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ORIGINAL RESEARCH

AN OBSERVATIONAL CLINICAL STUDY ON HEMODYNAMIC RESPONSE AND EASE OF INSERTION IN CLASSIC LMA, PROSEAL LMA AND I-GEL DURING SURGERY UNDER GENERAL ANAESTHESIA

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ABSTRACT

INTRODUCTION- Laryngeal mask airway (LMA), which is a useful alternative for airway management during spontaneous or controlled ventilation. It can also be used for difficult airway management and emergency resuscitation especially by untrained personnel .It is also found to be useful in many patients to provide general anaesthesia. Supraglottic airway devices also eliminate many other problems associated with tracheal intubation.

AIMS AND OBJECTIVES:-To observe the hemodynamic response and ease of insertion of cLMA, proseal LMA or I-GEL in terms of:-

- Attempts required for supraglottic device insertion
- Duration required for supraglottic device insertion
- Ease of insertion
- Hemodynamic responce during insertion

To observe any adverse effect during cLMA, proseal LMA or I-GEL insertion.

MATERIAL AND METHODS:-It is an observational hospital based study conducted at Department of Anaesthesiology Gandhi Medical College and associated Hamidia Hospital, Bhopal M.P., from January 2020 to July 2021. A total of 75 patients were included in study and divided into three groups (25 each).

OBSERVATION AND RESULTS:-The mean time taken for device insertion in group1 was17.56±1.66seconds, in group 2 it was 19.56±1.66 seconds and in group 3 it was

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12.36±2.08seconds. The insertion time in group 3(I-gel group) was shorter than other 2groups which was statistically significant with p<0.0001.

DISCUSSION:- In our study, the mean insertion time for classic LMA was 17.56±1.66 secs, for P-LMA it was 19.56±1.66 sec and for I gel it was 12.36±2.08 secs which was shortest among the 3 devices and difference was statistically significant (p value <0.0001). This significant shorter time to insert I gel as compared to classic LMA or proseal LMA could be attributed to the absence of an inflatable cuff in I-gel and anatomically designed thermo elastic laryngeal mask. Similar results were found in study of Reyhan polat et alwho compared I-gel and classic LMA and found insertion time for I-gel was 11.6±2.4 sec and for classic LMA it was 13.1±1.8 sec , Anjan D et alwho compared I gel and proseal LMA and found insertion time for I gel was 14.9 secs and for proseal LMA it was 20 secs , Gaurav C etal who compared I gel and proseal LMA and found insertion time for I gel was 11.12±1.81 secs and in proseal LMA it was 15.13±2.91 secs.

CONCLUSIONS:-From this study we concluded that all the devices classic LMA, proseal LMA and I–gel are safe and effective supraglottic airway devices, whereas I-gel is relatively easier and faster to insert when compared to classic LMA and proseal LMA . Insertion is smooth without any trauma to anatomical structures in both I-gel and classic LMA with majority being inserted in the first attempt in all three groups.

KEYWORDS: - LMA, hemodynamic response, ease of insertion

INTRODUCTION-

In 1983 Archie I.J.brain developed laryngeal mask airway (LMA), which is a useful alternative for airway management during spontaneous or controlled ventilation. It can also be used for difficult airway management and emergency resuscitation especially by untrained personnel .It is also found to be useful in many patients to provide general anaesthesia. Supraglottic airway devices also eliminate many other problems associated with tracheal intubation. The insertion technique for supraglottic devices can be learned easily than endotracheal intubation. But airway protection from secretion and blood is not as good as by endotracheal tube intubation. There are many types of supraglottic airway devices available now with their respective advantages and disadvantages[1].

LMA-Classic: - LMA-Classic is the first generation and most commonly used supraglottic device. This is also included in difficult airway society guidelines for difficult intubation management4.It is also considered the benchmark against which newer LMA judged.

LMA-Proseal:-The Laryngeal Mask Airway ProSeal is a reusable second generation supraglottic airway device with an additional gastric drain tube to channel that reduces the risk of gastric aspiration and a tighter seal against the glottic opening hence tolerate positive pressure ventilation better than classic LMA, with minimal increase in mucosal pressure.

I-GEL: - I-gel on the other side is a single use non inflatable supraglottic airway device with integrated gastric channel provided for passage of nasogastric tube for gastric suction. The mask is made of a gel like thermoplastic elastomer, the shape, softness, contours provides it to accurately mirror perilaryngeal framework itself and creates the perfect fit.

P P lu et al(2002), conducted a study in 2002 comparing 2 supraglottic devices proseal LMA and LMA classic in laparoscopic cholecystectomy in 80 anaesthetized, paralyzed patients of ASA grade 1 and 2 aged 18-80 years, variable compared in terms of Ease of insertion and

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efficacy of seal .They concluded that First-time insertion success rates were higher for the c LMA compared to pLMA (40/40 vs 33/40; P=0.02),Seven patients required two attempts with pLMA , oropharyngeal leak pressure was higher for the pLMA(29+/-6 cm H2O)compared to CLMA(19+/-4 cm H2O) wit p<0.001,PLMA is a more effective ventilatory device than LMA classic[2].

Anjan D et al (2008) conducted a study in 60 adult patients of ASA grade I, II between age 20 and 30 yrs of either sex, comparing I-gel with P-LMA in terms of ease of insertion and hemodynamic alterations in heart rate and blood pressure caused by the stress response by the devices. They found I-gel was more easy to insert (90% vs. 83.33%) and insertion time was shorter (14.9 vs.20 secs) compared to P-LMA. They also found hemodynamics was lesser altered with I-gel than P-LMA, which were statistically significant[3].

Richez B et al (2008)conducted a study on I–gel in 71 female patients of age group 18-60 years and of ASA grade 1 and 2 , It was a prospective , an observational study, conducted in gynaecological surgeries .They were able to insert i-gel in 100% patients at first attempt . They got score of very easy in more than 90% patients with I-gel. It could be used in IPPV ventilation because minimal gastrointestinal insufflations, high leak pressure (30+/-7 cm H2O) as well as low peak pressure (11+/-3 cm H2O). They also noticed less pharyngo-laryngeal complications and hence concluded that I gel is a reliable, easily inserted airway device which provide adequate seal with low morbidity[4].

AIMS AND OBJECTIVES:-

1-To observe the hemodynamic response and ease of insertion of classic LMA,PROSEAL LMA and I-GELin terms of:-

- Attempts required for supraglottic device insertion
- Duration required for supraglottic device insertion
- Ease of insertion
- Hemodynamic response during insertion

2-To observe any adverse effect during cLMA, proseal LMA or I-GEL insertion

MATERIAL AND METHODS:-

It is an observational hospital based studyconducted at Department of Anaesthesiology Gandhi Medical College and associated Hamidia Hospital, Bhopal M.P., from January 2020 to July 2021. A total of 75 patients were included in study and divided into three groups (25 each).Group **1** (classic LMA): n=25; Group **2** (proseal LMA) :n =25; Group **3**(I-gel) :n=25

Inclusion Criterias-

- Patients of ASA Grade I and II.
- Age ranging from 18 to 45 years of both genders.
- Patients scheduled for elective short surgical procedures (30-60min) in General Anaesthesia in supine position.
- Patients having mallampati grading of grade 1 or 2.

Exclusion Criterias-

- Patient refusal(negative consent).
- ASA grade III and IV.

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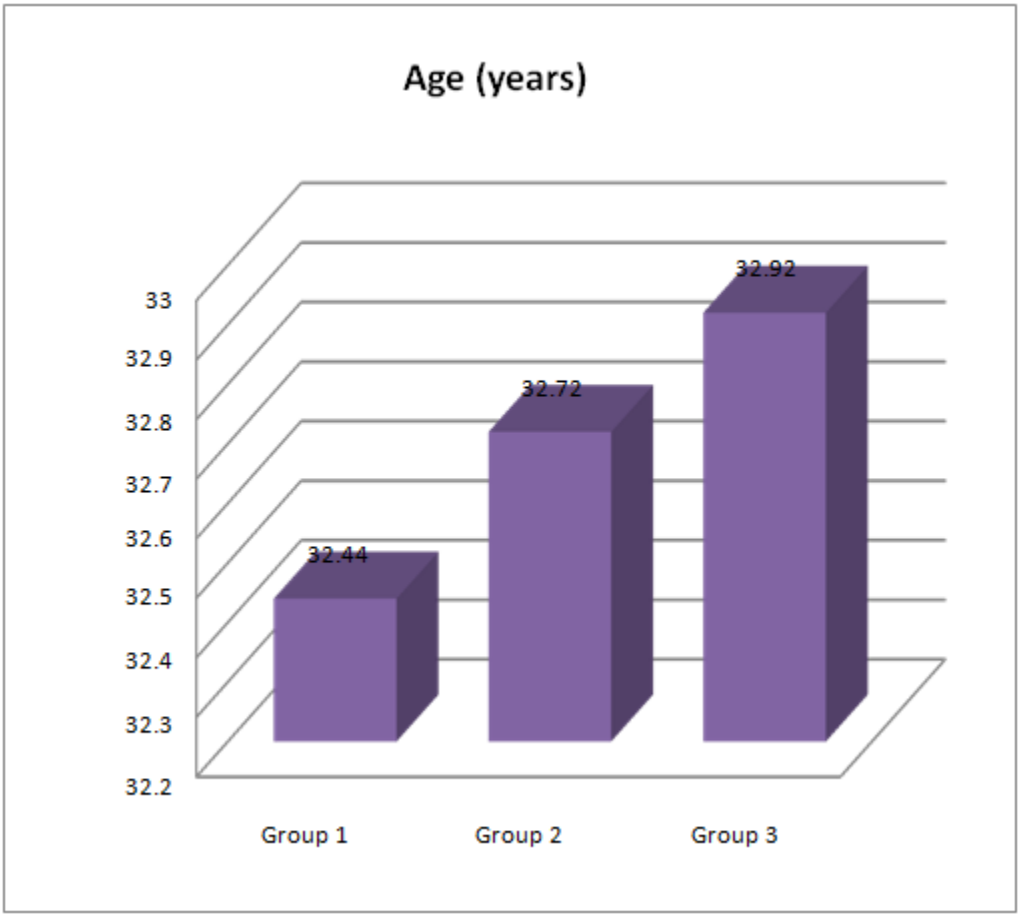
- High risk of aspiration(full stomach, Gastroesophageal reflex disease, Pregnancy)
- Abnormal airway anatomy,tonsillar hypertrophy,hematoma,abcess etc.
- Difficult airway- Mallampati grade 3 or 4
- Obese patient- BMI>30 kg/m2.
- Allergy to medications and latex Sample Size:

Statistical details all the data were performed using SPSS ver. 20 software .Frequency distribution and cross tabulation was used to prepare the table.

OBSERVATION AND RESULTS:-

Group	N	Age in years (Mean±SD)	p-value
1	25	32.44±6.219	0.965
2	25	32.72±6.767	
3	25	32.92±6.034	

Table-1: AgeDistribution



Graph-1: Age Distribution

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The mean age distribution in group1,group2 and group3 were 32.44±6.219years,32.72±6.767years and 32.92±6.034 years respectively which was not statistically significant(p=0.965)

Group	N	Weight in kg (Mean±SD)	p-value
1	25	61.52±3.41	0.350
2	25	60.76±4.00	
3	25	60.00±3.56	

Table-2: Mean Weight (In Kg) of Patients Among Groups

The mean weight of patients in group1was61.52±3.41kg,in group2 it was 60.76±4.00 kg and in group 3 it was 60.00±3.56 kg the difference was not statistically significant with p=0.350.

Group	N	Time ofInsertion in seconds (Mean±SD)	p-value
1	25	17.56±1.66	<0.0001
2	25	19.56±1.66	
3	25	12.36±2.08	

Table-3: Time Taken For Insertion of Device

The mean time taken for device insertion in group1was17.56±1.66seconds, in group 2 it was 19.56±1.66 seconds and in group 3 it was 12.36±2.08seconds.The insertion time in group 3(I-gel group) was shorter than other 2 groups which was statistically significant with p<0.0001.

	Group1	Group2	Group3
ASAphysicalstatus-I/II	16/9	16/9	14/11
Numberofattempts takenforinsertionofdevice -first/second	21/4	19/6	24/1
Bronchospasm	0	0	0
Laryngospasm	0	0	0
Bloodstaineddevice	0	1	0
Trauma tolip/teeth/pharynx	0	0	0
Nausea/vomiting	0	0	0
Postoperativesorethroat	3	4	0

Table 4.Overall comparison of three groups based on the results obtained.

DISCUSSION:-

Safe and efficacious airway management is one of the most important aspects of anaesthesia. Securing an airway and ventilation is a basic part of the management of all patients, regardless of whether the patient requires a short duration or daycare surgery.Today,the supraglottic airway devices has come to be widely used as analternative

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to endotracheal tube in airway management during short surgical procedures or day care anaesthesia.

In our study there were no significant difference in demographic data of all the three groups, mean age of group 1 patient was 32.44±6.21 years ingroup 2 it was 32.72±6.76 years and 32.92±6.03 years in group 3 with p=0.965 which was statistically not significant .The mean weight in threegroupswere61.52±3.45kg,60.76±4.00kgand60.00±3.56kgrespectively with p=0.35statistically not significant. Demographic distribution was similar to the study done by Revi N et al(with mean age weight distribution in I gel group 36.7±10.52 yrs and 67.88±12.47kg ,in pLMA group 37±8.68yrs and 66.44±14.48kg and in cLMA group 38.56±12.56yrs and 63.12±12.55kg), Shin WJ et al (with mean age and weight distribution were 42±16 yrs and 64±17 kg in I gel group ,44±15 yrs and 66±12 kg in pLMA goup and 48±13 yrs and 64±12 kg in cLMA group) and Gaurav et. al (mean age and weight in I gel group32.13±11.69 yrs and 57.1±8.482 kg and in pLMA group mean age was 32.43±7.27 yrs and mean weight was 58.15±11.24 kg)[5,6].

In our study, the mean insertion time for classic LMA was 17.56±1.66 secs, for P-LMA it was 19.56±1.66 sec and for I gel it was 12.36±2.08 secs which was shortest among the 3 devices and difference was statistically significant (p value <0.0001). This significant shorter time to insert I gel as compared to classic LMA or proseal LMA could be attributed to the absence of an inflatable cuff in I-gel and anatomically designed thermo elastic laryngeal mask. Similar results were found in study of Reyhan polat et alwho compared I-gel and classic LMA and found insertion time for I-gel was 11.6±2.4 sec and for classic LMA it was 13.1±1.8 sec , Anjan D et alwho compared I gel and proseal LMA and found insertion time for I gel was 14.9 secs and for proseal LMA it was 20 secs , Gaurav C etal who compared I gel and proseal LMA and found insertion time for I gel was 11.12±1.81 secs and in proseal LMA it was 15.13±2.91 secs , Amr et alwho compared I gel and classic LMA and found insertion time for I gel was 15.6±17.7 secs and for classic LMA it was 26.2±17.7 secs , Revi N et alwho compared I gel, clssic LMA and proseal LMA and found insertion time for I gel was 11.24±5.65 secs in for classic LMA it was 18.16±4.66 secs and for proseal LMA it was 20.36±5.65 secs,and Vinuth k et alwho compared I gel and proseal LMA and found that insertion time for I gel was 17.12±3.42 secs and for proseal LMA it was 25.62±5.28 secs in their studies[7-9].

In our study, classic LMA was inserted in first attempt in 84%(21/25) of patients and in second attempt in 16%(4/25) of patients whereas, P-LMA was inserted in first attempt only in 76%(19/25) of patients and in second attempt in 24%(6/25) of the patients, I-gel on the other hand inserted successfully in first attempt in 96%(24/25) patients and in second attempt in remaining 4%(1/25) patients, but the difference was statistically not significant (p value = 0.163).The similar observation was found in studies done by Brimacombe j et al who compared classic LMA and proseal LMA the 1st attempt insertion success rate for classic LMA was 91% and for proseal LMA it was 82% with P=0.015 ,P P lu et alwho compared c lassic LMA and proseal LMA the First-time insertion success rates for the classic LMA was (40/40) and for proseal LMA it was (33/40) with P=0.02, Siddiqui AS et al who compared classic LMA and I gel and found the 1st attempt success rate in classic LMA was 86% and and in I gel it was 90% , and Revi N et alwho compared I gel, proseal LMA and classic LMA and found that first attempt successful insertion in I gel was 96% for proseal LMA it was 80% and for classic LMA it was 88% . Contrary to that studies done by Janakiraman et al who compared I gel and classic LMA found i-gel was successfully inserted at the first attempt in 54% patients and the c- LMA was successfully inserted at the first attempt in 86% of patients and Ansar ali et alwho compared

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classic LMA and I gel found that first attempt successful insertion in classic LMA group was 94% while In I-gel group, first attempt successful insertion was achieved in 90% cases. Gasteiger L et al, in his studies, found that mean attempts for insertion of both the devices (PLMA and I-gel) were similar easy using a duodenal tube guided technique[10-12].

In our study, no incidence of complications like cough, laryngospasm, nausea / vomiting, trauma to lip / teeth / pharynx was noted. However the incidence of sore throat was noticed in 3/25(12%) cases of classic LMA (group 1) and 4/25(16%) cases of proseal LMA (group 2). And On the removal of devices, in proseal LMA group one device was found to be blood stained (1/25 or 4%), none of the devices found blood stained in other two groups I.e. classic LMA or I-gel group. The results of our study on any adverse event or complications induced by the device, had been supported by other studies done Singh I et al, whose study showed that the incidences of airway trauma and blood staining were statistically insignificant. Gaurav C et al also observed lesser complications with I-gel group than P-LMA group, contrary to that Gurudas K et al showed that the incidence of postoperative. Sore throat was insignificant in both the study groups (P-LMA and I-gel) [13,14].

CONCLUSIONS:-

From this study we concluded that all the devices classic LMA, proseal LMA and I–gel are safe and effective supraglottic airway devices, whereas I-gel is relatively easier and faster to insert when compared to classic LMA and proseal LMA . Insertion is smooth without any trauma to anatomical structures in both I-gel and classic LMA With majority being inserted in the first attempt in all three groups. Patients in all the groups were relatively free of post extubation cough, laryngospasm, nausea and vomiting. All the three devices I-gel, proseal LMA and classic LMA are safe and patient friendly tools in the hands of anaesthetists for surgeries under general anaesthesia with easier insertion of I-gel comparative to other two devices with no statistical difference in hemodynamic changes in all three groups. However following were limitations of this study which consists relative small sample size, only adult population were taken, proper positioning of the supraglottic airway device was not confirmed with fiberoscope, cost effectiveness of the reusable against the single use device was not taken into consideration,the anaesthesiologist performing the insertion of the device could not be blinded.

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