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Efficacy of the laryngeal mask airway gastro during trans-esophageal echocardiography in pediatrics: A randomized trial

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ABSTRACT

Background: Laryngeal mask airway gastro (LG) is a dual channel laryngeal mask airway. It has an endoscopy channel to facilitate esophageal intubation and a separate channel with terminal cuff for lung ventilation. It provides secure unobstructed airway and adequate seal for positive pressure ventilation. We evaluated the LG efficacy and feasibility compared to endotracheal tube (ETT) in pediatric trans-esophageal echocardiography (TEE).

Methods: The study was registered at Pan African Clinical Trials (No: PACTR202008749509618). The study included 154 pediatric patients, weighed ≥ 30 kg with non-cyanotic heart disease. Patients were assigned to ETT or LG groups. TEE insertion success rate was our primary outcome. TEE insertion success rate at the first attempt, number of attempts and ease of insertion of LG, cardiologist's satisfaction, extubation and recovery time, and complications were secondary outcomes.

Results: The success rate of TEE insertion was 95.8% (80.6% at first attempt) in ETT group and was 98.6% (90.5% at first attempt) in LG group. LG insertion success rate was 96.1% (95.9% at first attempt) and ease of insertion was reported in 91.9% of patients. Short extubation time and early recovery in LG group with significant difference between groups (P = 0.003 and 0.009, respectively). Cardiologist's satisfaction was higher in LG group (P = 0.006). Complications were lower in LG group with insignificant difference between t groups (P = 0.244).

Conclusion: The LG proved a suitable substitute for ETT in pediatric TEE. It is easy, and effective for securing the airway. It gains high cardiologist's satisfaction and provides early less eventful recovery of patients.

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1. Introduction

During the past years, the trans-esophageal echocardiography (TEE) played a fundamental role in the diagnosis and management of pediatric patients with acquired or congenital heart disease (CHD) in operating room, intensive care or catheterization laboratory. With advanced technology, this role continued to grow particularly when information could not be obtained from transthoracic echocardiography [1,2].

During TEE-guided procedure, use of endotracheal tube (ETT) under general anesthesia (GA) is usually preferred. The goal is to provide airway protection and TEE probe tolerance [3].

The laryngeal mask airway (LMA) [4] has many advantages over ETT. LMA insertion is simpler, with less hemodynamic changes and fewer problems in the upper airway. It is also, associated with quicker recovery times and shorter extubation period [5].

The LMA gastro (LG), a second-generation supraglottic airway device (SAD), is equipped with an endoscopy channel that facilitates esophageal intubation and a separate airway channel with terminal cuff that provides a secure, unobstructed airway with an adequate seal during positive pressure ventilation [6].

This study evaluated the feasibility and efficacy of LG, a novel airway device, in pediatric patients during TEE procedures.

We assumed that the LG use could have a high success rate of TEE with good airway control and no significant adverse effects.

2. Materials and methods

This randomized controlled single-blind trial was conducted from December 2020 to October 2021. The study was prospectively registered at Pan African Clinical Trials register (No: PACTR202008749509618, Approval date: 7 August 2020). After being approved from the research ethics committee, all the parents or legal guardians of the children whom included in the study signed an informed written permission form. The study included 154 pediatric patients aged 8–18 years old, weighed ≥ 30 kg (based on the manufacturer's recommendations),

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had non-cyanotic congenital heart disease, ASA II or III, and scheduled for elective interventional TEE.

Patients were evaluated the day before the procedure. Exclusion criteria were patients with known cervical spine disease, predicted difficult airway, neurodevelopmental delay, patients with risk of aspiration or any contraindication to supraglottic airway device (SAD) insertion, those requiring TEE for complex intervention (e.g., heart surgery, interventional procedures >60 min), hemodynamically unstable patients, or those who need ventilatory support.

Computer-generated random number concealed in sealed opaque envelopes was used to allocate the patients were randomly divided into two equal groups of 77 patients each at a ratio of 1:1 to have their airway maintained during the procedure by either the conventional endotracheal tube in group I (ETT group) or laryngeal mask airway LMA ® Gastro ™ (Teleflex Medical, Athlone, Ireland) in group II (LG group). The airway device was selected at random and revealed to the anesthetic team and the investigator collecting data just before to the induction of anesthesia.

Upon entering the cardiac lab, an intravenous cannula was inserted, and lactated Ringer solution was infused. Continuous ECG, non-invasive blood pressure monitoring, and pulse oximetry were used to monitor patients. Heart rate, systolic, diastolic blood pressure, arterial oxygen saturation, and end-tidal carbon dioxide were measured every five minutes. Any abnormal data in these parameters were reported as complications.

Induction of anesthesia was by fentanyl 2 µg/kg, intravenous propofol: ketamine in ratio of 5:1 and sevoflurane 2% was delivered through face mask until reach adequate anesthesia depth guided by end-tidal anesthetic gas concentration then selected airway device of appropriate size was inserted followed by insertion of 5.5/7.5-MHz TEE pediatric biplane transducer (GE Vingmed, model 6Tc, Horten, Norway).

Based on the manufacturer's recommendations and the patient's weight, the LG size was selected. Water-based gel was used to lubricate its convex surface, and it was then advanced behind the tongue from the hard to the soft palate, along the posterior pharyngeal wall, and into the hypopharynx, where resistance was noted. At this point the device was seated with cuffed airway channel at the distal end of posterior endoscopy channel at upper esophageal opening and the also around laryngeal opening. If positive airway pressure of 20 cm H_2O was provided, the cuff was inflated until there was no audible gas escape. The well-lubricated TEE device was introduced into the esophagus using the lubricated endoscopic channel of LG. Chin lift, jaw thrust, head extension, neck flexion and change to left lateral position were used to facilitate insertion of LG. If more than one manipulation were needed, the insertion was reported as difficult.

The chosen airway was connected to the breathing circuit in both groups.

The correct position of the airway device was confirmed by square capnographic waveform, audible bilateral breath sounds with symmetrical chest wall expansion and no audible air leak. If LG was unfitted, it was removed and reinserted (reported as a new attempt) and if more than 3 attempts were used, it was reported as failure, replaced with ETT, and excluded from the study.

Sevoflurane 1–2%, minimum alveolar concentration was age-adjusted, in air/oxygen mixture with spontaneous/assisted breathing was used to maintain anesthesia. There were no neuromuscular blocking drugs provided.

Subsequently, the TEE was removed, and sevoflurane administration ceased. The LG or ETT was removed after swallowing and normal spontaneous breathing movements resumed. When the modified steward scale reached ≥6 points, patients were released to the recovery area [7].

As soon as patients arrived in the recovery area, they were clinically examined and scored on the Aldrete scale. A patient was released after accumulating 10 points on the scale [8].

Our primary outcome was TEE insertion success rate (defined as no more than three attempts to pass the TEE probe through the LG endoscopy channel).

The secondary outcomes were:

TEE insertion success rate of at the first attempt through the endoscopy channel of LG, Success rate of LG insertion (failure defined as more than three attempts), number of attempts of LG insertion, cardiologist's satisfaction about ease of TEE insertion (graded by 4-point likert scale as 0 = not satisfied, 1 = fair, 2 = good, 3 = very good, 4 = excellent), ease of insertion of LG, which is graded as easy or difficult (difficult insertion was reported if more than one manipulation was required), recovery time (defined as time interval between extubation to discharge from the recovery room), extubation time (defined as time interval from discontinuation of anesthesia to removal of the airway), complications during the procedure until discharge from the recovery room e.g., sore throat, laryngeal spasm, visualization of blood on the airway after removal, or oxygen desaturation.

2.1. Statistical analysis

The sample size was estimated using the IBM[a] SPSS[a] SamplePower[a] version 3.0.1 (IBM[a] Corp., Armonk, NY, USA). A previous study [6] reported that the success rate of TEE in the laryngeal mask airway was 99%. Thus, 70 patients in each study group would achieve a power of 80% to detect expected success rate of 1% a significance level of 0.05. 7 cases were added to each group to overcome the dropout.

SPSS software package version 20.0. (Armonk, NY: IBM Corp) was used to analyze the data. Numbers and percentages were used to represent categorical data. Chi-square test was applied to investigate the association between the categorical variables. On the other hand, Fisher or Monte Carlo correction test was applied when the expected cell counts were less than 5. The normality of continuous data was established using the Kolmogorov-Smirnov test. The range, mean, standard deviation, and median of dispersed data were provided. The student t-test was developed to compare two quantitative groups with normally distributed variables. The Mann-Whitney test was devised to compare two populations with non-normal distributions. Significance level was obtained at P value less than 5%.

3. Results

In total, we evaluated 193 eligible patients for enrollment in our study. Our inclusion criteria were not met by sixteen cases (11 patients were weighed <30 kg, one patient expected to have complex prolonged intervention (> 60 minutes), one patient was hemodynamically unstable, and three patients needed ventilator support before intervention), and 23 individuals rejected to participate. A total of 154 patients were recruited and distributed evenly among the various study groups. Three patients in LG group did not receive the intervention (failure of LG insertion after three attempts). Five patients in ETT group were excluded from data analysis (three patients had unexpected, prolonged procedure and two patients were hemodynamically unstable post procedure). Final analysis was conducted on 72 patients in the ETT group and 74 patients in the LG group as shown in CONSORT flow diagram Figure 1.

Patients' Characteristics as well as duration the procedures and cardiac congenital anomalies did not differ between the two groups Table 1.

The success rate of the TEE insertion was 95.8% in ETT group and 98.6% in LG group. The TEE was successfully inserted on the first attempt in 80.6% of patients in ETT group and in 90.5% of patients in LG group. Success rate and number of the TEE insertion attempts were shown in Table 2.

Success rate of LG insertion was 96.1%. First-attempt LG insertion success rate was 95.9% and the remaining were placed on the second attempt Table 2.

Ease of the TEE procedure was better with the LG as indicated by cardiologist's satisfaction (P = 0.006). As for anesthesiologists, ease of LG insertion was reported in 91.9% of patients (no or one manipulation was used to assist insertion of the LG) and difficulty of insertion was reported in 8.1% of patients whom needed two or three manipulations. LG group had shorter recovery and extubation times when compared to ETT group (*P* = 0.009 and 0.003 respectively) Table 2.

There was no significant difference between the two groups regarding occurrence of laryngospasm

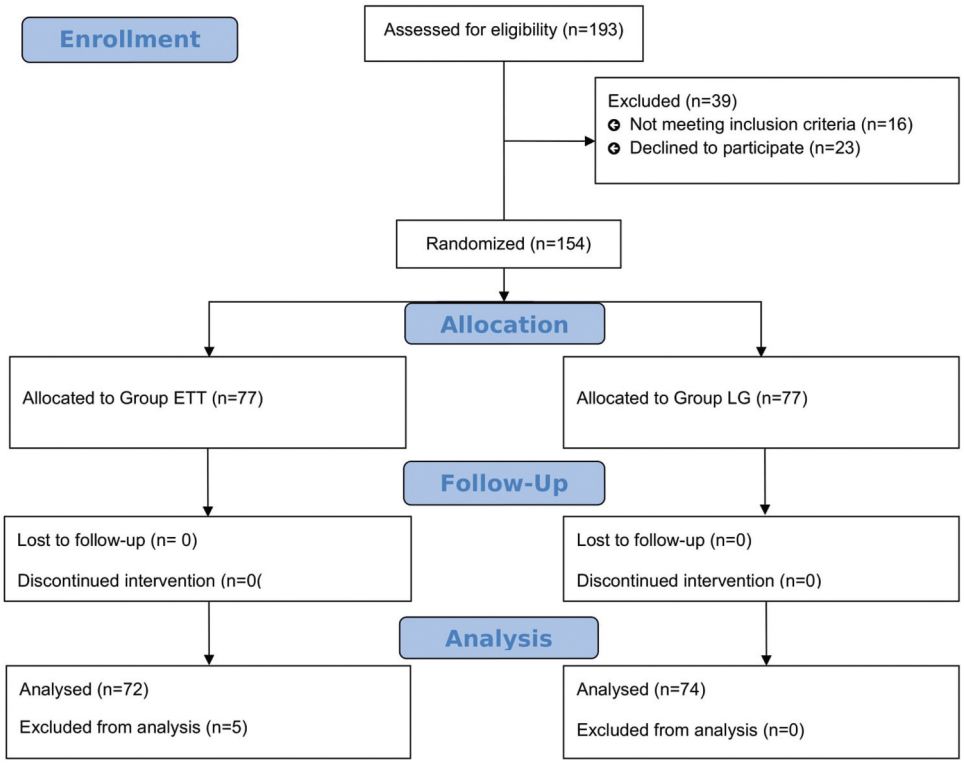

Figure 1. CONSORT flow diagram of participants through each stage of the randomized trial.

Table 1. Comparison between the two studied groups according to demographic data and Procedural characteristics.

	Group ETT (n = 72)	Group LG (n = 74)	*P*
Age (years)			
Mean ± SD	10.32 ± 2.13	10.08 ± 2.03	0.489
Sex			
Male	42 (58.3%)	42 (56.8%)	0.847
Female	30 (41.7%)	32 (43.2%)	
BMI (kg/m^2)			
Mean ± SD	19.49 ± 1.89	19.24 ± 1.66	0.384
ASA			
II	48 (66.7%)	47 (63.5%)	0.689
III	24 (33.3%)	27 (36.5%)	
Duration of cardiac catheterization (minutes)			
Mean ± SD.	43.81 ± 7.05	41.82 ± 6.09	0.071
Congenital cardiac anomalies			
PFO	36 (50%)	34 (45.9%)	0.828
VSD	21 (29.2%)	25 (33.8%)	
ASD	15 (20.8%)	15 (20.3%)	

Data presented as mean ± SD or patient's number (%).
SD: Standard deviation, n: number, %: Percentage, BMI: body mass index, ASA: American Society of Anesthesiologists, PFO: patent foramen ovale, VSD: ventricular septal defect, ASD: atrial septal defect.
P: p value for comparing between the studied groups Statistical significance at $P \leq 0.05$.

Table 2. Comparison between the two studied groups according to laryngeal mask airway gastro insertion and trans-esophageal echocardiography conditions parameters.

	Group ETT (n = 72)	Group LG (n = 74)	p
Success rate of insertion			
TEE			
1st attempt	58 (80.6%)	67 (90.5%)	$^{MC}p = 0.242$
2nd attempt	11 (15.3%)	6 (8.1%)	
3rd attempt	3 (4.2%)	1 (1.4%)	
<3	69 (95.8%)	73 (98.6%)	$^{FE}p = 0.363$
Failure (≥3 attempts)	3 (4.2%)	1 (1.4%)	
LMA Gastro			
	(n = 72)	**(n = 77)**	$^{FE}p = 0.245$
Failure	0 (0.0%)	3 (3.9%)	
Success	72 (100.0%)	74 (96.1%)	
Success rate at first attempt			
LMA Gastro			
1	72 (100.0%)	71 (95.9%)	$^{FE}p = 0.245$
2	0 (0.0%)	3 (4.1%)	
Cardiologist's satisfaction score			
Not	3 (4.2%)	1 (1.4%)	$^{MC}p = 0.006^*$
Fair	4 (5.6%)	1 (1.4%)	
Good	7 (9.7%)	5 (6.8%)	
Very	38 (52.8%)	26 (35.1%)	
Excellent	20 (27.8%)	41 (55.4%)	
Ease of LMA Gastro insertion			
Easy	72 (100.0%)	68 (91.9%)	$^{FE}p = 0.028^*$
Difficult	0 (0.0%)	6 (8.1%)	
E0	72 (100.0%)	57 (77.0%)	$^{MC}p < 0.001^*$
E1	0 (0.0%)	11 (14.9%)	
D2	0 (0.0%)	3 (4.1%)	
D3	0 (0.0%)	3 (4.1%)	
Recovery time (min.)			
Mean ± SD.	50.26 ± 9.04	46.55 ± 7.92	0.009*
Extubation time (sec.)			
Mean ± SD.	5.18 ± 2.0	4.19 ± 1.84	0.003*
Adverse effects			
Laryngeal Spam	3 (4.2%)	1 (1.4%)	$^{FE}p = 0.363$
Blood on airway	1 (1.4%)	0 (0.0%)	$^{FE}p = 0.4932$
Sore throat	21 (29.1%)	6(8.1%)	$^{X2}p = 0.0022$

Data presented as mean ± SD or patient's number (%). SD: Standard deviation, MC: Monte Carlo, FE: Fisher Exact, %: percentage, n: number, TEE: trans-esophageal echocardiography, LMA Gastro: laryngeal mask airway gastro.
P: p value for comparing between the two studied groups. *: Statistically significant at $p \leq 0.05$.

and presence of blood on airway device (P = 0.363 and 0.4932 respectively) while there was a significant difference regarding incidence of sore throat (P = 0.0022). No other adverse effects were reported Table 2.

4. Discussion

Increasing numbers of diagnostic and minor surgical procedures are being performed on children outside of the operating room. Therefore, the need for sedation during such procedures is vital [9].

In the adult, TEE is usually performed under light sedation and topical analgesia. On the other hand, the children often do not tolerate TEE under light sedation they require deep sedation or GA [10].

Although low rate but sedation induced adverse effects are life-threatening and pediatric patients are more vulnerable to these events, for example , airway obstruction, apnea, pulmonary aspiration, laryngospasm, and desaturation [9].

In pediatric TEE particularly, there is a significant potential for cardiorespiratory compromise during and after TEE, mainly due to airway obstruction [10]. Mohammed A. Shafi Ahmed et al. [5] proved that LMA is effective and safe for securing the airway in children undergoing TEE.

In this study, we use LG, a novel SAD, in children undergoing TEE. Our results show high success rate (98.6%) of TEE insertion in presence of LG compared with ETT with higher cardiologist's satisfaction. The LG facilitates TEE probe insertion through its endoscopy channel. It is easy to be inserted with high success rate of first insertion attempt (95.9%). Our results revealed better recovery and shorter extubation time in LG group than ETT group.

The SGA were used successfully, in children and adult, in several procedures which involve airway sharing [5,11–13]. Several studies have previously shown the effectiveness of LG in upper gastrointestinal (GI) endoscopic operations [6,14–19]. Only one study [20] tested the LG on 9 patients who underwent percutaneous patent foramen ovale closures.

This is the first randomized controlled trial to examine the effectiveness of LG insertion in pediatric trans esophageal echocardiography, to our knowledge.

In agreement with our results, Saxena et al. [20] reported the successful and simple insertion of a TEE probe into the endoscopic channel of the LG in 9 patent foramen ovale closure patients. Also, there were no adverse effects regarding anesthetic technique or airway management.

Irrespective of type of the procedure, our findings are broadly consistent with other studies in which the LG was used in pediatric upper GI endoscopy where airway maintenance can be particularly problematic. Hakim et al. [14], in a randomized trial in children and adult, found that the esophagogastroduodenoscopy ease had improved slightly in LG presence versus single channel LMA with infrequent and non-significant difference between both group regarding adverse effects.

Similarly, Taylor et al. [19] showed that the LG had a high success rate for adequate airway maintenance in pediatric upper GI endoscopy with no adverse effects. In spite of failure of LG in three out of 55 patients, it provided excellent conditions for endoscope insertion and reported as "easy" by the anesthetist and the gastroenterologist despite their relative inexperience as they described. Some anesthesiologists commented that LG need deeper anesthesia than required with LMA and also LG is easier to be inserted in left lateral position with deflated cuff. Indeed, one of the attempts we used to facilitate insertion of LG is turning patient to left lateral position. In contrast to the previous mentioned studies, we reported few adverse may be related to repeated attempts in LG insertion and in our opinion, it is to some degree bulky compared to the classic LMA.

Our study has some limitations. First, the double blindness was not possible as anesthetists and TEE operator were aware of airway type used. Second, intra-cuff pressure was not measured during insertion of the TEE probe. Third, the smallest size of LG is three thus limiting its use to the patients weighing ≥30 kilograms. Fourth, the LG is made of silicon while ETT is made of polyvinyl chloride so, bias in the measurements of adverse effects is probable. Hence, it is better to compare LG with another silicon LMA.

5. Conclusion

Based on the findings of our research, it can be concluded that choice of the LG, as an airway device, in children undergoing TEE is easy, safe, and effective for securing airway in these surgeries where surgeons and anesthesiologists are sharing the airway. The LG is a proper alternative to TEE, and it gained high cardiologist's satisfaction with early and less eventful recovery. In the future studies, the LG can be evaluated in high-risk patients, emergency situations, and younger patients (if a smaller size will be available by the manufacturer).

Availability of data and materials

Raw data are available upon reasonable request from the corresponding author.

Disclosure statement

The authors report there are no competing interests to declare.

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Trial registration

Pan African Clinical Trials register No. (PACTR202008749509618). Approval date (7 August 2020) Prospectively registered.

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