Original Article

A randomised controlled trial comparing ProSeal laryngeal mask airway, i-gel and Laryngeal Tube Suction-D under general anaesthesia for elective surgical patients requiring controlled ventilation

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ABSTRACT

Background and Aims: The ProSeal™ laryngeal mask airway (PLMA), i-gel™ and Laryngeal Tube Suction-D (LTS-D™) have previously been evaluated alone or in pair-wise comparisons but differing study designs make it difficult to compare the results. The aim of this study was to compare the clinical performance of these three devices in terms of efficacy and safety in patients receiving mechanical ventilation during elective surgical procedures. **Methods:** This prospective, randomised, double-blind study was conducted on 150 American Society of Anesthesiologists physical status I–II patients, randomly allocated into 3 groups, undergoing elective surgical procedures under general anaesthesia. PLMA, i-gel™ or LTS-D™ appropriate for weight or/and height was inserted. Primary outcome measured was airway sealing pressure. Insertion time, ease of insertion, number of attempts, overall success rate and the incidence of airway trauma and complications were also recorded. Intergroup differences were compared using one-way analysis of variance with *post hoc* correction for continuous data and Chi-square test for categorical variables. **Results:** Overall success rate was comparable between the three devices (i-gel™ 100%, LTS-D™ 94%, PLMA 96%). Airway sealing pressure was lower with i-gel™ (23.38 ± 2.06 cm H_2O) compared to LTS-D™ (26.06 ± 2.11 cm H_2O) and PLMA (28.5 ± 2.8 cm H_2O; $P < 0.0005$). The mean insertion time was significantly more in PLMA (38.77 ± 3.2 s) compared to i-gel™ (27.9 ± 2.53 s) and LTS-D™ (21.66 ± 2.31 s; $P < 0.0005$). **Conclusion:** Airway sealing pressure and insertion time were significantly higher in PLMA compared to i-gel™ and LTS-D™.

Key words: Airway management, Artificial, i-gel, Laryngeal Tube Suction-D, ProSeal laryngeal mask airway, respiration

INTRODUCTION

The most fundamental aspect of the practice of general anaesthesia is the maintenance of a clear upper airway. Airway management of patients has progressed from introduction of endotracheal tube (ETT) to the less invasive laryngeal mask airway (LMA).[1] In the past 10 years, there has been a phenomenal increase in the use of supraglottic airway devices (SADs) for elective and rescue purposes. Several second-generation devices, including the ProSeal™ laryngeal mask airway (PLMA, LMA North America, San Diego, CA), i-gel™ supraglottic airway device (Intersurgical Ltd, Wokingham, Berkshire, UK) and Laryngeal Tube Suction-D™ (LTS-D, VBM Medizintechnik Gmbh, Sulz a. N., Germany), have been introduced over the past decade.[2,3]

In this study, we compared PLMA, LTS-D™ and i-gel™ LMA under general anaesthesia for elective surgeries.

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Primary outcome measure was airway sealing pressure. We also compared insertion time, ease of insertion, number of attempts, overall success rate and the incidence of airway trauma and complications.

METHODS

After approval from the Institutional Ethical Committee, 150 patients were studied in a randomised prospective study, designed to compare PLMA with i-gel™ and LTS-D™. This study was conducted according to Good Clinical Practice standards and the Helsinki Declaration. The protocol was registered at ClinicalTrial.gov (clinical trial identifier NCT02877940). The period of the study was from June 2015 to June 2016. Our study followed the CONSORT recommendation (Chart 1).

The American Society of Anesthesiologists (ASA) physical status I and II patients, between 20–60 years of age, of either sex, weighing from 40 to 60 kg, undergoing elective surgical procedures of duration 1–1½ h not requiring endotracheal intubation were selected for the study. The exclusion criteria included patients with risk factors for difficult airway (mouth opening of <2 finger, Mallampati Score 4, limited neck extension, history of previous difficult intubation), any known pulmonary and cardiovascular diseases and risk of aspiration (full stomach, hiatus hernia, gastro-oesophageal reflux disease, emergency surgery). Neck Movement was assessed as Class: I-No reduction in movement, II-1/3rd reduction, III-2/3rd reduction, IV-Complete reduction.

Following detailed pre-anaesthetic check-up, informed written consent was obtained from all patients fulfilling the required criteria. One hundred fifty patients were equally randomised by block randomisation to three groups, namely, Group I (i-gel™, n = 50), Group P (PLMA, n = 50) and Group L (LTS-D™, n = 50) using computer-generated randomisation programme by an anaesthetist who was not involved in the operating room procedure. Participants were assigned to specific groups by the operating room nurse in charge.

After attaching pulse oximeter, non-invasive blood pressure and electrocardiography, patients were pre-medicated with injection midazolam 0.05 mg/kg, glycopyrrolate 0.2 mg, dexamethasone 4 mg and fentanyl 2 μg/kg intravenously. All patients were pre-oxygenated for 3 min, and anaesthesia was induced with injection propofol 2 mg/kg. Injection vecuronium 0.1 mg/kg was given for neuromuscular blockade and patients were ventilated with oxygen for 3 mins till complete relaxation set in.

PLMA or LTS-D™ or i-gel™ appropriate for weight or/and height (as in case of LTS-D™) of patient was selected, lubricated with water-soluble jelly and inserted as per the manufacturers guidelines.

After successful insertion, the cuff of PLMA and LTS-D™ were inflated with air according to the size and type of LMA as per manufacturers guidelines, to prevent audible and palpable air leak. An effective airway was confirmed by bilateral symmetrical chest expansion on manual ventilation, auscultation of breath sounds, square waveform on capnography, stable oxygen saturation, no audible leak of the gases and lack of gastric insufflation. Devices were fixed with adhesive tape applied to the maxilla on one side of the patient's face and passed over and under the tube in a single loop before fixing to the opposite maxilla.

Anaesthesia was maintained with oxygen, nitrous oxide and sevoflurane and intermittent positive pressure ventilation. Haemodynamic parameters were monitored after the insertion of the device. A lubricated gastric tube was placed in the stomach through the gastric channel. At the end of surgical procedure, anaesthesia was discontinued and residual neuromuscular blockade reversed with injection neostigmine and glycopyrrolate, followed by device removal. Complication if any was noted.

We assessed number of insertion attempts, ease of insertion, time of insertion, airway sealing pressure, number of attempts of gastric tube insertion and complications. One attempt was defined as picking up of the device and negotiating it beyond the incisors. In case of insertion attempts, maximum of three attempts were allowed. An attempt was considered unsuccessful, if there was failure to negotiate the device beyond oropharynx, significant leak present (both audible and auscultatory) or inadequate ventilation with $EtCO_2$ >45 mmHg. Failure of a device was defined as three unsuccessful insertion attempts or inadequate ventilation. After failure of three attempts, intubation was performed using conventional rigid laryngoscopy and case was recorded as failed and also deleted from the study. For ease of insertion of device, it was termed easy, if device was inserted in a single attempt/manoeuvre in to the pharynx with no resistance to insertion. It was

termed difficult if there was resistance to insertion or more than one manoeuvre/attempt was required for correct placement of the device. Insertion time was defined as time interval (in seconds) between placing the device into the oral cavity and securing an effective airway, which was recorded by an independent observer. Effective airway was confirmed by auscultation and square wave pattern on $EtCO_2$. The airway sealing pressure was measured by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min and recording the airway pressure at which equilibrium is reached. At this stage, a leak at mouth and stomach was ascertained. A maximum of two attempts were allowed for gastric tube placement. Its correct placement was confirmed by injection of air and epigastric auscultation or aspiration of gastric contents. Failure was defined as inability to advance the orogastric tube into the stomach within two attempts. Blood staining of the device and tongue, lip or dental trauma was noted. Incidence of laryngospasm or hypoxia (defined as oxygen saturation <92%), if any, in intra-operative period was noted and managed accordingly. In post-operative period, an investigator blinded to study asked the patients about the signs of sore throat, dysphagia and hoarseness of voice. Incidence of hoarseness and sore throat, whether present or absent, were enquired in 24 h post-operatively.

The primary outcome measure of the study was airway sealing pressure. We hypothesised that the airway sealing pressure of PLMA would be higher than i-gel™ and LTS-D™. Based on a previous study by Jadhav *et al*.,[4] we found mean airway sealing pressure in PLMA group as 25.73 cmH_2O and SD of 2.21. Based on that, taking alpha 0.05, $\beta = 0.8$ and 25% difference between the means as significant, we calculated 47 patients were required in each group; hence, the sample size was increased to 50 patients each.

The data were recorded in a Microsoft Excel Spreadsheet and analysed using SPSS statistics software version 24 (IBM SPSS Inc., Chicago, IL, USA). Continuous numerical variables were presented as mean (standard deviation) and intergroup differences were compared using one-way analysis of variance with *post hoc* correction. Categorical variables were presented as ratio or as *n* (%) and inter-group differences were compared using Chi-square test. The $P < 0.05$ was considered statistically significant.

Table 1: Comparison of demographic parameters between i-gel™, LTS-D™ and PLMA

Parameters	Group I (*n*=50)	Group L (*n*=50)	Group P (*n*=50)
Age (years)	42.54±13.84	41.46±12.29	42.78±12.7
Gender (female/male)	33/17	36/14	37/13
ASA (I/II)	30/20	24/26	24/26
MPS (I/II/III)	26/16/8	28/16/6	28/17/5
Neck movement (Class I/II/III/IV)	46/4/0/0	47/3/0/0	47/3/0/0
Weight (kg)	53.9±3.69	54.32±3.51	55.24±5.18
Height (cm)	155.22±6.79	157.34±6.62	158.46±4.91
Surgical duration (min)	61.3±9.94	64.5±10.94	62.1±13.56

Data are presented as mean±SD or number of patients. SD – Standard deviation; ASA – American Society of Anesthesiologists; MPS – Mallampati score

RESULTS

There was no statistical difference in demographic data between the three groups [Table 1].

The mean time for the effective placement of device was lowest for LTS-D™ (21.66 ± 2.31 s), followed by i-gel™ (27.9 ± 2.53 s). PLMA group had the maximum mean insertion time of (38.77 ± 3.2 s) of all the three devices ($P < 0.0005$). Overall success rate for insertion of the three devices was comparable, and it was 100%, 96% and 94%, respectively, for Group I, Group P and Group L after three attempts. PLMA had the highest mean airway sealing pressure (28.5 ± 2.8 cm H_2O) compared to i-gel™ (23.38 ± 2.06 cm H_2O) and LTS-D™ (26.06 ± 2.11 cm H_2O) ($P < 0.0005$). The rate of success of gastric tube insertion through i-gel™, LTS-D™ and PLMA was 98%, 96%, 98%, respectively [Table 2].

With regard to adverse events, no differences were found in the number of episodes of laryngospasm and hypoxia between the three devices. Traces of blood at removal of the device were reported with 3 patients each of LTS-D™ and i-gel™, and in 2 patients with PLMA. One of the 3 patients with blood-tinged LTS-D™ also described the presence of sore throat 1 h after surgery.

DISCUSSION

This study compared the performance of three different second-generation supraglottic airway devices (SADs) in elective surgical cases under general anaesthesia with controlled ventilation. The main findings are that the most suitable devices for use in this scenario are the PLMA and i-gel™ airway, where i-gel™ had better insertion characteristics and PLMA

Table 2: Comparison of insertion attempts, overall success rate, ease of insertion, insertion time, airway sealing pressure, gastric tube placement and complications between i-gel™, LTS-D™ and PLMA

Parameter	Group I (*n*=50)	Group L (*n*=50)	Group P (*n*=50)	*P*
Insertion attempts (1st/2nd/3rd/fail)	45/5/0/0	41/4/2/3	44/4/0/2	0.307
Overall success rate (%)	100	94	96	-
Ease of insertion (easy/difficult)	44/6	40/7	43/5	0.799
Insertion time (s)	27.9±2.53	21.66±2.31	38.77±3.2	<0.0005
Airway sealing pressure (cmH_2O)	23.38±2.06	26.06±2.11	28.5±2.8	<0.0005
Number of attempts in drain tube placement (1st/2nd/fail)	48/1/1	42/3/2	46/1/1	0.654

Data as number or percentage of patients and mean±SD. SD – Standard deviation

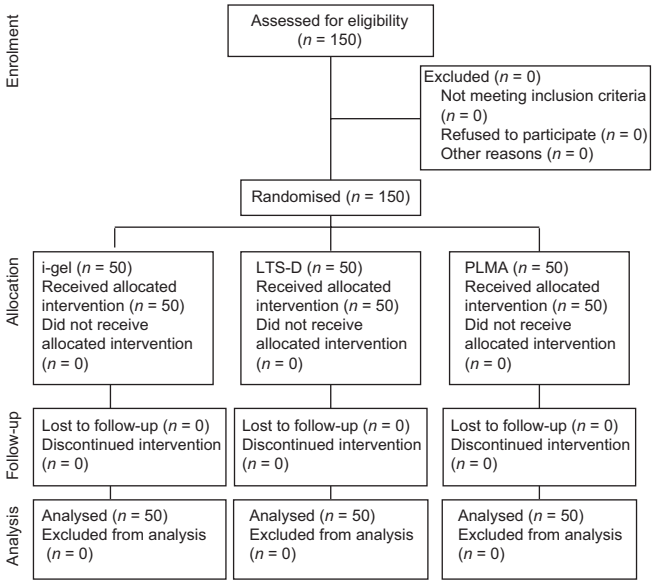

Chart 1: Consort diagram

had higher sealing pressure. The LTS-D™ though had the shortest insertion time, it had poorer insertion success as compared to other. Most attributes of the LTS-II described in the literature are assumed to be valid for the LTS-D™.[5,6]

The results of our study can be compared with other evidence related to second-generation SADs. The first attempt insertion success achieved in our study was comparable to data from multiple studies.[7-12]

The ease of insertion was similar for all the devices. However, the i-gel™ showed a higher probability of insertion success without resistance than the PLMA and LTS-D™ of all the successful insertions which may be partly explained by the non-inflatable cuff in the i-gel™. Difficulties in PLMA insertion can be due to its large cuff, which can impede digital intraoral positioning and propulsion into the pharynx, and also, the lack of a back-plate which makes the cuff more likely to fold over at the back of the mouth.[13] Although the insertion time for LTS-D™ was less than other two devices of our study, its slimmer and more pointed distal end may make it more prone to bending when pushed against the posterior pharyngeal wall, which can impede its insertion.

Insertion time was shorter with the i-gel™ than with the PLMA; similar results have been seen in various studies in the past.[14,15] The i-gel™ is considered easier to insert due to its unique gel-like material, shape and contour, buccal stabilizer and epiglottis blocker which minimises epiglottis down folding. Furthermore, the studies from the past indicate a near similar insertion time between PLMA and LTS-D™/LTS-II.[10-12,16] In our study, we report mean insertion time of LTS-D™ being significantly lower than i-gel™ and PLMA. This may be because LTS-D™ has a slimmer profile and requires little or no manipulation at all for insertion into oropharynx. When extra resistance is felt during insertion of the LTS-D™, the possibility of tracheal misplacement should be considered.[16]

Moreover, studies comparing insertion time between i-gel™ and LTS-D™ are limited and require further evaluation with future discourse. In the previous study by Russo *et al*., LTS-D™ had a mean insertion time of 14 s and i-gel™ of 10 s, the difference being statistically insignificant.[17]

There was difference in definition of insertion time and ease of insertion between the studies. Different studies allowed different numbers of attempts as successful insertion (two to three) before considering it as a failure. The use of neuromuscular blocking drugs and the experience of the person inserting the device may also affect the ease and insertion time for airway devices. These potential methodological differences could be responsible for the heterogeneity associated between devices as seen in the literature. The subjective nature of this assessment may have introduced a bias.

Airway sealing pressure has been commonly used to assess successful airway placement in SAD studies. The leak pressure is an important indicator of both the

success of positive pressure ventilation and the degree of airway protection.[18] In two systemic reviews and meta-analyses,[19,20] there was clear superiority of PLMA in comparison to i-gel™ in terms of airway sealing pressure in mechanically ventilated patients with neuromuscular blockers.

Design changes in the PLMA that make it a more effective ventilatory device include a second cuff attached to the dorsal surface, which pushes the ventral cuff more firmly into the periglottic tissue[21] and a ventral cuff that is larger proximally, to improve the seal by plugging potential gaps. As a result, it provides a better seal that equates to higher tidal volumes without leak. This may be of particular relevance in patients receiving high airway pressure, such as obese patients undergoing intra-abdominal or laparoscopic surgery, patients in the lithotomy position, patients undergoing surgery in the head-down position or patients with restrictive pulmonary disease.[13]

Our findings for complications with use of the three devices are similar to the results obtained by other authors.[16,22,23] Soliveres *et al*. found that the use of PLMA produced more sore throat as compared to the i-gel™.[24] Various studies have reported similar findings, wherein the incidence of sore throat is minimal with i-gel™ in comparison with other supraglottic airway devices.[25-28] Majority of the patients from our study did not have post-operative sore throat, which could be due to the high success rate in first insertion attempts in all the groups.

During the course of our study, we also observed certain limitations. It was not possible to eliminate potential researcher bias because of his awareness of the device being used. Fibreoptic assessment of studied airway tools position was not performed. Neuromuscular monitor to assess the adequacy of block during tube insertion was not used; clinical signs to judge the same were exercised. All insertions were performed by a single-experienced anaesthesiologist; therefore, our results may not be generalised. The results also may not be applicable to novice users. This study was carried out on ASA I and II physical status and patients with normal airways; thus, further trials are recommended to include both high-risk patients and those with anticipated difficult airways. The oropharyngeal leak pressure was only measured once, at the start of the procedure, although the leak pressure is a dynamic entity and may change over time.

CONCLUSION

The airway sealing pressure of PLMA was higher compared to i-gel™ and LTS-D™, but the insertion time of LTS-D™ was least among the three devices.

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Conflicts of interest
There are no conflicts of interest.

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