"OVERVIEW OF IGEL VERSES UNCUFFED ETT IN PEDIATRIC POPULATION: A PROSPECTIVE, RANDOMIZED CONTROLLED TRIAL"

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ABSTRACT:

BACKGROUND:
Controlled ventilation with an endotracheal tube (ETT) has been considered gold standard. However, ETI is associated with hemodynamic instability during laryngoscopy and intubation and post operative complications which can be overcome by using IGEL. As there are only limited studies comparing its ventilatory efficacy to ETT, our comparative study evaluated adequacy of ventilation and clinical performance
METHODS:
90 patients undergoing elective surgeries were randomly divided into GROUP A(IGEL) & GROUP B (UNCUFFED ETT). **Primary Objective** was to measure adequacy of volume control ventilation by comparing the Oropharyngeal Leak Pressure (OLP), Oxygen Saturation (SPO2), End Tidal Carbon Dioxide (ETCO2), Peak Airway Pressure (PAP), Tidal Volume (TV) Leak % Airway Sealing Quality (ASQ) Score. **Secondary objective** was to assess the clinical performance by evaluating Hemodynamic response, Ease of Insertion and Post operative Complications
RESULTS:
The mean OLP For IGEL was 24.52 cmH_2O. The SPO_2, $ETCO_2$, PAP and TV LEAK% were all comparable with non-significant p-values of 0.140, 0.059, 0.387, 0.308 respectively. The mean insertion time (12.84 seconds) was less in IGEL group. The mean HR, SBP and DBP were more in patients with ETT than in patients with IGEL with significant p-value for (HR, SBP, DBP) at 1 min (0.019, 0.033, 0.021), 5 mins (0.014, 0.023, 0.033) and extubation (0.042, 0.016, 0.010) respectively. Increased incidence of cough in patients receiving ETT with p value (0.024).

CONCLUSION:

IGEL is safer alternative for short duration procedures, as it provides adequate ventilation comparable to ETT. with better hemodynamic stability reduced post-operative complications and ease of insertion.

KEY WORDS:
Supraglottic Airway Device, Igel, Uncuffed Endotracheal Tube, Volume Control Ventilation, Pediatric Population, Hemodynamics, ease of Insertion,

INTRODUCTION:

Controlled ventilation with an endotracheal tube (ETT) has been considered gold standard. However, Tissue irritation during laryngoscopy and tracheal intubation produces Sympatho-adrenal response.[1] Despites various control measures, activation of proprioceptors causes increase in blood pressure, heart rate and catecholamine concentration.[2] Supraglottic Airway Device (SAD) offering simple, effective, relatively non-invasive alternative has gained its acceptance over endotracheal intubation. However, the 1st generation SAD like classic LMA had drawback of lack of protection from aspiration, airway leak and gastric distension, which were overcome by advent of the advanced 2nd generation SAD'S. I-GEL, a trending SAD introduced by (Intersurgical Ltd), mirrors the laryngeal anatomy in design with a soft, gel-like, non-inflatable cuff that is intended to provide an anatomical fit over the laryngeal inlet. The curves, suppleness and shape closely resemble the perilaryngeal anatomy and capable of providing higher oropharyngeal leak pressure thus protecting from aspiration. But there are only limited studies comparing safety profile and ventilatory efficacy of IGEL to ETT in paediatric age group. Hence our study was designed to compare adequacy of ventilation and clinical performance overall in paediatric patients undergoing elective surgeries.

MATERIAL AND METHODS

A prospective, randomized, comparative study was conducted on 90 pediatric patients undergoing elective surgeries under general anesthesia. Institutional ethics committee approval and clinical trial registry of India (CTRI) registration done prior to the commencement of the study. Estimation of sample size was based on M.Kohli's study "Comparative evaluation of I-gel vs. endotracheal intubation for adequacy of ventilation in paediatric patients undergoing laparoscopic surgeries".[3] Ease of insertion in 1st attempt was 97.5% and 77.5% in (ETT) and IGEL group respectively. Using WINPEPI software with Allowable difference of +-5, Confidence Interval of 95%, sample size was calculated to be 88, rounded off to 90, considering drop outs.

American Society of Anaesthesiologists (ASA) physical status classification I or II patients, aged 2 to 8 years of either sex with stable hemodynamics and normal laboratory investigations were included in the study. Patients with full stomach, increased risk of aspiration, GERD, hiatus hernia, previous gastric surgery, history of lung disease, neck pathology, facial anomalies or URI or those children with known or predicted difficult airway were all excluded from the study. Pre operative visit was done day prior to surgery. History, general and systemic examination, vitals and routine laboratory investigations were noted. The parent or guardian's written informed consent was obtained preoperatively. Patients were kept nil by mouth midnight prior to surgery. Peripheral venous access was established with a 24G/22 G intravenous (IV) cannula.

The patients were divided into two equal groups by using computer generated random number table. On day of surgery, experienced anaesthesiologist who was involved in administration of anaesthesia and patient care would open the opaque sealed envelope with assigned group just prior to the induction of general anaesthesia. The monitoring and data collection was done by the other investigator thereby avoiding observer bias. The patients were blinded about study groups.

Premedication with Inj.glycopyrolate0.004 mg/kg IV and inj. Midazolam 0.02 mg/kg IV was given. Standard monitoring devices like ECG, non-invasive Blood pressure and Spo2, ETCO2 were attached. Pre oxygenation with 100% O2 for 3 minutes done. Inj. Fentanyl 2microgram/kg IV was given. induction was done with Inj. Propofol 2mg/kg IV. Inj. Atracurium 0.5 mg/kg was given only after confirming ventilation.

In group A: I-GEL of appropriate size, WEIGHT: 25-35 KG :2.5 SIZE; 10-25:2 SIZE; 5-12 KG: 1.5 SIZE as per manufacturer guidelines were inserted. In group B: Uncuffed ETT of appropriate size were inserted using formula: AGE/4+4 (Modified Coles formula) **[4]** Age 2-4 years: 4 /4.5/5mm; Age 4-6 years: 5/5.5 mm; Age 7-8 years: 5.5/6mm. Both the devices were fixed. Lubricated gastric tube was placed in I-gel for draining gastric channel. Successful insertion and ventilation were confirmed by tracing capnograph, bilateral chest movements and auscultation. The presence of gastric insufflation was determined by epigastric auscultation.

Number of insertion attempts were noted. Failed attempt was removal of the device from the mouth before re-insertion. **Insertion time** in Seconds was noted from when the device was picked up in hand and until the connection to breathing circuit and appearance of 1st square wave capnograph trace. **Ease of insertion** was accounted subjectively as Easy (no adjustments needed); Satisfactory (slight rotation needed for proper placement)**;** Difficult (when deep rotation and jaw thrust needed).

Following insertion of device, the expiratory valve of the circle system was closed at a fresh gas flow of 3L/min, until an audible gas leak was heard with a stethoscope, recording the oropharyngeal leak pressure (OLP) when equilibrium was achieved. The OLP was not allowed to exceed 40 cm H2O to avoid barotrauma. ***[3]***

Adequacy of ventilation was measured by oxygen saturation (spo2), end tidal CO2 (ETCO2), peak airway pressure (PAP), and Airway Sealing Quality Score (ASQ). Tidal volume loss / leak was calculated by subtracting expiratory tidal volume on the ventilator display screen from inspiratory tidal volume that was set in volume control mode. (ASQ) [45] was then calculated as follows. Score 1: No leak detected; Score 2: Minor leak of tidal volume (TV loss <20%); Score 3: Moderate leak of tidal volume (TV loss 20-40%); Score 4: Insufficiency (TV loss >40%).[5]

In IGEL group, if oropharyngeal leak was present, then it was exchanged with appropriate size uncuffed ETT. In ETT group if TV leak was observed, it was exchanged with greater size tube and noted as airway device size exchange. Haemodynamic parameters like heart rate, and mean arterial pressure were noted at timely intervals.

Anaesthesia was maintained with isoflurane or sevoflurane with oxygen and nitrous (50:50) Neuromuscular block maintained with atracurium in both groups. At the end of surgical procedure, anaesthesia was discontinued and reversal was given with inj. glycopyrrolate 0.008mg/kg plus inj. neostigmine 0.05 mg/kg and the device removal was done. During removal l presence of blood on device was recorded. Postoperative complications in form of sore throat, cough, laryngospasm, stridor, immediately after regaining consciousness, after 6 hours and until 24 hrs were recorded.

STATISTICAL ANALYSIS:

Analysis was done with statistical package for social sciences **(SPSS) version 26.** For describing the qualitative variables, frequency and percentages were used and for quantitative data, mean and standard deviation were used. Difference in distribution of qualitative variable between the experimental arms was found by **"chi-square test"** and difference in mean between two groups by "**independent samples T test"**. To find out the difference in change of mean between the groups for a repeatedly measured variables, "**Repeated measures analysis of variance (RM-ANOVA)"** was used. A P value of less than 0.05 was considered to be statistically significant.

RESULTS:

A total of 90 patients were enrolled for this study, and there were no dropouts [Figure 1]. Baseline demographic profile and surgeries performed and duration of surgery were comparable between the two groups.

Clinical performance: assessment by insertion parameters is shown in [Table 1]. The mean insertion time was less and ease of insertion was better in IGEL group while insertion attempts and within group airway device size exchange were comparable between both groups. In our study no IGEL was exchanged to ETT.

The Ventilatory response: The oropharyngeal leak pressure was measured for IGEL group and showed a mean value of 24,52 cmH2O with SD of 5.62 cm H2O. The ventilatory parameters (SPO2) oxygen saturation, (ETCO2) END TIDAL CARBON DI OXIDE, (PAP) PEAK AIRWAY PRESSURE and ASQ score were all comparable with non-significant p values. ASQ score was recorded as score 2 for all 90 patients. Both the groups were comparable in terms of adequacy of ventilation as shown in [Table 2]

The hemodynamic response: The mean heart rate at base line for I gel and Uncuffed ETT were 109.53 ± 17.08 beats per minute (bpm) and 112.38 ±12.78 bpm, respectively (Graph 1). Within group P value: 0.001 and between group P value :0.150. The P value for within the group was significant indicating considerable change in heart rate over the follow up. The mean systolic blood pressure (BP) at baseline was 95.49 ± 6.14 mmHg for I gel and 98.49 ± 10.12 mmHg for uncuffed ETT (Graph 2). The mean diastolic BP at baseline was 59.51 ± 5.89 mmHg for I gel and 60.78 ± 9.96 mmHg for uncuffed ETT (graph 3). Within the groups P value was 0.174 and 0.516 for systolic and diastolic BP indicating not much change during the follow up period in both the groups. The between group P value was 0.020 for systolic and 0.006 for diastolic, indicating the trend was not similar in both the groups. The mean heart rate, systolic BP and diastolic BP were more in the uncuffed ETT than in the Igel group at 1 min, 5 mins and extubation.

Complications: In GROUP A, 13.3% had cough and 4.4% hoarseness, In group B, 22.2% had cough and 8.9% had hoarseness in the immediate postoperative period. There was no cases of laryngospasm, bronchospasm or blood on device. The late post op complications are shown in [table 3] with increased incidence of cough in uncuffed ETT group with significant p value of 0.024.

DISCUSSION:

Endotracheal intubation is considered to be the gold standard treatment for airway management.[6] ETT prevents gastric insufflations and thus pulmonary aspiration. Haemodynamic changes like tachycardia and increased blood pressure produced by laryngoscopy [7] are initiated within seconds and further increases while passing the endotracheal tube. The response peaks in 1–2 min and returns to normal values by 5 min – 10 min. [8] Similar type of response is seen during extubation. Various postoperative disadvantages such as, cough, sore throat and hoarseness [9] of voice necessitates to find suitable alternatives.

The SAD like IGEL can also be used for intermittent positive pressure ventilation. The advent of such SAD which produces less hemodynamic response and provide easy insertion, has turned pediatric anesthesia practice making them an important asset of airway management.

Similar to our study, the mean insertion time was 18seconds for IGEL and 32seconds for ETT in Jeong's study.[10]

The airway pressure needed to cause gastric distension during mechanical ventilation is known as OLP which is the principal signal for determining airway sealing and gas leakage. Lower OLP can easily result in elevated intra-abdominal pressure, restricted breathing, and a higher risk of gastroesophageal reflux. Hence SAD with high OLP is better to avoid aspiration related complications and also provide effective ventilation in young children. The gel material of I-cover gels allows for small amplitude shaping based on the children's oropharyngeal features to create a better sealing effect even though it does not contain a cuff and cannot seal the airway by regulating the cuff pressure. The OLP of 24.52+/-5.62 provided by IGEL was fairly high. Similar result was noted by Zhiqing Gu et al, in the study "Observation of ventilation effects of I-gel, Supreme and AmbuAuraOnce with respiratory dynamics monitoring in small children ". The Leak pressure in the Ambu group was significantly lower than that in the I-gel group. OLP (cm H2O) was 24.38 ± 6.06 immediately after insertion,24.38 ± 5.89 at 10 mins,24.44 ± 5.79 at 20 mins, 24.41 ± 5.75 at 30 mins respectively.[11]

The mean ETCO2 of I gel group and ETT group were similar with P value of 0.059. In 2018, Jeong In Hong, conducted a study in Korea on 60 patients under 10 years old, ETCO2 after intubation (T1),5 min before (T2) and after (T3) the creation of pneumoperitoneum and 5 min before (T4) and after (T5) the end of pneumoperitoneum. ETCO2 showed no differences between both groups.[10]

The mean PAP of both the groups were found to be similar with non-significant P value of 0.734 although the PAP of ETT group was slightly higher. Study Conducted on Eighty children by Megha Kohli et al In 2018 showed significant difference in the increase in peak airway pressure between the two groups 12.2 for ETT and 9.2 for IGEL with P value of $<$ 0.005. [3]

The mean leak percentage of groupA and groupB were similar with non-significant P value of 0.308. Similar results were found in study Chih-Jun Lai conducted in Taiwan,[12] In the supine position, the leak fraction (%) was 7.01 [3.73] for Igel and 5.76 [2.67] for ETT. In the supine position, the leak volume (ml) for IGEL was 31.99 [14.54] and for ETT it was 26.06 [9.62] with a p value of 0.327. Less leakage (6.20 [3.49] %) was seen in the laparoscopic pneumoperitoneum and Trendelenburg (LPT) position for the i-gel group compared to the supine position (7.01 [3.73] %) (P = 0.179). Leakage (median [IQR]) in the ETT group was comparable in both places (supine: 5.76 [2.67] %; LPT: 6.38 [3.71] %, P = 0.194). [12] In study conducted by Gaurav Chauhan et al, ASQ score for IGEL was 1 for 32 (80%) patients, 2 for 8 (20%) patients, while for proseal also ASQ SCORE was 1 for 32 (80%) 2 for 8 (20%) patients, with a p value of 1 which was not significant.[13]

Unlike our study, in Jeong in Hong's study, changes in heart rate during surgeries were similar in both groups. However, Systolic (P = 0.001, 0.002, and 0.001 respectively) and diastolic (P < 0.001, P = 0.003, and < 0.001 respectively) blood pressures differed between the groups following intubation, as well as before and after the creation of pneumoperitoneum. Blood pressure was higher in the ETT group, compared with the i-gel group, following intubation, as well as 5 min before and after the creation of pneumoperitoneum.[10]

According to Maharjan in 2012, there was increase in heart rate and systolic blood pressure in LMA and tracheal group with significant difference after intubation and extubation. But with I gel group of patients, the haemodynamics were stable and no significant increase was noted during the procedures.[14]

In Megha Kohli et al study, the increase in PR from preoperative values was 9.0% for the ETT group and 2.4% for the Igel group at 1 min. The increase in MAP from preoperative values was 2.9% for the ETT group and 3.0% for the Igel group at1 min. The PR and MAP decreased to values below preoperative at 5 min. no significant difference in the rise in heart rate or mean arterial pressure between the groups on device insertion, though the increase was less in group I-gel.[3]

In 2015, Gilles Guerrier's study "Comparison of a Supraglottic Gel Device and an Endotracheal Tube in Keratoplasty, there was a significantly greater incidence of coughing at extubation and/or after extubation in the tracheal group (40/55; 73%) than in the IGEL (3/55; 5%) (P < 0.001). There were no significant differences in the incidence of sore throat and hoarseness between both devices.[15]

CONCLUSION:

IGEL provides adequate ventilation comparable to endotracheal tube in terms of SPO2, ETCO2, PAP, TV loss & ASQ Score. IGEL is a safe, non-invasive, alternative to endotracheal tube in terms of better hemodynamic stability, reduced post operative complications ease of insertion

LIMITATIONS:

The study was limited to routine shorter duration paediatric procedures with normal airway anatomy and no risk of aspiration.
The study sample size was generalised to 2-8 years, Extremes of age group and weight were not studied. Larger sample size is reuires for assessing safety profile.

FURTHER SCOPES:

- While further studies are required in establishing use of IGEL in neurosurgical cases, neck surgeries, ophthalmological and prone position surgeries.

- There are case reports of fibre optic intubations being successfully completed with the help of the I-GEL, suggesting that the I-GEL may also play a role in the treatment of the difficult airway. [16,17] hence further large-scale studies are required.
- The study can be extended to outside OT anaesthesia, in areas of CT, MRI where spontaneous ventilation with sedation could offer better airway protection and cooperation.

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FIGURE 1: CONSORT FIGURE REPRESENTING ENROLMENT DATA

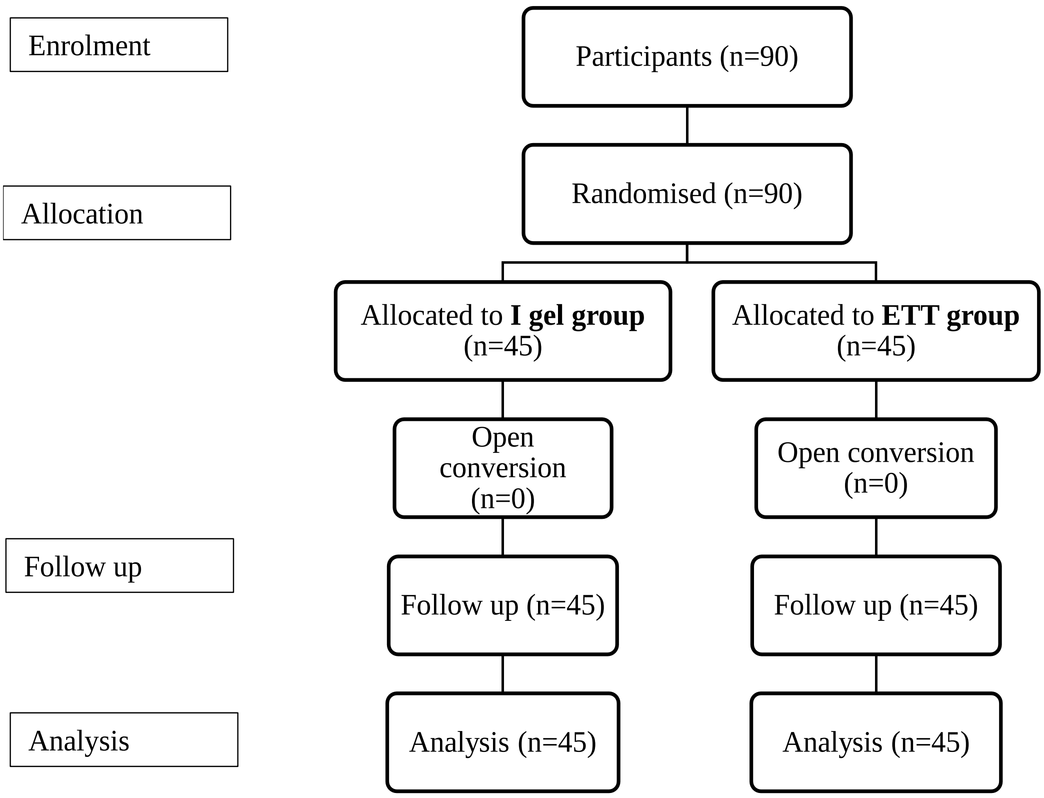


TABLE 1: DEMOGRAPHIC PROFILE AND INSERTION PARAMETERS

PARAMETERS	IGEL	ETT	T VALUE / X^2	P VALUE
AGE (in years)	4.49+/-2.19	3.98+/-1.91	1.18	0.240
Weight (in kgs)	16.2+/-3.77	15.51+/-4.44	0.792	0.430
Sex (male)	32(71.1%)	23(51.1%)	3.787	0.052
Sex (female)	13(28.9%)	22(48.9%)		
Asa 1	31(68.9%)	28(62.2%)	0.443	0.506
Asa 2	14(31.1P%)	17(37.8%)		
Insertion attempts (1/2)	43/2	44/1	0.344	0.557

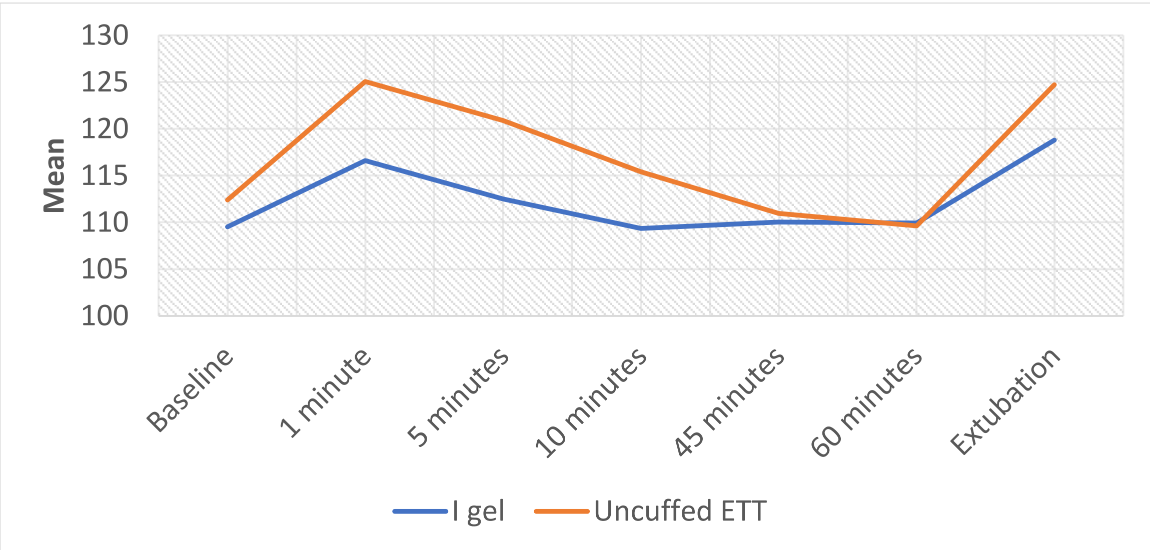
Airway device size exchange (yes/no)	2/43	7/38	3/08	0.079
Insertion time (In seconds)	12.84+/-0.95	24,01+/-3.71	19.57	0.001
Ease of insertion (easy /satisfactory)	45/0	31/14	16.57	0.001

TABLE 2: ADEQUACY OF VENTILATION:

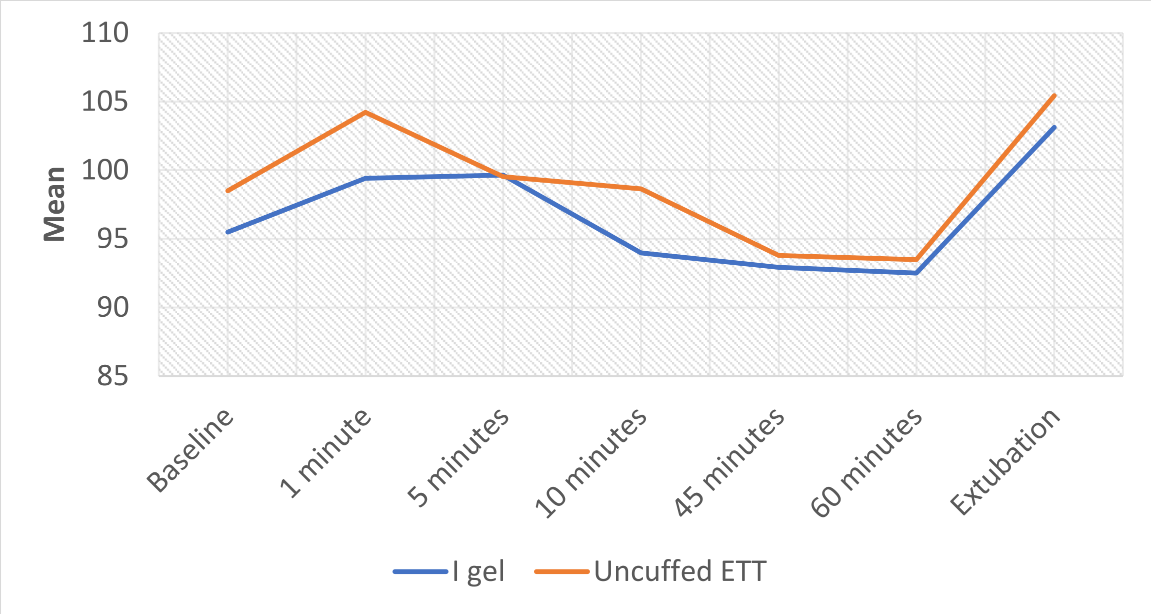
Parameter	**Igel**	**Uncuffed ETT**	**T VALUE**	**P VALUE**
SPO2	99.67+/-0.47	99.78+/-0.42		0.14
Etco2	36.80+/-4.17	35.31+/-3.14	1.91	0.059
PAP	13.33+/-2.57	13.51+/-2.37	0.34	0.734
TIDAL VOLUME INSPIRATION	144.67+/-37.65	134.00+/-40.07	1.301	0.196
TIDAL VOLUME EXPIRATION	137.76+/-38.07	128.33+/-39.61	1.15	0.253
TIDAL VOLUME LEAK	6.82+/-2.53	5.67+/-3.06	1.945	0.055
MEAN LEAK %	5.02+/-2.27	4.51+/-2.48	1.026	0.308

TABLE:3 DISTRIBUTION OF LATE OPERATIVE COMPLICATIONS BETWEEN THE GROUPS

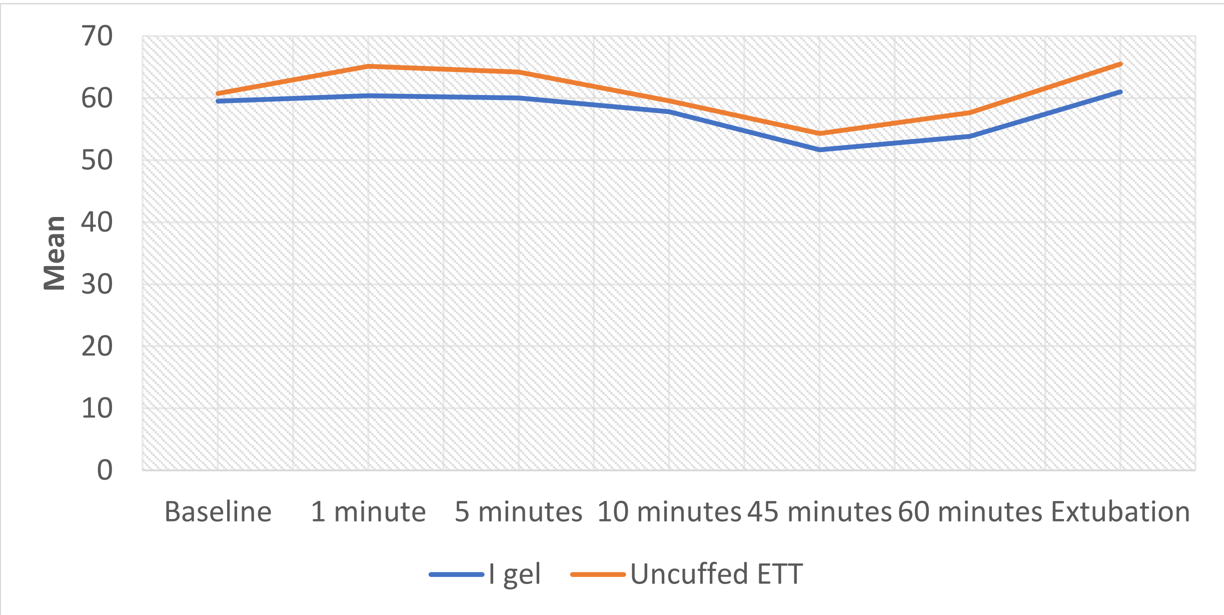
	I gel		**Uncuffed ETT**		**X^2**	**P value**
	N	%	N	%		
COUGH	2	4.4	9	20	5.075	0.024
SORE THROAT	1	2.2	4	8.9	1.90	0.167
HOARSENESS	1	2.2	3	6.7	1.04	0.306



Graph 1: Line chart showing trend of HR during follow up



Graph 2: Line chart showing trend of systolic during follow up.



Graph 3: Line chart showing trend of diastolic blood pressure during follow up.