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A randomised Comparative study of efficacy of i-gel and laryngeal tube in mechanically ventilated gynaecological laparoscopic surgeries.

Anaesthesiology

KEYWORDS: I-gel ,Laryngeal tube,Mechanical ventilation,Laparoscopic surgeries.

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ABSTRACT

Background and aims: To avoid the complications associated with endotracheal intubation (1)the efficacy of newer supraglottic devices(2) are being tested in term of ventilating patient.This randomised study was conducted with aim of comparing I-gel and Laryngeal tube in terms of ease of insertion,ventilatory parameters like Leak pressures,Peak pressures,Dynamic airway compliance.

Materials and methods: a total of 60 patients ,scheduled for gynaecological laparoscopic surgeries were randomly allocated to group I (n=30)to be ventilated with i-gel and group L (n=30)to be ventilated with laryngeal tube. Ease of insertion,Ventilatory parameters like Leak pressures,Peak pressures,Dynamic airway compliance were noted. Sample size was calculated at 90% study power and alpha error 0.05, assuming standard deviation of 13ml/cm for all devices for the minimal detectable difference of 12ml/cm in dynamic airway compliance.Statistical analysis was done using Microsoft excel software using the students t-test and chi-square test (level of significance p=0.05).

Results : Ease of insertion in terms of number of attempts and time taken for insertion was better with I-gel. Leak pressures were higher for I-gel and Dynamic airway compliance were comparable in both groups..

Conclusion:I-gel is a better alternative to endotracheal intubation in compared to Laryngeal tube in electively ventilating gynaecological laparoscopic surgeries..

Introduction

Maintaining a patent airway is a prime responsibility of an anaesthesiologist.

At times it may pose great challenges to the anaesthetist as well. Tracheal intubation using a laryngoscope has been considered as GOLD STANDARD of airway management

Supraglottic devices produce lower haemodynamic instability , do not cause translocation of oral/nasal bacterial colony and secretions into the lower respiratory tract., prevent inadvertent bronchial intubations,are easy to insert and smooth awakenings are related.

Even some of supraglottic devices permit endotracheal intubations through them. Additional gastric drainage port were incorporated in newer supraglottic devices like I-gel and Laryngeal tube (LTS-D) for gastric decompression and provide some degree of protection from aspiration. Hence the present study was undertaken to compare the effectiveness of both, as an airway device with respect to oxygenation and ventilation parameters in to assess and compare Ease of Insertion(attempts of successful insertion And Time of insertion of device),to compare Leak pressures and Dynamic Airway Compliance.

Materials and methods

- The present randomised,comparative study was conducted after obtaining permission from institutional ethical committee on 60 ASA grade 1 and 2 patients ,Age 18-48 yrs ,Height =140 - 155cm,Weight 30-50kg,Undergoing elective surgical intervention in supine position with predicted anaesthesia duration between 30 and 45 mins. Patients using alpha2 receptor antagonist, calcium channel blockers, angiotensin converting enzyme inhibitors ,having dysrhythmias or a BMI >35 were excluded from the study.

- Informed written consent was taken from all patients. The patients were allocated to two groups using chit in box method. Group I patients airway was secured with i-gel and group L patients airway secured with laryngeal tube.

- Standard anaesthetic protocol was followed in all patients. On arrival in the operation theatre Baseline parameters [SpO_2, Pulse rate (PR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP)] were recorded. Mean arterial blood pressure (MAP) was calculated by formula- (2 x DBP) + SBP/3. , IV line with 18G cannula secured .Ringer lactate drip started through IV cannula.

- Premedication was given. Following induction and adequate paralysis, the corresponding airway was inserted in each patient. In group A size 3 i-gel airway (according to weight) used for all cases. The posterior surface of i-gel was well lubricated with water soluble jelly. The patient's head was maintained in the sniffing position. In group B, Laryngeal tube suction size 3(according to height) was inserted following standard blind insertion technique.

Device insertion time was calculated from keeping the device in front of mouth to correct placement in mouth and checked after observing the chest rise by manually ventilating through the breathing circuit

In our study we limited the number of insertion attempts to two and set somewhat higher criteria for a successful insertion i.e.absence of any air leak at sufficient tidal volumes in addition to simply being able to ventilate.In case we could not insert in two attempts we decided to intubate the patient.

Leakage is defined as minimum peak airway pressure at which air escapes and becomes audible with a stethoscope placed over the larynx .The pressure limit of anaesthesia circuit was set to 35 cm water and oxygen flow at 3l/min

Dynamic airway compliance were decided on the basis of peak airway pressure required to achieve comparable tidal volumes.. Lower the peak airway pressure required to achieve comparable tidal volumes better is the dynamic airway compliance..

During emergence, the occurrence of any complications like coughing, sore throat, blood staining of the device were noted. After removal of both airway the patients were monitored throughout the

perioperative period till stay in the post-anaesthesia care unit.

STATISTICAL METHODS

All the data were entered on Excel sheet ,SPSS statistical analysis system and analyzed statistically using Primer software and XL- Stat. Student t-tests and chi-square tests were applied. The P <0.05 was considered statistically significant.

RESULTS

The demographic profile of patients in both groups was comparable with respect to Age (years), ASA grade, weight (Kg) and Mallampati grading.(Table 1)

Table no. 1

Distribution of patients according to Age, ASA grade, Weight and Mallampati grading.

Variables	Group A (I-gel)	Group B (LTS)	P value
Age(yrs)	27.0+2.8	25.5±3.5	0.0792
ASA grade 1	25/30	24/30	0.7438
Weight(kg)	43.9±7.3	41.0±5.3	0.0892
MPG 1	27/30	28/30	0.6472

NUMBER OF ATTEMPTS between two groups

Table no.2

Comparison of number of attempts between both the groups

Number of attempts	Group A(I-Gel)	Group B(LTS)	P-value between groups
1	29	23	0.0242
2	1	7	

The number of attempts were ONE in 29/30 patients for I-gel and 23/30 patients for LTS which significantly high for laryngeal tube suction with p=0.0242.

Table no.3

Comparison of mean time taken for insertion +/- S.D. (in sec) between both the groups

TIME TAKEN FOR DEVICE INSERTION

	Group A(I-gel)		Group B(LTS)		P-value between groups
	Mean	SD	Mean	SD	
Time taken for device insertion(sec)	22.9	10.0	36.5	9.0	0.0000

Time taken for insertion for i-gel were 22.0+/- 10.0 sec and 36.5+/- 9.0 sec for LTS which was highly significant with p=0.0000.Time taken for laryngeal tube suction was high as more time was taken for inflating two cuffs simultaneously

LEAK PRESSURE between two groups

Table no.4

Comparison of mean leak pressure +/- S.D.(cm H20)between both the groups

	Group A(I-gel)		Group B(LTS)		P-value between groups
	Mean	SD	Mean	SD	
Leak pressure LP(cm H_20)	24.6	5.3	22.3	3.0	0.0452

Leak pressure was 24.6+/-5.3 cm H20 for I-gel and 22.3+/-3.0 cm H20 for laryngeal tube suction .This was statistically significant with p=0.0452.,,thus I-gel leaked at higher pressure as compared for laryngeal tube suction.

DYNAMIC AIRWAY COMPLIANCE

Table no 5

	Group A(I-gel)		Group B(LTS)		P-value between groups
	Mean	SD	Mean	SD	
Dynamic airway compliance (ml/cm H_20)	37.2	8.9	34.4	10.4	0.2752
Tidal Volume (ml)(8ml/kg)	434.5	59.3	408.3	43.0	0.0654
Peak airway pressure (cm water)	17.1	2.5	18.1	4.5	0.2965

	Group A(I-gel)		Group B(LTS)		P-value between groups
	Mean	SD	Mean	SD	
Dynamic airway compliance (vt/PawP-PEEP) ml/cm H_20	37.2	8.9	34.4	10.4	0.2752

The dynamic airway compliance was 37.2+/-8.9 ml/cm H_20 for I-gel and for LTS it was 34.4+/-10.4 ml/cm H_20..Dynamic airway compliance was more for I-gel but was not significantly high statistically with p=0.2752.

DISCUSSION

Laparoscopic surgery has been shown to adversely affect intraoperative pulmonary mechanics, thus providing the most severe test of the efficacy of an airway device. Pulmonary compliance is decreased and the resistance is increased leading to high airway pressures. Intra-abdominal pressure of 15 - 20 mm Hg is associated with increase in the peak airway pressure of about 50 per cent, decrease in lung compliance by 25 per cent and an increase in $PaCO_2$ by 10 mmHg. Consistent with these results, we observed that following carboperitoneum, compliance decreased and the peak airway pressure, resistance increased [3].Laparoscopic surgery entails raised intra-abdominal pressure, typically 15 mm Hg, which could possibly increase the risk of aspiration.

Tracheal intubation is considered ideal for airway management in laparoscopic surgery as it provides adequate ventilation and protects against pulmonary aspiration even in the presence of raised airway pressures due to carboperitoneum. However, the device is not foolproof against aspiration and endobronchial intubation is also not uncommon during laparoscopic procedures. In order to take the advantage of haemodynamic stability of supraglottic devices over tracheal intubation along with studying the efficacy of these devices in ventilating the patients at higher airway pressures, we conducted a comparative study.

The present study aimed to compare two supraglottic devices in terms of haemodynamic parameters, ease of insertion and ventilator parameters like leak pressure and dynamic airway compliance.

Device insertion time

It was calculated from keeping the device in front of mouth to correct placement in mouth and checked after observing the chest rise by manually ventilating through the breathing circuit. Insertion time was more with laryngeal tube with 36.5+/-9.0 sec due to more time required for inflation of its two cuffs. Time taken for I-gel being 22.9+/- 10.0 sec. The difference was highly statistically significant with p=0.000.

This was in accordance with **Sebastian et al**[4] in which they had insertion time of 10+/- 5 sec for I-gel and 14+/-10 sec respectively for laryngeal tube. The lower time taken in both groups of Sebastian et al. may be due to the fact that they choose device insertion time as the time from placing the supraglottic device in front of the patients mouth to its placement in correct position .They did not include the time for observing chest rise (following ventilation) in the insertion time.

Pratheeba et al.[5] compared I-gel and laryngeal mask airway classic in terms of ease of insertion and haemodynamic response and showed mean duration of insertion attempts was 15.92+/-1.62 sec in I-gel group while it was 26.06 +/- 5.12sec in classic LMA and was statistically significant (p=0.0001).This may be due cuffless structure of I-gel.

Wroble et al, 2004 [6] in his study in which he compared insertion

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times of laryngeal tube and the laryngeal mask airway concluded that the time of insertion was significantly shorter for the LT compared to the LMA (35.4+/- 15.6 sec versus 54.0+/- 41.5 sec ,p<0.05). Ease of insertion was significantly better with the LT compared with the LMA (88% versus 70.4%). So LT could be a better alternative over LMA in terms of ease of insertion.

NUMBER OF ATTEMPTS

In our study we limited the number of insertion attempts to two and set somewhat higher criteria for a successful insertion i.e.absence of any air leak at sufficient tidal volumes in addition to simply being able to ventilate. In case we could not insert in two attempts ,we decided to intubate the patient. In our study success rate of first attempt of insertion was 96%(29/30 patients) for I-gel and 76%(23/30 patients) for laryngeal tube which was statistically significant with p value of = 0.0242.

Sebastian[4] in his study showed first attempt insertion success rates of 95% for I-gel and 70% with laryngeal tube (p<0.005)..It was in accordance with our study in which success rate was more with I-gel group.

The reason behind the lower first attempt success rate may be the dislodgement of laryngeal tube after inflating the cuffs.. Another reason may be the fact that Laryngeal tube is not being routinely employed in operating room at all.

Amr Helmy et al [7] in his study showed that insertion and ventilation was possible at the first attempt in 90% of patients in the I-gel group and in 80% in LMA group. In 5% of the patients in LMA group, intubation and ventilation was possible after the third attempt. This was in accordance to our results in which I-gel had the success rate of 90% of first attempt of insertion.

Ishwar et al[8] showed success rate of first attempt of insertion and ease of gastric tube insertion was more with I-gel (p>0.05)when compared with proseal LMA. They concluded that the success rate at first attempt of insertion were 30/30 (100%) for I-gel and 28/30 (93.3 %) for the LMA –proseal which was statistically not significant.

Michael Bernard et al[9] in his study compared laryngeal tube and laryngeal mask airway in emergency airway management and demonstrated a first pass insertion success rate of 77 % for LT an comparison to 78.7% first pass insertion success rate for LMA .The reason for low success rate of first attempt of LT insertion as compared to LMA may be explained as -firstly, anaesthetists are well trained in LMA usage in the operating room providing anaesthesia and airway management on daily basis.; Secondly, Laryngeal tube is not being routinely employed in operating room at all .

LEAK PRESSURES

Leak pressure is defined as minimum peak airway pressure at which air escapes and becomes audible with a stethoscope placed over the larynx. Leak pressure of a supraglottic airway depends on a tight contact with the surrounding tissues. The pressure limit of anaesthesia circuit was set to 35 cm H_20 and oxygen flow at 3l/min. In our study I-gel leak pressures were 24.6+/-5.3 cm H_20 and for laryngeal tube suction it were 22.3+/-3.0.cm H_20. Thus I-gel leaked at higher pressures with p value of 0.0452 and the result was clinically significant.

Sebastian et al in his study showed leak pressure of 25.9 cm H_20 and 24.0 cm H_20 for I-gel and laryngeal tube suction respectively..That is I-gel leaked at higher pressures.

Bimla et al [10] in their study showed leak pressure of 30 cm H_20 with I-gel in laparoscopic cholecystectomy surgeries and stated that higher leak pressures of I-gel signifies its better protection against aspiration and better suitability in patients with low compliance or higher airway pressures . This was in favour of our study . The reason for higher leak pressure may be the fact that I-gel is made of thermoplastic elastomer which forms better seal with perilaryngeal structures.

T. Asai et al.[11] compared laryngeal tube with laryngeal mask airway and concluded that success rate of obtaining patent airway through LT was high . Laryngeal tube provides good airtight seal in most patients and often there was no gas leak around the cuff at any airway pressure of 30 cm H_20. The leak pressure of LT was significantly higher than LMA. So LT was a better option over LMA in terms of airway sealing.

Roth et al 2005 [12] compared the Proseal laryngeal mask airway and the laryngeal tube suction for ventilation in gynaecological patients undergoing laparoscopic surgeries and found that the airway leak pressures were 45.4+/- 4.9 cm H_20 and 45.6+/- 6.7 cm H_20 for Proseal LMA and LTS respectively with cuff pressures adjusted to 60 cm H_20 . No gastric insufflations,gas loss or signs of regurgitation were detected

DYNAMIC AIRWAY COMPLIANCE

It was decided on the basis of peak airway pressure required to achieve comparable tidal volumes. Lower the peak airway pressure required to achieve comparable tidal volumes better is the dynamic airway compliance.. Dynamic airway compliance was lower for the Laryngeal tube suction.

Though LTS forms better seal but higher peak pressure with Laryngeal tube suction is seen, probably due to a narrower breathing tube and smaller distal apertures.

Dynamic airway compliance in my study were in range from 37.2+/-8.9 ml/cm H_20 for I-gel and for laryngeal tube suction it was 34.4+/-10.4 ml/cm H_20 (p=0.2752). Though there was difference in dynamic airway compliance performance with both devices but the result was statistically insignificant.

Sebastian et al[4] demonstrated in there study that dynamic airway compliance was highest with the I-gel and lowest with laryngeal tube suction when he compared I-gel, LMA supreme and LTS-D . They reported that a significantly higher Peak airway pressures was required to achieve the comparable tidal volume in case of Laryngeal tube suction. They showed dynamic airway compliance of 49.9+/-12.7 ml/cmH_20 for I-gel and 38.0+/-13.4 ml/cm H_20 for laryngeal tube which was in accordance to our study. .

Bimla Sharma et al[10] in their study compared proseal LMA with I-gel in patients with laparoscopic cholecystectomy and concluded that PLMA forms better seal but dynamic airway compliance was higher with I-gel. The reason behind the better ventilating compliance may be due to its wide bore airway tube delivering adequate tidal volume. Another advantage of the I-gel over the laryngeal tube would be the absence of rise of intracuff pressure in the presence of nitrous oxide anaesthesia since it is cuffless.

Limitations

1. Fibre optic scope for glottic visualization grading could not be used as the equipment was not readily available for all the cases at the time of the study.
2. We did not do intracuff pressure monitoring due to the cuffless structure of I-gel.
3. Obese patients and those with restrictive lung disease were not included in the study.

CONCLUSION

So, the present study showed that both I-gel and Laryngeal tube suction were comparable and acceptable alternatives for airway management during elective gynaecological laparoscopic surgeries. In the present study,I-gel was found to be superior to Laryngeal tube suction during gynaecological laparoscopic surgeries under general anaesthesia with controlled ventilation. I-gel airway was slightly better over a number of variables like insertion time and success rate

and optimal ventilation.

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