Anaesthesia Section

Comparison of Efficacy of a Novel Dual Channel Gastro Laryngeal Mask Airway versus Nasal Prongs for Airway Management in Day Care Gastrointestinal Endoscopy Procedures: A Randomised Clinical Study

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ABSTRACT

Introduction: The Gastro Laryngeal Mask Airway (LMA) is a newer supraglottic airway device specifically designed for Gastroinstestinal (GI) endoscopy procedures. Hypoxia is a common complication in endoscopy procedures performed under sedation without securing the airway. The Gastro LMA allows for oxygenation, ventilation, and the passage of a gastroscope through its integrated endoscope channel.

Aim: To evaluate the utility of the Gastro LMA compared to nasal prongs in maintaining oxygenation and airway control during upper GI endoscopy procedures.

Materials and Methods: The present double-blinded randomised, single-centre clinical study conducted in the Department of Anaesthesiology, GCS Medical College Hospital and Research Centre, Ahmedabad, Gujarat, India included 50 adult patients scheduled for elective GI endoscopy procedures in the supine or lateral position. The patients were divided into two equal groups: Group G (Gastro LMA) and Group N (Nasal prong). Preprocedural heart rate and SpO₂ levels were noted. All patients were observed for hypoxia (SpO₂ <92%), bradycardia, lowest heart rate and Saturation of Peripheral Oxygen (SpO₂) levels, conversion to endotracheal intubation, and any other intraoperative adverse

events. Postoperatively, patients were observed for four hours for adverse effects and discharged after assessment using the modified Aldrete's score. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 26.0, and the results were expressed as percentages, mean±SD, and p-values.

Results: Out of the 50 patients, 23 were male and 27 were female, with a median age of 59 years. The preprocedural mean lowest heart rate in Group G was 68/min, and in Group N it was 64/min. The mean lowest SpO₂ during the procedure was 94% in Group N and 96% in Group G. In Group N, two patients (8%) required conversion to endotracheal intubation. One patient had a longer duration of the procedure and experienced bronchospasm, while another patient with Chronic Obstructive Pulmonary Disease (COPD) developed bronchospasm. In Group G, one patient (4%) required endotracheal intubation, possibly due to increased intrabdominal pressure caused by air insufflation in an obese patient.

Conclusion: In patients undergoing gastrointestinal endoscopy procedures, the Gastro LMA appears to be effective for clinical use. It provides good airway control and enables deeper sedation without respiratory compromise. Ventilation was well maintained with minimal intraoperative and postoperative adverse events.

Keywords: Anaesthesia, Cardiorespiratory events, Non operation room, Sedation, Supraglottic airway device

INTRODUCTION

Gastrointestinal endoscopy procedures pose challenges for anaesthesiologists due to the non operating room set-up and airway sharing issues [1-3]. Administration of mild to deep sedation levels without securing the airway can result in airway obstruction, hypoventilation, hypoxia, and, in rare cases, bradycardia and cardiac arrest [4]. Nasal prong oxygen supply is commonly used to maintain oxygenation during endoscopy procedures performed with intravenous sedation. However, when a deeper level of sedation is required, upper airway obstruction due to soft tissue collapse or tongue fall becomes a major concern. In such cases, the use of a supraglottic airway device can be helpful in protection of the airway during Gl procedures [5-9].

While there have been several observational studies [10-12] on the use of gastro LMA, comparative studies [13,14] with other techniques for maintaining oxygenation during gastrointestinal endoscopy are relatively fewer. Therefore, present study aimed to evaluate the usefulness of gastro LMA in GI endoscopy procedures.

Gastro LMA is a second-generation supraglottic airway device specifically designed by Skinner in 2017 for upper GI endoscopy

procedures. This device secures the patient's airway and facilitates endoscope insertion through its integrated endoscope channel [Table/Fig-1]. Ventilation and oxygenation are possible through the connector, while the endoscope port (16 mm) allows for the passage of an endoscope with a maximum diameter of 14 mm. The bite block reduces the potential for damage or obstruction of the airway tube or endoscope due to biting. The silicone airway tube and cuff are designed for smooth insertion and patient comfort. The Cuff Pilot™ Technology, an integrated and colour-coded cuff pressure indicator, constantly monitors cuff pressure to prevent complications of cuff hyperinflation. The device also features an adjustable holder and strap fixation system to maintain its neutral position during endoscope manipulation [15]. As a newer and innovative device, there are relatively fewer references available [16]. The present study aimed to evaluate the utility of gastro LMA compared to nasal prongs in maintaining oxygenation and airway control during upper GI endoscopy procedures.

MATERIALS AND METHODS

The present double-blinded randomised, single-centre clinical study was conducted in the Department of Anaesthesiology



at the tertiary care GCS Medical College Hospital and Research Centre, Ahmedabad, Gujarat, India between April 2021 and October 2021, after obtaining approval from the Institutional Ethics Committee (GCSMC/EC/Research project/APPROVE/2021/265) and registration with the Clinical Trial Registry of India (CTRI/2021/07/035273). The data collector and data analyst were blinded for the study.

Inclusion criteria: Patients with co-morbidities such as hypertension, diabetes, asthma, ischemic heart disease, chronic obstructive pulmonary disease, and obstructive sleep apnoea required proper evaluation and assessment as they are prone to intraoperative complications.

Exclusion criteria: Pregnant and lactating females, patients who were not nil by mouth, and procedures to be performed in the prone position were excluded from the study.

The primary objective of present study was to evaluate the utility of gastro LMA as an airway technique to improve airway control. The secondary objective included comparing any upper airway-related side effects, such as hoarseness of voice, sore throat, or dysphagia, between the groups.

Study Procedure

During the study period, approximately 100 endoscopy procedures were performed at hospital. Out of these, 50 patients required anaesthesia for various procedures. To compare the two groups, authors evenly distributed the patients into two groups of 25 each.

The study included 50 adult patients of either gender, aged between 18 and 60 years, with American Society of Anaesthesiology (ASA) physical status 1, 2, and 3, and a mouth opening of two to three fingers, scheduled for elective day care upper gastrointestinal procedures in the supine or lateral position (esophageal band ligation, Upper Gastroinstestinal (UGI) scopy with biopsy, diagnostic or therapeutic endoscopic retrograde cholangiopancreatography, etc.) [17].

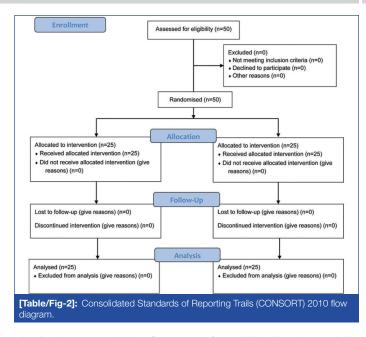
Computer-based randomisation was performed, and the patients were randomly divided into two equal groups of 25 each following the CONSORT statement guidelines 2010 [Table/Fig-2].

Group G (Gastro LMA): Gastro LMA

Group N (Nasal Prong): Nasal Prong

Preanesthetic check-up included a detailed airway assessment by evaluating mouth opening, Mallampatti grading, thyromental distance, hyomental distance, interincisor gap, and an overall assessment to rule out difficult mask ventilation [18] on the day of the procedure, and written informed consent was obtained. Electrocardiogram (ECG), non invasive blood pressure, and pulse oximeter were attached and monitored throughout the procedure. A wide-bore 18 or 20 gauge intravenous line was secured.

In both groups, premedication included injection glycopyrrolate 0.004 mg/kg i.v. (intravenous), injection midazolam 0.02 mg/kg i.v. (intravenous), injection ondansetron 0.08 mg/kg i.v. (intravenous), and injection fentanyl 1-2 µg/kg i.v. (intravenous). Proper depth of anaesthesia in both groups was maintained with incremental doses



of injection propofol i.v. (intravenous) and injection fentanyl i.v. (intravenous) as required.

In Group G (Gastro LMA group), after premedication, adequate oxygenation was performed with a bag and mask, followed by the administration of injection propofol 2 mg/kg i.v. (intravenous). After the loss of the eyelash reflex and apnoea, a gastro LMA of an appropriate size, as per the user manual instructions, was inserted. A maximum of three attempts for gastro LMA insertion was allowed to achieve proper placement and adequate ventilation. Proper LMA placement and effective ventilation were clinically assessed by auscultation, capnography, visible bilateral chest rise, and the absence of an audible leak. In case of improper placement, endotracheal intubation was used as an alternative [12]. After proper placement of the Gastro LMA, ventilation was maintained with a Bain's circuit. In Group N, oxygenation was maintained with nasal prongs (4-6 L/min).

All patients were observed for hypoxia (SpO₂ <92%), bradycardia, any other intraoperative adverse events, and conversion to endotracheal intubation. Preprocedural heart rate and SpO₂, as well as the lowest heart rate and lowest SpO₂ during the procedure, were noted. All patients were observed for four hours postoperatively for any adverse effects and were discharged after being assessed using the modified Aldrete's scoring system [19]. Patients were assessed at 60 minutes and then 120 minutes post-procedure. They were discharged from the hospital when the Aldrete's score reached \geq 9.

STATISTICAL ANALYSIS

The data was systematically collected in an MS Excel sheet and analysed using SPSS version 26.0. The results were presented as numbers (percentage), mean±SD, and p-value. An independent student t-test was used to compare haemodynamic data between the two groups. A Chi-square test was used to analyse categorical data and test the association between the two groups. A p-value <0.05 was considered statistically significant.

RESULTS

Out of the 50 patients, 23 were male and 27 were female, with a median age of 59 years. Both groups were comparable in terms of age, gender, Body Mass Index (BMI), ASA grading, and duration of surgery [Table/Fig-3]. There was no statistically significant difference in the co-morbidities of patients and the types of procedures performed between the two groups [Table/Fig-4,5].

Preprocedural heart rate and SpO₂ were comparable in both groups. The lowest heart rate and SpO₂ during the endoscopy procedure were significantly lower in Group N. Intraoperative hypoxia developed in one patient (4%) in Group G and two patients (8%) in Group N. The p-value was 0.186, which was not statistically significant but

Parameters	Group G (25 patients)	Group N (25 patients)	p-value
Age (years)	46.4±9.6	49.12±14.5	0.44*
Gender (numbers) {Male (%)/Female (%)}	10 (40%)/15 (60%)	13 (52%)/12 (48%)	0.39^
BMI (kg/m²)	23.4±2.4	22.6±2.4	0.29*
ASA 1,2,3 (number/%)	8 (32%)/12 (48%)/ 5 (20%)	8 (32%)/13 (52%)/4 (16%)	0.92^
Mean duration of procedure (minutes)	31.04±16.00	32.2±24.25	0.84*
[Table/Fig-3]: Demographic data presented as mean+SD, or percentage.			

'p-value calculated by applying t-test. ^p-value calculated by applying Chi-square test. p-value <0.05 is considered significant</p>

Parameters	Group G (25 patients)	Group N (25 patients)	p-value
HTN	5 (20%)	4 (16%)	0.71
Diabetes	3 (12%)	6 (24%)	0.26
IHD	3 (12%)	2 (8%)	0.63
COPD	1 (4%)	2 (8%)	0.55
Asthma	1 (4%)	1 (4%)	1.0
ТВ	0	1 (4%)	0.31
OSA	1 (4%)	2 (8%)	0.55

[Table/Fig-4]: Co-morbidities in patients.

Data presented as numbers/percentage. Chi-square test was applied. The p-value <0.05 was considered statistically significant

HTN: Hypertension; Diabetes, IHD: Ischemic heart disease; COPD: Chronic obstructive pulmonary disease; Asthma; TB: Tuberculosis; OSA: Obstructive sleep apnea

Procedures	Group G (25 patients)	Group N (25 patients)	p-value
ERCP	8 (32%)	7 (28%)	0.75
UGISCOPY	3 (12%)	4 (16%)	0.68
Band ligation	4 (16%)	6 (24%)	0.72
Biopsy	6 (24%)	5 (20%)	0.73
UGI + Colon	4 (16%)	3 (12%)	0.68
[Table/Fig-5]: Type of endoscopy procedures. Data presented as numbers/ percentage. Chi-square test was applied. The p-value <0.05 was considered statistically significant ERCP: Endoscopic retrograde cholangiopancreatography: UGISCOPY: Upper GI scopy: Band ligation			

clinically significant as hypoxia in the gastro LMA group was lower compared to the nasal prong group. All three patients required conversion to endotracheal intubation. No postoperative adverse events such as sore throat, hoarseness of voice, or dysphagia were observed in any of the patients [Table/Fig-6].

Parameters	Group G	Group N	p-value
Preprocedural heart rate (per minute)	79 (8.8)	80 (8.3)	1*
Lowest heart rate during procedure (per minute)	68 (6)	64 (5.5)	0.017*
Preprocedural SpO ₂ (%)	98 (1.1)	98 (0.4)	1.00*
Lowest SpO ₂ during procedure (%)	96% (0.6)	94% (4.6)	0.03*
Intraoperative SpO ₂ < 92%	1 patient (4%)	2 patient (8%)	0.186^
Airway conversion to endotracheal tube	1 patient (4%)	2 patient (8%)	0.186^
Adverse intraoperative events	1 patient (4%)	2 patient (8%)	0.186^
Postoperative adverse events in 4 hours	0	0	-
[Table/Fig-6]: Comparison of heart rate, SpO ₂ and adverse events between the two groups. *p-value calculated by applying independent t-test. ^p-value calculated by applying chi-square test. p-value <0.05 is considered significant			

In Group G, one case developed hypoxia, for which a muscle relaxant was used to secure the airway with an endotracheal tube. In Group N, muscle relaxant was used and intubation was performed in two patients, and atropine was given to one of them due to simultaneous bradycardia [Table/Fig-7]. The modified Aldrete's scoring in both groups was comparable at 60 minutes and 120 minutes. The p-value at 60 minutes was 0.87, and at 120 minutes, it was 0.67 [Table/Fig-8].

Agents	Group G (25 patients)	Group N (25 patients)	p-value
Propofol+fentanyl	25 (100%)	25 (100%)	-
Muscle relaxant	1 (4%)	2 (8%)	0.5515
Atropine	0	1 (4%)	0.3124
[Table/Fig-7]: Anaesthetic agents used in patients. Data presented as numbers/percentage. Chi-square test was applied. p-value <0.05 was considered			

statistically significant

Parameters	Group G (25 patients)	Group N (25 patients)	p-value
Modified Aldrete's score at 60 min	6.84±0.92	6.88±0.85	0.87 (ANOVA)
Modified Aldrete's score at 120 min	9.16±0.67	9.08±0.62	0.67 (ANOVA)
[Table/Fig-8]: Modified Aldrete's scoring at the time of discharge. t-test was applied p-value <0.05 was taken as statistically significant; Analysis of Variance (ANOVA)			

DISCUSSION

In present randomised clinical study, the gastro LMA, a newer novel device, was found to be useful for gastrointestinal endoscopy procedures as a valuable tool for maintaining a patent airway. It has an integrated bite block and adjustable straps that facilitate easy passage of the endoscope. It also has cuff pilot technology that prevents cuff hyperinflation and associated complications such as sore throat, dysphagia, and nerve palsies. Unlike endotracheal tube insertion, muscle relaxant is not required for its insertion. Securing the airway with the gastro LMA allows for deep sedation and the maintenance of an appropriate plane of anaesthesia for prolonged procedures [20]. These factors contribute to the usefulness of the gastro LMA for gastrointestinal endoscopy procedures.

In the gastro LMA group, one patient experienced intraoperative hypoxia (SpO₂ <92%), leading to endotracheal intubation. The patient had an anticipated difficult airway due to obesity (BMI=31.1 kg/m₂). Ventilation was inadequate, resulting in hypoxia, and therefore endotracheal intubation was necessary. Despite confirming proper device insertion with ventilation assessment, bilateral chest rise, and SpO₂ monitoring, the patient desaturated once the procedure started. This may have been caused by increased intrabdominal pressure due to air insufflation in the colon, combined with the patient's obesity, leading to slight displacement of the LMA. The procedure was paused and the airway was secured with endotracheal intubation before completing the procedure.

In the nasal prong group, two patients experienced intraoperative adverse events. One patient undergoing Endoscopic Retrogade Cholangiopancretography (ERCP) for a longer duration (approximately 50 minutes) developed bronchospasm associated with hypoxia and bradycardia. The intraoperative SpO2 reached 75%, prompting endotracheal intubation. The second patient, who underwent diagnostic UGI scopy and had a short neck and obesity, developed intraoperative hypoxia, leading to endotracheal intubation. Terblanche NCS et al., conducted a study using the gastro LMA for GI endoscopy in 292 ASA 1 and 2 patients and found it effective in maintaining oxygenation during endoscopy procedures, with a median lowest intraoperative saturation of 98% [21]. Tran A et al., compared the gastro LMA with low flow nasal cannula in 59 and 85 ERCP patients, respectively. Only one patient in the gastro LMA group required conversion to an endotracheal tube due to difficulty in negotiating the endoscope through the LMA. Conversion to endotracheal intubation was required in one patient in the low flow cannula group due to an apneic episode and desaturation [16]. Schmutz A et al., studied the feasibility of the gastro LMA in 214 high-risk patients undergoing endoscopic procedures and found that placement and ventilation with the gastro LMA were not possible in four patients, who had a history of oral cancer and radiotherapy, due to difficulty in positioning the LMA [10]. Hagan KB et al., studied the gastro

LMA in 30 patients undergoing ERCP and found that hypoxia was observed in only one patient (SpO_ of 93%) [3].

No postoperative adverse events were observed in any patient in both groups in this study. Hagan KB et al., studied the gastro LMA in 30 patients and found sore throat in 6.6% of patients [3]. Terblanche NCS et al., studied 292 endoscopy procedures with the gastro LMA and found an incidence of 37% of sore throat in the postoperative period. The smaller sample size in this study group may explain the lower incidence observed [21].

In present study, all 24 patients in the gastro LMA group underwent successful procedures. No difficulties were encountered during gastro LMA insertion and ventilation, and the gastro physician did not experience difficulty in passing the endoscope through the LMA.

Limitation(s)

The present study has several limitations. Firstly, it is an interventional single-center study with a small number of patients and a short duration, which limits the generalisability of the conclusions. Additionally, present study did not compare the efficacy of the gastro LMA with general anaesthesia and endotracheal tube insertion. Therefore, a multicentric study with a larger population should be conducted to further explore factors such as the utility of the gastro LMA in patients with high body mass index or high-risk patients.

CONCLUSION(S)

Respiratory depression during endoscopy procedures performed under sedation without securing the airway can lead to potentially life-threatening hypoxemia, necessitating the interruption of the procedure and emergent airway management. The gastro LMA, a newer supraglottic airway device, helps maintain an open airway by preventing airway obstruction due to the falling tongue. This facilitates spontaneous breathing and reduces the occurrence of hypoxemia when deeper sedation is used during gastrointestinal endoscopy procedures. The present study concludes that the gastro LMA appears to be an effective airway technique for clinical use in patients undergoing gastrointestinal endoscopy procedures performed under sedation, providing better oxygenation compared to using nasal prongs alone without securing the airway.

Declaration: This study was presented at the 68th Annual National Conference of ISA, ISACON 2021, held in Ahmedabad.

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