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Comparison of I-Gel insertion conditions with two different induction methods in children: a prospective observational study

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ABSTRACT

Aim: Insufficient depth of anesthesia is one of the important causes of laryngospasm in pediatric patients undergoing surgery. Propofol is a widely used anesthetic agent for induction of anesthesia in children. Its use alone in induction may be insufficient to suppress laryngeal reflexes during laryngeal mask insertion and may lead to complications such as cough, hiccups, and laryngospasm. The aim of this study is to compare the effects of two different methods of induction of anesthesia on the conditions of laryngeal mask (I-Gel) insertion and haemodynamics in paediatric patients.

Material and Method: The study included 60 patients aged 2-10 years, of ASA I-III class, who underwent ambulatory surgery. For anesthesia induction, the KF group (n:30) were administered intravenous (iv) 1 mcg/kg fentanyl + 0.5 mg/kg ketamine followed by 3 mg/kg propofol, and the R group (n:30) were administered iv 0.5 mcg/kg remifentanil followed by 3 mg propofol. The I-gel insertion conditions were evaluated by scoring the six variables of mouth opening, ease of insertion, swallowing, coughing, movement, and laryngospasm. Pain during propofol injection was graded using a four-point scale.

Results: No statistically significant difference was determined between the groups in terms of I-gel insertion conditions total score values ($p>0.05$). The pain of the propofol injection was determined at a significantly higher level in Group R ($p<0.05$).

Conclusion: Both induction methods were seen to be easy to apply and provide sufficient success in I-gel insertion. No laryngospasm was observed in either group. More effective relief of propofol injection pain in the fentanyl-ketamine group provided calmer and more stable induction conditions. In this respect, it may be preferable to use fentanyl and low-dose ketamine together as co-induction.

Keywords: Co-induction, ketamine, remifentanil, fentanyl, child

INTRODUCTION

The development of laryngospasm during general anesthesia is known to occur more often in children than adults. One of the important reasons leading to laryngospasm is insufficient depth of anesthesia. A recent study reported that insufficent anesthesia depth in induction increases the risk of laryngospasm development by 7.9-fold (1). Propofol is an anaesthetic agent widely used in the induction and maintenance of anesthesia in paediatric patients. When used alone, the recommended dose of propofol (3 mg/kg) for induction in children may not be sufficient to suppress laryngeal reflexes, and may therefore threaten airway safety by leading to complications such as cough, hiccups, and laryngospasm (2,3). Children require a higher dose of propofol than adults because of the greater distribution volume and higher cardiac flow (4). However, when a higher dose than recommended is used, it may cause hemodynamic instability (5). Recent studies have reported that several co-induction agents used before propofol provide a more stable condition during insertion of the laryngeal mask in the airway (6-8). Co-induction agents administered before propofol in induction may have the advantage of preserving hemodynamic stability by allowing the propofol dose to be reduced while providing sufficient depth of anesthesia. The aim of this study is to compare the effects of two different methods of induction of anesthesia on the conditions of laryngeal mask (I-Gel)

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insertion and haemodynamics in paediatric patients. Evaluation was also made of the whether or not there was propofol injection pain following co-induction agent administered intravenously.

MATERIAL AND METHOD

The study was carried out with the permission of Ankara City Hospital No: 2 Clinical Researches Ethics Committee (Date: 23.11.2022, Decision No: E2-22-2879). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki. Written informed consent for participation in the study was provided by the parents or legal guardians of all the children. The study included 60 patients aged 2-10 years, of ASA I-III classification, who underwent elective surgery as a day patient. The study exclusion criteria were defined as respiratory tract infection within the last 4 weeks, the presence of airway anomaly, hyper-reactive airway disease, or suspected difficult airway. The patients underwent preoperative evaluation, and were admitted to the operating theatre 20 mins after the administration of premedication with 0.5 mg/kg oral midazolam in the premedication unit. A vascular route was opened in the right or left hand with a 24-gauge Intracath and crystalloid fluid was started at 5ml/hour. A 3-way valve was placed between the serum set and the Intracath and the anaesthetic drugs were administered through this 3-way valve. All the patients were monitored with electrocardiography (ECG), pulse oximetry, and non-invasive blood pressure measurements. For anesthesia induction, the KF group (n:30) were administered intravenous (iv) 1 mcg/kg fentanyl + 0.5 mg/kg ketamine (in the same injector) followed by 3 mg/kg propofol, and the R group (n:30) were administered iv 0.5 mcg/kg remifentanil followed by 3 mg propofol. For both groups, the drugs to be given before propofol were prepared as 10ml in a single injector and after slow push in 10 secs, propofol was also administered in 10 secs.

When the eyelash reflex was lost, the lungs were ventilated with 100% oxygen. At 60 secs after the propofol injection, the I-Gel insertion procedure was performed on all patients by an anesthetist of the same seniority. Effective ventilation was confirmed by chest wall movements and the observation of square wave capnograph tracing. In the maintenance of anesthesia, both groups were administered 40/60% oxygen/nitrous oxide together with 3% sevoflurane. The I-Gel insertion conditions were evaluated by scoring the six sub-variables of mouth opening, ease of insertion, swallowing, coughing/gagging, involuntary body movements, and laryngospasm. Pain during the injection was evaluated using the 4-point scale recommended by Cameron et al. (9). During induction, a record was made for each patient of the time to the loss of the eyelash reflex, the time to apnea, jaw slackness, degree of mouth opening, and the occurrence of laryngospasm, cough, swallowing, gagging, and involuntary body movements. Heartbeat rate (HR) and mean arterial pressure (MAP) were recorded for all patients before induction and at 1, 3, 5, and 10 mins after induction.

Statistical Analysis

Data obtained in the study were analyzed statistically using IBM SPSS vn. 25.0 software (IBM Corpn., Armonk, NY, USA). Descriptive statistical methods were used in evaluations with results stated as mean±standard deviation (SD), median, minimum, maximum, and interquartile range (IQR) values, or number (n) and percentage (%). In the comparisons of categorical data, the Chi-square (2) test was used. Conformity of the data to normal distribution was assessed with the Kolmogorov-Smirnov and Shapiro-Wilk tests, skewness-kurtosis, and graphic methods (histogram, Q-Q Plot, Stem and Leaf, Boxplot). Quantitative data showing normal distribution were compared between the groups using the Independent Samples t-test, and for comparisons of groups of data not showing normal distribution, the Mann Whitney U-test was applied. It was determined necessary to have sample size of 20 patients per group to determine a difference within the group of at least 20% with the Paired Samples t-test (α=0.01, two-sided, power=90%). A value of $p<0.05$ was accepted as statistically significant.

RESULTS

In the comparisons between the groups, no statistically significant difference was determined in respect of age, gender, weight, and ASA values ($p>0.05$). The difference in the duration of anesthesia between the groups was determined to be statistically significant, with a shorter duration of anesthesia in the R group patients ($p<0.05$).

No statistically significant difference was determined between the groups in respect of the total scores of the I-Gel insertion conditions of the time to the loss of the eyelash reflex, the duration of apnea, jaw slackness, degree of mouth opening, the occurrence of laryngospasm, cough, swallowing, gagging, and involuntary body movements, and ease of I-Gel insertion ($p>0.05$). The difference between the groups in respect of propofol injection pain values was statistically significant, with greater levels of propofol injection pain felt in the R group patients ($p<0.05$).

No statistically significant difference was determined between the groups in respect of the HR and MAP values ($p>0.05$).

Table 1. Comparisons of the demographic data of the patient groups

	Group KF (n=30)	Group R (n=30)	P
Gender			0.531[a]
Female	5 (16.7%)	8 (26.7%)	
Male	25 (83.3%)	22 (73.3%)	
Age (years)	4.7±2.3	5.4±2.4	0.251[b]
Weight (kg)	21.1±9.0	21.0±8.3	0.953[b]
ASA classification			0.371[a]
I	26 (86.7%)	23 (76.7%)	
II	3 (10.0%)	3 (10.0%)	
III	1 (3.3%)	4 (13.3%)	
Surgical Intervention			--
Inguinal Hernia	14 (46.7%)	12 (40.0%)	
Hydrocele	4 (13.3%)	3 (10.0%)	
Orchiopexy	4 (13.3%)	2 (6.7%)	
Port Attachment	1 (3.3%)	5 (16.7%)	
Cystoscopy	2 (6.7%)	3 (10.0%)	
Bilateral Inguinal Hernia	2 (6.7%)	1 (3.3%)	
Excision	--	3 (10.0%)	
Epispadias	1 (3.3%)	--	
Hypospadias	1 (3.3%)	--	
Retrograde Intrarenal Surgery	--	1 (3.3%)	
Circumcision	1 (3.3%)	--	
Anesthesia duration (mins)	51.3±15.9	41.5±15.9	0.020[b]

a: Chi-Square Test (n (%)), b: Independent Samples t Test (Mean±SD), KF Group: Ketamine-fentanyl group, R Group: Remifentanil Group, ASA: American Society of Anesthesiologists

DISCUSSION

The results of this study demonstrated that there was no statistically significant difference between the two induction methods in respect of the I-Gel insertion conditions and ease of insertion. Generally, both methods provided sufficient ease of application and success in I-Gel insertion. Laryngospasm was not observed in any patient in either group. Moreover, the hemodynamic and respiratory data were found to be stable and similar before and throughout 10 mins after I-Gel insertion in both groups.

Effective and safe insertion of a laryngeal mask requires sufficient mouth opening and a sufficient depth of anesthesia. Traumatic laryngeal mask insertion can cause postoperative throat pain (2). In a study of adult patients by Güçlü et al. (11) it was reported that the addition of ketamine and remifentanil to propofol showed similar effects in respect of laryngeal mask insertion conditions, and these were both agents that could be selected in induction. Goh et al. (12) compared groups administered ketamine or fentanyl with a placebo group, and while both agents provided similar conditions in laryngeal mask insertion, they were found to be significantly superior to the placebo group. In a study of paediatric patients by Goel et al. (13) it was reported that a combination of ketamine or midazolam with propofol resulted in a lower dose of propofol required together with stable hemodynamics and appropriate laryngeal mask insertion conditions. The

Table 2. Comparisons of the I-Gel insertion conditions, time to loss of eyelash reflex, and time to halting of spontaneous respiration of the groups

	Group KF (n=30)	Group R (n=30)	P
Time to loss of eyelash reflex (secs)	22.2±18.4	25.6±24.8	0.545[a]
Time to halting of spontaneous respiration (secs)	28.8±23.1	28.5±25.7	0.962[a]
Jaw slackness			
Poor	--	1 (3.3%)	0.331[b]
Satisfactory	10 (33.3%)	6 (20.0%)	
Excellent	20 (66.7%)	23 (76.7%)	
Swallowing			
None	28 (93.3%)	27 (90.0%)	1.000[b]
Mild	2 (6.7%)	3 (10.0%)	
Cough/gagging			
None	29 (96.7%)	29 (96.7%)	1.000[b]
Mild	1 (3.3%)	1 (3.3%)	
Involuntary body movements			
None	14 (46.7%)	20 (66.7%)	0.278[b]
Mild	15 (50.0%)	9 (30.0%)	
Laryngospasm			1.000[b]
Severe	1 (3.3%)	1 (3.3%)	
None	30 (100.0%)	30 (100.0%)	
Mouth opening			1.000[b]
Full	28 (93.3%)	28 (93.3%)	
Partial	2 (6.7%)	2 (6.7%)	
I-Gel Insertion			0.536[b]
Easy	20 (66.7%)	21 (70.0%)	
Difficult	10 (33.3%)	8 (26.7%)	
Impossible	--	1 (3.3%)	
I-Gel insertion conditions total score	5.7±0.9	5.6±0.9	0.468[a]
Propofol Injection Pain	0.03±0.18	1.23±1.17	<0.001[a]
None	29 (96.7%)	12 (40.0%)	<0.001[b]
Mild	1 (3.3%)	4 (13.3%)	
Moderate	--	9 (30.0%)	
Severe	--	5 (16.7%)	

a: Independent Samples t Test (Mean±SD). b: Chi-Square Test (n (%)). KF Group: Ketamine-fentanyl group, R Group: Remifentanil Group,

Table 3: Comparisons of the hemodynamic data of the groups

	Group KF (n=30)	Group R (n=30)	P
Heartrate (beats per min)			
Basal	110.4±22.9	112.0±15.6	0.757[a]
After induction	93.4±19.5	99.2±17.9	0.240[a]
After LMA Placement	96.7±20.9	101.5±20.0	0.360[a]
1 min	94.5±18.9	97.7±19.3	0.519[a]
3 mins	96.1±18.1	98.0±18.9	0.703[a]
5 mins	98.0±17.3	100.1±19.0	0.656[a]
10 mins	98.4±16.5	102.2±18.4	0.407[a]
MAP (mmHg)			
Basal	80.4±10.2	83.7±13.0	0.289[a]
After induction	71.8±11.3	71.3±15.5	0.902[a]
After LMA Placement	70.0±11.2	68.5±12.9	0.633[a]
1 min	65.3±10.2	64.3±9.4	0.703[a]
3 mins	63.0±7.8	62.1±7.8	0.657[a]
5 mins	62.5±5.9	60.5±6.9	0.234[a]
10 mins	65.4±7.9	62.8±8.3	0.218[a]

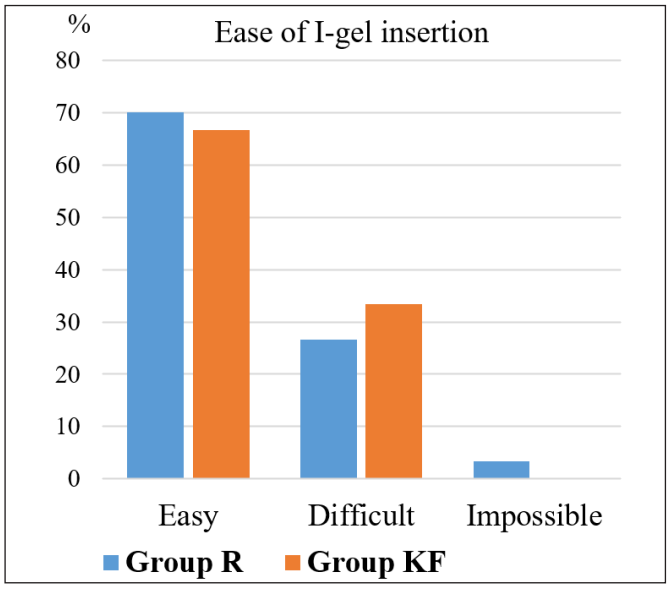

Figure 1.

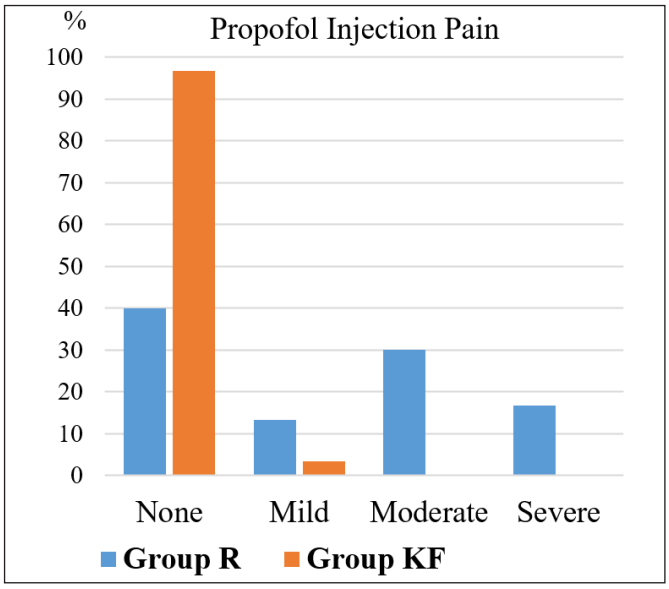

Figure 2.

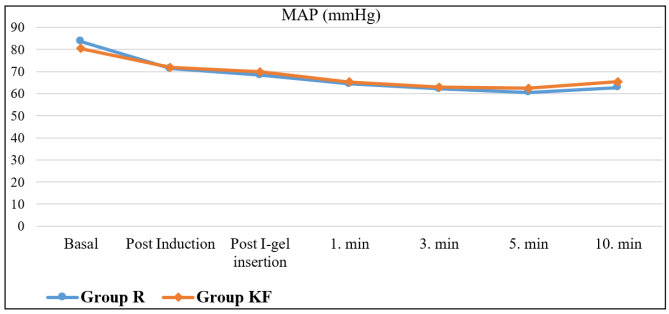

Figure 3.

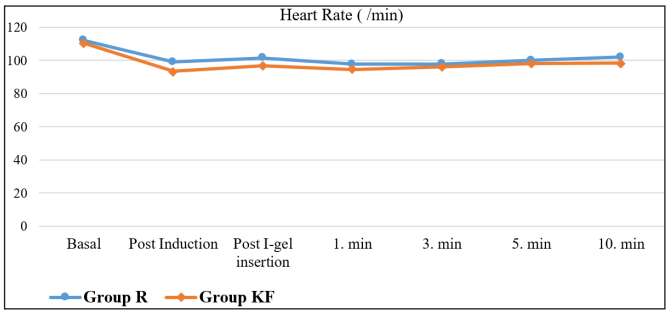

Figure 4.

main concern related to the adddition of ketamine for children is of secretion increase and that this could lead to negative outcomes. However, in the current study, this complication was not observed in the fentanyl-ketamine group during or after the I-Gel insertion procedure. It has been reported that ketamine administered at a sub-anesthetic dose can eliminate the side-effects of propofol.

Previous studies have stated that it is necessary to suppress the swallowing reflex together with cough and gagging to be able to correctly place the LMA in the hypopharynx. In a study by Singh et al. (14) conducted using 3.5 mg/kg propofol in children, comparisons were made of co-induction with 0.2 mcg/kg fentanyl or 0.5 mg/kg ketamine. The results showed that significantly more gagging, coughing and swallowing symptoms were seen in the ketamine group compared to the fentanyl group. There were also observed to be significantly more involuntary body movements in the ketamine group during LMA insertion. In the current study, with fentanyl added to ketamine at the same dose, these findings were observed in fewer patients, but the difference in comparison with the remifentanil group was not statistically significant. Similar findings related to ketamine have been reported in studies by Goh et al. (12) and Sağır et al. (15). These results in the current study suggest that the addition of fentanyl to ketamine provides more suitable conditions for laryngeal mask insertion. To reduce the side-effects associated with induction agents in children, the use of substances such as fentanyl as an induction agent together with ketamine or propofol has been recommended during the LMA insertion procedure. A synergistic interaction between ketamine and opioids has been reported in some studies (16,17). Using lower doses of different anaesthetics and opiods together in the two groups of the current study was observed to provide sufficient depth of anaesthesia and optimal hemodynamic conditions. Remifentanil is an ultra short-effect potent opioid, which is metabolised by non-specific plasma and tissue esterases. It is a slightly more potent agent than fentanyl, and in a similar study it has been shown that when combined with propofol, it is an appropriate agent to improve conditions without the use of a muscle relaxant in laryngeal mask insertion (18). It has also been reported that remifentanil administered before propofol achieves stable hemodynamics and reduces the propofol requirement (19,20). In a study by Kwak et al. (5) the bolus dose of remifentanil was found to be 0.56 mcg/kg in children with 50% probability (ED50)

of successful laryngeal mask insertion with propofol 2.5 mg/kg. In the current study, 0.5 mcg/kg remifentanil was used with 3 mg/kg propofol in induction and successful insertion conditions were observed to be obtained.

The insertion procedure was able to be performed in all the patients in the fentanyl-ketamine group. In one patient in the remifentil group, the I-Gel insertion procedure could not be accomplished at all. In a study of infants by Kayhan et al. (21) 1 mcg/kg remifentanil and 3mg/kg propofol were administered to all the patients in induction, and the insertion procedure was unsuccessful in 1 patient in the group which used I-Gel. In the same study, the I-Gel insertion total score was found to be 6.2±0.5. In the current study, the total score was determined to be similar at 5.7±0.9 in the remifentanil group, and 5.7±0.9 in the fentanyl-ketamine group. Ghatak et al. (22) compared ketamine and fentanyl with a control group, and reported that the LMA insertion total scores were significantly better in the ketamine group (6.33±0.88) and fentanyl group (6.59±0.95), than in the control group (8.12±0.52).

Ketamine creates sympathetic stimulation which leads to an increase in vascular resistance and myocardial contractility, resulting in increased arterial pressure and heart rate (12). When applied together with propofol for anesthesia induction, it can provide hemodynamic stability, even at sub-anesthetic doses. In a study by Begeç et al. (8) the administration of 0.5 mg/kg ketamine with 4 mg/kg propofol was found to preserve hemodynamic stability in LMA insertion. In the current study, it was similarly observed that hemodynamic stability was obtained with the addition of 3 mg/kg propofol and 1 mcg/kg fentanyl to ketamine at the same dose. In Group R, following the slow injection of 0.5 mcg/kg remifentanil, although there was a rapid decrease in heart rate, this was observed to be very short-term. In a similar study, higher heart rate and higher mean arterial pressure were recorded continuously in the ketamine group compared to the fentanyl and saline groups, even in patients administered premedication with clonidine (23). Previously cconducted co-induction studies have shown that the addition of fentanyl to propofol increased depressive effects on blood pressure and heart rate (10, 22). Like fentanyl, remifentanil also shows a vagotonic effect related to a significant increase in sympathetic nerve activity mediated by arterial baroreflex, leading to bradycardia and hypotension. These effects have a rapid onset and short duration (2).

As propofol has rapid onset and short effect duration, it is the preferred drug for anesthesia induction in millions of patients each year. Despite these positive properties, approximately three in five patients experience pain during the propofol injection, and one of these patients reports severe or intolerable pain. Some patients remember anesthesia induction as the most painful part of the perioperative period. Consequently, pain associated with the propofol injection continues to be a problem (24).

In the current observational study, the effect of the drugs used as co-induction before propofol on the pain of the propofol injection was evaluated with a 4-point scoring system. In Group KF, the pain level was zero in 29 of the 30 patients and at a mild level in one patient. In Group R, no pain was reported in 40% of the patients, and severe pain in 16%. In a previous similar study of children, 0.5 mcg/kg remifentanil was administered before propofol, and while no pain was reported by 60% of the children, there was severe pain in approximately 7% (25). Başaranoğlu et al. (26) compared 1mcg/kg fentanyl and 1 mcg/kg remifentanyl with a saline group, and found that both drugs made no significant difference from the saline group in preventing propofol injection pain. In a study by Zhao et al. (27) 0.5 mg/kg ketamine administered before propofol was found to effectively eliminate pain and reduce the amount of propofol used. The similar result obtained in the current study with the addition of ketamine and fentanyl was concluded to have originated from ketamine, and fentanyl made a positive contribution to this.

There were some limitations to this study, primarily that it was observational in design so data could not be collected in a blind manner. Another limitation was that as the cases included were of different types and durations of surgical interventions, the two groups could not be compared in respect of postoperative recovery time, postoperative pain, nausea and vomiting, or hallucinations.

CONCLUSION

The results of this observational study showed that the success of I-Gel insertion and the hemodynamic conditions were similar in the remifentanil group and the ketamine-fentanyl group when those drugs were administered as co-induction before propofol. The effective elimination of propofol injection pain in the ketamine-fentanyl group provided more comfort and stable induction conditions. Therefore, this could constitute a reason to prefer the use of ketamine and fentanyl together as co-induction.

In conclusion; It was observed that I-gel insertion conditions were safe and successful at a similar rate between ketamine-fentanil and remifentanil used as co-induction before propofol, and hemodynamic conditions were stable in both groups. More effective improvement of propofol injection pain in the ketamine-fentanyl group provided calm and comfortable induction conditions.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Ankara City Hospital No: 2 Clinical Researches Ethics Committee (Date: 23.11.2022, Decision No: E2-22-2879).

Informed Consent: All patients signed the free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper and that they have approved the final version.

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