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A COMPARATIVE STUDY BETWEEN I-GEL AND ENDOTRACHEAL TUBE FOR VOLUME CONTROLLED VENTILATION IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT

INTRODUCTION: The endotrachealtube is the gold standard for controlling the airway. Laparoscopic procedures mark the new era. However, with various advantages they have their complications. Endotracheal intubation evokes significant hemodynamic changes. We have used I-gel, to find a suitable alternative. The study was conducted to compare haemodynamic changes, efficacy of ventilation, and complications laparoscopic cholecystectomy.

MATERIALS AND METHODS: After ethical approval the study was completed with 100 ASA PS I or II patients undergoing elective laparoscopic cholecystectomy. They were randomly allocated into either: Group-I (I-gel) or Group-E (ETT). Ease of insertion of device, haemodynamic and ventilatory parameters and perioperative complications were recorded.

RESULTS: Ease of insertion was difficult in Group E compared to Group I. HR variation and MAP variation was highly significant between the groups.

Leak Pressures were high throughout in GroupE. Mean Peak Airway Pressure was though higher in I-gel but was less than leak pressure and was clinically acceptable.

CONCLUSION: I-gel may be an alternative to endotracheal intubation for laparoscopic cholecystectomy under general anaesthesia for its design, less haemodynamic perturbations and similar efficacy in maintaining oxygenation and ventilation.

KEYWORDS : I-gel, Endotracheal tube, laparoscopic cholecystectomy, endotracheal intubation

INTRODUCTION

The development of laparoscopic surgeries have revolutionised the surgical field and in turn the anaesthetic management. One of the most commonly done procedure is the laparoscopic cholecystectomy[1] and with the success in healthy individuals the array of endoscopic surgeries have found their way to extremes of age, pregnant patients and sick individuals. Even though laparoscopic procedures have many advantages they are not without their set of disadvantages, often with lifethreatening complications of regurgitation of gastric contents to aspiration, and complications of pneumoperitoneum unlike open surgery, so us anaesthes iologists are always to well be prepared.[2]

Airway management continues to be of paramount importance to the anaesthesiologist. Till date, the cuffed tracheal tube was considered as gold standard for providing a safe glottic seal for procedures under general anaesthesia.However it has again its own set of complications.

The disadvantages of tracheal intubation, which involves rigid laryngoscopy are in terms of concomitant haemodynamic responses,may cause damage to the oropharyngeal structures at insertion and later postoperative sore throat.[3,4]This precludes the global utility of the tracheal tube and requires a better alternative.I-Gel is a single use second generation supraglottic airway device made of thermoplastic elastomer with a non inflatable cuff which conforms to the shape of perilaryngeal structures and provides an adequate seal during spontaneous and controlled ventilation.[5]

The study was undertaken to compare the clinical efficacy and safety profile of I-Gel and ET tube during general anaesthesia in healthy adult patients undergoing elective laparoscopic cholecystectomy.

SUBJECTS & METHODS

Patient selection

After Ethical committee clearance one hundred patients scheduled to undergo laparocopic cholecystectomy under general anaesthesia in Medical College hospital in DHB Surgical OT were selected. The study period was one year. Written informed consent was obtained from each patient and procedure was explained to all those between 18-60 years of either sex and ASA physical status I or II. Those patients with mouth opening < 2fingers, anticipated difficult airway, ASA PS III/IV, obese patient (BMI . >30KG/M^2), Obstructive sleep apnoea, presence of respiratory tract infection, history of un-optimised pulmonary disease, cardiac disease NYHA class>1, hiatus hernia, gastro-oesophageal reflux disorder were excluded from the study. The patients were randomly divided into two groups of fifty each. GROUP E ,the endotracheal tube or GROUP I , I Gel for securing the airway by a computer generated random number table.

Study Procedure

A thorough PAC was done the day before and the patients were advised Tab. Ranitidine 150mg before dinner and Tab. Alprazolam 0.5mg orally at night after light dinner , fasted for six hours for solid food and were allowed clear fluids and water till 2hours prior to surgery. Tab. Ranitidine 150mg orally at morning 6am. When the patient was taken to the OR the standard monitors ie. non invasive blood pressure, pulse oximeter,ECG were attached and intravenous access was secured with 18G canula lines and Ringer Lactate infusion started.They were given Inj.Glycopyrolate0.2mg and Inj.Midazolam 0.05mg/kg iv and pre-oxygenation with 100% oxygen was done for 3 minutes with tight fitting mask and 20degree head up position. Inj.Fentanyl 2 mcg/kg iv,Inj.Propofol 2mg/kg iv. After confirmation of adequate positive pressure ventilation with bag and mask, InjAtracurium 0.5mg/kg iv was given and maintained with Sevoflurane 1%.

The airway was secured thereafter as per random allocation:

GROUP I: I-Gel (No 3 for body wt 30-60kg, No 4 for body wt 50-90 kg)

GROUP E :cuffed ETT (7mm ID to 8.5mm ID)

By trained anaesthesiologist trained in placement of the device.

Proper placement of airway device was confirmed by auscultation and capnograph. In case of inadequate ventilation, gentle repositioning of the device without taking it out, chin lift, jaw thrust, head extension, or neck flexion. A 'failed attempt for a I-gel was defined as removal of the device from the mouth before re-insertion. When the device was not successfully inserted by the Second attempt,[6] that was recorded as a failure of the I-gel and patient was intubated with an ETTand excluded from the study. A failed intubation was considered after 3 attempts and was managed according to the "Difficult airway society" guidelines[6] and the subject was excluded from the study. The number of attempts required and ease of insertion were recorded. Those in the Group E , the cuff of the tube was inflated with air so as to achieve a cuff pressure of 25cm H_2O as recorded by a cuff pressure monitor.

A gastric tube was inserted either through the nasogastric route in Group E (14Fr) or through the gastric channel in Group I (12Fr for No3 & No4) and ease of insertion was noted.

After the airway device was secured in position (Group I IGel& Group E ETT)anaesthesia was maintained with Sevoflurane 1% in a mixture of 33% O2 and 66% N2O. Neuromuscular blockade was maintained with Inj.Atracurium 0.1mg/kg as and when required. Volume controlled positive pressure ventilation was administered via a circle system at a TV of 8ml/kg and respiratory rate of 12/min (Philips Siesta iWhispa anaesthesia work station with inbuilt spirometer) so as to maintain an ETCO2 of 30-40mmHg and arterial oxygen saturation >95%. In case of increasing ETCO2, ventilation was increased by increasing the respiratory rate.

Peak airway pressure, inspired and expired TV were measured by ventilator. Leak volume was measured as ITV-ETV and Leak fraction as Leak Volume/ ITV.

Leak pressure, Leak volume and leak fraction were measured after insertion of airway device just before start of surgery, 10 minutes after pneumoperitoneum after achieving Reverse Trendelenberg position, immediately before release of pneumoperitoneum and after release of pneumoperitoneum. Intra-abdominal pressure of 12-15mm Hg was maintained.

Paracetamol infusion 100ml and Diclofenac Sodium 75mg (aqueous solution) iv were given just after placement of airway device confirmation. Inj.Ondansetron 0.08mg/kg iv 15mins prior to reversal. After completion of surgery, neuromuscular blockade was reversed with Inj Neostigmine0.05mg/kg and InjGlycopylorate 0.01mg/kg iv. Then Sevoflurane was stopped.The airway device was removed after return of spontaneous ventilation and complete reversal of neuromuscular blockade.

SPO2, ETCO2, SBP, DBP, MAP were recorded at baseline, after insertion of device and at 15 minutes interval till removal of airway device.

Intraoperative complications if any like hypoxia, hypercarbia, aspiration, regurgitationwere recorded.

Postoperative airway complications like cough, laryngo spasm, sore throat, aspiration if any were recorded.

All the above data were recorded in individual data collection sheets with demographic details.

Statistical analysis was done by analyzed by SPSS 20.0.1 and Graph-Pad Prism version 5.Statistical analysis was performed using Chi-square test and Student t-test.(P value<0.05 = significant.) The results were expressed in Mean +/- SD for all comparisons.

Sample size was calculated using, "PS: Sample size calculator" [7,8,9] With 1 control per experimental subject the response within each subject group was randomized such that each response was normally distributed with standard deviation 3.5 as per previous studies. Difference in the experimental and control means approximated at 2.0 based on calculation from previous studies. The type 1 error probability was kept at 0.05 and the power of the study set at 0.8 as per previous similar studies to detect difference in ease of insertion. 49 experimental subjects and 49 control subjects were required to reject the null hypothesis.So a sample size of 100 was planned.

Observation And results

The 100 ASA I or II adult patients put up for laparoscopic cholecystectomy under general anaesthesia with either the ET tube or I-gel in whom the efficacy of positive pressure ventilation, hemodynamic changes, and complications if any were observed and compared.

The observation were compiled and results were analysed statistically. The observation are tabulated as:

Table1: Demographic data of the Groups.[Age ,Weight ,Height and Sex]

Group	Number of cases	ageyrs (Mean ± SD)	Weight kgs (Mean ± SD)	Height m (Mean ± SD)	Sex (F:M)
Group I	50	35.7 ± 9.03	55.96 ± 5.51	1.594± 0.0693	41:9
Group E	50	35.08 ± 8.65	57.54 ± 5.64	1.593 ± 0.058	42:8

Table1 shows the demographic data with respect to age, body weight, height and sex were comparable in both groups.

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Table 2 : Distribution of Ease of insertion of device Scale (5 point scale) in two groups

	GROUP		
Ease of insertion of device Scale	**Group-I**	**Group-E**	**TOTAL**
1 Row % Col %	47 52.8 94.0	42 47.2 84.0	89 100.0 89.0
2 Row % Col %	3 27.3 6.0	8 72.7 16.0	11 100.0 11.0
TOTAL Row % Col %	50 50.0 100.0	50 50.0 100.0	100 100.0 100.0

Table 2 shows distribution of Ease of insertion of device in two Groups

- It was observed that ETT insertion was easy (Scale 1) in 42 out of 50 patients. Difficult insertion (Scale 2) took place in 8 patients.
- It was observed that I-gel insertion was easy in 47 out of 50 patients Difficult insertion took place in 3 patients.
- The comparison of ease of insertion between the groups was not statistically significant (p>0.05). [Chi-square : 2.5536; p-value: 0.11004]

In the Group E the insertion was easy in 42 out of 50 patients and difficult insertion took place in 8 patients.

In Group I insertion was easy in 47 out of 50 patients and difficult insertion took place in 3 patients.

Our observations were consistent with observations of Richez

B et al (2008),Rukhsana Najeeb et al (2015) with respect to ease of insertion of these two airway devices.[10,11] though there is no statistical significance, this difficult insertion(I6% vs E 16%) may be of clinical relevance in a unanticipitated difficult airway scenario.

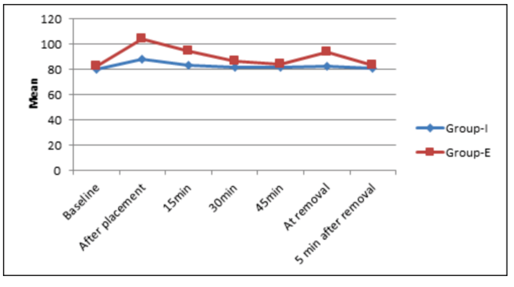
Table3: Distribution of mean HR in different time interval in two groups

HR		Number	Mean	SD	Minimum	Maximum	Median	p-value
Baseline	Group-I	50	80.2400	7.3027	66.0000	93.0000	80.0000	0.0951
	Group-E	50	82.4000	5.3643	70.0000	94.0000	83.0000	
After placement	Group-I	50	88.1600	8.9565	72.0000	111.0000	88.0000	**<0.0001**
	Group-E	50	104.4000	7.9334	89.0000	120.0000	103.0000	
15min	Group-I	50	83.7200	7.7671	70.0000	100.0000	84.0000	**<0.0001**
	Group-E	50	94.6400	5.0619	84.0000	110.0000	95.0000	
30min	Group-I	50	81.5200	7.0660	69.0000	96.0000	82.5000	**<0.0001**
	Group-E	50	86.9200	4.7503	73.0000	100.0000	87.5000	
45min	Group-I	50	81.4200	7.3209	68.0000	95.0000	82.0000	**0.0486**
	Group-E	50	84.0000	5.4623	68.0000	99.0000	84.0000	
At removal	Group-I	50	82.6400	6.9098	70.0000	95.0000	83.0000	**<0.0001**
	Group-E	50	93.7600	4.7448	80.0000	104.0000	94.0000	
5 min after removal	Group-I	50	80.7400	7.2726	68.0000	92.0000	80.5000	**0.0317**
	Group-E	50	83.4600	4.9947	71.0000	95.0000	84.0000	

Table 3 showsthe HR variation between Group I and Group E.

The rise in mean HR and HR variation was more with ET tube as compared to I-gel.HR variation was highly significant after device placement, at 15min, 30min and at the time of removal (p<0.01). At 45 min after placement of device and 5 min after removal of device the difference was statistically significant (p<0.05).

Graph 1Distribution of mean HR in different time interval in two groups



Graph 1, shows the HR variation between Group I and Group E.

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The rise in mean HR and HR variation was more with ET tube as compared to I-gel.The observations of current study relating to better heart rate stability of I-gel group in comparison to ET Tube group were in accordance with those byRukhsana Najeeb et al (2015) and Massoud (2014).[11,12]

Table 4: Distribution of mean MAP in different time interval in two groups

MAP		Number	Mean	SD	Minimum	Maximum	Median	p-value
Baseline	Group-I	50	95.8800	4.6801	82.0000	106.0000	96.0000	0.4510
	Group-E	50	95.2200	4.0168	86.0000	104.0000	95.0000	
After placement	Group-I	50	107.4200	8.5287	92.0000	126.0000	106.0000	**<0.00001**
	Group-E	50	114.3000	6.3415	101.0000	132.0000	114.0000	
15min	Group-I	50	96.5600	5.6610	78.0000	112.0000	97.0000	**<0.00001**
	Group-E	50	108.9200	4.7287	96.0000	121.0000	108.0000	
30min	Group-I	50	95.9800	5.1606	86.0000	110.0000	96.0000	0.4571
	Group-E	50	95.3400	3.1791	88.0000	102.0000	95.5000	
45min	Group-I	50	95.8200	3.8792	88.0000	104.0000	96.0000	0.6860
	Group-E	50	95.5000	4.0115	86.0000	105.0000	94.0000	
At removal	Group-I	50	95.7800	7.6593	80.0000	117.0000	95.0000	**<0.00001**
	Group-E	50	108.9000	6.0280	96.0000	126.0000	109.0000	
5 min after removal	Group-I	50	95.8600	7.3762	79.0000	120.0000	95.5000	0.8026
	Group-E	50	95.5600	4.1510	87.0000	105.0000	95.5000	

Table 4 shows the MAP variation between Group I and Group E.

At baseline there was no significant difference of MAP between 2 Groups. At the time of insertion of device, after 15 min and the time of removal of the device, the difference of MAP between 2 groups were highly significant (p<0.01). But 30min onward after insertion of device and 5 min after removal of device there was no significant difference in 2 groups. The rise in mean MAP was more with ET tube as compared to I-gel.

The observations made in this study relating to better haemodynamic stability of I-gel group than ET Tube group were in accordance with those by Rukhsana Najeeb et al (2015)and Massoud (2014).[11,12]

Oxygenation and ventilation:

We saw that in both Groups all throughout the study period the SPO2 varied between 99 to 100% in both the groups.

Table 5: Distribution of mean EtCO2 in different time interval in two groups

EtCO2		Number	Mean	SD	Minimum	Maximum	Median	p-value
After placement	Group-I	50	35.7200	2.3215	32.0000	39.0000	36.0000	0.5368
	Group-E	50	35.9800	1.8460	33.0000	39.0000	36.0000	
15min	Group-I	50	39.8800	1.3346	37.0000	43.0000	40.0000	**0.0337**
	Group-E	50	40.4600	1.3584	38.0000	43.0000	40.0000	

30min	Group-I	50	38.6400	1.6507	34.0000	41.0000	39.0000	**0.0005**
	Group-E	50	39.6800	1.2196	38.0000	42.0000	40.0000	
45min	Group-I	50	36.3600	1.8379	34.0000	40.0000	36.0000	0.0604
	Group-E	50	36.9400	1.1323	35.0000	39.0000	37.0000	
Just before Removal	Group-I	50	35.3000	1.8763	32.0000	38.0000	35.0000	0.3059
	Group-E	50	35.6600	1.6113	33.0000	38.0000	36.0000	

Table 5 shows the, EtCO2 variation between the Groups.

From the above table EtCO2was well maintained throughout in both groups except 15- 30 min when the difference between 2 Groups was statistically significant ($p<0.05$).

The quality of ventilation (EtCO2) and Oxygenation (SpO2) was satisfactory in both groups as suggested by Ibrahim M et al in 2011[13]and Rukhsana Najeeb2015.[11]

The statistically significant difference between these two groups in intraoperative period (15 -30min)though not clinically significant might be due to the effect of pneumoperitoneum.

Table 6: Distribution of mean Leak Pressure (cm of H_2O) in two groups

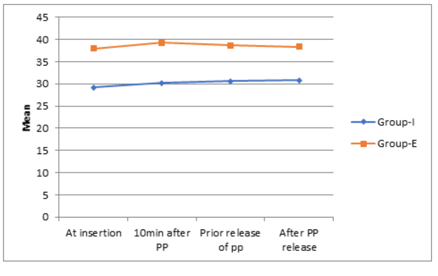
Leak ressure		Number	Mean	SD	Minimum	Maximum	Median	p-value
At insertion	Group-I	50	29.2000	5.0870	20.0000	35.0000	30.0000	<0.00001
	Group-E	50	37.9800	2.1332	35.0000	40.0000	38.0000	
10min after PP	Group-I	50	30.2000	3.7742	20.0000	35.0000	30.0000	<0.0001
	Group-E	50	39.3200	.9570	38.0000	40.0000	40.0000	
Prior release of PP	Group-I	50	30.6000	4.1206	20.0000	35.0000	30.0000	<0.0001
	Group-E	50	38.6400	1.6507	35.0000	40.0000	39.0000	
After PP release	Group-I	50	30.7800	3.9810	25.0000	35.0000	30.0000	<0.0001
	Group-E	50	38.3400	1.9858	35.0000	40.0000	39.0000	

Table 6 shows the difference of mean leak pressure between two groups.

Mean Leak Pressure was high in all time in ET tube group (Group E) than the I-gel group (Group I).

Mean Leak Pressure difference was highly statistical significant ($p<0.01$) at the time of insertion, 10 min after Pneumoperitoneum, prior release of Pneumoperitoneum, and also after release of Pneumoperitoneum.

Graph 2 Distribution of mean Leak Pressure (cm of H_2O) in two groups



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Mean Leak Pressure was high in all time in ET tube group (Group E) than the I-gel group (Group I).

Mean Leak Pressure difference was highly statistical significant at the time of insertion, 10 min after Pneumop eritoneum, prior release of Pneumoperitoneum, and also after release of Pneumoperitoneum.

We observed in that mean peak airway pressure of I-gel group was always higher compared to that of ETT group ie. Group I during insertion was 19.44±3.1 cm-H_2O, 10 min after PP (Pneumoperitoneum) it was 22.7±1.2 cm-H_2O, prior release of PP it was 22.4±1.2 cm-H_2O and after release it was 19.8±0.72cm-H_2O where as in Group E during insertion the mean peak airway pressure was 18.2±1.5 cm-H_2O, 10 min after PP it was 21.72 ±2.2cm-H_2O, prior release of PP it was 20.64±1.6 cm-H_2O and after PP release it was 19.64±1.9 cm-H_2O.

It was also noted that the difference of mean Peak Airway Pressure between two groups were highly statistical significant ($p<0.01$) at the time of insertion, 10 min after and prior release of pneumoperitoneum however the differencewas statistically insignificant ($p>0.05$) after release of Pneumoperitoneum.

In our study we found mean Leak Pressure was high in all time in ET tube group (Group E) than the I-gel group (Group I).Mean Peak Airway Pressure was high in the I-gel group (Group I) than the ET tube group (Group E) but it was always less than the leak pressure so is consistent with that of Ibrahim M et al(2011)suggested that I-gel may be an alternative to ETT during VCV for laparoscopic cholecystectomy provided peak pressure does not exceed leak pressure.[13]

In our study occurrence of cough, sore throat among the patients of ETT group was 8% and there was no incidence of cough, sore throat in I-gel group. In Group I, out of 50 patients no one complained post-operative cough.

Even previous studies by Rukhsana Najeeb in2015 [11]have shown an an incidence of postoperative sore throat and cough after ETT to be around 20%.

In our study there was no incidence of post-operative laryngospasm or aspiration in both the groups.

CONCLUSION

So we may say that even though endotracheal tube is still the gold standard we may consider I-gel as an ideal supraglottic alternativeduring VCV for laparoscopic cholecystectomy for its ergonomic design, less haemodynamic perturbations and similar efficacy in maintaining oxygenation and ventilation during general anaesthesia.

However we are to keep in mind that both devices have their own profile of complications which need to be dealt with vigilance and caution.

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