Introduction

Supraglottic devices are presently used worldwide by anaesthesiologists for airway management in adults and children, and they are considered a novel route to provide general anaesthesia (1-3). Laryngeal mask airways have quickly become one of the most successful devices among the cascade of various supraglottic devices, since the introduction of endotracheal tube (4). Utilisation of laryngeal mask airways for airway management is rapidly expanding to a wide variety of surgical procedures, including laparoscopic and dental surgeries, where traditionally endotracheal tubes are employed (2, 4, 5). In addition, laryngeal mask airways have been considered in situations that were once deemed unsuitable, such as patients with a history of gastroesophageal reflux or morbid obesity (1, 2).

At present, there are several recognised versions of the laryngeal mask airways commercially available, which include the LMA-Classic, LMA-Unique, LMA-Fastrach, LMA-ProSeal, LMA-Supreme, Laryngeal mask airway-Ambu and Laryngeal mask-SoftSeal (1). Recently, an Australian company (Gnana Medical Australia Pvt. Limited) marketed a
newer version, the Gnana Laryngeal Airway (GLA; Figure 1). The design of this device is similar to the LMA-Classic, with an additional suction port on the convex portion of the laryngeal mask, which allows the mouth to be cleaned of secretions. This is important because intermittent supraglottic suctioning of a laryngeal mask can be useful to remove body fluids such as saliva and blood in healthy patients, and in patients with medical conditions such as post nasal drip, allergic rhinitis, allergic asthmatic sinusitis and rhinosinusitis associated with chronic obstructive pulmonary disease (COPD).

There are numerous clinical studies examining the use of various laryngeal mask airways, attesting to their safety and performance in various clinical situations (2, 4-12). To the best of our knowledge, there is no study published on the GLA. The purpose of this study, therefore, is to evaluate the GLA in terms of a success rate, ease and speed of insertion, performance during general anaesthesia and rate of complications in patients requiring anaesthesia for various surgical procedures.

**Methods**

The present study was conducted in a tertiary care hospital in northern India. After approval of the study protocol by the Institutional Ethics Committee (protocol number IEC-2017/27, dated 12 May 2017) and obtaining written informed patient consent, 70 adult patients were included in the study. It was registered in the Clinical Trials Registry of India (registration number: CTRI/2017/12/010782, registration date 6 December 2017, Principal Investigator Dheeraj Kapoor). Patients were enrolled after the trial was registered (the first patient was registered on 15 December 2017). Patients with the American Society of Anaesthesiologists (ASA) physical status 1 and 2 of either sex, aged 18–60 years, body mass index (BMI) <35 kg·m⁻², who had no concurrent participation in another study, who were scheduled for elective surgeries with duration <2h, and who required general anaesthesia with controlled ventilation, were included in the study. The exclusion criteria were as follows: emergency surgical procedures, upper respiratory tract infection, anticipated difficult airway, increased risk of aspiration, gastroesophageal reflux disease, non-fasting status, pregnancy, and patients with a medical history of cardiorespiratory or cerebrovascular disease.

The study design was a prospective, observational single-arm trial. The primary outcome was ease of insertion of GLA device, as measured by the proportion of times the device insertion was successful with a single attempt. Secondary outcomes measures were a total number of attempts, prevalence of successful insertion, time taken for successful insertion, oropharyngeal leak pressure (OLP), optimal placement of the device and complications, if any.

The sample size was calculated using the online tool “sampsize” [http://sampsize.sourceforge.net/iface/index.html]. Using data from a previous study that examined a different laryngeal airway device but with a similar design, it was seen that 77% of device insertions were successful at a single attempt. Using this as the clinically meaningful proportion and with a 12% precision, a sample of 48 was required for achieving the 95% confidence interval. Rounding up the figure, a sample size of 50 was deemed adequate.

Preoperative airway evaluation included opening of the mouth more than 2.5 cm, normal temporomandibular joint mobility, neck movement, and a modified Mallampati score to rule out difficult airway. Preoperative routine examinations were done as per hospital protocol. Any other relevant special investigation such as chest X-ray, electrocardiogram, and renal function tests were ordered whenever required.

**Main Points:**

- The Gnana Laryngeal Airway (GLA) device, a novel supraglottic airway device, is similar to the LMA-Classic in basic design, but with an additional suction port on the convex portion of the laryngeal mask to remove the saliva.
- We evaluated the GLA device in terms of ease and time to insertion, the number of attempts, oropharyngeal leak pressure (OLP), correct placement, and complications in adult patients undergoing elective surgical procedures.
- In 72% of patients, the GLA device was successfully placed on the first attempt and was effortless in 64%.
- Ease-of-insertion grade and insertion time progressively decreased; post-insertion, OLP and airway compliance progressively increased, while the cuff inflation volume, peak airway pressure and airway resistance progressively decreased, along with minimal side effects and malposition.
- In conclusion, the GLA device insertion became progressively easier and faster; thus, such a device is promising and warrants further clinical evaluation.
Anaesthesiologists with at least 3 years of experience in airway management using laryngeal masks and at least 10 successful insertions of the GLA in airway manikins participated in the investigation. They did not have prior experience with using GLA in humans because the ease of insertion was the primary outcome of interest in this study. There were a total of 3 anaesthesiologists who performed the procedure in this study. Another anaesthesiologist was present to record data as a blinded observer. Appropriately sized (Size 4) GLA devices were used for this study, which was appropriately prepared a priori for insertion (e.g., with cuff deflated completely and shaped with its dorsal surface lubricated with a water-soluble jelly).

The GLA device was inserted and secured according to the manufacturer’s recommendations (Table 1). The number of insertion attempts was recorded. A maximum of three attempts of device placement was permitted per patient. The size of the GLA device used for the first attempt was based on the patient’s weight as per the manufacturer’s instructions. If the device did not function effectively, the following manipulations were performed in the following sequence: the depth of insertion was increased; the device was rotated, and the device was withdrawn slightly. If these manoeuvres were unsuccessful in achieving an effective airway, the device was removed. If the remaining problem was predominantly related to a large leak, a device one size larger was re-inserted. If the GLA device size was deemed large, a smaller size GLA device was inserted. A Classic Laryngeal Mask Airway (CLMA) was inserted if insertion failed after three attempts. If this failed as well, tracheal intubation was performed.

A failed attempt was defined as the removal of the GLA device. The ease of insertion of both devices was recorded according to the following grading (Grade 1=Very Easy; 2=Easy; 3=Difficult and 4=Very Difficult) (13). The time between picking up the GLA device and obtaining an effective airway was recorded. An effective airway was defined by the presence of normal thoraco-abdominal movement and a square-wave capnograph trace. After insertion, the GLA device was inflated to the optimum intracuff pressure of 60 cm H₂O. The cuff pressure was measured using a handheld mechanical cuff inflator. The volume of air required to inflate the cuff to this pressure was recorded using a dedicated syringe.

Table 1. Manufacturer’s recommendation for the insertion of Gnana Laryngeal Airway

| Step | Instruction |
|------|-------------|
| 1.   | Before using the Gnana Laryngeal Airway, choose the appropriate size and check the Gnana Laryngeal Airway Mask cuff for inflation and deflation. |
| 2.   | Lubricate the back of the mask with a water-soluble lubricant before placement into the larynx. Lubrication of the front of the mask is not recommended. |
| 3.   | For placement of the Gnana Laryngeal Airway, flex the neck and extend the head. Holding the Gnana Laryngeal Airway near the mask end, press the tip of the mask end to the hard palate. |
| 4.   | Advance the Gnana Laryngeal Airway to the posterior pharyngeal wall with the index finger. |
| 5.   | At this point the index finger is removed and the tube of the Gnana Laryngeal Airway used to achieve a good fit. |
| 6.   | Inflate the mask until you see the mask move slightly out of the hypopharynx with inflation. |
| 7.   | Verify the placement of the Gnana Laryngeal Airway with auscultation after connecting to a low-pressure ventilator or to a bag valve mask device. |
| 8.   | The built-in suction can be used intermittently with low suction up to 80 mmHg or as needed to keep the supraglottic area clean. |

OLP was determined by transiently stopping ventilation and closing the adjustable pressure-limiting valve with a fresh gas flow of 3 L min⁻¹ using test lungs until the airway pressure reached a steady state (11, 13). The airway pressure was not allowed to exceed 40 cm H₂O. After the measurement of the OLP (at 0 and 5 minutes after the insertion), intermittent positive pressure ventilation was restarted.

A fibreoptic view of the larynx was determined by passing a 3.5 outer diameter size flexible fibreoptic bronchoscope (Pentax Medical, USA) through the airway tube of the GLA device to a position 1 cm proximal to the end of the tube, using a scoring system (14). Laryngeal views ranged from a score 4 (only vocal cords visible), 3 (vocal cords plus posterior epiglottis visible), 2 (vocal cords plus anterior epiglottis visible), and 1 (vocal cords not visible). Adjusting manoeuvres to obtain an optimum fibreoptic view (e.g., 3 or 4 views) of the larynx were undertaken and recorded; if the fibreoptic view was 1 or 2, then the device was removed and excluded from study.

Although the salivary secretion sucked out by the GLA was not the primary outcome variable in this study; nonetheless, this was also observed as an additional variable. This was done by the oropharyngeal secretions drawn in the syringe from the suction port of the GLA.

Postoperatively, a blinded observer assessed the patient for sore throat, hoarseness, dysphonia, cough or any other adverse effects just prior to discharge from the postoperative care area. Patients were asked about sore throat, hoarseness, dysphonia, cough or any other adverse effects once just before discharge from the postoperative care area. If the answer was yes to any of these questions, the intensity of the complaint was assessed using a 100-point numerical rating scale (NRS; 0=no discomfort to 100=extreme discomfort).
### Statistical analysis

Statistical analysis was carried out using IBM Statistical Package for Social Sciences (IBM SPSS Corp.; Armonk, NY, USA) version 23.0 for Windows. All quantitative variables were estimated using measures of central location (mean, median) and measures of dispersion (standard deviation and standard error). Normality of data was checked by measures of skewness and Kolmogorov–Smirnov tests of normality. Qualitative or categorical variables were described as frequencies and proportions. Parametric data were analysed using Student’s t-test, and non-parametric data were analysed using the Mann–Whitney U test. Categorical data were analysed using the Chi square test or Fisher’s exact test. All statistical tests were two-sided and were performed at a significance level of $\alpha=0.05$. The first 10 consecutive patients were compared with the last 10 consecutive patients on each of the study parameters.

### Results

After meeting the eligibility criteria and enrolment, no patients were excluded from the study (Figure 2). The majority of patients enrolled in the present investigation were females (74%), having breast pathology (64%), undergoing surgical interventions (modified radical mastectomy [32%]; breast lump excision [36%]). All patients belonged to the ASA 1 or 2 (ASA 1: 54%; ASA 2: 46%), and most were identified as the Mallampati Class 2 or 3 airways (Class 2: 56%; Class 3: 36%). The mean age of the patients enrolled was 41.54±14.5 years. The mean BMI of the patients was 24.47±2.49 kg m$^{-2}$.

In 36 out of 50 patients (72%) the device was successfully placed on the first attempt. In 32 out of the 50 patients (64%), the GLA device insertion was effortless (grades of ease of insertion: Grade 1 [very easy] 22%, Grade 2 [easy] 42%). The ease of insertion grade significantly decreased over time from a mean of 2.80±0.249 seconds (95% confidence interval [CI], 2.24–3.36) in the first 10 consecutive patients to 1.30±0.153 seconds (95% CI, 0.95–1.65) in last 10 consecutive patients ($p<0.01$) in a total of 50 patients (Figure 3). The mean time for insertion of device in patients was 22.14±6.9 seconds. The insertion time decreased significantly over the time from a mean of 28.70±1.874 (95% CI, 24.46–32.94) seconds in the first 10 consecutive patients to 14.20±0.786 (95% CI, 12.42–15.98) seconds in the last 10 patients ($p<0.05$), of the total 50 patients (Figure 4). There was no case of failed attempt defined as removal of the GLA device. None required CLMA insertion or tracheal intubation.
In 45 out of 50 patients (90%), the fibreoptic view seen after the placement of the GLA device showed the vocal cords with either an anterior or posterior part of the epiglottis (FOB Grade 2: 54%; FOB Grade 3: 36%). In 41 out of 50 patients (82%) there was no malposition observed in the GLA device placement.

The mean OLP immediately post-insertion of the GLA device at 0 minute (OLP 0) was 20.96±5.8 cm H\textsubscript{2}O. The mean OLP 0 in the first 10 patients was 14.20±0.593 (95% CI, 12.86–15.94), which increased significantly to 29.0±0.558 (95% CI, 27.74–30.26) in the last 10 patients of the total 50 patients (p<0.01). The mean OLP 5 minutes post-insertion of the GLA device (OLP 5) was 22.2±6.05 cm H\textsubscript{2}O. The mean OLP 5 minutes post-insertion of the GLA device in the first 10 patients was 15.10±0.586 (95% CI, 14.37–15.83), which increased significantly to 30.80±0.558 (95% CI, 29.38–32.22) in the last 10 patients of the total 50 patients (p<0.01) (Figures 5a, b).

The mean cuff inflation volume was 18.86±3.93 mL after the GLA device placement. The mean cuff inflation volume progressively decreased significantly from 20.5±1.108 (95% CI, 17.99–23.01) in the first 10 patients to 15.8±0.554 (95% CI, 14.55–17.05) mL in the last 10 consecutive patients (p=0.01) (Figure 6).

The differences in the mean Sp\textsubscript{O}2 (oxygen saturation) and ETCO\textsubscript{2} (end-tidal carbon-dioxide) at baseline, post-induction of general anaesthesia, immediately after the GLA device insertion and 5 minutes later were statistically non-significant (p>0.05). The mean “peak airway pressure” (Ppeak), immediately after the GLA device insertion (Ppeak1) and 5 minutes after the GLA device insertion (Ppeak 5) were 17.16±2.92 and 15.02±2.38 cm H\textsubscript{2}O, respectively.

The volume of oropharyngeal secretion drawn by the syringe through the suction port of the GLA typically ranged from 3.0 mL to 5.0 mL per patient.

**Discussion**

In this single-blind observational study, the GLA device was found to be progressively easier to be inserted without much difficulty. Post-insertion, OLP and airway compliance progressively increased, while cuff inflation volume, peak airway pressure and airway resistance progressively
decreased, along with minimal side effects and malposition.

As a class, laryngeal mask airways are firmly established at present with regards to efficacy, tolerability, safety, and ease of insertion across a wide variety of surgical procedures (5, 7, 12-15). There are already a sizeable number of different variants of the Classic LMA, each with their own advantages and caveats (9-16). Hence, any newer version of laryngeal airway must have some improvisation that extends the benefits of the existing versions or adds a new component or useful function. The present investigation revealed a lower initial insertion rate when compared with a higher initial insertion rate of the CLMA or other second-generation devices (11-13). However, the GLA device has an added advantage with the ability to suction fluids from the oral cavity while in situ. In this regard, this feature is highly beneficial from a clinical point of view in that the normal daily production of saliva varies between 0.5 and 1.5 litres. The whole unstimulated saliva flow rate is approximately 0.3–0.4 mL min⁻¹ (17).

Laryngeal masks placed in the mouth have been investigated with regard to quantities of secretions removed from the laryngeal mask airways when inflated and deflated (18). The difference in the weight of the laryngeal masks before insertion and after removal was taken to be the amount of secretions adhering to the laryngeal masks when removed. There was an increase in the weight of the laryngeal mask removed when inflated with approximately 0.5 g of secretions more than with the cuff deflated. It was observed that 3.03 g of secretions was removed with an inflated cuff as compared to 2.45 g of secretions removed with a deflated cuff. Therefore, inflation of the cuff was found to remove more secretions than deflation cuff.

The additional function of the GLA device to suck fluids from the oral cavity while in situ is important for numerous reasons. First, laryngospasm has been known to occur after laryngeal mask removal, and it can be precipitated by the presence of blood and secretions in the pharynx (19, 20). Second, intermittent supraglottic suctioning of secretions in the presence of a laryngeal mask can be useful to keep the mouth dry and remove secretions in healthy patients and especially in patients with medical conditions such as postnasal drip, rhinosinusitis and allergic asthma. Further, allergic rhinitis is a common problem affecting 15% of the industrialised nation populations (21). In addition, rhinosinusitis is an associated feature in patients with COPD (22). In this exploratory study, the volume of sucked oropharyngeal secretion through the GLA was relatively modest (maximum 5.0 mL). However, even this amount may be clinically meaningful in some patients. In the present investigation, a careful history of NPO status and other factors were controlled. In clinical practice, the ability of the GLA to suck oropharyngeal secretions would provide significant benefit over similar airway devices that do not possess this important feature.

For the above reasons, the GLA device with the presence of an oral suction tube incorporated in the design can help in attaining a dry cavity and might be used in such patients with added potential safety. A potential risk of the laryngeal mask airway is incomplete mask seal, which causes air leakage or insufflation of air into the stomach. Weiler et al. (3) completed a study on respiratory mechanics, gastric insufflation pressure and air leakage of the laryngeal mask airway. After the insertion of the laryngeal mask airway, patients were ventilated with increasing tidal volumes until one of the three following end points were reached: 1) gastric air insufflation, 2) airway pressure >40 cm H₂O or 3) limitation of further increase in tidal volume by air leakage. Respiratory mechanics were in the physiological range. Gastric insufflation occurred in 27% of the patients at inspiratory pressures between 19 and 33 cm H₂O. Air leakage of >10% was evident at inspiratory pressures between 25 and 34 cm H₂O. The authors concluded that the laryngeal mask airway is no better in preventing airway pressure transmission to the oesophagus than a conventional face mask (3). In the present study, the peak airway pressure immediately and 5 minutes post-insertion were observed to be 17.16±2.92 and 15.02±2.38 cm H₂O respectively, was well within the physiological range, and interestingly lower than conventional laryngeal mask airway observed in previous studies.

Joshi et al. (4) have extensively used laryngeal mask airway devices in “ambulatory” anaesthesia. However, they also highlighted the importance to recognise the limitations of these devices and their probable contraindications. Proper selection of patients and learning the correct insertion technique are necessary before the use of the laryngeal mask airway in ambulatory setting (12). In this setting, the most common problems associated with the laryngeal mask airways are the maintenance of adequate depth of anaesthesia, malposition, gastric distension, coughing and laryngospasm. In our study, minimum malposition was observed. With increasing experience, the use of the GLA device may be expanded to a wider variety of similar clinical situations.

Richez et al. (13) completed an observational study of a single-use supraglottic airway device, ‘i-gel’ with a noninflatable cuff and an oesophageal vent. They evaluated i-gel in 71 women. The insertion success rate was 97%. Insertion was easy and performed at the first attempt in every patient. The mean seal pressure was 30±7 cm H₂O, and the average peak pressure was 11±3 cm H₂O. The gastric tube was inserted in 100% of cases. The authors concluded that ‘i-gel’ is a reliable, easily inserted airway device that provides an adequate seal with a low mor-
bidity rate. Alexiev et al. (11) studied the ‘Baska Mask’, a novel supraglottic airway, in 30 low-risk female patients. A single investigator in the study inserted the aforesaid device. The overall success rate for device insertion was 96.7% (95% CI, 82.8%–99.9%), while the success rate for the first insertion attempt was 76.7% (95% CI, 57.7%–90.1%). The device was easy to insert, with a mean difficulty score of 0.9±1.6 on a 10 cm scale. The mean airway leak pressure was 35.7±13.3 cm H₂O (11). Our observations were similar to these findings.

Keller et al. (6) compared four methods for assessing the airway-sealing pressure with the laryngeal mask airway in adult patients. They found that the manometric stability test had a higher mean airway-sealing pressure (p<0.001) and a better interobserver reliability (p<0.001) compared with the three other tests. Similar tests were done in the present study to obtain a mean OLP of 20.96±5.3 and 22.2±6.05 cm H₂O immediately and 5 minutes post-insertion of GLA.

Keller et al. (14) also used a fiberoptic scoring system to assess the position of laryngeal mask airway devices. They determined the interobserver reliability and comparison of a fiberoptic scoring system for assessing the position of the laryngeal mask airway, the flexible laryngeal mask airway and the intubating laryngeal mask airway. In the present study, similar objective scoring system was instituted to determine any malposition of GLA.

There are certain limitations to this study. It was an initial observational study, and hence, patients with anticipated difficult airway, morbid obesity, those who were pregnant, and with associated co-morbidities, such as cardiorespiratory or cerebrovascular disease, were excluded. Thus, the results cannot be extrapolated in these patients. Therefore, although a sample size calculation was performed, this study does not establish the absence of harm in higher risk populations (23, 24). Further, the sample size of 50 may appear rather small despite a prior sample size calculation. Being the first study using GLA, our primary focus was on the ease of insertion and other physical characteristics of this device.

Laparoscopic surgeries and gastrointestinal surgeries were also excluded related to the intrinsic properties of the device (first-generation supraglottic device) with non-accessibility of gastric drain. In the future, incorporation of gastric drain tube may offset this limitation, and, with an additional suction port opening in mouth, may result in a promising supraglottic device in these patients. Comparative evaluation with other standard first-generation devices (e.g., Classic LMA) is warranted to assess its competence and safety in airway management. Finally, the ability of the GLA device to suction fluids from the oropharyngeal area was not formally tested in this study design, because the primary aim of this study was an initial exploration into its basic properties, ease of insertion, and safety. Having established these parameters, the next phase of study will focus on the suctioning efficacy and adequacy of the GLA device. For the same reason, it is premature to recommend the GLA device for routine clinical use at this stage according to the ADEPT standards formulated by the Difficult Airway Society (25).

Conclusion

The results of the present investigation demonstrate that there is a progressive and significant decrease in the case of insertion grade and insertion time from initial GLA device insertion, probably related to the experience and familiarity of the device over time. Post-insertion OLP progressively increased, the cuff inflation volume decreased, and the placement of device improved (improved FOB grades and minimum malposition). Post-insertion peak airway pressure and airway resistance progressively decreased and airway compliance progressively increased. Insignificant side effects and malposition were observed with this new and promising device. Thus, with attainable practice, the GLA device can be easily, safely and rapidly inserted, and it creates satisfactory periglottic seal in optimum position. It has the unique advantages of maintaining superior quality of airway with clearing of oropharyngeal secretions after device insertion. Hence, it is potentially a promising advancement in technology that merits its clinical use and application. Further controlled clinical trials with robust methodology on larger samples are required to establish the role of the GLA device in wider clinical situations and various subsets of patients. The GLA device with the presence of an oral suction tube incorporated in the design can help in attaining a dry cavity and might be used in such patients with added potential safety.

Ethics Committee Approval: Ethics committee approval was received for this study from the institutional ethics committee of Government Medical College and Hospital (IEC-2017/27).

Informed Consent: Written informed consent was obtained from patient who participated in this study.

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