

Safety and Limitation of the I-gel Laryngeal mask airway in the Lithotomy Position. An Observational study

Original Article

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ABSTRACT

Background: Laryngeal mask airway is used in different types of surgery requiring different position, recommendation was raised regarding the use of LMA in Lithotomy position with pressure controlled mode of ventilation. This raise a concern whether the mode of ventilation is a limitation for the use of LMA in these position, especially with the use of the i-gel LMA with the characteristic non-inflatable jelly cuff, that provides an excellent seal.

Aim of the study: The safety and efficacy of I-gel LMA in the lithotomy position with volume controlled mode of ventilation.

Results: No significant change in the EtCO₂ among the two groups (37.8 mmHg vs 36.08 mmHg), Peak inspiratory pressure (PIP) was 16.9 ± 4.1 mmHg in group T vs 17 ± 5 mmHg. Minimal difference between the inspired and expired Tidal volume in the two groups (22.5 ml in group T vs 21.7ml in group L). the rate of complications was 53.3% in group T vs 3.3% in group L.

Conclusion: I gel could be safely used with the patients in lithotomy position using volume controlled ventilation.

Key Words: 2nd generation, lithotomy, LMA, position, safety.

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INTRODUCTION

The laryngeal mask airway (LMA) is an alternative to mask ventilation and endotracheal intubation. As it is easily placed and is less invasive than endotracheal intubation, but it does not neither fully protect against aspiration nor does it prevent laryngospasm^[1].

First-generation supraglottic airway device (SADs) (The original LMA and similar devices are Known as first-generation SGAs) is considered as a simple device and include cLMA, flexible LMA, and all LMs. First-generation SADs include an airway tube with a mask-like cuff. It offers some protection against aspiration in case of regurgitation but have no specific design features that lessen this risk^[1].

But for the Second-generation SADs, it has design features to reduce the risk of aspiration. These include: i-gel, Supreme LMA, Laryngeal tube suction II^[2].

Some devices, from a variety of manufacturers, incorporate other unique features. Where some include Flexible, reinforced LMAs have wire-reinforced to be positioned away from the surgical field, which is

particularly useful wherever there is an airway competition, other incorporate a preformed curved airway tube to facilitate insertion, has a self-inflating, low-pressure cuff or a conduits for endotracheal intubation^[3].

The i-gel differs from other SGAs in that it provides an excellent seal and eliminates concerns about cuff pressures through the non-inflatable gel cuff. The i-gel has a gastric vent, an integral bite block, and a flange designed to prevent epiglottic folding^[1].

Adequate depth of anesthesia with intravenous (IV) or inhalational anesthetics should be guaranteed before SGA placement in order to avoid coughing, gagging, laryngospasm, breath holding, or straining. Awake intubation with SGAs with topical anesthesia has also been documented^[4].

With correct insertion, the LMA fit the glottis, with the epiglottis lying within the mask aperture. Clinical confirmation of correct positioning is established by easy positive pressure ventilation (PPV) with a low ventilation pressures under 20 mmHg with no detectable leak, Appropriate chest rise with each breath and capnography trace^[5].

SGAs can be used with the spontaneously breathing patient breathing or with positive pressure ventilation (PPV). Since the SGA does not seal the pharynx, the pressure that can be safely used to ventilate is limited due to the leak around the device and associated gastric insufflation and/or hypoventilation. Therefore, pressure limited ventilation (ie, pressure support or pressure control) is usually preferred with a SGA in place, rather than volume control ventilation^[1].

Neuromuscular blocking agents (NMBAs) can be administered to facilitate SGA placement to prevent gagging, coughing, and laryngospasm, particularly in special circumstances^[6].

SGAs with esophageal vents are preferred in patients with mild GERD that is well controlled with medication, as it can decompress the esophageal pressure and allow drainage of gastric contents^[7-8]. It does go without saying that endotracheal intubation for patients with significant gastroesophageal reflux disease (GERD) is a must. The use of SGAs for patients at high risk for aspiration under general anesthesia is contraindicated, other than during airway rescue^[1].

Complications of SGA use include failed placement, aspiration, and airway complications, including airway trauma. Sore throat, dysphonia, and dysphagia may be related to high SGA cuff pressures^[9].

The aims is to study the safety and limitations of using i-Gel LMA in the lithotomy position.

PATIENTS AND METHODS

2. Methods

2.1 Study Population:

This study is an observational study that was carried out in the operating room. The study was performed on 60 adult patients of ASA I, II physical status undergoing surgery that mandates lithotomy position over a period of six month.

2.2 Ethical approval and clinical trial registration:

After informed consent and after approval of the research ethics committee of the faculty of medicine, approval number FAMSU R 76/2021. This study is an observational study and accordingly clinical trial registration wasn't obligatory.

2.3 Sample size and study groups:

Using PASS 11 program for sample size calculation, setting power at 80% and alpha error at 0.05. According to previous literature (Hartmann *et al.*; 2004), the

expected mean time of induction of anesthesia in LMA group = 5.8+/- 1.5 min. and in ETT group = 7.4 +/- 1.8 min. sample size of 20 patients/group were needed to detect the difference between the two groups. The patients were randomly divided into two groups, group T and group E.

2.4 Inclusion criteria:

Aged over 18 years

Both gender

Surgery mandating lithotomy position

2.5 Exclusion criteria:

Patients refusal

Pregnant women

Obesity (BMI > 39)

Trendelenburg position.

Moderate to severe GERD

Lengthy procedures (more than 120 min)

2.6 Study outcomes:

The Primary outcome of the study was to test the efficacy of volume controlled.

Ventilation with laryngeal mask airway in the lithotomy position versus Endotracheal tube.

The secondary outcome of the study was to compare between Laryngeal mask airway and endotracheal tube in lithotomy position regarding the rate of complications and impact on ventilation.

2.7 Study procedures:

The patients underwent preoperative clinical assessment including evaluation of the medical history, airway assessment and general examination. Lab investigations were requested including CBC, coagulation profile, liver enzyme (ALT, AST), serum creatinine, others depending on special medical condition.

On the day of the surgery IV access was secured, anesthesia was conducted by Fentanyl 1ug/kg, propofol (Diprivan) 1.5mg/kg, Atracurium (Tracrium) 0.5mg/kg to facilitate intubation, then sevoflurane was started at 2%, Oxygen 60% in air were used.

The patients in group L were intubated with an Igel LMA (Intersurgical), the size was selected based on the body weight according to the manufacturer's instructions, the patients in group T were intubated with ETT (flexicare) size 7 for female and 8 for male.

The patients were then ventilated with a volume-controlled mode of ventilation at a Tidal Volume (TV) 7ml/kg, Respiratory Rate 12 /min, I: E 1:2. The patient was then positioned in the lithotomy position and secured.

Ventilatory parameters including expired TV, peak airway pressure, TV inspired- TV expired and the end-tidal CO₂ were all monitored and recorded every 5 min.

In case of leaking from the LMA that interfere with the ventilation before the patients were being positioned in the lithotomy position, the patients were excluded and replaced by another.

The incidence of aspiration as revealed clinically (witnessed vomiting followed by decreased oxygen saturation, increased airway pressure, tachycardia, etc..) and confirmed radiologically, Failure of insertion or intubation, sore throat and air leak were reported as a complications and appropriate management was done accordingly.

2.8 Statistical analysis

Sample size was calculated using CliniCal.com. setting the type-1 error (α) at 0.05, power (1- β) at 0.8 and confidence width level at 0.1. Calculation according to

values of similar studies produced a minimal sample size of 50 cases.

Mann Whitney and student t Tests were used to compare non-parametric and parametric continuous variables between the two study groups respectively. Chi square and Fisher's exact tests were used to examine the relationship between Categorical variables. *P-value* < 0.05 was considered statistically significant. All statistical procedures were carried out using SPSS version 20 for Windows (SPSS Inc, Chicago, IL, USA).

RESULTS

The demographic data among the patients' population in the two groups were comparable with non -significant statistical difference (Table 1).

The duration of the procedures done in the two groups were comparable and there was no significant difference in the EtCO₂ in both groups.

The mean value for Peak inspiratory pressure (PIP) was 16.9 ± 4.1 cm H₂O in group T vs 17 ± 5 mmHg. Minimal difference was noted between the inspired and expired Tidal volume (TV) in the two groups ($22.5 \text{ ml} \pm 2.5 \text{ ml}$ vs $21.7 \text{ ml} \pm 3. \text{ ml}$). Meanwhile the rate of complications related to using the airway devices was higher in group T than in group L (53.3% vs 3.3%) (Table 2). The rate of the complications was higher in group T, complications reported were Sore throat and difficulty in intubation for group T, while air leak was the main complication reported in the group L (Figure 1).

Table 1: Comparison between T and L groups as regard personal data

Variable	Group				<i>P</i>	Sig	
	T (n=30)		L (n=30)				
	Mean	±SD	Mean	±SD			
Age (years)	39.65	12.63	37.38	11.79	0.312*	NS	
BW (Kg)	71.88	9.76	74.20	8.73	0.173*	NS	
Ht (Cm)	167.5	12.5	172.5	13	0.412*	NS	
Sex	Male	17	56.6%	16	53.3%	0.068**	NS
	Female	13	43.3%	14	41.7%		

*Student t test

**Chi-Square Tests

Table 2: Comparison between Group T and group L as regard clinical data

Variable	Group					Median	p	Sig
	T (n =30)		L (n=30)					
	Mean	±SD	Median(IQR)	Mean	±SD			
ETCo2 (mmHg)	37.48	1.97		36.08	2.34		0.001 [‡]	HS
Exp.TV(ml)	417	34		409	33		.05	NS
PIP(cm H2O)	16.9	4.1		17	5		.05	NS
TV insp- TVexp(ml)	22.5	2.5		21.7	3.3		.0001	HS
Duration(min.)	33.50	20.49	30(15-42.5)	28.67	17.58	20(15-35)	0.234 ^{‡‡}	NS
Complications	32	53.3%		2	3.3%		0.001*	HS
Type of Complication	Sore throat	27	45.0%	0	.0		0.001*	HS
	Difficult intubation	1	3.3%	0	.0		0.057**	NS
	Air leak	0	0	2	3.3%		0.49**	NS
	Aspiration	0	0	0	0		0.05*	NS

‡Student t test
 ‡‡Mann Whitney test
 *Chi-Square Tests
 **Fisher exact test

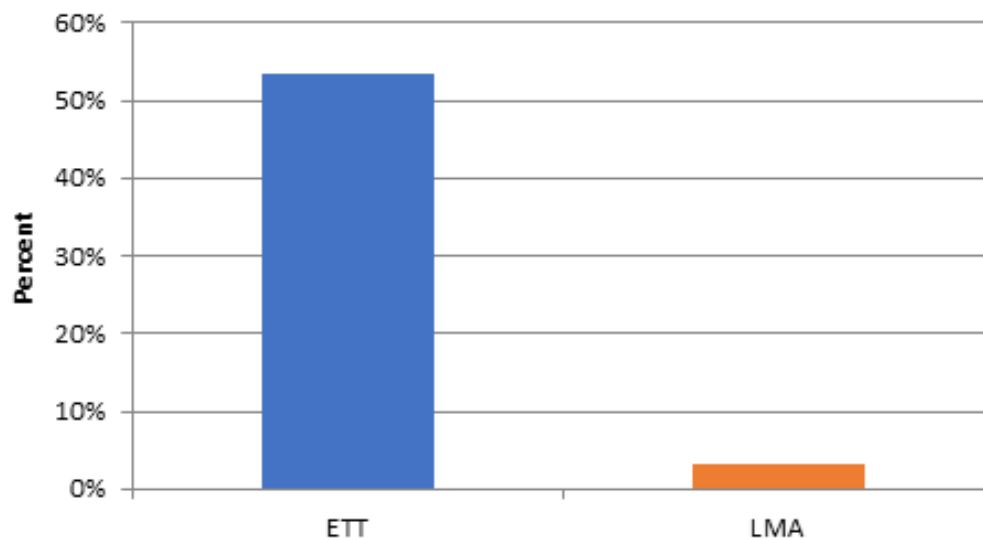


Fig. 1: The rate of complications among the two groups

DISCUSSION

The incidence of aspiration with SGA is unknown, but it is likely low in patients without risk factors for regurgitation (upper gastrointestinal disease, full stomach, obesity, multiple trauma, lithotomy position, intra-abdominal surgery, inadequate depth of anesthesia)^[14].

The devices with the least likelihood of aspiration are those with a high esophageal seal, a high pharyngeal seal, soft material, good pharyngeal volume, and a good drain tube that could permit regurgitant fluid to bypass the pharynx and the oral cavity completely^[15].

A meta analysis of approximately 550 studies with a first-generation laryngeal mask airway (LMA) showed that the incidence of aspiration was 1 in 5000, which is similar to the estimated risk of aspiration with the use of a facemask or endotracheal tube (ETT)^[16,17].

Resting intragastric pressure and esophageal pressure are usually between 10 and 30 cmH2O^[18] and can reach up to 60 cmH2O during vomiting^[19]. Cadaver studies have reported that the Classic LMA can prevent regurgitation of esophageal fluid into the pharynx^[20,21,22]. As regards the ProSeal LMA, whenever the esophageal vent is opened, the LMA can prevent the increase in esophageal pressure and can drain fluid away from the pharynx^[23].

However in 2011, Cook & Howes stated that there are limitations for cLMA, and those limitations are largely due to the moderate pharyngeal seal (mean 26-30 cm H₂O)^[2] and the associated risk of pulmonary aspiration of regurgitant matter. Owing to the poor pharyngeal seal, the increase in the airway pressure above the pharyngeal seal (during controlled ventilation) causes the ventilating gas to be lost, leading to a risk of hypoventilation, environmental pollution, moreover larger proportion of this leaking gas enters the esophagus and stomach, increasing the risk of regurgitation and aspiration.

Accordingly, It was established that Obesity, gastroesophageal reflux, laparoscopic surgery, and increased use of the lithotomy position are all challenges to use of the cLMA.

The regurgitation is exaggerated if the patients are in the lithotomy or Trendelenburg positions^[24,25], the regurgitation is due to the relaxed lower esophageal sphincter via a reflex mechanism similar to that with swallowing a bolus of food. A study including 40 patients reported that laryngeal mask placement was associated with a 15 percent decrease in lower esophageal sphincter pressure^[26]. Studies using pH electrodes have reported that the reflux of gastric juice to the mid to upper esophagus was higher with LMAs compared with facemask airway management^[27,28].

The choice of I-gel in our study was based on the fact that it can offer First-time insertion success rates up to 85% and this approaches 100% with three attempts^[29]. The drain tube has been reported to protect against aspiration and to provide an early recognition of regurgitation.

The i-gel is as well notably easy to insert: due to the very low coefficient of friction when lubricated and the fact there is no cuff to inflate.

In a randomized crossover study comparing PSV with continuous positive airway pressure (CPAP) using the LMA, PSV at 5 cmH₂O above positive end-expiratory pressure (PEEP) resulted in more effective gas exchange compared with spontaneous ventilation with CPAP at 5 cmH₂O^[12].

Limited study discussed the different ventilatory mode in the lithotomy position with LMA. The current study tested the safety of the volume controlled mode in these position using LMA.

CONCLUSION

The i-gel LMA can be safely used in the lithotomy position regardless the mode of the ventilation. The body mass index, and the presence of GERD are the major limitation in these regards.

ABBREVIATIONS

- (LMA): laryngeal mask airway
- SADs: First-generation supraglottic airway device
- PPV: Positive pressure ventilation
- NMBAs: Neuromuscular blocking agents
- GERD: Gastroesophageal reflux disease
- cLMA: Classic Laryngeal mask airway
- ALT: Alanine transaminase
- AST: Aspartate transaminase
- TV: Tidal volume
- RR: Respiratory rate
- CPAP: continuous positive airway pressure
- PSV: Pressure Support ventilation
- PEEP: positive end-expiratory pressure

CONFLICT OF INTEREST

There are no conflicts of interest.

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