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Original Research Article

A Comparative Study of Insertion Condition and Hemodynamic Changes for Baska Mask Insertion under Propofol and Propofol-Ketamine Mixture

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Abstract

Background: Baska mask is the latest addition to the Supraglottic Airway Devices (SAD) with additional safety features. For successful insertion of SADs, adequate mouth opening, and suppression of airway reflexes are required to prevent coughing, gagging, and laryngospasm, which is achieved with adequate depth of anaesthesia.

Aim and Objectives: We aimed to compare the insertion condition and hemodynamic changes of the Baska mask insertion, under the Propofol-Ketamine mixture(Ketofol) and Propofol alone.

Methodology: Sixty patients of the American Society of Anaesthesiology physical status 1 and 2, aged between18-60yrs were randomly allocated into Group-K(ketofol) and Group-P(propofol). Patients were induced with an induction agent either Ketofol(1mg/kg propofol+1mg/kg ketamine) or Propofol 2mg/kg according to group randomization. Baska mask was inserted after 30 seconds. The primary objectives were the ease of insertion, time taken for insertion, and jaw relaxation in either group. Secondary variables included hemodynamic parameters and complications if any.

Results: It was seen that it was easy to insert the Baska mask in 76.7% of cases in Group-K and in 86.7% of cases in Group-P(p=0.453). Baska mask insertion time in Group-K was 13.267±2.57s and in Group-P was 13.10±2.64s (p=0.805). The jaw relaxation was 73.3% in Group-K and 93.3% in Group-P which was statistically significant(p=0.038). Immediately after induction, minimal changes in hemodynamics were seen in Group-K compared to Group-P(p=0.038).

Conclusions: For insertion of the Baska mask, the Propofol-Ketamine mixture is effective, safe, and better as compared to propofol due to minimizing hemodynamic changes.

Keywords: Baska mask, Ketofol, Propofol, Coinduction, Hemodynamics.

Introduction

Supraglottic airway devices (SAD) include a group of medical devices that act as airway conduits for providing a clear airway, facilitate oxygenation and ventilation without endotracheal intubation, and have revolutionized airway management in modern-day practice. Baska mask is the latest addition to the supraglottic airway devices in 2012 and according to the new Miller's classification; it is included in the third generation SAD [1]. The newer Baska mask has many additional features which improve safety during spontaneous and controlled ventilation [2,3].

Insertion of Baska mask has certain prerequisites. The patient should have a mouth opening of at least 3cm. The upper airway reflexes like the pharyngeal reflex (gag reflex), cough reflex, and swallowing should be obtunded. These reflexes are lost in stage 2 and plane 1 of stage 3 level of anaesthesia, whereas endotracheal intubation reflexes require obtundation of the laryngeal and tracheal reflexes that happen in plane 3 and plane 4 of stage 3 anaesthesia. Hence, endotracheal intubation requires a greater depth of anaesthesia than the placement of a SAD [4].

Incidence and severity of laryngospasm, bronchospasm, and other pathophysiological effects of intubation such as increased intracranial and intraocular pressure are less with SAD [5]. There is no need to place the head in the sniffing position for the Baska mask insertion. Therefore can be used to secure the airway in cases of cervical spine instability. The choice of induction agent for insertion of the laryngeal mask airway (LMA) was inj. Propofol because it has the ability to suppress the airway reflexes and to cause the relaxation of skeletal muscles [6,7]. It causes pain on injection and severe hypotension which may be severe enough to cause bradycardia and cardiac arrest. It is also associated with a high incidence of apnea. Stoneham MD *et al* reported that- "easy insertion of LMA was seen in only approximately 62% of patients with propofol anaesthesia" [8].

Hence there was continuous research into alternative induction techniques for the insertion of SAD. Ketamine is an N-methyl-D-aspartate (NMDA) antagonist drug, through its sympathetic stimulating effects preserves the heart rate and blood pressure and is used for the induction of anaesthesia in haemodynamically unstable patients [9]. When combined with propofol or a benzodiazepine, its adverse effects like tachycardia, hypertension, and postoperative hallucinations are eliminated or attenuated. Coinduction is the practice of administration of a small dose of another anaesthetic agent to the induction agent, to reduce the total dose of the induction agent [10].

With this coinduction technique, there is the stability of the hemodynamics and attenuation of uneventful events. In modern-day practices, the addition of different doses of Ketamin to Propofol has gained increasing popularity among anaesthesiologist as the coinduction agent and also as a total intravenous anaesthesia technique (TIVA). Because of the addition of ketamine, there is the maintenance of stable haemodynamics and attenuation of ventilatory depression action of Propofol, allowing spontaneous ventilation [11,12].

There are a few studies regarding the Baska mask and there are no studies on the use of the coinduction agent like the mixture of Ketamine and Propofol for insertion of the Baska mask. Hence, we aimed to study the effects of the coinduction agent, a mixture of Propofol and Ketamine on the insertion conditions and haemodynamic changes for the Baska mask insertion in comparison to the induction agent Propofol alone.

Methodology

After approval of the institutional ethical committee (Approval No-092/19-I-S-094/Dt.25.01.2019) this randomized, double-blinded study was carried out at O&G OT and Surgery OT of the institution during the period from February 2019 to November 2020.

The sample size was calculated, considering the result of the study conducted by Amany K and colleagues [13], using the formula for comparing two proportions: $n= \{[p_1 \times (100-p_1) + p_2 \times (100-p_2)] (Z_{1-\alpha/2} + Z_{1-\beta})^2\} / (p_2-p_1)^2$, with 95% confidence interval and power of 80%. The minimum required sample size for each group was 20, considering attrition, 30 patients were recruited in each group.

The inclusion criteria were - patients posted for elective minor surgeries(<60 mins) under general anaesthesia, between 18-60yrs age group, both genders, ASA grade I and II, BMI between 18-30kg/m^2, and mallampati class I and II.

The exclusion criteria were - patient refusal, history of allergic reaction to the drug that is used, ASA grade III and IV, restricted mouth opening(<2.5cm), difficult airway, increased risk of aspiration, BMI > 30kg/m^2, obstructive and restrictive lung diseases, surgeries in the non-supine position, neck swelling/thyroid, patients with post burns contracture neck. Informed and written consent was obtained after explaining the procedure to the patients. The patients were randomized using sealed envelopes into Group-P and Group-K.

Group-P - Patients were induced with inj Propofol 2mg/kg.

Group-K – Patients were induced with inj Propofol 1mg/kg + inj Ketamine 1mg/kg. (Ketofol).

The primary anaesthesiologist prepared the inducing drugs depending on the group the patient was randomized. Two syringes were prepared in both the groups - one 20 ml and another 10 ml for rescue, if needed. In Group-P, the 20ml syringe contains 2mg/kg and the 10 ml syringe contains 1mg/kg of Propofol. In Group-K, the 20ml syringe contains 1mg/kg of Propofol and 1mg/kg of Ketamine and the 10 ml syringe contains 0.5mg/kg of Propofol and 0.5mg/kg of Ketamine. The drug in the 20ml syringe was made up to 20 ml and in the10 ml syringe made up to 10 ml by adding normal saline to appear identical to propofol, for blinding purposes. The other anaesthesiologist who was unaware of the group, inserted the Baska mask and collected the data.

A thorough pre-anaesthetic assessment was done the day before surgery. On the night before surgery, tab. Alprazolam 0.5mg and tab. Ranitidine 150 mg was given orally to all the patients and the patients were kept nil per orally for a minimum duration of 8 hours. In the operation theatre, patients were connected to the routine monitor showing heart rate (HR), non-invasive blood pressure (NIBP), electrocardiogram (ECG), oxygen saturation (SPO_2), and end-tidal carbon dioxide ($EtCO_2$).

The peripheral vein was secured with an 18G IV cannula and an infusion of ringer lactate was started. The basal values of HR, blood pressure, and SpO2 were recorded. All patients were pre-oxygenated with 100% oxygen and pre-medicated with inj. glycopyrrolate 0.004mg/kg iv, inj. midazolam 0.03mg/kg iv, inj. nalbuphine

0.2mg/kg iv, inj. Paracetamol 1gm iv, and inj. Ondansetron 0.1 mg/kg iv 5 minutes before induction. The induction of anaesthesia was done with propofol 2mg/kg in Group-P or with ketofol (propofol 1mg/kg +ketamine 1mg/kg) in Group-K and the drugs were given over 30 seconds. Patients were then be given the bag and mask ventilation (30-40secs) till the loss of eyelash reflex. Then the appropriate size Baska mask lubricated with 2%lignocaine applied on the dorsal surface was inserted as per the standard instructions of the manufacturers.

If any difficulty was experienced the position was adjusted by pushing or pulling the device through the tab provided on the dorsal surface and by the manipulations like jaw thrust, chin lift, head extension, or flexion. The correct position and ventilation adequacy was confirmed by the appearance of a square wave capnograph trace, chest expansion equally on both sides on the gentle application of intermittent positive pressure ventilation, no audible oropharyngeal leak, and stable oxygen saturation. During insertion coughing, gagging, swallowing and laryngospasm were noted, and if required rescue drug was given. If airway obstruction or an obvious leak was observed, the Baska mask was removed and another size was reinserted up to three times after giving a bolus dose of rescue drugs.

If the insertion failed even after three attempts and an alternative device was used and the case was excluded from the study. After the Baska mask's correct placement was confirmed, the patient was manually ventilated till the return of sufficient spontaneous ventilation. No muscle relaxant was used and allowed for spontaneous ventilation. Maintenance of anaesthesia was done with a mixture of nitrous oxide and oxygen in a ratio of 2:1 and Sevoflurane 2-3% vol. Till the 5mins of the study period, any surgical or other stimulations were not applied. Through the gastric channel of the Baska mask, the appropriate size gastric tube was inserted and the correct placement was assessed by auscultation of injected air at the epigastrium. Suction was attached intermittently to the suction port for removal of any secretion. Sevoflurane was withdrawn at closure and at the end of the surgery, nitrous oxide was cut off and the patient was allowed to breathe 100% oxygen. Recovery was assessed and gastric port suctioning was done. The Baska was removed when the patient was awake and breathed with adequate tidal volume. The patient was shifted to the postoperative recovery room and observed for any undesirable events for 1hr.

(A) The parameters of insertion condition recorded were –

- Jaw relaxation - by Young's criteria [14]
  Absolutely relaxed – there was no muscle tone.
  Moderately relaxed- there was some muscle tone.
  Poorly relaxed- there was full muscle tone.
- Ease of Baska mask placement graded on a four-point scale. Easy - single pass without significant resistance or manipulations. Slight difficulty - single pass with up to 2 manipulations. Difficult - >2 manipulations or ≥2 attempts. Impossible- three failures.
- Insertion time
- swallowing
- Coughing and gagging
- Laryngospasm.

(B) The hemodynamic parameters recorded were-

- Heart rate (HR)
- Systolic blood pressure(SBP)
- Diastolic blood pressure(DBP)
- Mean arterial pressure(MAP)

The above parameters were recorded at the following time intervals. Basal (1 min

before induction)-t_0, Immediately after induction-t_1, Immediately after Baska mask insertion-t_2, 2min after insertion –t_3, 3min after insertion-t_4, and 5min after insertion-t_5. The adverse events observed were excessive secretion, hallucination, bradycardia, muscular rigidity, and postoperative nausea and vomiting.

Data Analysis

Qualitative data were expressed in frequency and percentages and quantitative data were expressed in mean (standard deviation [SD]). The Student's t-test and Chi-square test were used to compare the continuous data and categorical data respectively between the groups. Intragroup variations were compared using the paired t-test. The p-value <0.05 was considered a statistically significant association. Statistical analysis was done using SPSS 23.

Results

In this study, sixty patients were enrolled and all are completed the analysis without any loss to follow-up [Fig-1].

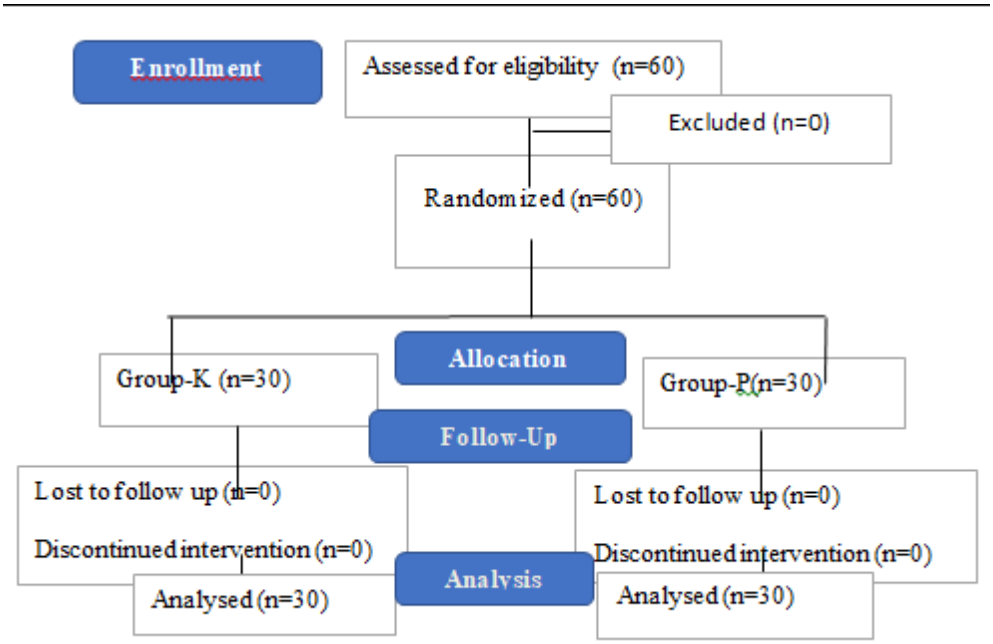

Figure 1: CONSORT flow chart.

Table 1: Demographic parameters in both groups.

Variables	Group-K(n=30)	Group-P(n=30)	p-value
Age(years)	45.4 ± 13.1	42.9 ± 12.7	0.462
Mean weight (kg)	54.233 ± 10.0024	58.173 ± 12.0518	0.174
Gender male female	 19(63.3%) 11(36.7%)	 18(60%) 12(40%)	0.791
ASA Grading. no (%) Grade-1 Grade-2	 17 13	 20 10	0.426
Mallmpatti score. no (%) 1	 15	 14	0 .796

2	15	16	
Mouth opening(cm)	4.407±0.348	4.410±0.343	0.970
Thyromental Distance(cm)	6.300±0.523	6.473±0.489	0.191
Duration of surgery(mins)	24.02 ± 4.61	25.14 ± 4.47	0.264

P-value <0.05 is significant.

The demographic parameters in both groups were comparable [Table-1]. The ease of insertion of the Baska mask was comparable in both groups(p=0.453). In Group-K, the Baska mask was easily inserted in the first attempt in 23(76.7%) patients, with some difficulty in 6(20%) patients, and with difficulty in 1(3.3%) patient. In Group-P, the Baska mask was inserted easily in 26(86.7%) patients, with some difficulty in 4(13.3%) patients. The incidence of jaw relaxation was significantly better (p=0.038) in Group-P as compared to Group-K. Absolute jaw relaxation was found in 22(73.33%) Group-K and 28(93.3%) Group-P. 8(26.66%) patients in Group-K and 2(6.7%) patients in Group-P had a moderate degree of jaw relaxation. No patients had poor relaxation in both groups. The mean time required for Baska mask insertion was 13.267±2.57s in Group-K and 13.10±2.64s in Group-P.(P=0.805). The incidence of coughing and gagging was 6.7% in Group-K and 3.33% in Group-P(p=0.554), swallowing was 13.3% in Group-K and 6.7% in Group-P (p=0.389), involuntary movements was 10% in Group-K and 3.33% in Group-P(p=0.301). [Table 2].

Table 2: Parameters evaluated during Baska mask insertion.

Variables	Group-K(n=30)	Group-P(n=30)	p-value
Ease of insertion			
Easy	23(76.7%)	26(86.7%)	0.453
Some difficulty	6(20%)	4(13.3%)	
Difficult	1(3.3%)	0	
Impossible	0	0	
Jaw relaxation			
Absolutely relaxed	22(73.3%)	28(93.3%)	0.038
Moderately relaxed	8(26.66%)	2(6.7%)	
Poorly relaxed	0	0	
Insertion time	13.267±2.57	13.10±2.64	0.805
Swallowing			
Absent	26(86.7%)	28(93.3%)	0.389
Present	4(13.3%)	2(6.7%)	
Coughing and gagging			
Absent	28(93.3%)	29(96.66%)	0.554
Present	2(6.7%)	1(3.33%)	
Involuntary movements			
Absent	27(90%)	29(96.66%)	0.301
Present	3(10%)	1(3.33%)	
Laryngospasm			
Present	0	0	---

p-value <0.05 is significant.

The pre-induction baseline hemodynamic variables like HR (p=0.651), SBP (p=0.8), DBP (p=0.369) and MAP (p=0.676) were comparable in both the groups. The decrease in heart rate at

all the measurement points compared to their baseline value was statistically significant in both the groups (p=0.001) except immediately after insertion in Group-K (p=0.182). When compared between the groups, the HR was statistically significantly low at the measurement points of t_3, t_4, and t_5 in Group-P than Group-K. In both groups, the decrease of SBP, DBP, and MAP from their baseline value was statistically significant (p=001), but in Group-K the decrease was gradual. In comparison to Group-P, the SBP, DBP, and MAP in Group-K were statistically significantly high at t_1, t_3, and t_4 measurement points. But at t_2 and t_5, both the groups are comparable. [Table-3, fig-2 and fig-3]. The adverse effects like bradycardia, hallucination, excessive secretion, or muscular rigidity were not recorded in any patients of both groups.

Table 3: Haemodynamic parameters in both groups.

Variables	t0	t1	t2	t3	t4	t5
Mean Heart rate. Mean(SD)						
Group-K	95.96 (6.72)	90.36 (5.89)	95 (5.27)	92.7 (4.61)	89.70 (4.18)	88.40 (3.03)
Group-P	96.76 (6.91)	91.5 (5.96)	93.43 (6.81)	85.16 (4.96)	80.16 (4.26)	77.63 (4.48)
p-value	0.651	0.462	0.279	0.013	0.000	0.000
Mean SBP Mean(SD)						
Group-K	119.26 (7.01)	114.9 (6.83)	116.83 (6.99)	113.43 (6.86)	111.66 (6.49)	108.26 (3.72)
Group-P	119.73 (7.18)	108.43 (5.84)	114.26 (6.2)	108.76 (6.61)	105.33 (4.69)	106.6 (3.92)
p-value	0.8	0.026	0.08	0.010	0.000	0.601
Mean DBP Mean(SD)						
Group-K	77.13 (3.78)	71.53 (3.78)	73.40 (3.27)	69.63 (3.48)	67.86 (3.50)	68.40 (3.82)
Group-P	76.23 (3.91)	68.66 (4.33)	72.83 (3.85)	66.23 (3.70)	65.30 (3.32)	66.86 (3.02)
p-value	0.369	0.008	0.542	0.001	0.005	0.587
Mean MAP Mean(SD)						
Group-K	91.17 (3.62)	86.65 (3.54)	87.87 (3.36)	84.23 (3.46)	82.46 (3.50)	80.58 (3.51)
Group-P	90.73 (4.51)	81.92 (4.13)	86.64 (4.02)	80.41 (3.54)	78.64 (2.99)	79.11 (2.68)
p-value	0.676	0.000	0.708	0.000	0.000	0.083

p-value <0.05 is statistically significant.

t0-basal (1min before induction), t_1- immediately after induction, t_2-immediately after Baska Mask insertion, t_3, t_4, and t_5, are 2, 3, and 5 min after Baska Mask insertion.

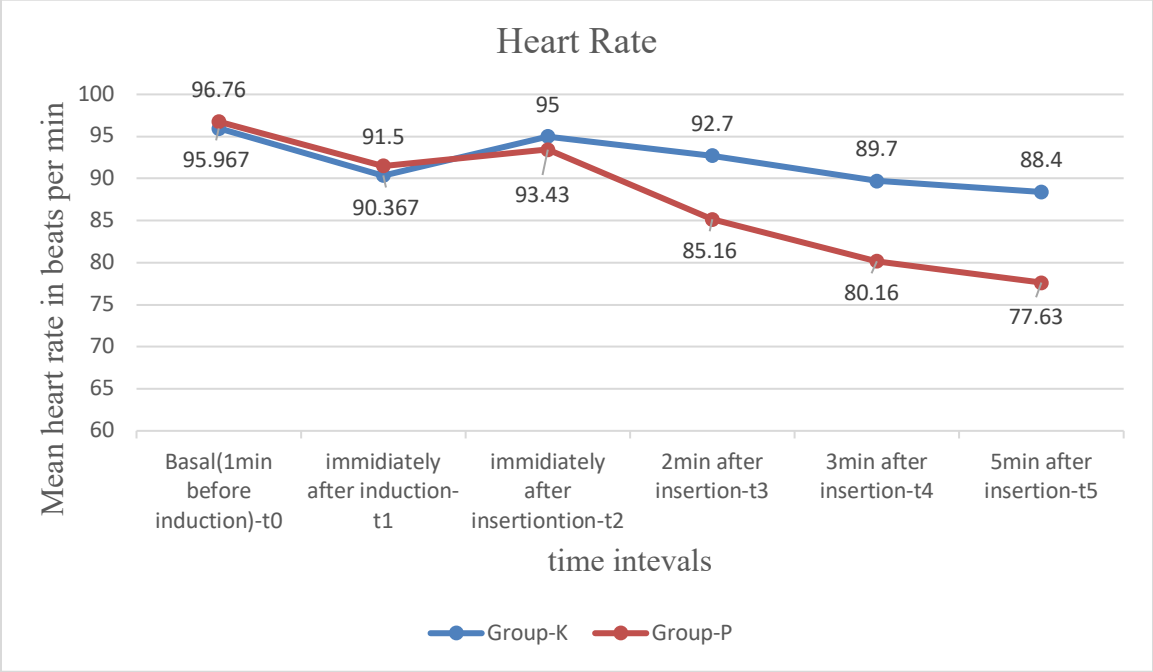

Figure 2: Comparison of the mean of HR at different time intervals during Baska mask insertion.

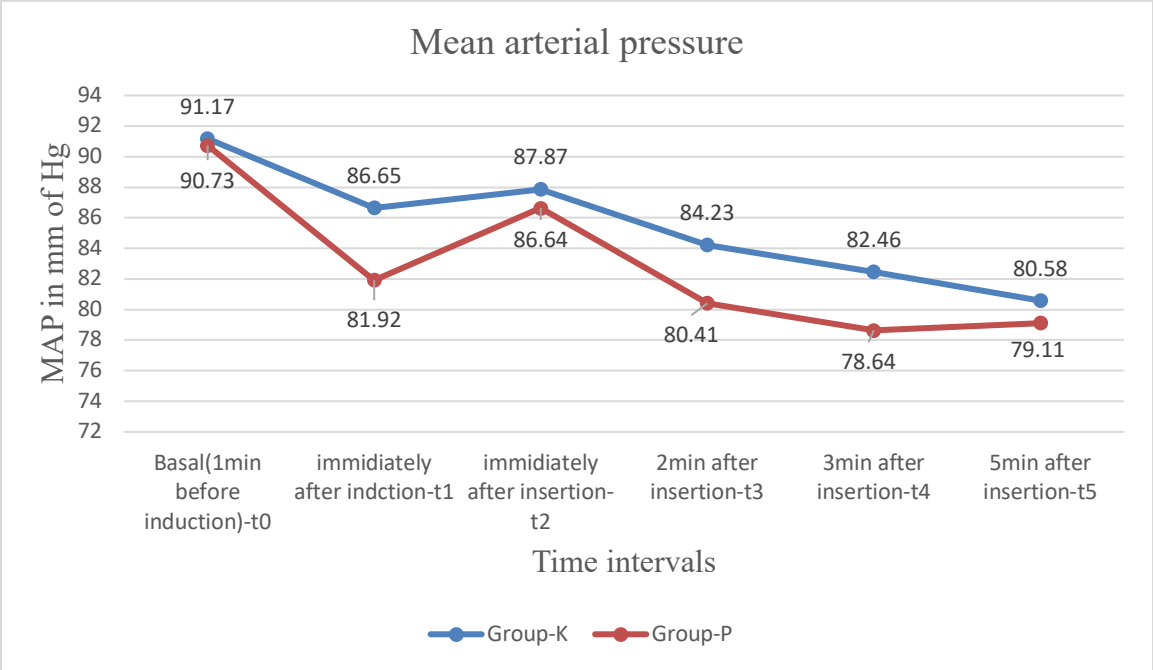

Figure 3: Comparison of the mean of MAP at different time intervals during Baska mask insertion.

Discussions

In our study, the ease of Baska mask insertion, and the time taken for insertion were comparable in both groups. The jaw relaxation was significantly better in group-P, maybe due to its ability to cause skeletal muscle relaxation [7]. This was in similarity

to the study conducted by Gupta *et al*., where Ketamine-Propofol, Fentanyl-Propofol, and Butrophanol-Propofol were compared for insertion condition of LMA and found that Butorphanol-Propofol group 28(93.33%) and Fentanyl-Propofol group 16(53.33%) had better jaw relaxation than Ketofol group 11(36.66%) [15]. Erdogan *et al*. observed that Ketofol provides similar insertion conditions as Propofol to Proseal LMA insertion in elderly patients [16]. The contrary results were observed in the study conducted by Amany K *et al*. where they observed a statistically significantly higher complete jaw relaxation and mouth opening in groups PK (80%) than in group P (40%) [13].

No significant difference was found in coughing, gagging, and swallowing in both the groups, but the incidence was higher in group-K which may be due to, the property of ketamine to preserve the airway reflexes i.e. pharyngeal and laryngeal reflexes [17] and also may be due to, we used the loss of eyelash reflex as the adequate depth of anaesthesia which may have been adversely affected Baska mask insertion conditions. The incidence of involuntary movements was more in Group K (10%) than in Group-P (3.33%), but it was statistically insignificant. In both groups, laryngospasm was not seen. Similarly, in the study by Goh PK *et al*., the head and neck movements were seen higher using ketamine in 40% of cases, and the coughing and gagging were seen in 10% of cases in both ketamine and fentanyl groups [18].

We observed a decrease in blood pressure and heart rate with induction in both the groups, but there was not seen any haemodynamic instability and the haemodynamic stability was better in the Propofol-Ketamine mixture compared to Propofol alone, during the first 5mins after placement of the Baska mask. The HR values were comparable in both the groups at induction and after placement of the device. But, at 2min, 3min, and 5min after placement of the device, there was a less decrease in HR in Group-K as compared to Group-P which was statistically significant. There was a statistically significantly less decrease in SBP, DBP, and MAP in Group-K than Group-P after induction, 2min, and 3min after placement of the device.

But after 5mins comparable in both the groups. Our results are similar to the study by Goh PK *et al*., in which they reported that the ketamine-propofol group had a higher heart rate and higher blood pressure than the fentanyl-propofol or propofol alone group [18]. The research conducted by Smischney NJ *et al*. reported that during the first 10mins after induction of anaesthesia there was improved hemodynamic stability in ketamine and propofol mixture than in propofol alone and they concluded that during emergency induction where stable haemodynamics are required, ketofol can be used as an alternative agent [19]. Ozgul *et al*. found that patients administered propofol had significantly lower MAP values after induction than those with ketofol [20]. Goel S *et al*. conducted a study on LMA insertion in children and reported that the decrease of SBP was statistically significantly more when propofol was used alone than when ketamine and propofol combination, was used for induction of anaesthesia [21].

The other studies which show a high degree of hemodynamic stability with the combination of Propofol-Ketamine mixture are Furuya *et al* [22], Gupta *et al* [15], Erdogan *et al* [16], Goh PK *et al* [18], Ozgul *et al* [20], Ghatak T *et al* [23], Aydoğan *et al* [24], Garg *et al* [25]. Saleem *et al* [26], Arora *et al* [27] and Gholipour *et al*. [28].

In our study, the adverse effects of ketamine (increase in secretions, emergence hallucinations, nausea, and vomiting) were not seen, which might be because all the patients were premedicated with

glycopyrrolate which reduces the secretions, midazolam which decreases emergence reactions, and also the addition of propofol eliminates the side effects of Ketamine [29]. The result of this study is similar to the studies conducted by Sawas *et al*. [30] and Gholipur *et al*. [28] in which they also observed that Ketamine and Propofol mixture (Ketofol) has fewer side effects than propofol alone.

Limitations

We have not measured the depth of anaesthesia. Before induction of anaesthesia, we used nalbuphine and midazolam routinely in all patients which may impair the effects of the induction agents on the haemodynamics. We have taken ASA grade 1 and 2 patients who didn't have any comorbidities and were vitally stable. We have included age groups less than 60yrs and Mallampatti scores 1 and 2. So further studies taking geriatric, higher ASA grade, and difficult airways are warranted to know the insertion condition and hemodynamic conditions.

Conclusions

From the present study, we concluded that the Propofol-Ketamine mixture as a coinduction agent, produces favorable conditions for smooth insertion of the Baska mask. It was hemodynamically more stable and did not produce any undue adverse effects. Hence, for insertion of the Baska mask, ketamine 1mg/kg as a coinduction agent added to Propofol 1mg/kg can be safely used in patients for better maintenance of hemodynamics.

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