

I - Gel Versus Cuffed Tracheal Tube in Elective Laparoscopic Cholecystectomy – A Clinical Comparative Study

Siddharam Jamagond¹, Anuradha H², Ramesh.K³

¹Senior resident, Department of Anesthesia, Koppal Institute of Medical Sciences, Koppal, Karnataka

²Assistant Professor, Department of Anesthesia, Koppal Institute of Medical Sciences, Koppal, Karnataka

³Associate Professor, Department of Community Medicine, VIMS, Ballari, Karnataka

Corresponding Author:

E-mail: ramspsm@gmail.com

ABSTRACT:

Background: This study aims to test and compare Endo tracheal tube and i-gel in terms of their: Efficacy: Difference in the leak fraction between two airway devices before and after pneumoperitoneum with different tidal volumes and comparison of oro pharyngeal leak pressure. Ease of insertion: Number of attempts required for optimal positioning.

Methods: Sixty patients, ASA I-II, were randomly selected to the study. Standard anaesthetic technique was used for all patients. The i-gel was then inserted. The lungs were ventilated at three different tidal volumes (6, 8 and 10 ml kg⁻¹) using volume controlled ventilation (VCV). The leak volume was calculated as the difference between the inspired and expired tidal volumes. The leak fraction was also calculated as the leak volume divided by the inspired tidal volume. These observations were recorded with every tidal volume before and after pneumoperitoneum with the i-gel and the conventional tracheal tube

Results: We found oro pharyngeal leak pressure for i gel as 26cm of H₂O and there was no leak in endotracheal tube group even at 40 cm of H₂O peak air way pressure. Before and after pneumoperitoneum there was no statistically significant difference in leak fraction or leak volume between i-gel and tracheal tube at tidal volume 6ml kg⁻¹. At 8 and 10 ml kg⁻¹ there was statistically significant difference between i-gel and tracheal tube both before and after pneumoperitoneum

Conclusion: In our study we found that i-gel airway can be used safely and effectively during volume controlled ventilation with low and moderate tidal volumes

Key words: I-gel; Leak fraction; Pneumoperitoneum; Cholecystectomy

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INTRODUCTION

Safe and effective airway management is the foundation of quality anesthetic practice. Supraglottic airway devices have revolutionized airway management since the invention of the LMA Classic (LMA North America Inc., California, USA) by Dr Archie Brain in 1988. They fill a niche between the face mask and the endotracheal tube in terms of both anatomical position and degree of invasiveness¹. The ease of insertion, safety and the global increase in the number of day care surgeries have led to their increased use in routine anesthetic practice.

Since the introduction of the LMA Classic, several laryngeal masks have been introduced which differ in shape, stiffness, cuff properties and constituent material². The Ambu Aura 40 (Ambu A/S, Copenhagen, Denmark) laryngeal mask and the I-gel (Intersurgical Ltd, Wokingham, U.K.) are two such devices. Apart from being used to maintain the airway routinely during an anaesthetic, laryngeal masks have

now come to play an important role in the management of difficult airways and in emergent situations such as cardio-pulmonary resuscitation¹.

The i-gel (Intersurgical Ltd., Wokingham, UK) is a new supraglottic airway device (SAD) made of thermoplastic elastomer which is soft, gel-like and transparent.³ Studies on Cadaver showed that i-gels effectively conformed to the per laryngeal anatomy and consistently achieved proper positioning for supraglottic ventilation⁴. Manikins studies and patients have shown that the insertion of the i-gel was significantly easier when compared with insertion of other SADs^{5,6}. Few studies had been done to evaluate the use of i-gel during controlled ventilation but they did not evaluate its use during procedures with airway pressure more than 25 cm H₂O⁷.

Our study was designed to evaluate the i-gel sealing pressure and as effective airway as cuffed tracheal tube during volume controlled ventilation in elective laparoscopic cholecystectomy. This study aims to test and compare cuffed endotracheal tube and i-gel in terms of their:

Efficacy: Difference in the leak fraction between two airway devices before and after pneumoperitoneum with different tidal volumes and comparison of oropharyngeal leak pressure. Ease of insertion: Number of attempts required for optimal positioning.

METHODOLOGY

The study was conducted in Malabar institute of Medical Sciences, a tertiary care centre during the period of June 2012 to may 2013. This is an institution-based randomised case-control study. The approval of institutional ethics committee was obtained prior to the commencement of the study. 60 patients of ASA 1 and 2, with BMI <35kg/m², between 18 and 60 years posted for elective laparoscopic cholecystectomy were enrolled into the study. The sample size was determined by considering a difference in the leak fraction more than 20% for the i-gel when compared to tracheal tube to be significant. They were randomized into two groups of equal number using the chit-in-a-box method for the use of either i-gel or endo tracheal tube for the maintenance of airway during the anaesthesia.

After induction of anaesthesia by a suitable intravenous induction agent and after achieving adequate anaesthetic depth, the randomly chosen, appropriately sized airway device was inserted and connected to the breathing circuit. The following parameters were then studied:

1. Number of attempts for correct positioning of the device.
2. Oropharyngeal leak pressure
3. Leak volume and leak fraction

The data was analysed using the Statistical Package for Social Sciences software for Windows. The paired t test, t test, fisher exact test, and Pearson's Chi square tests were used for comparing the data.

RESULTS

Table1: Comparison of age based on group

Age	I-gel		Endotracheal tube	
	Number	Percent	Number	Percent
20 - 29	9	30.0	7	23.3
30 - 39	6	20.0	6	20.0
40 - 49	5	16.7	4	13.3
50 - 60	10	33.3	13	43.3
Mean \pm SD	40.2 \pm 13		42.9 \pm 12.9	

t = 0.80, p = 0.427 (significant if p < 0.05)

The mean age of I-gel group was 40.2 years and whereas Endotracheal tube group was 42.9 years. This difference was not statistically significant.

Table2: Distribution according to American society of Anesthesiologists physical status classification

American Society of Anesthesiologists physical status classification	I gel		Endotracheal tube	
	Number	Percent	Number	Percent
Grade I	20	66.7	16	53.3
Grade II	10	33.3	14	46.7

$\chi^2 = 1.11$, p = 0.292 (significant if p < 0.05)

The airway characteristics of the patients studied i.e. mouth opening (Table 3), thyromental distance (Table 4) and the Mallampati (Table 5) score were also noted and statistically analysed, the results were not statistically significant.

Table 3: Distribution according to mouth opening

Mouth Opening	I gel		Endotracheal tube	
	Number	Percent	Number	Percent
5 cm designated	4	13.3	6	20.0
> 5 cm designated	26	86.7	24	80.0

$\chi^2 = 0.48$, p = 0.488 (significant if p < 0.05)

Table 4: Distribution according to thyromental distance

Thyromental Distance	I gel		Endotracheal tube	
	Number	Percent	Number	Percent
6 cm designated	4	13.3	3	10.0
> 6 cm designated	26	86.7	27	90.0

p = 0.500 (Fisher Exact test) (significant if p < 0.05)

Table5: Comparison of mallampati grade

Mallampati grade	I gel		Endotracheal tube	
	Number	Percent	Number	Percent
1	3	10.0	2	6.7
2	27	90.0	28	93.3

p = 0.500 (Fisher Exact test) (significant if p < 0.05)

The number of attempts at insertion needed to get a proper positioning of each device was noted and analysed. The i- gel could be positioned successfully with a single attempt in 86.2% of the patients in whom the device was used (26 out of the 30 patients studied), whereas successful placement at first attempt could be achieved in 93.3% of the subjects in endotracheal group (28 out of 30 patients). The i- gel and endotracheal tube could be positioned successfully in second attempt in remaining cases. I-gel had to be manipulated in 3 cases. There were no instances of failure to secure an airway with the chosen device. This result does not show a statistical significance (P = 0.335)

Table6: Comparison of no. of attempts required to insert the device based on group

No. of attempts required to insert the device	I -gel		Endotracheal tube	
	Number	Percent	Number	Percent
1	26	86.7	28	93.3
2	4	13.3	2	6.7

p = 0.335 (Fisher Exact test) (significant if p < 0.05)

Table7: Comparison of manipulation of airway to maintain adequate ventilation based on group

Manipulation of air way to maintain adequate ventilation	I -gel		Endotracheal tube	
	Number	Percent	Number	Percent
Yes	3	10.0	0	0.0
No	27	90.0	30	100.0

p = 0.119 (Fisher Exact test) (significant if p < 0.05)

The oropharyngeal leak pressure (OPLP) measured while using each device was measured and the average was calculated. It is as follows median value of OPLP in i-gel group is 26 cm H2O

Table8: Distribution according to oropharyngeal leak pressure(cm H2O)

Oropharyngeal Leak Pressure	I -gel		Endotracheal tube	
	Number	Percent	Number	Percent
20 - 29	21	70.0	0	0.0
30 - 39	9	30.0	0	0.0
> 40	0	0.0	30	100.0

Before and after pneumoperitoneum there was no statistically significant difference in leak fraction between i-gel and tracheal tube at tidal volume 6ml kg⁻¹ (P = 0.620 and 0.956). The mean difference in leak fraction was significant between i- gel and endotracheal group before and after pneumoperitoneum at 8 ml kg⁻¹ tidal volume (P = 0.000). At 10 ml kg⁻¹ there was statistically significant difference between i-gel and tracheal tube both before and after pneumoperitoneum (P = 0.000).

Before and after pneumoperitoneum leak volume at 6 ml kg⁻¹ showed no significant difference (P=0.212 and 0.972). But we found statistically significant difference before and after pneumoperitoneum at 8ml kg⁻¹ and 10 ml kg⁻¹.

Table 9: Comparison before pneumoperitoneum based on group

		Mean	SD	N	t	p
Leak Volume Before Pneumoperitoneum - 6	I- gel	14.8	1.8	30	1.26	0.212
	Endo tracheal tube	15.9	4.6	30		
Leak Volume Before Pneumoperitoneum - 8	I- gel	27.3	5.2	30	7.44**	0.000
	Endo tracheal tube	17.8	4.7	30		
Leak Volume Before Pneumoperitoneum - 10	I- gel	43.6	7.1	30	15.78**	0.000
	Endo tracheal tube	18.9	4.8	30		
Leak Fraction Before Pneumoperitoneum - 6	I- gel	0.0	0.0	30	0.50	0.620
	Endo tracheal tube	0.0	0.0	30		
Leak Fraction Before Pneumoperitoneum - 8	I- gel	0.1	0.0	30	7.35**	0.000
	Endo tracheal tube	0.0	0.0	30		
Leak Fraction Before Pneumoperitoneum - 10	I- gel	0.1	0.0	30	13.55**	0.000
	Endo tracheal tube	0.0	0.0	30		

** : significant at 0.01 level

Table10: Comparison after pneumoperitoneum based on group

		Mean	SD	N	t	p
Leak Volume After Pneumoperitoneum - 6	I-gel	16.2	2.5	30	0.04	0.972
	Endo tracheal tube	16.2	4.6	30		
Leak Volume After Pneumoperitoneum - 8	I-gel	29.7	3.9	30	13.07**	0.000
	Endo tracheal tube	17.4	3.4	30		
Leak Volume After Pneumoperitoneum - 10	I-gel	54.4	10.6	30	17.8**	0.000
	Endo tracheal tube	18.5	3.0	30		
Leak Fraction After Pneumoperitoneum - 6	I-gel	0.0	0.0	30	0.06	0.956
	Endo tracheal tube	0.0	0.0	30		
Leak Fraction After Pneumoperitoneum - 8	I-gel	0.1	0.0	30	8.81**	0.000
	Endo tracheal tube	0.0	0.0	30		
Leak Fraction After Pneumoperitoneum - 10	I-gel	0.1	0.0	30	13.88**	0.000
	Endo tracheal tube	0.0	0.0	30		

** : significant at 0.01 level

DISCUSSION

Laryngeal masks have played an important role in airway management since the introduction of the LMA Classic in 1988. Since then, several laryngeal masks varying in their shape, stiffness, cuff properties and clinical applications have come into existence. In addition to their use during routine anesthetics, they have also been recommended for use in difficult airway scenarios^{8,9} and in cardio-pulmonary resuscitation.

Supra glottic airway devices have several advantages including lower incidence of sore throat¹⁰, less hemodynamic upset during induction and maintenance of anaesthesia^{11,12} and better oxygenation during emergence¹³. I-gel is a relatively new disposable supraglottic airway device that has no inflatable cuff. It has an integral bite block, wide bore lumen, and an additional distal lumen that allows for the passage of a gastric tube. These features may give the i-gel an advantage over the LMA and even the Pro-Seal LMA.

There was too much debate among anesthesiologists about using these devices during procedures requiring positive pressure ventilation.

During high tidal volume ventilation and laparoscopic procedures peak airway pressure rises and exceeds airway sealing (leak) pressure leading to increase in leak volume and fraction. These findings explain difficulties in maintaining optimum ventilation

We analyzed 60 patients undergoing elective laparoscopic cholecystectomy. They were randomized into two groups of equal numbers using the chit-in-a-box method for the use of either i-gel or endotracheal tube for the maintenance of airway during the anesthesia.

Both groups were comparable in terms of age, sex and ASA status. Height, weight and BMI were also statistically comparable. The airway characteristics of all patients studied in terms of mouth opening, thyromental distance and the mallampati scores were also comparable

Ease of Insertion

After induction of anesthesia, the randomly chosen device (i gel or endotracheal tube) of appropriate size was inserted and the number of

attempts needed for proper positioning of the device was noted. In our study we did not find any significant difference between two and number of attempts require to secure i-gel in our study is comparable to other international studies.¹⁴

Oropharyngeal Leak Pressure (OPLP)

The oropharyngeal leak pressure is the airway pressure at which gases begins to leak around the cuff of the laryngeal mask airway device

Uppalet al.⁷ found leak pressure for i-gel 28 (20–35) cm H₂O by both auscultation and manometer stabilization methods. In our study we concluded that airway leak pressure for i-gel was 26 cm H₂O. Ishwar et al.¹⁴ concluded that airway leak pressure for i-gel was 25.27 cm H₂O using same methods.

Lu et al.¹⁵ compared Pro-Seal laryngeal mask airway (PLMA) with Classic laryngeal mask airway (LMA) for positive pressure ventilation during laparoscopic cholecystectomy. They concluded that PLMA is more effective ventilator device for laparoscopic cholecystectomy than classic LMA. This was attributed to higher leak pressure due to large cuff size (leak pressure was 29± 6 cm H₂O). We thought that i-gel could be used during such procedures but unfortunately during our study we found leak pressure for i-gel was 26 cm H₂O which is less than peak pressure during pneumoperitoneum especially at moderate and high tidal volumes¹⁶. In our study we found oropharyngeal leak pressure more than 40 cm of H₂O for endotracheal tube. We did not correlate anatomical position of i-gel with clinically evident leaks by using fiberoptic bronchoscope¹⁷

Leak fraction and leak volume

Before and after pneumoperitoneum there was no statistically significant difference in leak fraction or leak volume between i-gel and tracheal tube at tidal volume 6ml kg⁻¹. At 8 and 10 ml kg⁻¹ there was statistically significant difference between i-gel and tracheal tube both before and after pneumoperitoneum.

CONCLUSIONS

Our study supports the use of i-gel during VCV in elective laparoscopic cholecystectomy using low to moderate tidal volumes provided that peak airway pressure not more than device leak pressure. Although leak volume was significant, ventilation and oxygenation were optimal in most cases. Tracheal tube should be inserted if failed ventilation and oxygenation.

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