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Original research article

The efficacy of ketamine or fentanyl with propofol induction for classic laryngeal mask airway insertion in paediatric patients undergoing elective surgeries:A prospective randomized comparative study

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Abstract
With increasing scope for the use of laryngeal mask airway in children, it has led to the imperative change in practice of modern general anaesthesia. Being the preferred induction agent used for LMA insertion, propofol has many undesirable effects. To identify the ideal combination of drugs for induction to augment smooth insertion of LMA in children many studies are going on comparing different adjuncts. This study is designed to determine the efficacy of ketamine which produce cardiostimulatory effect and fentanyl which provides analgesia and reduces the dose of propofol for insertion LMA in children. After taking parental informed, written and valid consent, patients were randomly allocated into 2 groups, Group KP (ketamine-propofol, n=30) receiving 0.5mg/kg ketamine and Group FP (fentanyl-propofol, n=30) receiving 2mcg/kg fentanyl before induction with propofol 3mg/kg. Classic LMA of appropriate size is inserted following induction. The ease of insertion was found to be similar in both groups.The time for jaw relaxation and time for insertion of cLMA was statistically more in ketamine group with p value< 0.05.
Keywords: Fentanyl, ketamine, propofol,paediatric LMAinsertion

Introduction

The development of small sized laryngeal mask airways allowed its increasing use in paediatric anaesthesia because of ease of insertion and minimal disturbances in cardio respiratory system and lesser risk of airway injury during perioperative period as compared to endotracheal tube. It is also simple, well-tolerated, safe, reusable, cost effective method of airway management in paediatric patients[1].

These patients have different airway characteristics such as high larynx, large tongue, funnel shaped laryngeal cartilaginous skeleton, lack of teeth and short neck which makes the possibility of difficult intubation higher than in adult patients. Added to this is the rapid development of hypoxemia during trials of intubation in a rather difficult airway [3,4]. Effective insertion of the LMA entails optimum anaesthetic depth to elude undesirable airway reflexes such as swallowing, gagging, coughing or involuntary movements to severe problems such as laryngospasm[2].

Propofol is one of the most useful induction drugs for insertion of supraglottic airways, in children because of its superior relaxation of the jaw and suppression of airway reflexes.It is a non-opioid, non-barbiturate, sedative-hypnotic agent with rapid inductionand recovery times and antiemetic effects. However ithas some adverse effects which include cardiorespiratory depression, pain on injection with higher doses. Lighter plane of anaesthesia with lower dose produces coughing, gagging, laryngospasm and movement. Also, it do not have analgesic property. The large central compartment volume in children makes the induction dose calculation difficult when it is used as a sole induction agent. To combat these problems many studies undertaken to see the effect of adjuvants[3].

Ketamine has little or no cardio-respiratory depression and unlike propofol, has pain relieving properties. Its use as a single induction agent is limited by emergence hallucinations, elevation of blood pressure and heart rate due to its sympathomimetic effects and increased intracranial pressure. It is well-known for its airway reflexes preservation[4].

These properties make ketamine desirable in paediatric anaesthesia along with propofol. The

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combination of propofol- ketamine attenuates hemodynamic depression intraoperatively without causing respiratory depression. Effectiveness of the two agents-propofol and ketamine - in combination (ketofol) has been recently demonstrated and may provide a novel induction agent with favourable haemodynamics and reduced side effects attributed to either drugs[5].

The addition of opioids such as fentanyl has shown to improve the insertion conditions with an overall success rate of up to 85-95%. Fentanyl pre-treatment also reduces propofol requirement and provides analgesia for LMA insertion. But fentanyl also has problems like respiratory depression and suppression of airway reflexes in dose-related manner[6].

This prospective randomized double blind study was done to assess and compare efficacy of ketamine and fentanyl for insertion of classic laryngeal mask airway in children undergoing elective surgeries. Ketamine and fentanyl will be compared for ease of LMA insertion and incidence of complications such as coughing/gagging, sore throat and laryngospasm.

Methodology

Approval for this prospective, randomized double blind comparative study was obtained from the institute ethical committee. A total number of 60 patients of either sex aged 3-11 years belonging to ASA status I-II scheduled for elective surgery under general anaesthesia and satisfying the inclusion criteria was enrolled in the study after taking parental informed, written and valid consent. Patients were randomized into two groups.

Group KP (n=30): Patients receiving ketamine and propofol for induction. Group FP (n=30): patients receiving fentanyl and propofol for induction.

Inclusion criteria

- Age 3-11 years.
- American society of anaesthesia (ASA) physical status: 1 and 2.
- Undergoing elective surgeries.
- Informed, written and valid consent by parents or guardians of patients.

Exclusion criteria

- Mouth opening less than 2.5 cm.
- Patients who are at risk of aspiration.
- Patients with reactive airway disease.
- Patients with seizure disorder.
- Patients with anticipated difficult airway.
- Known case of neuromuscular disease.

Method of study

This study was a prospective, randomized study of individuals satisfying all inclusion criteria. All patients in the inclusion criteria were assessed by an anaesthsiologist a day prior to surgery. Parental informed, valid and written consent was obtained after pre-anaesthetic evaluation. All patients were advised to be nil per oral as per current ASA guidelines.

On arrival to the operating room, the patients were allocated into two groups by computer generated random numbers and allocation concealment was done by serially numbered closed envelopes.

1. Group KP (n=30) received ketamine (0.5mg/kg) and propofol (3.5mg/kg).
2. Group FP (n= 30) received fentanyl (2mcg/kg) and propofol (3.5 mg/kg).

An intravenous access was secured on the non-dominant hand and infusion of ringer lactate started according to fluid requirement of child.

The patients were connected with non-invasive multi-parameter monitor which includes pulse oximeter(spO2), noninvasive blood pressure (NIBP), electrocardiogram (ECG) and end-tidal CO2 are noted. Administration of intravenous midazolam 0.05 mg/kg 30min prior to induction and intravenous glycopyrrolate 0.005 mg/kg 5 minutes prior to induction was done. A pre-procedure self-testing of the anaesthesia machine and circuit was done. Propofol was prepared in a 10 ml syringe with 1ml of 1% preservative free lidocaine. Both ketamine and fentanyl was taken as per calculated doses based on body weight and that volume was subsequently diluted in normal saline to make a volume of 10ml. The study drug preparation and administration was done by an anaesthesiologist who is not involved in investigation of study.

All patients were pre-oxygenated with 100% oxygen for 3 minutes. Group KP received IV ketamine 0.5 mg /kg over 10seconds.

Group FP received IV fentanyl 2mcg/kg over 10seconds.

Generalanaesthesiawasinducedwithintravenouspropofol(premixedwith preservative free lidocaine) in the

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dose of 2-3mg/kg given over 15seconds.
The adequacy of anaesthesia was assessed by -
1) Loss of response to verbal commands.
2) Loss of eyelash reflex.

Appropriate size classic LMA was choosen based on the child weight. It used to be lubricated with a water based jelly and cLMA of appropriate size was inserted 90 seconds following intravenous propofol administration using index finger with Dr.Brain`s techniques by an investigator who was not aware of drug administered. Following insertion investigator assessed the Classic LMA insertion conditions using following parameters involving 3 point score. The investigator as well as patient was blinded to the drug injected.

Results

Table1: Distribution based on age category, gender and ASAphysicalstatus

Sl.No.	Features	Group-1 (N=30) n (%)	Group-2 (N=30) n (%)	p value#
1.	**Age category**			
	3 – 6	13 (43.3)	16 (53.3)	0.44
	7 – 11	17 (56.7)	14 (46.7)	
2.	**Gender**			
	Male	24 (80)	25 (83.3)	0.74
	Female	6 (20)	5 (16.7)	
3.	**ASA grade**			
	Grade-I	30 (100)	30 (100)	NA

Note:#pvaluebasedonChi-squaretest,NA-NotApplicable

It is evident that age distribution of participants in group fentanyl -propofol and ketamine-propofol are comparable. Comparision is done with chi square test and p value of 0.44 which is more than 0.05.
It is evident that both groups are comparable with respect to gender distribution. Chi square test was used for the comparison.
Group fentanyl- Propofol has 24(80%) male and 6 female (20%) patients. Group ketamine-propofol has 25 male (83.3%) and 5 female (16.7%) patients. The p value is 0.74 which is statistically insignificant.

Table 2: Comparison of time to jaw relaxation and time to insertion of CLMA

Sl.No.	Features	Group-1 (N=30)Mean (SD)	Group-2 (N=30)Mean (SD)	p value#
1	Time to jaw relaxation	50.2 (2.8)	60.3 (3.5)	<0.001*
2	Time for insertion	58.1 (3.6)	69.4 (3.9)	<0.001*

Note: # p value based on independent sample t test. * Statistically significant (p<0.05)

The mean time for jaw relaxation in Group Fentanyl- propofol was 50.2 seconds with a SD 2.8 seconds. In Group Ketamine-propofol, the mean time for jaw relaxation was60.3 seconds with a SD 3.5 seconds. Independent samples t test was used for the comparison of two groups.The p value of was found between the two groupsis<0.001.
The mean time to insertion of laryngeal mask airway in Group Fentanyl- propofol was58.1 seconds with a SD 3.6seconds. In Group Ketamine-propofol, the mean time to insertion was 69.4 seconds with a SD 3.9 seconds. Independent samples t test was used for the comparison of two groups. The p value of was found between the two groups is <0.001.

Table3: Comparison of ease of insertion of CLMA

Sl.No.	Features	Group-1 (N=30) n (%)	Group-2 (N=30) n (%)	p value#
1	Resistance to MO			
	1	27 (90)	25 (83.3)	0.45
	2	3 (10)	5 (16.7)	
2	Resistance to insertion			
	1	28 (93.3)	27 (90)	0.64
	2	2 (6.7)	3 (10)	
3	Number of attempts			
	1	30 (100)	29 (96.7)	0.31
	2	0	1 (3.3)	

Note: # p value based on Chi-square test

The resistance to mouth opening was nil in 27(90%) and significant in 3(10%) participants among group fentanyl-propofol and it was nil in 25(83.3%) and significant in 5(16.7%) among ketamine-prpofol

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group. Both groups are compared using chi square test. The p value is 0.45 that is more than 0.05 hence the result was insignificant.
The resistance to insertion in fentanyl-propofol group was easy in 28(93.3%) and difficult in 2(6.7%) participants. In ketamine-propofol group the resistance was easy in 27(90%) and difficult in 3(10%) participants. Both groups are compared using chi square test. The p value is 0.64 which is more than 0.05 hence the results are insignificant.
It is evident that in fentanyl-propofol group the number of attempts taken for insertion is single in all 30 participants. In ketamine-propofol group number of attempts is single in 29(96.7%) and twice in 1(3.3%) participants. Both groups are compared by using chi square test. The p value is 0.34 which is more than 0.05 hence the results are insignificant.
The above three parameters time for resistance to mouth opening, resistance to LMA insertion and number of attempts determine the ease of insertion and the results are insignificant because p value is more than 0.05. Hence the ease of insertion is similar in both groups.

Table4: Comparison of incidence of complications

Sl.No.	Incidence of complications	Group-1 (N=30) n (%)	Group-2 (N=30) n (%)	p value#
1	Coughing and gagging			
	No	28 (93.3)	22 (73.3)	
	Yes	2 (6.7)	8 (26.7)	0.04*
2	LH movements			
	Nil	27 (90)	26 (86.7)	
	Slight	2 (6.7)	3 (10)	0.89
	Gross	1 (3.3)	1 (3.3)	
3	Laryngospasm	0	0	NA
4	Sore throat			
	No	28 (93.3)	28 (93.3)	0.99
	Yes	2 (6.7)	2 (6.7)	
5	Dysphagia	0	0	NA
6	Hoarseness	0	0	NA

Note:# p valuebasedonChi-squaretest,NA-NotApplicable,*statistically significant (p<0.05)

Statistical analysis is done using chi square test. In the fentanyl propofol group 6.7% patients had slight coughing and gagging compared to 26.7% in ketamine propofol showing statistically significant results**.** Incidence of mild sore throat is 6.7% patients in both groups, which is statistically insignificant.
There was slight limb and head movements in 6.7% of fentanyl-propofol compared to 10% in ketamine-propofol group. However the results were statistically insignificant**.** There was nil result for incidence of hoarseness, dysphagia and laryngospasm in both the groups. The analysis have shown that the difference in incidence and severity of complications as statistically insignificant except for coughing and gagging which was more in ketamine-propofol group.

Discussion

The mean time for jaw relaxation in Group Fentanyl- propofol was 50.2 seconds with a SD 2.8 seconds. In Group Ketamine-propofol, the mean time for jaw relaxation and time for insertion was 60.3 seconds with a SD 3.5 seconds. The results were statistically significant with p value of <0.001. Jaw relaxation was measured by Young`s criteria in our study and time taken for grade 1 jaw realaxation that is absolute relaxation with no muscle tone is noted before attempting to insert LMA.
The mean time to insertion of laryngeal mask airway in Group Fentanyl-propofol was58.1 seconds with a SD 3.6seconds. In Group Ketamine-propofol, the mean time for jaw relaxation and time for insertion was 69.4 seconds with a SD 3.9 seconds. The results were statistically significant with p value of <0.001.
A prospective, randomized study conducted by Saravanan Ravi, KarthikKrishnamoorthy and IlangoGanesan, to compare sevoflurane and propofol for laryngeal mask airway insertion in children has shown significant results for time to jaw relaxation and time to LMA insertion[7].
Propofol has shown earlier jaw relaxation of 49.4± 5.69 seconds compared to sevoflurane (107±17.51) and also shorter time to cLMA insertion of 59.3 ±6.8 seconds compared to sevoflurane (117.9±19.2 seconds).
In our study induction with fentanyl- propofol has shown earlier jaw relaxation and shorter time to insert cLMA similar to above mentioned study and induction with ketamine-propofol has shown significant prolongation of both time to jaw relaxation and time to cLMA insertion.
Ease of insertion was assessed by three parameters resistance to mouth opening, resistance to insertion and number of attempts.
The resistance to mouth opening was nil in 27(90%) and significant in 3(10%) participants among group fentanyl-propofol and it was nil in 25(83.3%) and significant in 5(16.7%) among ketamine-prpofol group. The results were statistically comparable between two groups with p value 0.45.

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The resistance to insertion in fentanyl-propofol group was easy in 28(93.3%) and difficult in 2(6.7%) participants. In ketamine-propofol group the resistance was easy in 27(90%) and difficult in 3(10%) participants. The results were statistically comparable between two groups with p value was 0.64.

In fentanyl-propofol group the number of attempts taken for insertion is single in all30 participants. In ketamine-propofol group number of attempts is single in 29(96.7%) and twice in 1(3.3%) participants. The p value is 0.34 which is more than 0.05 hence the results are insignificant. Both groups are comparable in terms of number of attempts.

A randomized double blind study conducted by Ranju Singh, Madhur Arora and Homay Vajifdar to compare ketamine-propofol and fentanyl-propofol for insertion of laryngeal mask airway in children undergoing elective surgery. This study has shown results consistent with our study[8].

In both groups resistance to mouth opening, resistance to insertion and number of attempts were comparable. The study concluded both groups were comparable in terms of ease of insertion.

A randomized, comparative study conducted by Z. Begec*et al*. to compare ketamine or alfentanyl administration prior to propofol anesthesia and the effects on proseal laryngeal mask airway insertion conditions and heamodynamic changes in children. In this study both groups were comparable with regards of ease of insertion. The results are in consistent with our study[9].

In our study we compared incidence of coughing/gagging and limb/head movements at the time of insertion and postoperative pharyngolaryngeal morbidity.

In the fentanyl propofol group 6.7% patients had slight coughing and gagging compared to 26.7% in ketamine propofol showing statistically significant results with p value 0.04. Hence ketamine and propofol has shown increased incidence of coughing and gagging compared to fentanyl and propofol.

A randomized double blind study conducted by Ranju Singh, Madhur Arora and Homay Vajifdar to compare ketamine-propofol and fentanyl-propofol for insertion of laryngeal mask airway in children undergoing elective surgery had shown results in consistent with our study with regards to incidence of coughing and gagging[8].

A prospective, double blind and randomized controlled study done by TanmoyGhatak, Dinesh Singh, RajniKapoor and JaishreeBogru to compare effect of addition of ketamine, fentanyl and saline with propofol induction on hemodynamics and laryngeal mask airway insertion conditions in oral clonidine premedicated children.

It has shown increased incidence of coughing and gagging in ketamine-propofol group compared to fentanyl-propofol group similar to our study but was statistically insignificant.

A randomized, comparative study conducted by Z. Begec*et al*. to compare ketamine or alfentanyl administration prior to propofol anesthesia and the effects on proseal laryngeal mask airway insertion conditions and heamodynamic changes in children. In contrast our study, the results of above mentioned study has shown that incidence of coughing and gagging were comparable in both groups[9].

Incidence of mild sore throat is 6.7% patients in both groups, which is statistically insignificant. Hence both groups were comparable interms of incidence of sorethroat.

There was nil results for incidence of hoarseness, dysphagia and laryngospasm in both groups.

A randomized double blind study conducted by Ranju Singh, Madhur Arora and Homay Vajifdar to compare ketamine-propofol and fentanyl-propofol for insertion of laryngeal mask airway in children undergoing elective surgery had shown similar results with regards to incidence of hoarseness, dysphagia and laryngospasm[8].

A randomized, comparative study conducted by Z. Begec*et al*. to compare ketamine or alfentanyl administration prior to propofol anaesthesia and the effects on proseal laryngeal mask airway insertion conditions and haemodynamic changes in children had shown similar results with regards to incidence of hoarseness, dysphagia and laryngospasm[9].

There was slight limb and head movements in 6.7% of fentanyl-propofol compared to 10% in ketamine-propofol group. Limb and head movements were more in ketamine group compared to fentanyl but results were statistically insignificant with p value of 1.89. Hence both groups were comparable.

A randomized, comparative study conducted by Z. Begec*et al*. to compare ketamine or alfentanyl administration prior to propofol anesthesia: the effects on proseal laryngeal mask airway insertion conditions and heamodynamic changes in children. Incidence of limb/head movements were comparable in both groups similar to our study[9].

A randomized double blind study conducted by Ranju Singh, Madhur Arora and Homay Vajifdar to compare Ketamine-propofol and Fentanyl-propofol for insertion of laryngeal mask airway in children undergoing elective surgery. The results shown highly significant increased incidence of limb and head movements with ketamine- propofol group compared to fentanyl-propofol group in contrast to our study[8].

Overall conditions for LMA insertion were noted and scaled according to modified scheme of LUND and STOVENER which depends on 3 parametrs coughing and gagging, limb and head movement and incidence of laryngospasm[10].

According to above mentioned scheme, the overall conditions were excellent with fentanyl-propofol

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group and good with ketamine-propofol group.

Conclusion

We conclude that addition of fentanyl or ketamine with propofol as an induction agent for insertion of classic LMA in children undergoing elective surgeries are equally effective in terms of ease of insertion. Considering the overall conditions including time to jaw relaxation, time to insert cLMA and complications, we conclude that induction with fentanyl-propofol group provided excellent conditions for cLMA insertion than induction with ketamine-propofol group.

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