criteria.
- Patients who are at risk of aspiration.
- Patients with Airway abnormalities
- In patients with anticipated difficult airway.
- Reactive airway diseases.
- Known asthmatic
- Known egg allergy.
- Seizure disorder
- Neuro muscular diseases.

Materials

LMA - 2 size and 2.5 size, 16G, 20 G IV Cannula
Drugs-Propofol, Ketamine, Fentanyl, Oral Midazolam, Emergency drugs
Ringer Lactate
Monitors – Cuff pressure monitor, ECG, NIBP, SPO2

Methods

- 70 children were enrolled for the study over a period of three months. Preoperative assessment, investigations and evaluation were done. Informed consent got from the parents.
- Children were fasted 6hrs for solids and 4hrs for fluids. Oral Midazolam 0.5mg/kg, was given as premedication, 30mins prior to induction of anaesthesia. Midazolam (5mg/ml) IV preparation was mixed with honey in a syringe and given to all children, as oral preparation was not available.
- All children were monitored using sedation score :
  Grade I:anxious;agitated
  Grade II: oriented;calm, and co-operative
  Grade III: drowsy; responding to verbal commands
  Grade IV: responds to painful stimuli, but not to oral commands
  Grade V: does not respond to painful stimuli

Most of the children were under grade II sedation (57 out of 70).IV access was obtained in the dorsum of the hand with 22 G cannula without any agitation because of quietening effect of oral Midazolam.

- In the operation theatre, baseline parameters like heart rate (HR),blood pressure(NIBP) and oxygen saturation (SPO2) were recorded. Inj.glycopyrrrolate (0.005mg/kg) was given i.v 5 mins, prior to the administration of test drug. Patients were selected randomly by sealed envelope into 2 groups: Group F-Fentanyl group (n=35) and Group KKetamine
  group (n=35) as per the calculated doses based on body weight both Fentanyl and Ketamine were taken and subsequently diluted in normal saline. It was diluted to 10 ml by a blinded observer not involved in the study.
- Fentanyl of 2µg/kg was injected intravenously to group F over 10 seconds and 0.5mg/kg of Ketamine was injected intravenously to group K over 10 seconds.
- Pre-oxygenation was done with 100% oxygen for 3 minutes. Heart rate, blood pressure, SpO2 and respiratory rate were observed. Both the groups were induced with intravenous Propofol (prepared in a 10 ml syringe with 1 ml of 1% preservative free Lidocaine) in the dose of 2.5mg/kg was given over 15 seconds.
- Heart rate, blood pressure, SPO2 and respiratory rate were observed. After 90 seconds of start of Propofol injection, LMA (size selected according to body weight) was inserted by standard finger insertion technique.
- Cuff inflated with air to maintain a cuff pressure of not more than 60cms of H_2O ideally kept at 45cm of H_2O using cuff pressure monitor.
- Also HR, BP, SPO2 and RR noted just before LMA insertion.

Statistical Analysis

Descriptive statistics was done for all data and were reported in terms of mean values and percentages. Suitable statistical tests of comparison were done. Continuous variables were analyzed with the help of unpaired t-test. Categorical variables were analyzed with the help of Chi-Square Test and Fisher- Exact Test. Statistical significance was taken as $P < 0.05$. The data was analyzed using SPSS version and Microsoft Excel.

Results

Table 1: Age Distribution

Age Distribution	Ketamine + Propofol Group	%	Fentanyl + Propofol Group	%
≤ 3 years	5	14.29	6	17.14
4-6 years	25	71.43	19	54.29
7-9 years	4	11.43	10	28.57
> 9 years	1	2.86	0	0.00
Total	35	100	35	100

Age Distribution	Ketamine + Propofol Group	Fentanyl + Propofol Group
N	35	35
Mean	4.89	5.50
Sd	1.76	1.74
P value Unpaired t Test		0.1507

Majority of the Ketamine + Propofol Group patients belonged to the 4-6 years age class interval (n=25, 71.43%) with a mean age of 4.89 years. In the Fentanyl + Propofol Group patients, majority belonged to the 4-6 years age class interval (n=19, 54.29%) with a mean age of 5.50 years. The association between the intervention groups and age distribution is considered to be not statistically significant since $p > 0.05$ as per 2 tail unpaired t test.

Table 2: ASA

ASA Physical Classification System	Ketamine + Propofol Group	%	Fentanyl + Propofol Group	%
ASA 1	27	77.14	25	71.43
ASA 2	8	22.86	10	28.57
Total	35	100	35	100
P value Chi Squared Test			0.2991	

Majority of the Ketamine + Propofol Group patients belonged to the ASA 1 class interval (n=27, 77.14%). In the Fentanyl + Propofol Group patients, majority belonged to the ASA 1 class interval (n=25, 71.43%). The association between the intervention groups and ASA physical classification is considered to be not statistically significant since $p > 0.05$ as per Chi squared test.

Table 3 : Height Distribution

Height Distribution	Ketamine + Propofol Group	%	Fentanyl + Propofol Group	%
≤ 0.9 mts	9	25.71	4	11.43
1.0-1.1 mts	20	57.14	21	60.00
1.2-1.3 mts	6	17.14	10	28.57
0	0	0.00	0	0.00
Total	35	100	35	100

Height Distribution	Ketamine + Propofol Group	Fentanyl + Propofol Group
N	35	35
Mean	1.03	1.06
SD	0.11	0.10
P value Unpaired t Test	0.2263	

Majority of the Ketamine + Propofol Group patients belonged to the 1.0-1.1 mts height class interval (n=20, 57.14%) with a mean height of 1.03 mts. In the Fentanyl + Propofol Group patients, majority belonged to the 1.0-1.1 mts height class interval (n=21, 60%) with a mean height of 1.06 mts. The association between the intervention groups and height distribution is considered to be not statistically significant since p > 0.05 as per 2 tail unpairedt test.

Table 4 : BMI Distribution

BMI Distribution	Ketamine + Propofol Group	%	Fentanyl + Propofol Group	%
Underweight (≤ 18.49)	33	94.29	35	100.00
Normal (18.50 to 24.99)	2	5.71	0	0.00
Overweight (25 to 29.99)	0	0.00	0	0.00
Obese	0	0.00	0	0.00
Total	35	100	35	100

BMI Distribution	Ketamine + Propofol Group	Fentanyl + Propofol Group
N	35	35
Mean	12.95	13.59
SD	2.02	1.53
P value Unpaired tTest	0.1417	

Majority of the Ketamine + Propofol Group patients belonged to the underweight BMI class interval (n=33, 94.29%) with a mean BMI of 12.95. In the Fentanyl + Propofol Group patients, majority belonged to the underweight BMI class interval (n=35, 100%) with a mean BMI of 13.59. The association between the intervention groups and BMI distribution is considered to be not statistically significant since p > 0.05 as per 2 tail unpaired t test.

Table: 5 LMA Insertion Ease

LMA Insertion Ease	Ketamine + Propofol Group	%	Fentanyl + Propofol Group	%
Satisfactory	21	60.00	33	94.29
Difficult	14	40.00	2	5.71
Total	35	100	35	100
P value Fishers Exact Test			0.0007	

In patients belonging to Ketamine + Propofol Group, the satisfactory LMA insertion procedure was 60% (n=21). In Fentanyl + Propofol Group, the satisfactory LMA insertion procedure was 94.29% (n=33). The increased percentage of satisfactory LMA insertion procedure in Fentanyl + Propofol Group compared to the Ketamine + Propofol Group is statistically significant as the p value is 0.0007 as per fisher's exact test indicating a true difference among study groups.

The percentage of satisfactory LMA insertion procedure was significantly more in Fentanyl + Propofol Group compared to Ketamine + Propofol Group by 34.29 percentage points. This significant difference of 1.57 times increase in percentage of satisfactory LMA insertion procedure in Fentanyl + Propofol Group compared to Ketamine + Propofol Group is true and has not occurred by chance. Satisfactory LMA insertion was significantly and consistently more in Fentanyl + Propofol Group compared to Ketamine + Propofol Group, when used for Laryngeal Mask Airway insertion in Children.

Table 6: LMA Insertion Attempts

LMA Insertion Attempts	Ketamine + Propofol Group	%	Fentanyl + Propofol Group	%
One	29	82.86	32	91.43
Two	6	17.14	3	8.57
Total	35	100	35	100
P value Fishers Exact Test			0.3139	

Ketamine + Propofol Group patients had 1 attempt on successful LMA insertion (n=29, 82.86%). In the Fentanyl + Propofol Group patients, majority patients had one attempt on successful LMA insertion (n=32, 91.43%). The association between the intervention groups and LMA insertion attempts is considered to be statistically not significant since p value is greater than 0.05 as per fishers-exact test.

Table: 7 Problems during LMA Insertion

LMA Insertion Problems	Ketamine + Propofol Group	%	Fentanyl + Propofol Group	%	P value Fishers Exact Test
Nil	21	60.00	33	94.29	REF
Limb Movements	8	22.86	1	2.86	0.0148
Resist to Insertion	5	14.29	0	0.00	0.0268
Gagging	1	2.86	1	2.86	0.9999
Total	35	100	35	100	

In patients belonging to Ketamine + Propofol Group, limb movement was the main LMA insertion problem noted (n=8, 22.86%). In Fentanyl + Propofol Group too, the limb movement was the main LMA insertion problem (n=1, 2.86%). The decreased percentage of limb movement is the main LMA insertion problem in Fentanyl + Propofol Group compared to the Ketamine + Propofol Group which is statistically significant as the p value is 0.0148 as per fishers exact test indicating a true difference among study groups. Similarly thepercentage of resistance to insertion is found to be decreased in Fentanyl + Propofol Group compared to the Ketamine + Propofol Group, which is statistically significant as the p value is 0.0268 as per fishers-exact test indicating a true difference among study groups.

The percentage of limb movement as the main LMA insertion complication was statistically less in Fentanyl + Propofol Group compared to Ketamine + Propofol Group by 22 percentage points. This significant difference of 87% decrease in percentage of limb movement as the main LMA insertion complication in Fentanyl + Propofol Group compared to Ketamine + Propofol Group is true and has not occurred by chance.

The percentage of resistance to insertion as the other LMA insertion complication was statistically less in Fentanyl + Propofol Group compared to Ketamine + Propofol Group by 14.29 percentage points. This significant difference of 100% decrease in percentage of resistance to insertion as the other LMA insertion complication in Fentanyl + Propofol Group compared to Ketamine + Propofol Group is true and has not occurred by chance LMA insertion complication like limb movements and resistance to insertion were significantly and consistently lower in Fentanyl + PropofolGroup compared to Ketamine + Propofol Group when used in insertion of Laryngeal Mask Airway in Children.

Table : 8 Systolic Blood Pressure (SBP)

Systolic Blood Pressure		Baseline	Pre Ind	Pre LMA	1 min	3 Mins	5 Mins
Ketamine + Propofol Group	N	35	35	35	35	35	35
	Mean	101.06	109.03	92.94	91.40	90.83	92.60
	SD	8.80	8.60	10.97	7.03	8.92	10.49

Fentanyl + Propofol Group	N	35	35	35	35	35	35
	Mean	103.40	98.60	84.46	85.69	88.00	88.26
	SD	9.04	10.36	9.02	8.23	9.45	9.10
P value Unpaired T Test		0.2759	0.0000	0.0008	0.0027	0.0022	0.0488

By conventional criteria the association between the intervention groups and SBP status among study subjects is considered to be statistically significant since $p < 0.05$. In patients belonging to Ketamine + Propofol Group, the mean SBP is 96.31 mm Hg. In Fentanyl + Propofol Group the mean SBP is 91.40 mm Hg. The increased the mean SBP measurement in Ketamine + Propofol Group compared to the Fentanyl + Propofol Group is statistically significant as the p value is 0.0000, 0.0008, 0.0027, 0.0022 and 0.0488 between preinduction and 5 minutes on induction as per unpaired t- test indicating a true difference among study groups.

The mean SBP measurement was statistically more in Ketamine + Propofol Group compared to the Fentanyl + Propofol Group by 1.05 times with a mean difference of 4.91 mm Hg. This difference is true and significant and has not occurred by chance. The mean systolic blood pressure measurement was significantly and consistently higher in Ketamine + Propofol Group compared to the Fentanyl + Propofol when used in insertion of Laryngeal Mask Airway in Children.

Table 9: Diastolic Blood Pressure (DBP)

Diastolic Blood Pressure		Baseline	Pre Ind	Pre LMA	1min	3Mins	5 Mins
Ketamine + Propofol Group	N	35	35	35	35	35	35
	Mean	63.20	66.80	58.43	53.60	53.94	55.26
	SD	9.01	8.36	8.80	7.64	8.31	9.61
Fentanyl + Propofol Group	N	35	35	35	35	35	35
	Mean	66.29	61.77	50.46	48.97	51.37	51.00
	SD	10.11	8.62	8.05	6.71	8.08	7.99
P value Unpaired T Test		0.1822	0.0157	0.00022	0.0089	0.0140	0.0480

By conventional criteria the association between the intervention groups and DBP status among study subjects is considered to be statistically significant since $p < 0.05$. In patients belonging to Ketamine + Propofol Group, the mean DBP is 58.54 mm Hg. In Fentanyl + Propofol Group the mean DBP is 54.98 mm Hg. The increase in the mean DBP measurement in Ketamine + Propofol Group compared to the Fentanyl + Propofol Group is statistically significant as the p value is 0.0157, 0.0002, 0.0089, 0.0140 and 0.0480 between preinduction and 5 minutes on induction as per unpaired t- test indicating a true difference among study groups.

The mean DBP measurement was statistically more in Ketamine + Propofol Group compared to the Fentanyl + Propofol Group by 1.06 times with a mean difference of 3.56 mm Hg. This difference is true and significant and has not occurred by chance. The mean diastolic blood pressure measurement was significantly and

consistently higher in Ketamine + Propofol Group compared to the Fentanyl + Propofol when used in insertion of Laryngeal Mask Airway in Children.

Table 10: Respiratory Rate (RR)

Respiratory Rate		Baseline	Pre Induction	Pre LMA	1 Minute	3 Minutes	5 Minutes
Ketamine + Propofol Group	N	35	34	34	34	35	35
	Mean	18.60	20.50	18.85	24.38	24.11	22.34
	SD	3.47	3.63	5.23	5.81	4.01	3.16
Fentanyl + Propofol Group	N	35	32	32	34	35	35
	Mean	17.83	16.69	14.19	18.15	19.43	18.89
	SD	3.66	3.91	4.46	5.06	5.16	3.79
P value Unpaired T Test		0.3689	0.0001	0.0002	0.0000	0.0001	0.0001

By conventional criteria the association between the intervention groups and respiratory rate status among study subjects is considered to be statistically significant since $p < 0.05$. In patients belonging to Ketamine + Propofol Group, the mean RR is 21.47. In Fentanyl + Propofol Group the mean DBP is 17.53. The increased themean RR measurement in Ketamine + Propofol Group compared to the Fentanyl + Propofol Group is statistically significant as the p value is 0.0001, 0.0002, and 0.0000 between preinduction and 5 minutes on induction as per unpaired t- test indicating a true difference among study groups. The mean RR measurement was more in Ketamine + Propofol Group compared to the Fentanyl + Propofol Group by 1.22 times with a mean difference of 3.94 breaths per minute. This difference is true and significant and has not occurred by chance. The mean respiratory rate measurement was significantly and consistently higher in Ketamine + Propofol Group compared to the Fentanyl + Propofol when used in insertion of Laryngeal Mask Airway in Children

Table 11: Apnoea

Apnoea Time	Ketamine + Propofol Group	%	Fentanyl + Propofol Group	%
≤ 2 minutes	4	80.00	9	75.00
2.01-5 minutes	1	20.00	2	16.67
> 5 minutes	0	0.00	1	8.33
Total	5	100	12	100

Apnoea Time	Ketamine + Propofol Group	Fentanyl + Propofol Group
N	5	12
Mean	98.00	122.92
SD	113.00	131.09
P value Unpaired t Test		0.0025

In patients belonging to Ketamine + Propofol Group, the mean apnoea time is. 98.00 seconds. In Fentanyl + Propofol Group, the mean apnoea time is 112.92 seconds.. The increased mean apnoea time in Fentanyl + Propofol Group compared to the Ketamine + Propofol Group is statistically significant as the p value is 0.0025 as per unpaired t- test indicating a true difference among study groups. Also, only 8.33% of Fentanyl + Propofol showed prolonged apnoea> 5mins which is statistically insignificant.

The mean apnoea time was more in Fentanyl + Propofol Group compared to Ketamine + Propofol Group by 24.92 seconds. This significant difference of 1.25 times increase in mean apnoea time in Fentanyl + Propofol Group compared to Ketamine + Propofol Group is true and has not occurred by chance. The mean apnoea time was significantly and consistently higher in Fentanyl + Propofol Group compared to Ketamine + Propofol Group when used in insertion of Laryngeal Mask- Airway in Children

Table 12: LMA Extubation Complications

LMA Extubation Complications	Ketamine + Propofol Group	%	Fentanyl + Propofol Group	%	P value Fishers Exact Test
Nil	31	88.57	35	100.0	REF
Blood Stain	1	2.86	0	0.00	0.9999
Cough	3	8.57	0	0.00	0.1196
Total	35	100	35	100	

Majority of the Ketamine + Propofol Group patients had cough as the main LMA extubation complication (n=3, 8.57%). In the Fentanyl + Propofol Group patients, majority patients had no LMA extubation complication (n=35, 100%). The association between the intervention groups and LMAextubation complications is considered to be not statistically significant since $p > 0.05$ as per fishers exact test.

Discussion

Endotracheal intubation is a routine procedure to conduct general anaesthesia and also a secured way of having a control over airway. But laryngoscopy and tracheal intubation, produce stress response that leads to reflex surge in sympatho-adrenal activity .This causes a raise in heart rate and blood pressure leading to dysarrhythmias, which are lethal to cardiac patients.
Face masks are routinely used for short surgical procedures during induction and maintenance under TIVA (Total intravenous anaesthesia) and for volatile induction. But it has the disadvantage of holding the mask continuously in spontaneously breathing patients. Laryngeal Mask Airway started gaining popularity as an alternative to endotracheal intubation as well as facemask because it causes less hemodynamic changes, associated with negligible raise in intraocular pressure after inserting LMA, causes decreased incidence of sore throat and also frees the hands of the anaesthesiologist to perform other

important tasks during the surgical procedures. It also provides a beneficial outcome especially in ENT and ophthalmic surgeries where excessive straining is potentially harmful, as it has a low incidence of coughing during emergence.

Even for the inexperienced provider, the LMA acts as an excellent airway device in many clinical areas that includes the emergency room, the operating room, and in ambulatory care as it is easy to handle even by untrained hands. Nearly 100% success rate for LMA placement occurs in the operating room. A lower rate of achievement for LMA placement may be expected in the emergency setting.

Use of LMA in children is becoming increasingly common. To achieve easy LMA insertion, obtundation of airway reflexes is a must, so that coughing, gagging, head and limb movements or laryngospasm can be avoided Sufficient depth of anaesthesia is needed for adequate mouth opening. Succinylcholine can be used for suppressing these sequelae, but with the disadvantage of muscle pain. Propofol is currently used as induction agent for LMA insertion, as it depresses airway reflexes more than Thiopentone. However, when Propofol is used alone higher doses are required to reduce pharyngeal and laryngeal reflexes which might cause cardiac depression and also makes LMA insertion conditions unsatisfactory.

Combination therapy termed as co-induction, may provide enhanced effects, more of desired effect rather than adverse effects, with minimal costs. Recently, in various anaesthetic procedures, the concept of co-induction has been proved better. Various combinations of drugs like Propofol-Fentanyl, Propofol-Ketamine, Propofol-Midazolam have been tried. Comparisons have been made between Propofol 2.5mg/kg with Fentanyl 2μg/kg and Propofol 2.5mg/kg with Ketamine 0.5mg/kg with reference to ideal LMA insertion conditions.

In my study, the insertion conditions of LMA were observed on the basis of 6 variables such as resistance to mouth opening, resistance to insertion, swallowing, coughing, gagging, limb and head movements and laryngospasm as proposed in Sivalingam *et al*[7] and Cheam *et al*[2] study. In our study the patients showed 94.29 % satisfactory insertion condition with Fentanyl + Propofol group compared to Ketamine + Propofol with 60%.

The frequent variable that we encountered was limb and head movements that too especially limb movements. The higher incidence of head and limb movements in Group Propofol + Ketamine could be due to the combined effects of excitatory movements caused by Propofol and increased muscle tone caused by Ketamine. Also the incidence of head and limb movements in Group PF (2.86%) was less compared to Group Propofol + Ketamine (22.86%) with $p<0.0148$ which is significant. Ranju Singh et al, in their study also found that a statistically highly significant head and limb movements ($p=0.007$) were encountered in Group PK(Propofol+Ketamine) compared to Group PF (Propofol+Fentanyl).

The study done by Goh PK *et al*[4], showed greater occurrence of head and limb movement in Ketamine group(40%) than Fentanyl group (16%), the incidence was more than what we noted. There was no laryngospasm in both the groups in our study. This has been supported by the study done by Ranju Singh *et al*[5],

which showed nil occurrence of laryngospasm Group Propofol + Fentanyl had adequate (100%) jaw relaxation showing nil case of resistance to insertion with 14.29% resistance to insertion in Group Propofol + Ketamine of p<0.0268. Our results are consistent with the study conducted by Asha Gupta and Sarabjit Kaur[1] in which they compared jaw relaxation according to Young's criteria. Their results showed that the incidence of absolute jaw relaxation was highest in Group PB (Propofol + Butarphanol) - 28(93.33%), intermediate in Group PF (Propofol + Fentanyl) - 53.33% and lowest in Group PK(Propofol + Ketamine) -11 patients (36.66%).

Tanmoy Ghatak et al, also compared the efficiency of Ketamine +Propofol, Fentanyl + Propofol or Saline + Propofol for hemodynamic features and insertion conditions for LMA in children premedicated with oral Clonidine. Ketamine and Fentanyl group showed a significantly better LMA insertion summed score (P<0.004) and was similar in both the groups than saline group.

But the dose of Fentanyl they used was 1µg/kg. In a study by Gamal T Yousef et *al*[3], used Ketofol as induction agent, that lead to adequate jaw relaxation and adequate mouth opening in the KP group i.e., Ketamine + Propofol {n=45 (90%)}than in the Propofol group {n=38(76%)}. Bahk JH *et al*[10], studied ideal insertion conditions with different doses of Propofol along with Ketamine + Lidocaine spray for inserting LMA. The study concluded that, dosage more than 3 mg/kg of Ketamine achieved satisfactory degree of jaw relaxation.

Goh PK *et al*[4] in his study reported 23% of patients in Fentanyl group required additional bolus dose of Propofol compared to 10% of patients in Ketamine group. Our study showed only 8.5% of patients in Fentanyl group required additional bolus dose of Propofol with second attempt, compared to 17.1% of patients in Ketamine group. He has also reported that inserting LMA and resistance to mouth opening was found to be higher in Fentanyl group. The incidence of coughing/gagging between the two groups was not significant in our study. There was higher occurrence of coughing & gagging in KP Group (Ketamine-Propofol),of the study conducted by Asha Gupta et al, compared to Fentanyl-Propofol and Butorphanol-Propofol.

The overall insertion ease was significantly good with Group PF compared to Group PK (p=0.0007). Statistically, a high incidence of apnoea was observed in Group PF with p<0.0025 in our study. Supporting our study, the study conducted by Asha Gupta et *al,* the incidence of apnoea was greater with Propofol – Fentanyl compared to Propofol-Butorphanol because of Butorphanol receptor specificity and µ antagonism. The incidence is greatest with Group PF and also the mean duration of apnoea was greatest with Group PF. Also the study conducted by Cheam EWS and Chui PT et al[2], showed that Fentanyl improved the conditions during Laryngeal Mask Airway insertion, but showed prolonged duration of apnoea. Study conducted by Ranju Singh *et al*[5], showed more incidence of apnoea with 40 children out of 50 in Fentanyl group (80%) compared to 25 children out of 50 in Ketamine group (50%). Also in my study, prolonged apnoea was shown in 1 child out of 35 with Fentanyl group compared to none in Ketamine group. But study conducted by Ranju Singh et al[5], showed prolonged apnoea in Ketamine + Propofol group (14%) as compared to Fentanyl + Propofol

group (12%).In the study conducted by Goh PK et al[4], the occurrence of sustained apnoea was higher in group Fentanyl (23.1%) than group Ketamine(6.3%). Sustained apnoea happened more with Fentanyl than Ketamine or saline group by Gatak et al[8] study.

The apnoea caused by either Fentanyl or Ketamine has little clinical significance and this parameter may in fact allow enough time in checking the LMA position after insertion by manual ventilation. Kodaka et al[11] noted that a Fentanyl dose of 0.5 µg/kg is adequate to reduce predicted EC-50LMA (the effective concentration for 50% of the attempts to secure laryngeal maskinsertion of Propofol using a target-controlled infusion with minimum respiratory depression and without a high BIS value.)

In our study, the baseline parameters like heart rate (p=0.7), systolic blood pressure (SBP) (p=0.264) and diastolic blood pressure (DBP) (p=0.182) were same for the both the groups. Group PK showed a significant rise in systolic, diastolic blood pressure and mean arterial pressure during preinduction, pre LMA insertion, 1 min after LMA insertion and 3 mins after LMA insertion. This effect of Ketamine is due to indirect sympathomimetic action on sinus node. Our results were similar with those of Ranju Singh et al[5] in which Ketamine showed higher mean arterial pressure throughout the study period as compared to the Fentanyl group. Studies done by Goh PK *et al[4], Ghatak*et[8] and Asha Gupta et al[1] also showed similar results supporting our study.

Heart rate was found to be higher in Group PK compared to Group PF in our study .This similar outcome was observed in studies of Goh Pk et al[4], Ghatak et al[8] and Asha Gupta et al[1]. Pain while injecting Propofol is considered as a negligible complication, but it might lead to uncooperation and distress to the child. Pain can be due to activation of kininogens or by the free aqueous concentration of Propofol in the emulsion.

In our study, pain following Propofol injection was similar in all the groups and was statistically insignificant between two groups. This was analogous to the study done by Ritu Goyal et al[6]. The study done by Ritu Sinha also found that, apart from addition of Propofol with Lignocaine (preservative free), Thiopentone mixed with Propofol causes decreased release of kinins and altered pH in admixture preventing injection pain during Propofol.

Conclusion

In this study, I conclude that co-induction with Fentanyl (2µg/kg) prior to Propofol (2.5 mg/kg) for insertion of Laryngeal Mask Airway in children provided better insertion conditions and minimal alteration in haemodynamic parameters than co-induction with Ketamine (0.5 mg/kg) and Propofol (2.5 mg/kg).

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