



Use of the gastro-laryngeal tube in endoscopic retrograde cholangiopancreatography cases under sedation/analgesia

BILIARY

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ABSTRACT

Background/Aims: In this study, we aimed to analyze the effects of Gastro-Laryngeal Tube (GLT) use on intraoperative and postoperative hemodynamic parameters, comfort of the procedure, and patients' satisfaction in endoscopic retrograde cholangiopancreatography (ERCP).

Materials and Methods: A total of 80 patients between the ages of 20 and 75 years who were scheduled for elective ERCP were enrolled. The patients were randomly assigned to two groups: groups N and G. Those in group N underwent the procedure with sedation without any airway instruments and those in group G underwent procedure after sedation and airway management with GLT. Intraoperative and postoperative vital signs as well as the satisfaction of the patients were recorded.

Results: The duration to esophageal visualization was found to be significantly higher in group N (16 s) than in group G (7 s) ($p=0.001$). The mean Visual Analogue Scale for Pain (VAS) was significantly higher in group G (1.85) than in group N (0.45) ($p=0.016$). Group G had higher endoscopist satisfaction scores than group N. The incidence of desaturation during ERCP was significantly higher in group N (60%) than in group G (0%) ($p=0.000$).

Conclusion: In conclusion, ERCP should be performed under optimal conditions to avoid the occurrence of unwanted complications, such as aspiration-related disorders. Therefore, according to the structural properties of GLT, sedation anesthesia application with GLT in ERCP will be safer, more comfortable, and more effective.

Keywords: Gastro-laryngeal tube, sedation/analgesia, endoscopic retrograde cholangiopancreatography

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is normally performed in the prone position under deep sedation or general anesthesia (1). There is an ongoing debate about the anesthetic method that should be applied in ERCP because of the dilemma between the anesthesiologists' concern about airway safety and the gastroenterologists' desire for a speedy and comfortable intervention (2,3). During general anesthesia, there are issues with the need for muscle relaxants, prolonged extubation time, and instrumentation of the entire airway along with related disadvantages. Under deep sedation, however, problems with airway safety can occur, aspiration risk is increased, and cardiovascular complications can be involved (4).

The Gastro-Laryngeal Tube (GLT) (VBM=Medizintechnik GmbH; Sulz am Neckar, Germany) is a modified laryngeal

tube containing a channel for the endoscope; it provides a conduit that allows for manipulations with an instrument, while simultaneously enabling controlled ventilation (Figure 1). Under deep sedation and analgesia, it is inserted into the hypopharynx and esophagus. The distal cuff of GLT is inflated inside the esophagus to prevent aspiration of the stomach contents. The proximal cuff is inflated in the oropharynx to stabilize the instrument and thus enable controlled ventilation. The present study aimed at analyzing the effects of GLT use in ERCPs on intraoperative and postoperative hemodynamic parameters and also on doctors' and patients' satisfaction.

MATERIALS AND METHODS

The required approval for the study was obtained from the Bezmialem Vakıf University Ethics Committee (ap-

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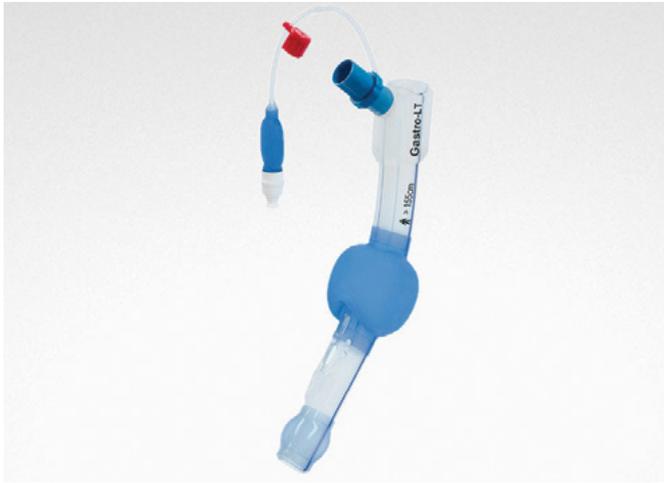


Figure 1. Gastro-Laryngeal Tube



Figure 2. A patient with Gastro-Laryngeal Tube

proval nr. 71306642/050-01-04/76). All patients were informed about the applications to be put in place before the intervention, and written consent was obtained. The study included 80 patients aged between 20 and 75 years, ASA status 1-2, undergoing elective ERCP. Excluded were emergency operations, morbidly obese patients (BMI>35), patients with previous neurologic disease or symptoms (transient ischemic attack, syncope, dementia, etc.), and those with allergies to the drugs to be used. The patients were randomly assigned to two groups. In the first group (group N; n=40), the intervention was performed without any airway instrumentation under nasal oxygen with sedation and analgesia, whereas in the second group (group G; n=40), together with sedation, airway control was achieved with GLT.

All patients received preoperative premedication of 0.03 mg/kg iv midazolam and were then taken into the operating theater and attached to non-invasive monitoring (heart rate (HR), arterial tension (AT), and peripheral oxygen saturation (SpO₂)). After administration of 1 mg/kg lidocaine (Aritmal 2%, Osel ilaç San. ve Tic. Corp.; Beykoz, İstanbul, Turkey) and 0.01 mg/kg atropine sulfate (Drogsan İlaçları San. Corp; İstanbul, Turkey), sedation was induced with 1.5 mg/kg propofol (Propofol-Li-

puro® 1%, Braun Melsungen AG, Carl-Braun-Straße 1; Melsungen, Germany) and 1.5 mcg/kg fentanyl (Johnson & Johnson Sihhi Malzeme San. ve Tic. Ltd. Comp.; İstanbul, Turkey). In both groups, anesthesia was maintained with 4 mg/kg/h propofol infusion. In case of insufficient sedation, additional doses (0.1 mg/kg bolus) of propofol (iv) were administered. The additional doses were noted. In group G, after indication, airway instrumentation with GLT was applied and oxygenation was achieved through spontaneous respiration. Patients in group N were given oxygen, beginning at 3 L/min, through the nasal cannula from the beginning of sedation. Patients in group G, after insertion of GLT, were connected to the ventilation circuit and received O₂ beginning at 2 L/min (Figure 2). Intra-operatively, each patient's Richmond Agitation Score (RAS), heart rate (HR), systolic-diastolic-mean blood pressure (S/D/M BP), and peripheral oxygen saturation (SpO₂) were recorded at 5 minute intervals. The total duration of the intervention and the total propofol used during that period were recorded. In group N, when SpO₂ was ≤92, increased oxygenation was achieved by jaw thrust maneuver. If desaturation continued, the procedure was suspended until oxygenation improved. In group G, if oxygenation was low, ambulation was initiated.

Training in the use of GLT was given to anesthesiologists and gastroenterologists entering this study. The period between inserting the endoscope into the mouth and the first image of the esophagus being seen on the screen was recorded as "duration to esophageal visualization."

Hypertension was defined as an SBP increase >30% from the baseline values or over 160 mmHg. Tachycardia was defined as a HR greater than 100 beats/min. Desaturation was defined as SpO₂ of less than 92%. Incidences of hypertension, tachycardia, and desaturation were recorded throughout the study.

GLT was removed when the patient had sufficient spontaneous respiratory effort.

After the intervention, when the hemodynamic values were appropriate, the patients were taken to recovery; their vital statistics were monitored in the recovery unit for at least 30 min. There, post-operative nausea was assessed with the Numeric Rank Score for emesis and recorded. Pain was recorded after assessment with the Visual Analogue Scale for Pain (VAS). If VAS>4, 1 mg/kg tramadol was administered intravenously. When the Aldrete recovery score was >9 and the waiting time was completed, the patients were taken to the wards.

Endoscopists and patients were requested to score their satisfaction with points between 1 and 4 as very good (4), good (3), bad (2), and very bad (1), and the results were recorded.

Statistical analyses were performed using SPSS (SPSS PC Ver. 22; IBM® SPSS Inc.; New York, U.S.). Descriptive statistics for demographic data and constant variables (operation types and

ASA grades) were indicated as mean±standard deviation. Student's t-test was used to compare group quantitative data, and repeated measures analysis of variance (ANOVA) was used to analyze hemodynamic changes over time, using time as the between-subject factor. The chi-square test was used to analyze categorical variables. A p-value<0.05 was considered statistically significant.

RESULTS

Included in the study were 80 patients undergoing ERCP under elective conditions and under sedation. The study was completed within a period of three months. There were no significant differences between the groups in terms of demographic data (Table 1).

There were no significant differences between the groups regarding indications for ERCP and the presence of additional diseases (Table 2).

There were no significant differences between group G and group N regarding total duration of operation and total duration of anesthesia. Duration to esophageal visualization was 16.2±5.8 sec in Group N and 7.20±2.2 sec in group G, the difference being statistically significant (p=0.001). In group G, the mean time required for GLT insertion was determined to be 17 sec.

While no significant difference was observed regarding intraoperative occurrence of tachycardia or hypertension, the incidence of desaturation was significantly higher in group N compared to group G (p=0.00) (Table 3).

The period in the postoperative recovery unit required to reach an Aldrete recovery score ≥9 differed significantly. In group N, 16.5±9.04 min were required to reach the score, while in group G 6.55±6.2 min were required (p=0.001). Postoperatively, the patients' headaches were assessed in the recovery unit using VAS; in group N, the mean VAS was 1.85±2.2, while in group G, it was 0.45±1.14; the difference was statistically significant (p=0.016) (Table 4). However, no significant difference was observed clinically, as the VAS scores were low in both groups.

Endoscopists' satisfaction in group N were very bad/4, bad/16, good/16, very good/4; in group G, it was good/2, very good/38 (Figure 3). The "very good" score was significantly higher in group G.

Patients' satisfaction was evaluated as bad/4, good/34, very good/2 in group N and bad/0, good/4, very good/36 in group G; these results appear to be parallel to the endoscopists' satisfaction results (Figure 4).

The incidence of desaturation during ERCP was significantly higher in group N (24/40) (60%) than in group G (0/40) (0%) (p=0.00) (Table 5). For group N, the occurrence rates for tachycardia and hypertension were relatively higher compared to

Table 1. Demographic parameters of the patients

	Group G (n: 40)	Group N (n: 40)
Age, years	57 (±2.3)	55 (±3.9)
Weight, kg	82 (±4.1)	79 (±2.4)
Height, cm	168 (±1.9)	171 (±1.3)
Sex: male/female (n)	22/18	26/14
ASA grade 1 or 2 (n)	20/20	22/18

Table 2. Operation types

	Group G (n: 40, %)	Group N (n: 40, %)
Cholelithiasis	30 (75%)	24 (60%)
Anastomotic stricture	2 (5%)	0 (0%)
Pancreatitis	2 (5%)	4 (10%)
Post-operative biliary leakage	1(2.5%)	3 (7.5%)
Distal bile duct tumor	3 (7.5%)	2 (5%)
Pancreas tumor	2 (5%)	4 (10%)
Papilla tumor	0 (0%)	2 (5%)
Gall bladder tumor	0 (0%)	1 (2.5%)
Total	40 (100%)	40 (100%)

n: patient number; G-LT: Gastro-Laryngeal tube; N: nasal

Table 3. Adverse effects

	Group G (n: 40)	Group N (n: 40)	p
Hypoxia	0	24	*0.000
Hypertension	4	10	0.07
Tachycardia	4	7	0.259

*statistically significant

n: patient number; N: nasal; G: Gastro-Laryngeal tube

Table 4. Evaluation results

	Group N (n: 40)	Group G (n: 40)	p
Total duration of operation (h)	28.25 (15.14)	20.30 (11.41)	0.069
Total time under anesthesia (h)	30.30 (15.17)	26.45 (11.46)	0.371
Duration of esophagus imaging (s)	16.20 (5.8)	7.20 (2.2)	*0.000
Duration until Aldrete recovery score of ≥9 (min)	16.5 (9.04)	6.55 (6.2)	*0.000
VAS headaches	1.85 (2.2)	0.45 (1.14)	*0.016
Endoscopists' satisfaction (n)			
very bad/bad/good/very good	4/16/16/4	0/0/2/38	*0.000
Patients' satisfaction (n)			
very bad/bad/good/very good	0/4/32/4	0/0/4/36	*0.000
Total propofol dose (mg)	299.00 (168.9)	271 (99.7)	0.527

*statistically significant

n: patient number; N: nasal; G: Gastro-Laryngeal tube

Table 5. SpO₂ values

Time (min)	SpO ₂ (%)							
	Baseline	1 after induction	5	10	15	20	25	30
Group G (n=40)	97 (1.9)	98 (1.8)	98 (2.1)	99 (0.9)	99 (0.6)	99 (0.8)	99 (0.9)	98 (0.9)
Group N (n=40)	97 (1.4)	92 (5.8)	93 (4.6)	95 (3.2)	96 (2.69)	95 (3.5)	95 (3.6)	95 (1.8)
p	p=0.708	p=0.000*	p=0.000*	p=0.000*	p=0.000*	p=0.001*	p=0.001*	p=0.001*

*statistically significant

n: patient number; N: nasal; G: Gastro-Laryngeal Tube

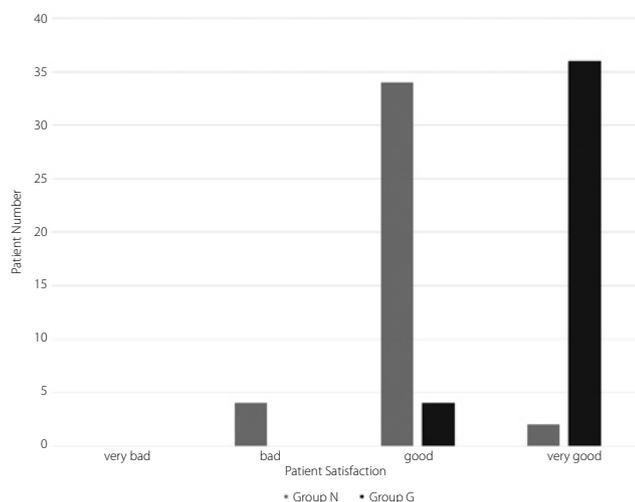


Figure 3. Endoscopists' satisfaction

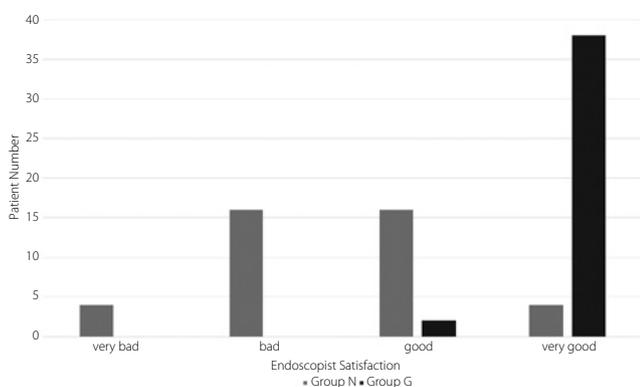


Figure 4. Patients' satisfaction

group G. However, there were no statistically significant differences between the groups.

DISCUSSION

ERCP is an important diagnostic and interventional method in diseases of the bile ducts and the pancreas. While ERCP is used for a diagnostic purpose, necessary invasive interventions can be carried out during the procedure (5). ERCP is generally a painful intervention performed in a prone position, and the preferred method of anesthesia varies from institution to institution; superficial sedation, deep sedation, or general anesthesia are applied (4-6). While endoscopy of the upper gastrointestinal system can be performed under superficial sedation, for

ERCP it is assumed that deeper sedation is needed (7). ERCP is usually applied to patients in an advanced age group, possibly involving comorbidities (hypertension, heart diseases, diabetes, etc.) (5). For this reason, it is recommended to conduct the intervention with hemodynamic data monitoring and under deep sedation or general anesthetic (8,9).

According to a study by Raymondos et al. (4), ERCP under sedation led to a failure rate twofold higher than that of a group treated under general anesthetic. It has been pointed out that a main reason for the high failure rate in the group treated under sedation was early termination of the intervention. An important factor for complications in the application of sedation is the need for high-dose drug use and a lack of sufficient monitoring (10). It has also been shown that ERCP under sedation entails a higher risk of airway loss, hypoxemia, and aspiration (11).

In the last decade, patients' comfort and satisfaction have been given greater importance; also, endoscopists are insisting on working more safely and sharing responsibility, which has led to an increasing demand for anesthetic procedures in endoscopic interventions to be performed by professional anesthetists (2). This increase in demand was an important incentive for the development and design of new pharmaceutical agents and medical instruments to be used in these procedures. GLT is a new tool designed and introduced to allow for a more comfortable application of endoscopic procedures in the upper gastrointestinal tract under deep sedation with greater airway safety. GLT is a modified laryngeal tube, offering a channel for the endoscope inside, providing a conduit allowing for manipulations with an instrument and at the same time allowing control of the supraglottic airway (1). The tube has two cuffs, one of which is inflated inside the esophagus, the other inside the hypopharynx. These cuffs ensure airway safety by protecting from aspiration and at the same time stabilizing the gastro-laryngeal tube. GLT is inserted under deep sedation, without using neuromuscular blockers, and is subsequently fastened at the wall of the throat by inflating the two cuffs. After fixation, the endoscopist can very swiftly begin direct esophageal visualization through the available oro-esophageal channel (lumen of GLT). In our study, the average duration of GLT insertion was determined to be 17 sec. After the anesthetist gave the endoscopist the go-ahead for the intervention, esophagus visualization was achieved on average within 7 sec in group

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G and within 17 sec in group N. This is a big difference at this point, given that in group N the damage done to the oral cavity by the endoscope, which is some 13 mm wide and made of stiff material, becomes much more of an issue. In the procedure using GLT, the endoscopist can start the intervention more quickly, reaching the esophagus directly from within GLT, without causing any harm to the oral cavity (mucosa lesion, dental damage, hematoma at the root of the tongue). Given that the use of GLT does not require laryngoscopy, the patient is not exposed to the related complications (tachycardia, hypertension, tongue-mucosa lesions, dental damage, etc.) (12).

A high rate of systemic diseases being present highlights the necessity to apply an anesthetics protocol offering airway safety and allowing for close monitoring. In addition to comorbidities, the fact that the intervention is performed in a prone position requires enhanced attention and safety measures (13,14). In our study, a comorbidity rate of around 50% was observed (hypertension, diabetes mellitus, chronic obstructive pulmonary disease, etc.)

In literature reviews, it has been reported that procedures without any use of airway instruments, performed with sedation only, led to a high rate of premature termination (4). In our study, as we monitored the cases intra-operatively, we established that group N showed more frequent periods of desaturation, while group G displayed a more stable and efficient oxygenation pattern. The desaturation problems experienced in group N did not reach a level that would require termination of the intervention; they could be resolved with airway-opening maneuvers, stimulation, and higher O₂ flow. In group G, during the entire intervention, stable oxygenation values could be preserved at a level close to the initial values. Considering that patients undergoing ERCP are usually from an elderly population with comorbidities, the relevance of inadequate oxygenation values is even greater. By analyzing the SpO₂ values during the entire duration of the operation, it was shown that the use of GLT achieved successful airway control and stabilization of intraoperative oxygenation.

This kind of outpatient anesthesia with early recovery and early discharge from the post-anesthesia care unit is important from the perspective of hospital economy. The patients' period in the recovery unit until reaching an Aldrete score of ≥ 9 in group G was significantly shorter than that in group N. A short recovery time enables earlier transfer of the patients to their respective clinics. In our study, we were unable to analyze the relationship between short recovery time and cost effectiveness. This can be considered as a limitation of our study.

Headache and sore throat are among the most common patient complaints after endoscopic interventions. In our study, there was a significant difference in headache VAS scores between patients postoperatively. In group G, headache and throat ache scores were significantly lower.

We observed that fluctuations in anesthetic level during the procedure were less frequent while using GLT. Efficient oxygenation during the entire operation and trauma caused by the endoscope in the oropharyngeal cavity at the beginning of the intervention may be important factors contributing to this difference.

In addition to the variety of interventions performed in endoscopy units, the satisfaction of operators and service recipients is also currently considered to be an important quality parameter (15). At the end of each procedure, we asked the endoscopists and patients to define the experience of the procedure (very bad, bad, good, or very good). In our study, the endoscopists' satisfaction in group G was rated "very good" by 95%, whereas in group N, 10% gave rated their satisfaction as "very good" and 40% rated it as "good" (Figure 3).

In comparison, 90% of the patients in group G rated their satisfaction as "very good" and 10% rated it as "good," while in group N, the grades given were 5% "very good," 85% "good," and 10% "very bad" (Figure 4). These results show that the use of GLT increases both endoscopists' and patients' satisfaction to a high degree.

In conclusion, it is now possible to efficiently perform ERCP and other painful and complicated invasive operations, such as papillotomy or stenting and dilatation of the bile ducts, under sufficiently deep anesthetics. One of the most important aspects of anesthesia is airway safety; thus, anesthetists are prompted to use airway instrumentation, particularly during interventions that are generally performed in the prone position. While conventional supraglottic airway instrumentation is not applicable in endoscopic procedures, the use of GLT, which has been introduced in the last few years, provides effective airway safety as well as a comfortable endoscopic access.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Bezmialem Vakif University Local Ethical Committee.

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

Peer-review: Externally peer-reviewed.

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