Journal of Cardiovascular Disease Research

ISSN:0975-3583,0976-2833 VOL13, ISSUE04,2022

Original research article

The I-Gel and the Baska mask in spontaneously ventilating anaesthetised patients: Hemodynamic changes on inserting and after inserting the device

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Abstract

LMAs are excellent alternatives to the use of bag masks to reduce the risk of gastric inflation, thus decreasing the risk of aspiration but still far less protective than endotracheal tube. They are also an effective method of ventilation in patients requiring prolonged mask ventilation. The Baska Mask® (PROACT Medical Systems, Frenchs Forest NSW, Australia), designed by Australian anaesthetists Kanag and MeenaBaska, is a new CE-approved and internationally patented extraglottic airway device, provided in single use and multi-use versions. After ethical committee clearance, the present study was conducted on 60 patients aged between 18 to 60 years of ASA physical status I and II, of either sex, posted for elective surgeries under general anaesthesia with spontaneous ventilation. Statistical analysis using independent samples t test shows that there is no statistically significant difference between the baseline as well as subsequent readings of mean heart rate between the two group (P>0.05). Both the groups are comparable to each other in terms of comparison of heart rate at different time intervals.

Keywords: I-Gel, the baska mask, hemodynamic changes

Introduction

The laryngeal mask airway (LMA; LMA North America, San Diego, CA) was one of the first extraglottic airways invented by Dr. Archie Brain of United Kingdom in 1981. It became commercially available in the United Kingdom in 1988 and in the United States in 1991[1].

Laryngeal mask airways can be used as a primary airway management devices in the operative setting in preselected, fasted patients[2].

In the emergency setting, LMAs are used as a temporary bridge to intubation by pre-hospital providers, in cardiac arrest situations.

LMAs are excellent alternatives to the use of bag masks to reduce the risk of gastric inflation, thus decreasing the risk of aspiration but still far less protective than endotracheal tube[3].

They are also an effective method of ventilation in patients requiring prolonged mask ventilation.

The Baska Mask® (PROACT Medical Systems, Frenchs Forest NSW, Australia), designed by Australian anaesthetists Kanag and MeenaBaska, is a new CE-approved and internationally patented extraglottic airway device, provided in single use and multi-use versions.

The Baska mask obviates the need for an oro-gastric tube and replaces it with a sump and two drains.

The Baska Mask, is made of medical grade silicone, except for the 15 mm connector, which fits into the proximal ends of the main (ventilation/breathing) airway tube and clearance tubes and an interchangeable (left or right) swivel suction elbow, attached to either of the suction/air inflow ports[4].

The I-gel (Intersurgical Ltd., Wokingham, Berkshire, UK) is a new single-use non-inflatable supraglottic airway device invented by Muhammed Nassir in 2003 (Ostermayer). It is a 2nd generation supraglottic airway device composed of a soft, gel-like, transparent, thermoplastic elastomer.

It is designed to achieve a mirrored impression of the pharyngeal and laryngeal structures and to provide a perilaryngeal seal without cuff inflation. A drain tube is placed laterally to the airway tube and allows the insertion of a gastric tube[5].

The device has buccal cavity stabilizer which has propensity to adopt its shape to or pharyngeal curvature of the patients. It is widened and concaved to eliminate the potential for rotation, thereby reducing the

ISSN:0975-3583,0976-2833 VOL13, ISSUE04,2022

risk of malposition[6].
The device also has an epiglottic blocker which prevents downfolding of the epiglottis and obstruction of the distal opening airway.

Methodology
Source of data
After ethical committee clearance, the present study was conducted on 60 patients aged between 18 to 60 years of ASA physical status I and II, of either sex, posted for elective surgeries under general anaesthesia with spontaneous ventilation.

Methods of data collection
A prospective randomized comparative study was conducted after obtaining written informed consent from the patients.
A computer generated randomization was done.

Inclusion criteria
- Patients belonging to ASA physical status I and II
- Age 18-60 years, belonging to either sex
- Non-obese (BMI<30kg/m^2) adult patients
- Patients giving informed, written and valid consent
- Surgical procedures in the supine position with SAD placement of ≤ 1 hour duration.

Exclusion criteria
- Mouth opening less than 2.5 cm
- Patients with difficult airway
- Patients at risk of aspiration of gastric contents
- Patients posted for emergency surgeries and caesarean sections
- Patients with cardiac, renal, hepatic and cerebral diseases

Method of study
This was a prospective randomized study of patients satisfying all inclusion criteria.
An informed consent was obtained from all the patients participating in the study.
The study population was divided into 2 groups of 30 patients each.
1. Group B (n=30), was Baska mask group.
2. Group I (n=30), was I-GEL group.

All the patients of 2 groups, with their informed consent, were kept nil per oral for 6 hours. After careful pre-anaesthetic evaluation and airway assessment, patients were premedicated with Tab. Diazepam 5 mg and Tab. Ranitidine 150 mg the evening before the day of surgery.

Results

Table 1: Comparison of HR at different time points (n=60)

ParametersMean (SD) HR	Baska mask group(n=30)	I-GEL group (n=30)	p-value
Pre-operative	87.6 (13.7)	82.5 (12.9)	0.136
at insertion	88.9 (12.4)	84.2 (10.7)	0.122
3 mins	85.4 (12.9)	83.6 (13.7)	0.616
5 mins	86.6 (11.7)	81.1 (13.5)	0.101
10 mins	83.7 (12.5)	81.7 (10.6)	0.514
15 mins	81.8 (11.7)	80.6 (10.3)	0.655
30 mins	81.7 (11.5)	79.9 (10.3)	0.518
Post-operative	80.9 (12.0)	80.8 (11.3)	0.974

*p value by independent samples to test

The above table and figure compares the mean heart rate at different time intervals between the two groups. Statistical analysis using independent samples t test shows that there is no statistically significant difference between the baseline as well as subsequent readings of mean heart rate between the two group (P>0.05). Both the groups are comparable to each other in terms of comparison of heart rate at different time intervals.

ISSN:0975-3583,0976-2833 VOL13, ISSUE04,2022

Table 2: Comparison of SBP at different time points (n=60)

ParametersMean (SD) SBP	Baska mask group(n=30)	I-GEL group (n=30)	p-value
Pre-operative	118.7 (11.9)	123.4 (10.6)	0.112
at insertion	113.5 (10.9)	114.4 (8.3)	0.701
3 mins	112.2 (9.5)	112.6 (9.3)	0.881
5 mins	111.7 (9.1)	109.4 (10.1)	0.373
10 mins	111.1 (9.5)	111.9 (10.2)	0.764
15 mins	112.0 (9.3)	111.9 (7.4)	0.964
30 mins	112.7 (9.1)	111.8 (8.4)	0.702
Post-operative	119.7 (11.1)	119.3 (9.8)	0.873

*p value by independent samples to test

The above table and figure compares the mean SBP at different time intervals betweenthe two groups. Statistical analysis using independent samples to test shows that there is no statistically significant difference between the baseline as well as subsequent readings of mean SBP between the two groups (P>0.05). Both the groups are comparable to each other in terms of comparison of SBP at different time intervals.

Table 3: Comparison of DBP (diastolic blood pressure) at different time points (n=60)

ParametersMean (SD) DBP	Baska mask group(n=30)	I-GEL group (n=30)	p-value
Pre-operative	75.1 (9.7)	72.9 (8.5)	0.369
at insertion	72.9 (9.0)	68.0 (8.7)	0.035
3 mins	71.1 (9.1)	69.8 (9.5)	0.601
5 mins	70.5 (8.6)	67.8 (11.0)	0.306
10 mins	69.6 (8.3)	67.3 (10.5)	0.336
15 mins	70.8 (8.3)	69.6 (7.7)	0.587
30 mins	71.5 (9.8)	69.9 (8.3)	0.506
Post-operative	75.2 (9.6)	75.5 (8.6)	0.877

*p value by independent samples to test

Theabove table and figure compares the mean DBP at different time intervals betweenthe two groups. Statistical analysis using independent samples to test shows that there is no statistically significant difference between the baseline as well as subsequent readings of mean DBP between the two groups (P>0.05). Both the groups are comparable to each other in terms of comparison of DBP at different time intervals.

Table 4: Comparison of map (mean arterial pressure) at different time points (n=60)

ParametersMean (SD) MAP	Baska mask group(n=30)	I-GEL group (n=30)	p-value
Pre-operative	89.6 (9.9)	89.8 (7.1)	0.948
at insertion	86.5 (9.1)	83.5 (7.9)	0.183
3 mins	84.8 (8.6)	84.1 (8.5)	0.746
5 mins	84.2 (7.7)	81.7 (9.9)	0.281
10 mins	83.5 (8.0)	82.2 (9.5)	0.563
15 mins	84.5 (7.8)	83.7 (6.7)	0.677
30 mins	85.2 (9.1)	83.9 (7.4)	0.538
Post-operative	90.0 (9.6)	89.9 (8.5)	0.988

* P value by independent samples to test

The above table and figure compares the mean MAP at different time intervals between the two groups. Statistical analysis using independent samples to test shows that there is no statistically significant difference between the baseline as well as subsequent readings of mean MAP between the two groups (P>0.05). Both the groups are comparable to each other in terms of comparison of MAP at different time intervals.

Table 5: Comparison of spo_2 (oxygen saturation) between two groups (n=60)

ParametersMean (SD) SpO_2	Baska mask group(n=30)	I-GEL group (n=30)	p-value
SpO_2	99.1 (0.25)	99.3 (0.6)	0.053

*P value by independent samples to test

The above table and figure compares the SpO_2 between the two groups. Statistical analysis using independent samples t test shows that there is no statistically significant difference in the readings of SpO_2 between the two groups (P>0.05). Both the groups are comparable to each other in terms of

ISSN:0975-3583,0976-2833 VOL13, ISSUE04,2022

comparison of SpO_2.

Discussion

Hemodynamic parameters were continuously monitored. Values were recorded at baseline, after induction at-the time of insertion, 3mins, 5 mins, 10 mins, 15 mins then every 15 minutes till end of surgery and post-operatively. HR, SBP, DBP, RR, SpO_2 were monitored.

The mean baseline heart rate was 84.57 ± 3.67 in Group B and 81.8 ± 1.9 in Group I. Heart rate was assessed at various time intervals after the insertion of LMA. The readings at subsequent intervals between two groups were found to be statistically insignificant (p value >0.05).The mean basal systolic blood pressure (SBP) in Group B was 118.7 ± 11.9 mmHg and in Group I was 123.4 ± 10.6 mmHg. The readings of subsequent SBP at different time points between two groups were clinically and statistically insignificant. (P value >0.05). The mean basal diastolic blood pressure (DBP) in Group B was 75.1 ± 9.7 and in Group I was 72.9 ± 8.5. The changes in the subsequent readings between two groups was found to be statistically insignificant. (p value > 0.05). The basal mean arterial pressure (MAP) in Group B was 89.6 ± 9.9 and in Group I was 89.8 ± 7.1. The changes in the subsequent readings between two groups was found to be statistically insignificant. (P value > 0.05). There was no statistically significant difference between readings of SpO2 between the two groups. (P value > 0.05).

A comparative study conducted by ShivaniFotedar between I Gel and the Baska mask in spontaneously ventilating anaesthetised patients undergoing elective surgery had a comparable results in both the groups with regards haemodynamic parameters, similar to our study and were statistically insignificant[7]. Rehab Abdel Raof Abdel Aziz, Yasser Mohamed Osman conducted a study comparing I Gel with Baska mask airway for controlled ventilation in obese patients undergoing ambulatory surgery. They found that the changes in haemodynamic parameters were comparable in both the groups and were statistically insignificant similar to our study[8].

Conclusion

The hemodynamic parameters such as the heart rate, the systolic, diastolic and mean arterial blood pressures were comparable between the I-Gel and Baska mask group.

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