A PROSPECTIVE RANDOMIZED COMPARATIVE STUDY TO COMPARE THE HEMODYNAMIC AND METABOLIC STRESS RESPONE DUE TO ENDOTRACHEAL INTUBATION AND I-GEL USAGE DURING LAPAROSCOPIC CHOLECYSTECTOMY

Saumya Biswas*, Soumen Mandal**, Tapobrata Mitra***, Suprio De Ray****, Ranabir Chanda***** and Debajyoti Sur******

Background: Surgery and endotracheal intubation both causes an increase in metabolic stress response.. This is further aggravated during laparoscopic surgeries. In this study we aimed at comparing hemodynamic and metabolic parameters which are reflective of intraoperative stress response while using I-GEL against endotracheal tube (ETT) during laparoscopic cholecystectomy.

Material and Methods: This is a prospective randomized comparative study among 64 cases of American Society of Anesthesiologists(ASA) physical status class I and II, undergoing laparoscopic cholecystectomy who were randomly allocated into two groups of 32 each using computer generated random number table. Patients were put under general anesthesia using standard protocol.. After anesthesia induction and 20 minutes afterinduction venous blood samples were obtained for measuring adrenalin, noradrenalin, dopamine and cortisol levels. Hemodynamic and respiratory parameters were recorded at the 1^{st}, 5^{th}, 15^{th}, 30^{th} and 45^{th} minutes after the insertion of airway device.

Results: Although there was no significant difference regarding ventilatory parameters there was significant increase in heart rate at 1^{st} and 45^{th} minutes(p=0.02 and 0.034) respectively and increase in mean arterial pressure at 15^{th} and 30^{th} minutes(p=0.034 and 0.026) respectively in the ETT group compared to I-GEL group. Stress hormone intergroup analysis revealed significant increase in serum cortisol 20 minutes after induction in ETT group as compared toI-GEL group (p=0.03).

Conclusion: I-GEL usage is a suitable, effective and safe alternative to ETT in laparoscopic cholecystectomy patients with lower metabolic stress response.

Keywords: Endotracheal Tube, I-GEL, Hemodynamic Response, Metabolic Response, Laparocsopy.

* Dr. Saumya Biswas, MD, ASTT. Professor, Dept. of Anesthesiology, Malda Medical College (MMCH), Malda, India.
** Dr. Soumen Mandal, MD, Clinical Tutor, Dept of Anesthesiology, Burdwan Medical College, Burdwan, India.
*** Dr. Tapobrata Mitra, Astt. Professor, Mursidabad Medical College, Mursidabad, India.
**** Dr. Suprio De Ray, Md, ASTT. Professor, Dept of Anesthesiology, Malda Medical College, Malda.
***** Dr. Ranabir Chanda, MD, ASTT. Professor, Dept of Anaesthesiology, Burdwan Medical College, Burdwan, India.
****** Dr. Debajyoti Sur, MD, Clinical Tutor, Mursidabad Medical College, Mursidabad, India.
Institution Where The Sudy Was Conducted: Malda Medical College Hospital (MMCH).
Corresponding author: Dr. Saumya Biswas, Address: 815/C Block-A, Laketown. Kolkata, 700089. Phone number: 9433127430. E-mail: saumya.biswas@gmail.com Source(s) of support: NIL, Conflict of Interest: NIL.

Introduction

Endotracheal intubation has been shown to impose the most intense stress response to organism under general anesthesia[1,2]. Opioids, inhalational agents fails to prevent release of chatecholamines which causes significant hemodynamic response after laryngotracheal manipulation[3,4,5]. Surgical stress response further leads to activation of sympathetic nervous system and release of catabolic and hormones[6]. Carboperitoneum itself cause significant hemodynamic and metabolic changes. These stress responses may be life threatening in patients with co-morbidities likehypertension, diabetes mellitus, ischemic heart disease. Airway devices which evokes less stress response would be beneficial in these circumstances. This study assess the hemodynamic and metabolic alterations caused with the use of I-GEL and endotracheal tube (ETT) in laparoscopic cholesystectomy where carboperitoneum is created with increase in intraabdominal pressure.

Material and Methods:

After approval of institutional ethics committee of Malda Medical College and obtaining patients informed consents, 70(seventy) ASA (American Physical Status) I and II patients aged between 20-60 yrs scheduled for elective laparoscopic cholecystectomy were included in the study. Exclusion criteria were a known predicted difficult airway, hypertension, diabetes mellitus, chronic obstructive pulmonary disease, cardiac disease, history of allergic reaction and body mass index greater than 35 kg/m^2. Excluding those who failed to satisfy the selection criteria the remaining patients were randomly allocated into two groups of thirty two (n=32) patients each using a computer generated random number table.

Patients were premedicated with diazepam, ranitidine, and metaclopropamide the evening before and in the morning of the day of surgery. Consent and fasting status were confirmed and an intravenous line was obtained. Routine monitoring including electrocardiogram (ECG), noninvasive blood pressure (NIBP), pulse oxymetry (SpO_2) and end-tidal carbondioxide ($EtCO_2$) were applied to each patient in the operating room. Anesthesia was induced in both groups using propofol 2 mg/kg, fentanyl 2 microgram/kg, and airway placement was facilitated by atracurium 0.5 mg/kg.

In the ETT group (Group-E) (n=32) cuffed ETT of internal diameter (I.D.) 7.0 mm for females and 8.0 mm I.D. for males were used. The cuff pressure of ETT was maintained in the range of 25-30 cm of H_2O using a cuff manometer. In the other group (Group-I) (n=32) I-GEL: size 4.0 were used for both males and females as recommended by the manufacturer. Difficult intubation cases and more than one attempt of airway manipulation were excluded from the study.

Anesthesia was maintained with 1-2% Isoflurane and 50% NO_2 & 50% O_2. Patients were mechanically ventilated with a tidal volume of 8ml/kg and a respiratory rate of 12 breaths/min. SpO_2 and $EtCO_2$ were maintained >95% and < 45mm of Hg respectively. Intra-abdominal pressure was maintained < 15mm of Hg during the operation. Mean arterial blood pressure (MAP), heart rate(HR), SpO2, peak airway pressure, $EtCO_2$ and tidal volume were recorded at the 1st, 5th, 15th, 30th and 45th minutes after insertion of airway devices. Side effects like bronchospasm, laryngospasm, coughing, gagging, hoarseness, aspiration were evaluated. Hemodynamic alterations like hypotension (<25% decrease in MAP from the baseline), hypertension (>25% increase in MAP from the baseline), tachycardia (heart rate >120/min), bradycardia (heart rate<50/min) were recorded and manipulated by titration of inhalational anesthetics at 0.5% concentrations and administration of intravenous 0.5mg atropine sulphate.

After induction of anesthesia and 20 mins after CO_2 insufflation, venous blood samples were obtained for measuring adrenaline, noradrenaline, dopamine and cortisol levels. Blood samples were centrifuged immediately and plasmas were stored at -80°C until hormonal analysis. For analyzing catecholamine levels, high pressure liquid chromatography (HPLC) method was applied using eureka kits (Enrico Fermi 25 60033 Chiaravalle (An) Italy).

Statistical analysis was performed by $SPSS_{11.5}$ (Statistics Package for Social Sciences) for Windows. Data was presented as mean, median and standard deviation. Comparison between groups were performed by unpaired student-t-test and Mann-Whiteny U-test for continuous variables and chi-square test for intermittent variables. Paired sample t-test and Wilcoxon test were used for comparisons within each group. A p value less than 0.05 was considered as statistically significant.

Results

No statistically significant differences were found in demographic variables between the two groups (Table-1). SpO_2, peak airway pressure, $EtCO_2$, and minute ventilation were not statistically significantly different when compared between and within groups at all evaluation times (Table-2). Optimal ventilation was maintained in both groups before and after carboperitoneum as indicated by $EtCO_2$ <45mm of Hg in all patients of both groups.

Table-1
Demographic data. Data is expressed in mean ± SD or numbers.

PARAMETER	ETT (n=32)	I-GEL (n=32)	P-value
AGE (yrs)	47.84±10.23	46.02±8.68	0.868
BMI(kg/m²)	27.89±8.42	28.90±8.42	0.732
ASA PS(I/II)	28/4	30/2	0.989
OPEARTION TIME (MINUTES)	44.54±10.12	42.13±9.81	0.865

ETT = Endotracheal Tube; ASA PS = American Society of Anesthesiologists.

There was a significant increase in the heart rate at 1st minute and 45th minutes after insertion of airway device respectively in the ETT group. Comparison of mean arterial pressure between the two groups revealed statistically significant differences between the two groups at 15th and 30th minutes after airway insertion (Table-3).

Serum cortisol level 20 minutes after induction of anesthesia was significantly lower in the I-GEL group than the ETT group (Table-4). When serum cortisol levels were compared within groups, cortisol levels 20 minutes after induction of anesthesia were significantly higher than cortisol levels after anesthesia induction in both groups (Table-5).

Discussion

Laparoscopic surgeries present a challenge for the anesthesiologist as there are hemodynamic and ventilatory changes due to pneumoperitonium which may further be aggravated in patients with obesity and chronic systemic illness. Safe airway management remains the principal aim of the anesthesiologist during laparoscopic surgeries as there is increased intra-abdominal pressure which may lead to gastroesophageal and biliary reflux. ETT although commonly used has also some postoperative disadvantages like laryngospasm, hoarseness, and sore throat. In addition laryngoscopy itself induces hemodynamic stress response due to supraglottic manipulation which causes release of chatecholamine and cortisol[5,7]. Newer second generation supraglottic airway device like I-GEL made of thermoplastic elastomer may be used as an effective and safe alternative to ETT in elective surgeries.

Table-2
ventilator parameters. Data is expressed as mean ± SD.

SpO2(%)		Peak Airway Pressure(cm of H_2O)		EtCo2 (mm of Hg)		MV(Lit)		
Time	ETT	I-GEL	ETT	I-GEL	ETT	I-GEL	ETT	I-GEL
1st min	98.16±1.21	98.45±0.97	19.45±3.45	18.36±3.75	30.39±3.54	31.24±3.76	5.06±1.67	5.14±1.67
5th min	99.23±1.45	99.28±0.45	20.21±2.34	20.13±3.56	31.23±2.43	32.45±3.24	5.13±1.08	5.00±1.34
15th min	98.14±1.13	97.28±0.34	20.19±3.24	19.86±2.45	33.23±2.35	34.76±2.56	5.07±3.07	5.23±1.34
30th min	97.45±1.24	98.23±1.16	22.45±1.34	21.27±2.34	31.34±3.34	32.56±2.67	5.45±3.06	5.67±1.34
45th min	98.23±1.17	98.05±0.98	20.76±2.35	22.34±2.65	32.45±3.56	33.56±2.58	5.08±3.45	5.34±1.46

SpO2 = Oxygen saturation; EtCo2 = End tidal carbon di-oxide; MV = Minute Ventilation; ETT = Endotracheal Tube.

Table-3

Haemodynamic Parameters. Data is expressed as mean ± SD.

Mean Arterial Pressure		P value	Heart Rate		P value	
TIME	ETT	I-GEL	ETT		I-GEL	
1st min	90.85±31.23	89.68±23.13	0.867	98.46±12.57	79.23±12.30	0.002
5th min	102.36±20.16	100.73±18.68	0.840	82.70±13.26	83.47±13.60	0.845
15th min	98.64±13.63	79.23±16.18	0.034	85.67±12.31	84.32±17.45	0.945
30th min	90.32±20.56	76.14±15.28	0.026	86.32±16.71	87.45±10.04	0.856
45th min	100.23±16.86	89.82±13.68	0.762	98.23±12.06	82.32±12.10	0.034

ETT = Endotracheal Tube.

Table-4

Comparison of stress hormones between groups. Data is expressed as Mean (range).

Parameter	ETT	I-GEL	P-value
At Induction:			
Adrenaline	73(4-545)	80(4-210)	0.621
Noradrenaline	261(84-815)	288(89-1056)	0.504
Dopamine	30(7-345)	35(12-500)	0.435
Cortisol	11.35(2.84-90.32)	15.23(4-45.30)	0.124
20 min after induction:			
Adrenaline	47.16(5-370)	68(8-206)	0.846
Noradrenaline	260(80-798)	263(90-1043)	0.764
Dopamine	34(2-210)	27(3.2-412.4)	0.856
Cortisol	48.2(9.8-168.9)	22(8.6-98.6)	0.030

ETT = Endotracheal Tube.

Table-5

Comparison of stress hormones within groups. Data is expressed as mean.

ETT				I-GEL		
	After induction of anesthesia	20 mins after induction of anesthesia	P-value	After induction of anesthesia	20 mins after induction of anesthesia	P-value
Adrenaline	7(3-500)	30(5-484)	0.632	84.6(4-200)	78.6(9-210)	0.986
Noradrenaline	255(82-812)	263(52-918)	0.416	280(87-1276)	260(68-910)	0.874
Dopamine	32(9-316)	36(3-210)	0.826	36(10-610)	30(4-410)	0.423
Cortisol	10.6(3-94.6)	48.3(8-168)	0.002	15(4-44)	38(9-121)	0.002

ETT = Endotracheal Tube.

Maltby et al compared classic LMA (Laryngeal Mask Airway) and Proseal LMA (PLMA) as alternatives to tracheal intubation in laparoscopic gynaecological procedures with respect to pulmonary ventilation. There was no significant difference with respect to airway pressure, oxygen saturation, and end tidal carbon dioixide before and after peritoneal insufflations. They recommended that tracheal tube could safely be substituted with correctly placed LMA and Proseal LMA during gynaecological laparoscopy[8]. *Sinha et al* compared ETT and PLMA in pediatric laparoscopy patients by means of EtCO2, peak inspiratory pressure and SpO2. They did not report any statistically significant difference in SpO2, EtCO2 and peak inspiratory pressure between the groups. They concluded that the two devices had comparable ventilator efficacy in laparoscopic pediatric surgeries[9]. *Won Jung Shin et al* made a comparative study among I-GEL, proseal LMA, classic LMA, during general anesthesia and didn't find any significant difference in ventilator response[10]. *Maharjan et al* found the I-GEL to be as effective as ETT in laparoscopic surgeries. There was no difference in leak volume, leak fraction and airway pressure between the two study groups[11]. In this study I-GEL was used effectively as ETT during laparoscopic cholecystectomy and ventilator parameters between the two groups were similar.

Jindal P et al compared haemodynamic effects of three supraglottic airway devices I-GEL, LMA and streamlined pharyngeal airway(SLIPA) during general anesthesia with controlled ventilation I-GEL revealed least haemodynamic changes during device use[12]. *Ismail SA et al* compared intraocular pressure, heart rate, blood pressure before and after I-GEL, LMA, and tracheal tube. Use of LMA and ETT resulted in significant increase in intraocular pressure and haemodynamics compared to I-GEL[13]. *Oczenski et al* reported that cardiovascular responses induced by laryngoscopy and intubation were more than twice as high as those produced by insertion of an LMA[7]. In the present study I-GEL usages showed significantly less haemodynamic perturbation when compared to ETT (Table-3) as indicated by heart rate and mean arterial pressure.

Walder and Aitkenhead evaluated if pneumoperitoneum affected haemodynamic and stress responses in laparoscopic cholecystectomy patients. They observed that plasma vasopressin concentration significantly increased during peumoperitoneum, noradrenalin and adrenalin concentrations and rennin activity did not change[14]. Carbon dioxide(C02) insufflation for pneumoperitoneum in long periods may cause stress hormone increase due to carbon dioxide diffusion. In our study mean duration of operation was nearly 45 minutes in both groups. Therefore it is considered that the reason of increase in cortisol level in the ETT group was not CO2 insufflation. *Lentschener et al* found that both humoral and hemodynamic responses initiated in the pneumoperitoneum by contact with CO_2 have been prevented by continuous adequate depth of anaesthesia and normovolaemia[15]. In the current study, the patients were operated in elective circumstances and depth of anaesthesia and volume were controlled easily and strictly so humoral and hemodynamic responses caused by pneumoperitoneum were lower than the estimations. We observed a significant increase in serum cortisol in both the groups 20 minutes after induction. But inter group analysis revealed the increase in ETT group was greater than I-GEL group. As dopamine, adrenalin and noradrenalin have short duration of activity with the plasma half time shorter than 2 minutes, they were not efficient enough for reflecting the metabolic stress response in our study.

Present study evaluated hemodynamic and ventilator parameters along with definitive stress hormone markers like catecholamine and cortisol but we were unable to take in consideration leak pressure of individual airway devices and other unwanted effects like sore throat, trauma, gastric distension and aspiration. Hence a large scale study is needed to draw a definitive conclusion.

Conclusion

Correctly placed I-GEL is a safe and efficient airway option to ETT and PLMA in laparoscopic cholecystectomy operations with lower incidence of metabolic stress responses. It can be used in selected elective surgical cases where these stress responses may be undesirable and better avoided.

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