A Comparative Study Regarding the Haemodynamic Stress Response and Efficacy of Endotracheal Intubation and i-gel Insertion During Infraumbilical Surgery

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ABSTRACT

BACKGROUND

Endotracheal Intubation is the Gold Standard for maintenance of airway, but it has several complexities. Deleterious haemodynamic consequences may occur during intubation due to reflex sympathoadrenal stimulation. i-gel is a new single use, non-inflatable supraglottic airway device being used in anaesthesia during spontaneous or intermittent positive pressure ventilation. The aim of the study was to compare the clinical efficacy and complications of i-gel with standard endotracheal tube during general anaesthesia.

METHODS

One hundred healthy adult patients undergoing elective infraumbilical surgery were randomly included by computer generated randomization into two groups, Group E: Endotracheal tube and Group: I i-gel. Uniform premedication drugs, induction agents, muscle relaxants and anaesthesia technique were used in both groups of patients. Haemodynamic parameters like heart rate, blood pressure, SpO_2, $ETCO_2$ were recorded after induction, immediately after intubation and at 1, 3, 5, 10 min after intubation. Ease of insertion, time taken for placement of device, insertion attempts, attempts at gastric tube insertion and any airway trauma were also noted for comparison.

RESULTS

Increase in mean Heart Rate, Blood Pressure and $ETCO_2$ were relatively less in i-gel group when compared with group E at different time intervals immediately after Intubation. Ease of insertion and number of attempts had no statistical significance, but time taken for insertion of i-gel was significantly less than endotracheal tube.

CONCLUSIONS

i-gel is an effective and safe alternative to endotracheal tube for airway management and it takes less time to insert and causes less haemodynamic perturbations.

KEYWORDS

Haemodynamic Stress Response, Endotracheal Intubation, i-gel, Intubation Surge

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BACKGROUND

Tracheal intubation provides the most effective means of direct airway ventilation and protection against aspiration, but has deleterious haemodynamic consequences due to reflex sympathoadrenal stimulation.[1,2] Difficult tracheal intubation and 'Cannot Intubate, Cannot Ventilate' can arise anytime with anyone and anywhere. These are important cause of anaesthetic morbidity and mortality. Numerous devices and techniques available, which can bail us out of such situations where conventional laryngoscopy and intubation fail. I- gel, a new supraglottic airway device, is very effective in establishing a patent airway and lifesaving in the setting of unanticipated difficult airway. It is also effective for spontaneous or intermittent positive pressure ventilation.[3,4] Present study was undertaken to compare the clinical efficacy and complications of I- Gel with Endotracheal Tube during general anaesthesia in patients undergoing elective infraumbilical surgery.

METHODS

After approval of the Institutional Ethical Committee, a total of 100 healthy, adult, ASA I & II, patients were selected for this randomised comparative study. Patients were randomized into two groups of 50 each by using systematic random sampling table. One of the groups was administered the i-gel (Group I) and the other group was given Endotracheal Intubation (Group E). Patient with history of obesity, upper respiratory tract infection, sleep apnoea, pulmonary disease, chronic systemic disease like hypertension, diabetes mellitus, Surgery duration more than 90 min Bleeding Disorders, Pregnant patient, Mallampati Grading III/IV were excluded from the study. A thorough preoperative assessment was done before selecting the patients. Demographic data, physical examination findings and laboratory investigations were recorded systematically in the proforma. Fasting was ensured as per ASA guidelines. Written informed consent was taken. After shifting the patient to operation theatre, intravenous line was established and standard monitors like noninvasive blood pressure (NIBP), continuous 5 lead ECG and Pulse Oximetry were attached. Base line vital parameters were recorded. Each patient was premedicated uniformly with inj ranitidine (50 mg iv), inj. Ondansetron (0.1 mg/kg), inj. glycopyrrolate (0.004 mg/kg), inj. Midazolam (0.05 mg/kg) and inj Fentanyl (1 mcg/kg iv). Anaesthesia was induced with i.v. Propofol 2 mg/kg. Atracurium 0.5 mg/kg was used as neuromuscular blocking agent (NMBA) for relaxation.

Maintenance

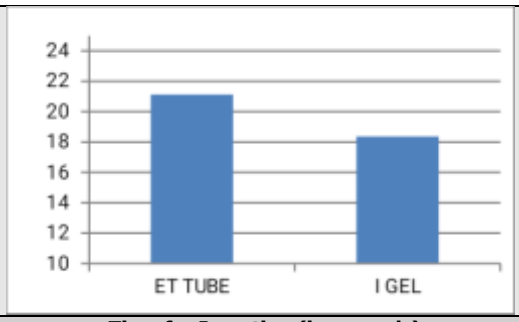
Anaesthesia was maintained with 66% N_2O, 33% O_2 and Isoflurane. Patients were ventilated using closed circle breathing system with soda lime. Neuromuscular blockade was maintained with intermittent injection of Atracurium. At the end of the surgery residual neuromuscular blockade was reversed with injection Neostigmine (0.05 mg/kg) and injection Glycopyrrolate (0.01 mg/kg). After adequate reversal of neuromuscular paralysis, I –gel or ET tube was removed. Postoperative oxygenation was done for 10 minutes in operation theatre and the patients were transferred to recovery room.

Parameters Recorded

Ease of insertion, 2) Time taken for placement of device, 3) Insertion attempts, 4) Attempts at gastric tube insertion, 5) Airway trauma by postoperative blood staining of the device, and tongue-lip-dental trauma. 6) Haemodynamic responses, changes in SpO_2 and $ETCO_2$. Statistical tests done were Chi-square test with Yates's correction, Fischer's exact test, Paired and Unpaired t-test. P value <0.05 was considered to be statistically significant.

RESULTS

Demographic profile (age, sex, weight, height, BMI, ASA, Mallampati Grade) and preoperative vital parameters (HR, SBP, DBP, MAP, SpO_2) were comparable between the two groups and there was no significant difference between two groups. The comparison of Ease of insertion of airway devices and insertion attempts between the two groups did not reveal any statistical significance (p>0.05). Endotracheal tube insertion was easy in 40 out of 50 patients. Difficult insertion took place in 10 patients whereas i-gel insertion was easy in 45 out of 50 patients. Difficult insertion took place in 5 patients. Endotracheal tube was placed in first attempt in 42 out of 50 patients and 8 patients needed second attempt and no patients needed third attempt whereas i-gel was placed in first attempt in 47 out of 50 patients and 3 patients required second attempt and no patients needed third attempt. The mean time taken for insertion of endotracheal tube in group E is 21.12 seconds. The minimum time taken was 16 seconds and maximum was 25 seconds. The mean time taken for insertion of i-gel in group I was 18.36 seconds. The minimum time taken was 12 seconds and maximum was 22 seconds. The calculated p value was <0.001 and by conventional criteria this difference is considered to be extremely statistically significant. Table -1 and Chart -1.



Time for Insertion (in seconds)		
	Mean	SD
ET TUBE	21.12	± 2.14
I GEL	18.36	± 2.26
p value	< 0.001	

Table 1. Time for Insertion (in Seconds)

Group		Baseline	After Placement	1 min.	3 min.	5 min.	10 min.	at removal	5 mins After Removal
E	Mean ± SD	82.5±5.56	105.76±9.59	99.8±7.87	96.64±6.61	85.82±5.02	82.62±5.80	92.54±5.45	82.86±5.60
I	Mean ± SD	83.36±5.96	93.78±9.22	89.64±7.42	83.66±5.10	83.24±5.68	83.22±5.87	83.68±0.32	83.38±6.02
	t	-0.746	6.367	6.640	10.116	3.202	-0.514	8.190	-0.447
	P value	0.457	0.000	0.000	0.000	0.002	0.608	0.000	0.656
	Inf	P>0.05	p<0.01	p<0.01	p<0.01	p<0.01	P>0.05	p<0.01	P>0.05

Table 2. Heart Rate Variation

Group		Baseline	Placement After Placement	At 1 min.	At 3 min.	At 5 min.	At 10 min.	At Removal	Removal At 5 min After Removal
E	Mean ± SD	122.4±7.85	144.9±9.02	142.66±6.39	139.7±55.78	127.64±6.16	122.58±7.37	138.34±7.12	122.5±7.98
I	Mean ± SD	123.7±7.35	136.76±11.53	135.06±11.17	130.9±13.10	124.02±9.97	123.78±6.60	123.88±8.02	123.42±6.57
	t	-0.84135	3.932	4.175	4.348	2.184	-0.858	9.530	-0.629
	P value	0.402	0.000	0.000	0.000	0.031	0.393	0.000	0.531
	Inf	P>0.05	p<0.01	p<0.01	p<0.01	p<0.05	P>0.05	p<0.01	P>0.05

Table 3. SBP Variation

Group		Baseline	After Placement	1 min.	3 min.	5 min.	10 min.	at Removal	5 mins After Removal
E	Mean ± SD	82.36±4.44	98.12±6.09	97.08±5.46	94.34±5.23	82.76±4.27	82.46±5.15	92.5±4.45	82.78±3.88
I	Mean ± SD	82.22±4.69	92.76±8.34	86.68±5.43	82.68±3.92	82.74±4.55	82.72±4.06	83.06±7.74	82.56±6.35
	t	0.153	3.671	9.548	12.612	0.023	-0.280	7.475	0.209
	P value	0.879	0.000	0.000	0.000	0.982	0.780	0.000	0.835
	Inf	P>0.05	p<0.01	p<0.01	p<0.01	P>0.05	P>0.05	p<0.01	P>0.05

Table 4. DBP

Group		Baseline	After Placement	1 min.	3 min.	5 min.	10 min.	at Removal	5 mins After Removal
E	Mean ± SD	95.22±4.02	114.3±6.34	111.94±6.10	108.88±4.75	95.3±3.18	95.5±4.01	108.9±6.03	95.56±4.15
I	Mean ± SD	95.88±4.68	107.42±8.53	102.7±6.60	96.56±5.66	95.98±5.16	95.82±3.88	95.78±7.66	95.86±7.38
	t	-0.757	4.577	7.234	11.785	-0.747	-0.405	9.518	-0.251
	P value	0.451	0.000	0.000	0.000	0.457	0.686	0.000	0.803
	Inf	P>0.05	p<0.01	p<0.01	p<0.01	P>0.05	P>0.05	p<0.01	P>0.05

Table 5. MAP

Group		Baseline	After Placement	1 min.	3 min.	5 min.	10 min.	At Removal	5 min After Removal
E	Mean ± SD	99.54±0.50	99.54±0.50	99.52±0.50	99.48±0.50	99.58±0.50	99.66±0.48	99.68±0.47	99.56±0.50
I	Mean ± SD	99.4±0.49	99.34±0.48	99.28±0.45	99.64±0.48	99.36±0.48	99.34±0.48	99.58±0.50	99.6±0.49
	t	1.402291	2.036	2.501	-1.617	2.237	3.344	1.031	-0.401
	P value	0.164	0.044	0.014	0.109	0.028	0.001	0.305	0.689
	Inf	P>0.05	p<0.05	p<0.05	P>0.05	p<0.05	p<0.05	P>0.05	P>0.05

Table 6. SpO_2 Variation

Heart Rate variation was highly significant after device placement, at 1 min, 3 min and 5 min. Thereafter, HR variation was insignificant until device removal when again HR variation was highly significant between the two groups which became insignificant 5 mins after device removal. The rise in mean HR was more with ET tube as compared to i-gel. From table -3 it was found that SPB variation was highly significant ($p<0.01$) during device placement, at 1 min and 3 min, and 5 min ($p<0.05$) after which the variation was insignificant till removal of the devices when again the SBP variation was highly significant and it became insignificant 5 mins after device removal. The increase in mean SBP during device placement and removal was more with ET tube than i-gel.

From table 4, it was found that there was highly significant DBP variation between the two groups during device placement, at 1 min. and 3 min. after which variation was insignificant. DBP variation was again highly significant at device removal and became insignificant 5 min afterwards. Rise in DBP was significantly more with ET tube than with I- gel. From table 5, it was found that among the two groups MAP variation was highly significant after device placement, at 1 min and 3 mins, after which the MAP variation was insignificant till device removal when again the MAP variation was highly significant. MAP variation became insignificant 5 mins after device removal. The increase in MAP during device placement and removal was significantly more with ET tube than with i-gel.

From table 6, SpO_2 was well maintained throughout the procedure in both the Groups. Statistically significant SpO_2 variation after device placement, at 1 min, 5 min and 10 min but it was clinically acceptable. Individual values of SpO_2 in both the groups ranged between 99 to 100%. $ETCO_2$ was well maintained throughout the procedure in both the groups and there was no statistically significant change in $ETCO_2$ within each group at various time interval as well as between the two groups ($p>0.05$). Incidence of post-operative trauma to lip, tongue, and teeth-

Group	Incidence of Airway trauma (to lip, tongue, and teeth)	
	No	Yes
Group ET	40	10
Group I	47	3

Table 7

Though patients of group E suffered from post-operative airway trauma than group I, the comparison of airway trauma between the two groups did not reveal any statistical significance (p value 0.07). It was seen that 6 out of 50 patients in group E complained of post-operative sore throat and 2 out of 50 patients in group I complained of post-operative sore throat. Though patients of group E had more incidence of post-operative sore throat, the comparison of incidence of post-operative sore throat between the two groups did not reveal any statistical significance ($p>0.05$).

DISCUSSION

The introduction of I -gel in clinical practice revolutionized the airway management and changed the scenario from "unable to intubate and ventilate" to "unable to intubate but able to ventilate". This device has successfully combined the concept of non-cuffed supraglottic airway device like the SLIPA and gastric tube of PLMA. The shape, softness and contour of i-gel accurately mirror framework of pharyngeal, laryngeal and perilaryngeal anatomy. In this study we compared ET Tube with i-gel in terms of ease of insertion, time taken for placement of device, insertion attempts, attempts at gastric tube insertion, airway trauma and haemodynamic responses, any change in SpO_2 and $ETCO_2$. We compared our findings with the findings of other studies.

The demographic data in terms of mean age, weight, height, sex distribution, and BMI of both groups were comparable and found no significant difference. In the present study, ET tube was easily inserted in 40 patients (80%) While in i-gel group easy insertion was in 45 patients (90%). Insertion was difficult in 10 patients (20%) in Group E while in Group I difficult Insertion took place in 5 patients (10%). Some of the other studies like Richez B et al[5] (i-gel*:* Very easy 93%, Easy 7%), Singh I et al[6](i-gel*:* Easy - 96.67%, Difficult - 3.33%)*,* Rukhsana et al[7] (i-gel*:* Easy 92.5%, Difficult 7.5% and ET tube: Easy 82% Difficult 82%) also found same observation. Our study consistent with their study. In the present study ET Tube and i-gel was successfully inserted in 42 patients (84%) and 47 patients (94%) respectively. The second attempt needed in 16% and 6*%* patients in group ET Tube and group i-gel respectively. No patients in both groups needed third attempt.

Some other study like Gatward JJ et al[8] (i-gel: 1st attempt-86%, 2nd attempt- 11%, 3rd attempt- 3%), Wharton NM et al[9] (i-gel: 1st attempt-82%, 2nd attempt-12%, 3rd attempt-2.5%), Kannaujia A et al[10] (i-gel: 1st attempt-90%, 2nd attempt-10%), Uppal V et al[11] (i-gel vs ET Tube: i-gel-100% 1st attempt), Jigisha P Badheka et al[12] (i-gel: 1st attempt—83.4% 2nd attempt—16.6%) also found i-gel placement was more successful in 1st attempt. So our study is consistent with their study. The mean time required for inserting the ET Tube and i-gel in was 21.12 ± 2.14 seconds (range 16-25 seconds) and 18.36 ± 2.26 seconds (range 12 - 22 seconds) respectively and was statistically significant. Many author like Wharton NM et al[9] (i-gel: 17.5 sec.), Gatward JJ et al[8] (i-gel: 15 sec), Kannaujia A et al[10] (i-gel: 11 sec), Amr M. Helmy et al[13] (i-gel 15.5 sec), M G Patel et al[14] (ET tube: 33.03±4.61) found mean insertion time was less in i-gel. Our observations can be compared to above studies, that mean insertion time of I- gel is much shorter than Endotracheal Tube insertion time. However median insertion time of i-gel according to study of Kannaujia et al[10] was much shorter than our result and mean insertion time of Endotracheal Tube according to study of M G Patel et al[14] (2010) was much longer than our result. This difference with some authors might be a result of using different criteria to measure the total time needed that are different from those used in this study. In our study it can be observed that the mean heart rate in Group E was 82.5 bpm and in Group I was 83.36 bpm (as baseline). After instrumentation HR increased to 105.76 bpm in group E and 93.78 bpm in Group I. At 1 min HR was 99.8 bpm in Group E and 89.64 bpm in Group I. At 3 mins HR was 96.64 bpm in Group E and 84.28 bpm in Group I. At 5 mins HR was 85.82 bpm in Group E and 82.3 bpm in Group I. Thus, it can be interpreted that the HR increased after both ET tube and i-gel placement, but the magnitude and duration of this increase was less in Group I as compared to Group E. At removal of ET tube, there was a significant rise in HR but, HR change was insignificant during i-gel removal. In our study the mean SBP in group E was 122.42 mmHg and in Group I was 123.7 mmHg as baseline (Table 2). After intubation in SBP increased to 144.9 mmHg and in Group I the increase in SBP after i-gel placement was 136.76 mmHg. This rise persisted till 5 mins in Group E ($p<0.01$) and for 3 mins in Group I. In Group E again there was a significant increase in mean SBP ($p<0.01$) during extubation and it returned to baseline at 5 mins after extubation. The SBP change in group I was insignificant at device removal as well as at 5 min after device removal.

In our study the mean DBP was 82.36 mmHg in Group E and 82.22 mmHg in Group I as baseline. In Group E there was a highly significant increase in DBP after intubation (98.12 mmHg) and persisted for 3 mins. DBP was a baseline value 5 mins after extubation in Group E. In Group I there was also a highly significant elevation in DBP after placement of i-gel (92.76 mmHg). However, DBP reached baseline values at 3 min and DBP change from baseline remained insignificant thereafter till device removal and 5 mins afterwards in Group I. When intergroup comparison was done, the difference between the two groups was statistically significant after instrumentation, and at 1 min and 3 min.

It was observed that rise in MAP was significantly higher ($p<0.01$) in Group E as compared to group I during instrumentation (20.04%, Group E vs 12.04%, Group I). MAP variation remained significant between the two groups at 1 min and 3 mins with higher MAP values in Group E. MAP variation was insignificant from 5 min onwards till device removal when again MAP variation was highly significant between the two groups with Group E showing increased MAP (14.37%, Group E vs - 0.10%, Group I). The observations relating to haemodynamic changes in group E are in accordance with those by Shribman AJ et al[2] (1987), Suresh L et al (2012), Ebra Salman et al (2012).

The observations made in this study relating to better haemodynamic stability of i-gel group than ET Tube group are in accordance with those by Hosam M Atef et al[13] (2013) and Rukhsana Najeeb et al[7] (2015). The observation of Jindal P et al[15] (2009) also supports better haemodynamic stability of i-gel. At last we can say that i-gel offers better haemodynamic stability than ET Tube. The quality ventilation ($ETCO_2$) and Oxygenation (SpO_2) were satisfactory in both the groups. The values were similar and statistically insignificant both in the individual group and

between the two groups. Other studies which are relevant in this context are consistent with our study.

Post-operative airway trauma is more frequent in ET Tube group (20%) as compared to i-gel group (6%) in our study. Our result of incidence of post-operative airway trauma is comparable to the result of Singh I et al,[6] Amr M. Helmy et al,[13] Rukhsna Najeeb et al[7] but we got lesser incidence of post-operative airway trauma in i-gel group (6%) as compared to study of Uppal V et al[11] (12%) but incidence is more as compared to the study of Richez B et al[5] (0%) and Kannaujia A et al[10] and we got greater incidence (20%) of post-operative airway trauma in group ET Tube as compared to study by Saraswat N et al[16] (16.67%) and Rukhsana Najeeb et al[7] (15%).

In our study occurrence of sore throat among ET Tube group was 12% and i-gel group was 4%. From other studies it is noted that post-operative sore throat after tracheal intubation varies from 20% to 65% and after i-gel insertion it may occur from 2.5% to 11% of patients within 24 hours. It is clear from the above-mentioned studies that incidence of sore throat is more frequent after tracheal intubation than i-gel insertion.

CONCLUSIONS

Time taken to insert i-gel is significantly less when compared to Endotracheal Tube. i-gel causes significantly less haemodynamic perturbations at various time intervals. i-gel and ET tube show similar efficacy in maintaining ventilation and oxygenation status. Both the devices have their own profile of complications which need to be dealt with vigilance and caution. Hence, we conclude that i-gel is an effective and safe alternative to endotracheal tube for airway management in adult patients undergoing elective lower abdominal surgery under general anaesthesia.

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