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Direct laryngoscope guided method and a second-generation airway (i-gel) guided method for endotracheal intubation: a randomized clinical study

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Abstract: Background: Intubation is one of the most commonly done procedures in a hospital. Endotracheal intubation is the gold standard for securing airway. Direct laryngoscopy (DL) using Macintosh laryngoscope (MCL) has long been in use as a conduit for intubation. I-gel a second generation airway has been designed to conduct intubation, which reduces the pressure response and also eliminates the disadvantages of the LMA such as aspiration of gastric contents, compression of vascular structures, trauma and nerve injury. One of the most important advantages of the I-gel is it's ability to maintain oxygenation and ventilation during periods of apnea at the time of intubation.
Aim: The present study has been undertaken with an aim to evaluate and compare the intubation time and success rate of direct laryngoscopy and I-gel guided method for endotracheal intubation.
Material and Methods: In this comparative study, 80 patients of ASA grade I and II, aged 20-60 years undergoing elective surgeries under general anesthesia were included and divided into two groups - A DL and B- I-gel as a conduit for endotracheal intubation.
Result: The mean total intubation time was 18±1 seconds for direct laryngoscopy method and 26±5 seconds for I-gel guided method ($p<0.05$).Although the total number of attempts required in group A were 43 as compared to 47 in group B ,the difference was statistically insignificant ($P=0.38$).The changes in mean HR and mean MAP from baseline were less in group B in comparison to group A ($p<0.05$). The incidence of postoperative sore throat and hoarseness were also found to be less in group B as compared to Group A ($p<0.05$).
Conclusion: I-gel guided intubation can be an effective alternative to the conventional DL method as it offers more hemodynamic stability and less post operative adverse events.

Keywords: MCL; Supraglottic airway devices; I-gel; Endotracheal intubation.

1. Introduction

Endotracheal intubation, being a gold standard to secure airway, has long been studied in terms of equipments of choice, techniques, intubation time, hemodynamic responses etc. Direct laryngoscopy is the conventional technique to guide endotracheal intubation [1]. As scientific advancement is based on finding the least traumatic method to achieve the procedure, newer techniques and equipments have been evolved to decrease the complications associated with the use of direct laryngoscope. Dr. Archie Brain, a British Anaesthesiologist, introduced a supraglottic airway device, Laryngeal Mask Airway (LMA) in 1985 [2], which made it possible to control ventilation during anaesthesia.

The I-gel is a modified version of the LMA first described in 2007 by Dr. Muhammed Aslam Nasir. It is also a single use second generation supraglottic airway device (SAD) comprising a non-inflatable , soft gel-like cuff less mask, a narrow-bore gastric drain tube and a integral bite block [3]. The rim of the mask on the I-gel is unique for its ability to mimic the anatomical contours of the larynx. Because of this, the device can function without a cuff mechanism to create an airtight seal. The mask is made of styrene ethylene butadiene styrene (SEBS), tube consisting of breathing and a drain tube. It is possible to intubate the trachea through breathing tube and to insert a gastric tube through the drain tube [4].

This device also permits ventilatory control and oxygenation between intubation attempts during periods of apnea. I-gel has been shown to have advantage over laryngoscopy as a method for intubation, in terms of eliminating head and neck manipulation on insertion in cervical trauma patients. It is able to guide the tracheal tube directly to the glottis without causing stress on the anatomical structures, hence is theoretically expected to show less sympathoadrenal response as compared to direct laryngoscope.

With this background, we tried to further explore whether there was any clinically relevant difference in intubation time and hemodynamic response between the I-gel guided and direct laryngoscopic intubation. We have also tried to document and compare the success rates of two methods by evaluating intubation attempts. In addition to this, complications like post operative sore throat, dysphagia and hoarseness were also compared.

2. Material and Methods

This randomized clinical study was conducted in the department of Anaesthesiology, MGM Medical College and M. Y. Hospital, Indore (M.P.) after approval from the Institutional Ethics and scientific Committee [IEC approval EC/MGM/JULY-21/36] of MGM Medical College and M.Y. Hospital, Indore (M.P.). The study was conducted from April 2021 to September 2022. Sample size was calculated using the formula $\frac{2x\sigma^2(\frac{Z\alpha}{2}+Z\beta)}{d^2}$, $n = 40$ in each group direct laryngoscopy and I-gel Z= coefficient of difference, d= degree of differentiation ?=level of significance, β= type two error, σ=standard deviation. Adequate sample size based on above given information was 40 cases in each group. A total 80 patients satisfying inclusion criteria were randomly allocated by sealed envelope method, into 2 groups with 40 patients in each group. In Group A- direct laryngoscopy was done using Mac Intosch laryngoscope and in Group B- I Gel was used as a conduit for endotracheal intubation. Intubation time and number of attempts were noted for both the methods. Hemodynamic response and adverse events were also noted [5]. The patients with American Society of Anaesthesiologist (ASA) grade I and II, male sex 20 to 60 year of age and BMI < 30 kg/m^2 with Mallampatti grading 1 and 2 were included in the study. The patients with psychiatric disturbances and Head and neck surgeries, procedures not performed on supine position and having abnormality in neck, anticipated difficult airway, upper respiratory tract infection, history of obstructive sleep apnea were excluded from the study.

3. Allocation

A thorough pre-anaesthetic evaluation was performed. Eighty (80) patients satisfying inclusion criteria were randomly allocated by sealed envelope method into 2 groups with 40 patients in each. Direct laryngoscopy (mac-intosch) group (n=40) and A second-generation airway (i-gel) group (n=40), see Figure 1.

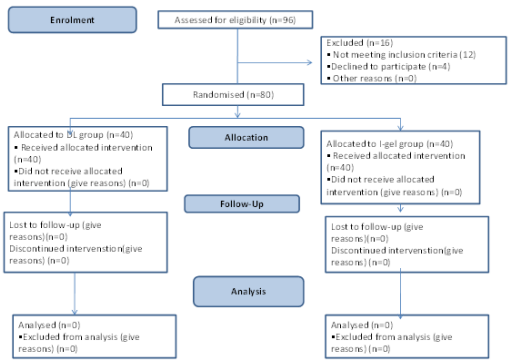

Figure 1. Consort flow chart

The patients were pre-medicated with glycopyrrolate 0.01mg/kg and midazolam 0.02mg/kg. Patients of both groups were induced with fentanyl 2 μg/kg and Propofol 2 mg/kg intravenously. Muscle relaxation was achieved with succinylcholine 2 mg/kg intravenously. Then the patient was intubated with adequate size endotracheal tube by one of two approaches as mentioned. Direct laryngoscopy method and I-gel method [6].

In both groups Intubation time was recorded as the time from the picking up of the device, to the appearance of first capnographic square waveform and included the following.

- **D**evice insertion time, DT(T1) was noted as the time from picking up the i-gel/MCL to complete insertion(visualization of both the vocal cords in MCL method and definitive resistance feel in i-gel method) .
- **T**ube insertion time, TT(T2) was noted as the time from visualization of both the vocal cords in MCL method and definitive resistance feel in i-gel method to insertion of ETT.
- **T**ime to first ventilation (VT) (T3) was noted as the time from insertion of ETT to successful ventilation/appearance of first capnographic square waveform.

  The attempt was defined as successful when the first capnographic waveform appeared. A maximum of 3 attempts were considered as a successful intubation. In Group A patients, the MacIntosh blade employed was either size 3 or 4, which is mostly used in adult patients. In Group B patients the size of I- gel was determined according to weight of patients in 30-50kg (size-3),in 50-90kg(size-4)and >90kg (size-5) [7] .We defined insertion failure of the device as one comprising more than three unsuccessful attempt in which case the airway was secured as per the discretion of the senior anesthesiologist supervising the case. In both the groups, heart rate (HR), blood pressure (BP), oxygen saturation (SpO2) were recorded before induction (baseline), before device insertion (T0), just after insertion of the device, after first ventilation and 5 mins after first ventilation. After the intubation positive pressure ventilation was started and maintained in volume-controlled mode by anesthesia workstation [8]. General anesthesia was maintained with oxygen and nitrous oxide (50%;50%) isoflurane in a titrated manner (0.6%-1.6%). The muscle relaxation was achieved with and injection atracurium in a dose of 0.5 mg/kg (loading dose) followed by maintenance in a dose of 0.1mg/kg. Reversal of neuromuscular blockade was achieved with inj neostigmine 0.05 mg/kg and inj glycopyrolate 0.01 mg/kg. Patients were extubated uneventfully when clinically adequate tidal volume was attained and shifted to recovery room. Post operative complication like sore throat, dysphagia and hoarseness of voice were assessed on arrival in recovery room [9].

4. Statistical Analysis

The data was initially entered into the Microsoft excel from the customized proforma for analysis. Statistical Software Mini Tab Version 17.0 was used for calculating the P values. Comparison of means between the two groups was done using Unpaired 't' test, association between two non-parametric variables was done using Pearson Chi-square test and comparison of proportions was done using Fisher's Exact Test. A p value of < 0.05 was taken as statistically significant. The final data was presented in the form of tables and graphs.

5. Results

Both the groups were comparable demographically i.e., Age, sex, body weight and Mallampati grading (Table 1). The difference in mean intubation time between both the groups was statistically significant (p=0.0001) showing a lower intubation time in the direct laryngoscopy group (18$\pm$1min) than with I-gel group (26$\pm$5 min) (Table 2). However the difference in total number of attempts for intubation was not significant, (p>0.05) (Table 3). There was significant increase in mean heart rate in the direct laryngoscopy group when compared to I-gel group from device insertion to the end of 5 minutes after device insertion (P<0.05) (Table 4). It was also found that there was statistically significant increase in mean systolic blood pressure, diastolic blood pressure and mean arterial pressure (MAP) seen in the direct laryngoscopy group when compared to I-gel group (p value < 0.05) (Table 5). The incidence of postoperative sore throat and hoarseness were lower in group B as compared to group A (P<0.05) (Table 7).

Table 1. Demographic profile of the patients in two groups

		Group	
		A	B
Age mean*	Mean ± SD	36.25±15.81	37.5 ± 7.63
Sex*	Male	28	21
	Female	12	19
ASA*	I	32	32
	II	8	8
Mallampati*	I	30	34
	II	10	6
BMI*(Kg/m^2)	20	3	4
	21-25	22	24
	26-30	15	12

Table 2. Comparison of intubation time in two groups

Group			
TIME (seconds)	A	B	
	Mean ± SD	Mean ± SD	p-value
Device Insertion Time(T1)	9±1	15±4	0.0001
Tube Insertion Time (T2)	5±1	6±2	0.0001
Time to first ventilation(T3)	4±1	5±1	0.0001
I.T.	18±1	26±5	0.0001

Unpaired 't' test applied. P value < 0.05 was taken as statistically significant

Table 3. Comparison of SUCCESS RATE in two groups

Success rate	Group				P value No. of patients	P value No. of attempts
	A		B			
	No. of patients(%)	No. of attempts	No. of patients(%)	No. of attempts		
Ist attempt	37(92.50%)	37 × 1 = 37	34(85.00%)	34× 1 = 34	0.288	0.13
2nd attempt	3 (7.50%)	3 × 2 = 6	5(12.50%)	5 × 2 = 10	0.45	0.32
3rd attempt	0(0.00%)	0	1(2.50%)	1 × 3 = 3	0.31	0.61
Total	40	43	40	47	0.434	0.38

Unpaired 't' test applied. P value < 0.05 was taken as statistically significant

Table 4. Comparison of heart rate in two groups

	Group		
Heart rate (beats/minute)	A	B	Unpaired t –test
	Mean ± SD	Mean ± SD	p-value
Before induction (baseline)	78±8	77±5	>0.05
Before device insetion	76±8	77±5	>0.05
After device insertion	87±8	82±4	0.001
After first ventilation	85±8	81±4	0.002
Five minute after first ventilation	83±7	77±5	0.001

Unpaired 't' test applied. P value < 0.05 was taken as statistically significant

Table 5. Comparison of mean SBP DBP MAP between Group A and Group B

		GROUP A	GROUP B	P value
Before induction (baseline)	MEAN SBP	121 ±7	121±5	>0.05
	MEAN DBP	78±7	79±6	>0.05
	MAP	92.1±5.8	94.3±4.2	>0.05
Before device insetion	MEAN SBP	121±6	120±5	>0.05
	MEAN DBP	77±7	78±5	>0.05
	MAP	91.5±5.6	92.9±2.94	>0.05
After device insertion	MEAN SBP	134±8	124±5	.0001
	MEAN DBP	86±7	84±3	.033
	MAP	102.0±6.6	97.1±2.32	0.0001
After first ventilation	MEAN SBP	130±7	126±4	.007
	MEAN DBP	83±6	76±3	0.02
	MAP	98.4±5.6	92.7±2.1	0.0003
Five minute after first ventilation	MEAN SBP	124±7	120±5	.009
	MEAN DBP	80±5	72±6	0.001
	MAP	94.4±5.6	89.2±3.6	0.0004

Unpaired t–test applied. P value<0.05 was taken as statistically significant

Table 6. Comparison of MEAN SPO2 between Group A and Group B

		Group A	Group B	P Value
Before induction(baseline)	MEAN SPO2	99.00%±0.52%	99.00%±0.03%	>0.05
Before device insetion	MEAN SPO2	99.00%±0.52%	99.00%±0.23%	>0.05
After device insertion	MEAN SPO2	99.00%±0.52%	99.00%±0.00%	>0.05
After first ventilation	MEAN SPO2	99.05%±0.32%	99.00%±0.21%	>0.05
Five minute after first ventilation	MEAN SPO2	99.05%±0.32%	99.00%±0.02%	>0.05

Unpaired 't' test applied. P value < 0.05 was taken as statistically significant

Table 7. Comparison of post operative adverse events in Group A and Group B

ADVERSE EVENT		Group A No. (%)	Group B No. (%)	P-VALUE
Sore throat	On arrival in recovery room	12(30%)	4(10%)	0.003
Hoarseness	On arrival in recovery room	7(12.5%)	3(7.5%)	0.04
Dysphagia	On arrival in recovery room	5 (12.5%)	1(2.5%)	0.09

Unpaired 't' test applied. P value < 0.05 was taken as statistically significant

6. Discussion

Endotracheal intubation is the gold standard for securing airway. Direct laryngoscopy using Macintosh laryngoscope has long been in use as a conduit for intubation. Laryngoscopy and endotracheal intubation are two separate stimuli that induce a pressure response, increasing the heart rate and blood pressure. This pressure response has been associated with cardiovascular events in patients. There has been a need to eliminate such responses during intubation.

So, laryngeal mask Airway (LMA) , an invention by Brain [2], made it possible to provide ventilation and oxygenation in difficult airway scenarios with less hemodynamic response. However, this device had its own limitation in terms of its inability to provide protection from aspiration, making intubation necessary. I-gel was designed by Nasir [3] with the purpose of eliminating the problems of LMA by using it as a conduit for intubation.

The present study aimed to evaluate and compare above two methods for endotracheal intubation in terms of intubation time, number of attempts ,hemodynamic response and adverse events. From the observation and results of the study it was interpreted that although overall intubation time for I- gel guided method, was more than direct laryngoscopic method, there was no significant difference in total number of

attempts for two methods. There were less haemodynamic response and adverse events with the I-gel guided tracheal intubation.

In the present study, it was observed that the device insertion time (T1), tube insertion time (T2), time to first ventilation (T3) and total intubation time (I.T.) were all more in Group B as compared to Group A and the difference was statistically significant ($p<0.05$). The results of the present study varied from the results of the study conducted by Kim et al. [10], found that there is no significant association between the above two compared groups (P= 0.12). This could be attributed to the fact that, they did the study on manikin and present study was done on patients, which influenced the difference in the Variable of two studies. They also found that device insertion time (DT) and tube insertion time (TT) for I-gel were significantly shorter than Air-Q, LMA-Fastrach and MCL. DT and TT for LMA Fastrach was the longest among the 4 devices (all $P<0.0083$). DT and TT were also found to be higher in direct laryngoscopy as compared to I-gel. Since I-gel is a non-inflation-cuff device, it could be inserted easily and faster than an inflation-cuff device such as a LMA Fastrach. DT and TT were shortest in I-gel but not significantly different from MCL (P=0.05).

Although in the present study, the total number of attempts required for tracheal intubation in I-gel guided method was higher(47) as compared to 43 in DL method, the difference was statistically not significant (0.434). These findings were in con-cordance with the findings of a manikin study done by Kim et al. [10], where also the difference in number of attempts was statistically significant for the two methods (P=0.12).

In present study the rise in mean HR and MAP was less after device insertion, one and five minutes after ventilation in I-gel guided group as compared to DL group and the difference was statistically significant ($p<0.05$). These results were coherent with the finding of Jighisa et al. [11] in a study conducted on 60 patients. They had concluded that there was a significant rise in HR just after, 3 and 5 minutes after intubation in two groups comparing endotracheal tube and I-gel insertion. However there was no significant change in mean MAP in the two groups after first ventilation and 5 minutes after first ventilation.

The present study is probably the first of its kind of study which has compared the I-gel as a conduit to the conventional direct laryngoscopic method for endotracheal intubation in patients undergoing general anaesthesia. Only a single similar study has been reported in part done on mannikin.

There was no significant difference in the SpO2 of the patients of two groups in our study after device insertion and endotracheal intubation.

In the present study only 10% patients in group B reported post operative sore throat in comparison to 30% in group A. Similarly the incidence of hoarseness was 7.5% in group B as compared to 17.5% in group A. The difference was statistically significant ($p<0.05$).

7. Limitation

Possibly, due to the overall experience in the use of I-gel being vastly lower than, the direct laryngoscope, the more number of attempts for successful intubation was observed In I gel guided intubation. Hence, it can be noted that efficacious use of I-gel in terms of time taken for intubation, is limited in the hands of novice health care providers. These limitations are likely to be eliminated as the experience with I gel increases, so that it can then become the technique of choice not just in routine intubations but also in more unanticipated difficult intubation scenarios.

8. Conclusion

From the observation and results of the study. It can be stated that in-spite of longer intubation time, I-gel guided method of endotracheal intubation was as effective as DL method in term of number of attempts. The hemodynamic response, postoperative sore throat and hoarseness were also less in I-gel method. Thus, it can be safely used to guide endotracheal intubation in patients were exaggerated sympathetic response drive to laryngoscopy can prove to be deleterious.

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Conflicts of Interest: "Authors declare no conflict of interests."

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