

Research article

Tolerability of Endoscopic Variceal Ligation in Cirrhotic Patients without Sedation

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Abstract

Background: Endoscopic variceal ligation (EVL) in patients with portal hypertension is generally performed either with propofol or conscious sedation using midazolam. **Objective:** Study was aimed to grade the comfort level for patients, endoscopists and nurses while performing EVL without sedation. **Methods:** 100 patients were included in this prospective study and randomly assigned into group A (receiving EVL) and B (diagnostic gastroscopy ± biopsy). All patients received 100 mg of lidocaine oral spray prior to the procedure. Doctors, patients, and nurses' comfort levels were measured using the Modified Gloucester Comfort Scale. **Results:** 63% of patients were male. Among group A vs B, comfort score was ranked 0 by patients (58% vs 62%), doctors (68% vs 62%), and nurses (65% vs 52%). Comfort score was ranked 1 by patients (32% vs 34%), doctors (26% vs 34%), and nurses (36% vs 42%) in groups A and B respectively. It was ranked 2 by patients (0% vs 4%), doctors (0% vs 4%), and nurses (0% vs 6%) in groups A and B respectively. Comfort scores 3 and 4 were not reported by any participant. There was no statistically significant difference between the comfort scores assessed by patients ($p=0.23$), doctors ($p=0.14$), and nurses ($p=0.08$) between the two groups. **Conclusion:** EVL in cirrhotic patients could be safely performed without propofol and conscious sedation. Tolerability of EVL without sedation is comparable to the diagnostic gastroscopy without sedation. EVL without sedation is cost-effective with shorter hospital stays, reduced caring needs, and sedation-related adverse events.

Keywords: Endoscopic variceal ligation, Liver Cirrosis, Non-sedation

Introduction

Esophagogastroduodenoscopy (EGD) is a non-surgical procedure to examine the digestive tract including the esophagus, stomach, and proximal parts of the small intestine. It is a valuable diagnostic and therapeutic tool for a variety of upper gastrointestinal conditions [1]. Major indications include upper GI bleeding, dysphagia, odynophagia, gastroesophageal reflux disease, anemia, etc [2]. This minimally invasive procedure offers various benefits over traditional surgery including shorter hospital stay and recovery time, less pain, and fewer complications. However, an upper GI endoscopy also carries the risk of complications. Although the frequency of these complications is low, this procedure could cause bleeding, perforation, infection, and a drug reaction [1,3-4]. Innovation in endoscopic technology and better training has improved technical success and safety profile with

better tolerability [5].

Risks associated with procedural sedation for upper GI endoscopy have always been a challenge for endoscopists, particularly cardiopulmonary unplanned events (CUEs). The CUEs have been reported to constitute 40% of all reported events. The reported incidence of cardiopulmonary unplanned events varies from 1 in 10000 to 1 in 170 [6]. The CUEs include hypotension, angina, arrhythmias, and myocardial infarction occurring within twenty-four hours of an endoscopic procedure [7].

The use of sedatives and analgesics during EGD may not be safe with advanced age and medical comorbidities particularly cardiopulmonary disorders [8]. EGD could be safely performed with local anesthetic and is a potentially viable alternative in high-risk patients [9]. The majority of patients require sedative

medications for therapeutic endoscopic interventions. One of the major factors influencing the decision to sedation for such procedures is a high level of anxiety before the procedure [10-12].

Intravenous benzodiazepines and opiates have been used to give anxiolytic, amnesic, and analgesic effects during such procedures since the early 1980s [13-15].

Furthermore, conscious intravenous sedation is frequently blamed for a significant portion of the cost and complications related to endoscopic procedures, particularly in liver cirrhosis patients. This indirect cost manifests itself in the form of unexpected hospitalization at times, but more importantly, loss of ability to perform normal activities and work-related absenteeism following endoscopic interventions [16-18]. Hence, few studies have considered the use of various forms and modalities of topical anesthetics, such as lidocaine throat spray, lidocaine lollipop, lidocaine lozenge, and lidocaine viscous with mixed results [11,19].

Aims and study design

The objective of this study was to assess the tolerability of endoscopic variceal ligation (EVL) with lidocaine throat spray compared with diagnostic EGD. This was a prospective study conducted at Pakistan Kidney and Liver Institute and Research Center (PKLI&RC), Lahore. This study was approved by the Institutional Ethical Committee of PKLI&RC, Lahore, Punjab, Pakistan (Ref: PKLI-IRB/AP/0126).

Inclusion and exclusion criteria

Consecutive patients scheduled for upper gastrointestinal endoscopy for diagnostic purposes and those requiring variceal screening and EVL for portal hypertension independent of the Child-Pugh class were included. Patients with severe cardiopulmonary disease, severe coagulopathy, and allergy to lidocaine were excluded.

Materials and Methods

A total of 100 patients were included in the study and were randomly assigned equally into groups, A and B. Informed written consent of study participation and procedure was signed by each participant. Patients' medical records were reviewed from the electronic hospital database. Patients who underwent EVL were assigned Group A, whereas those undergoing diagnostic gastroscopy with or without biopsy were assigned Group B. EVL was performed as a primary or secondary measure while diagnostic gastroscopies with or without biopsies were performed for various medical indications including nausea, vomiting, weight loss, anemia, and dyspepsia. All patients received 100 mg of lidocaine throat spray. Doctors, patients, and nurses' comfort levels were measured using the Modified Gloucester Comfort Scale, which has a scale range of 0 to 5 as mentioned below. Following the procedure, all patients were observed for 30 minutes before discharge for any immediate complications. Patients were followed for any delayed complications. Qualitative and quantitative variables are reported as frequency (%) and median (range). Statistical analysis was performed using Chi-square and independent t-test. A p-value < 0.05 was considered significant.

Modified gloucester scale

1. No discomfort – resting comfortably throughout

2. Minimal: One or two episodes of mild discomfort, well tolerated

3. Mild: More than two episodes of discomfort, adequately tolerated

4. Moderate: Significant discomfort, experienced several times during the procedure

5. Severe: Extreme discomfort, experienced frequently during the procedure

Results

Each group consisted of 50 patients with male predominance (63%). In groups A and B, the median age was 48.26 years and 47.32 years respectively. 58% of patients were below the age of 50. 68% of patients were decompensated cirrhotics, whereas, 20% and 12% were well-compensated cirrhotics and non-cirrhotics respectively. Hepatitis C was the most frequent etiology of chronic liver disease (p value= 0.001) (Table 1).

Comfort score was ranked 0 in groups A and B using the modified Gloucester comfort scale by patients (58%) vs. (62%), doctors (68%) vs. (62%), and nurses (65%) vs. (52%) respectively. Comfort score was ranked 1 by patients (32%) vs. (34%), doctors (26%) vs. (34%), and nurses (36%) vs. (42%) respectively. Comfort score was ranked 2 by patients (0%) vs. (4%), doctors (0%) vs. (4%), and nurses (0%) vs. (6%) respectively. Comfort scores 3 and 4 were not given by any of the assessors including patients, doctors, and nurses in groups A and B (Table 1).

There was no statistically significant difference between the comfort scores assessed by patients (p=0.23), doctors (p=0.14), and nurses (p=0.08) between the two groups (Table 1). There were no immediate or delayed complications.

Comfort scores were comparable and statistically insignificant among decompensated and compensated cirrhotics and non-cirrhotic patients (Table 2).

Discussion

EGD is a commonly performed gastrointestinal procedure for various diagnostic and therapeutic indications. Propofol sedation is considered a safe strategy for minimizing the sympathetic reaction to the procedure [14]. Though propofol sedation is considered safe, still around 30% of patients experience retching and gag reflex [15].

When endoscopes are inserted through patients' mouths, they experience anxiety, and discomfort and have an unpleasant experience altogether, requiring the use of sedatives.

The decision regarding the type and dose of sedatives to a great extent relies upon age, comorbidities such as renal failure, cardiopulmonary disease & history of excess alcohol. Additionally, the decision of using sedation varies greatly among endoscopists throughout the world. By and large, more profound sedation is involved in the USA than in Europe [19]. A meta-analysis showed sedation to accomplish better tolerance, and technical and clinical success with the willingness to undergo repeat procedures [20].

However, serious and even life-threatening adverse effects were observed with sedation, particularly with propofol. Clarke et al. evaluated five-year endoscopy data and showed 6.5 per

Table 1. Comparison of comfort score and various variables between Group A & B

Variables	Category	Group A	Group B	P-Value
		N=50	N=50	
Age	17-49	30 (60%)	28 (56%)	0.68
	≥ 50	20 (40%)	22 (44%)	
Gender	Male	33 (66%)	30 (60%)	0.53
	Female	17 (34%)	20 (40%)	
Etiology of Liver disease	HCV	39 (78%)	38 (76%)	0.001
	HBV	5 (10%)	2 (4%)	
	Cryptogenic Cirrhosis	6 (12%)	1 (2%)	
Nurse Comfort score	Comfortable (0 score)	32 (64%)	26 (52%)	0.14
	Minimal pain (1 score)	18 (36%)	21 (42%)	
	Mild pain (2 score)	0 (0%)	3 (6%)	
Doctor Comfort score	Comfortable (0 score)	37 (74%)	31 (62%)	0.21
	Minimal pain (1 score)	13 (26%)	17 (34%)	
	Mild pain (2 score)	0 (0%)	2 (4%)	
Patient Comfort score	Comfortable (0 score)	34 (68%)	31 (62%)	0.33
	Minimal pain (1 score)	16 (32%)	17 (34%)	
	Mild pain (2 score)	0 (0%)	2 (4%)	

Abbreviations: HCV= Hepatitis C virus; HBV = Hepatitis B virus

Table 2. Comfort score assessment for non-cirrhotics and cirrhotics (compensated and decompensated)

Total Non-Cirrhotic (n=14) 14 %			
	Comfort Score of Nurses (n) %	Comfort Score of Doctors (n) %	Comfort Score of Patients (n) %
No pain (0 score)	6 (42.9%)	6 (42.9%)	6 (42.9%)
1 to 2 times mild pain (1 score)	6 (42.9%)	7 (50%)	6 (42.9%)
More than 2 times mild bearable pain (2 score)	2 (14.2%)	1 (7.1%)	2 (14.2%)
Total Compensated Cirrhotic (n=20) 20%			
	Comfort Score of Nurses (n) %	Comfort Score of Doctors (n) %	Comfort Score of Patients (n) %
No pain (0 score)	11 (55%)	13 (65%)	12 (60%)
1 to 2 times mild pain (1 score)	9 (45%)	7 (35%)	8 (40%)
More than 2 times mild bearable pain (2 score)	0 (0%)	0 (0%)	0 (0%)
Total Decompensated Cirrhotic (n=66) 66%			
	Comfort Score of Nurses (n) %	Comfort Score of Doctors (n) %	Comfort Score of Patients (n) %
No pain (0 score)	41 (62.1%)	48 (72.7%)	46 (69.7%)
1 to 2 times mild pain (1 score)	24 (36.4%)	17 (25.8%)	19 (28.8)
More than 2 times mild bearable pain (2 score)	1 (1.5%)	1 (1.5%)	1 (1.5%)

thousand serious adverse effects with propofol sedation during EGD requiring cardiopulmonary resuscitation and mechanical ventilation [4]. Furthermore, Wadhwa et al. conducted a meta-analysis comprising 27 studies comparing the side effects of propofol and non-propofol anesthetic agents (Midazolam, Meperidine, Pethidine, Remifentanyl, and/or Fentanyl) in patients who underwent endoscopy for various indications. The study concluded that all sedative anesthetic drugs had an equal ratio

of cardiopulmonary adverse events with an odd ratio of 0.82 and a similar risk of unplanned events noted between propofol and non-propofol groups [21].

The concerns with over-sedation and cardiopulmonary tradeoffs have driven the UK to reduce the dose of midazolam to 2-5 mg in patients less than 70 years old and 1-2 mg in patients above the age of 70 [22]. Moreover, endoscopy cost increase significantly

with the use of sedation. Furthermore, the patient requires hospitalization until recovery. In addition, it has implications requiring 24-hour care and time off from work [23].

Hence, non-sedated endoscopic procedures with local anesthetic agents could be more cost-effective in the avoidance of sedation-related adverse events. Certain Scandinavian centers regularly perform colonoscopies without sedation and numerous European nations don't give sedation for EGD. Published literature has proposed the use of a variety of different local anesthetics such as lidocaine spray, viscous solution, lollipops, lozenges, etc. But implications of these agents are under debate as unpleasant experiences have been reported regarding their tolerability and efficacy [4,24,25].

Intubation techniques in EGD have been modified with the invention of slimmer endoscopes that allow intubation to be performed under direct vision. This can be less traumatic and local anesthesia could allow the examination to be accomplished more effectively. Serious hypersensitive reactions were considered a risk with the utilization of local anesthesia in earlier publications, but this is rare in current practice. There's a bigger concern about overdosing with local anesthetics causing cardiac arrhythmias and even cardiopulmonary arrest. This is perhaps due to the quick absorption of local anesthetics by mucous membranes [12]. Therefore, the dose has been restricted to 200mg and 100mg in adults and youngsters respectively to prevent adverse events. Patients who have received local throat anesthesia are at increased risk of aspiration and post-procedure respiratory disorder. This could be avoided by restricting oral intake until the throat sensation is recovered [25,26].

Many published studies showed better tolerance and acceptability of EGD with local throat anesthetics agents. Ayoub et al. showed lidocaine throat spray is superior to lollipops and lozenges as it is associated with more patient satisfaction and comfort and reduces anxiety and pain. They also suggested that lidocaine spray when combined with pharyngeal anesthesia on the endoscope tip can help improve patient experience thereby enhancing tolerability to EGD compared to pharyngeal anesthesia alone [27].

In a large trial comprising around 900 patients, Amornyotin et al. showed that the use of lidocaine spray for EGD has been demonstrated with improved procedure completion rate, ease of intubation, and better patient and endoscopist satisfaction. Pre-EGD topical lidocaine spray may provide more effective pharyngeal anesthesia than viscous lidocaine solution and lozenges [28].

Park et al. conducted a large trial comprising 1300 participants, comparing emergency endoscopic variceal ligation with and without sedation in cirrhotic patients presenting with variceal bleeding. Their study concluded that there was no significant difference in procedure failure and completion rate and 30-day mortality among the two groups. However, procedure time was shorter in the sedation group as compared to the non-sedation group (12.4 ± 9.5 min versus 13.8 ± 9.4 min). However, this study did not assess the comfort score between the two groups [29].

Our findings suggest that EVL in cirrhotic patients can be conducted safely while using lidocaine throat spray. Patients who had diagnostic gastroscopies with or without biopsies reported equal

comfort scores. EVL without propofol and conscious sedation has many advantages including a higher safety profile, shorter hospital stays, and minimal requirements for overnight care and time off from work. Further well-controlled randomized studies are required to guide the transition from sedation to local anesthetics.

Abbreviations

EVL: Endoscopic variceal ligation; EGD: Esophagogastroduodenoscopy; GI: Gastrointestinal; CUEs: Cardiopulmonary unplanned events; PKLI&RC: Pakistan Kidney and Liver Institute and Research Center; HCV: Hepatitis C virus; HBV: Hepatitis B virus

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Conflict of Interest

The authors declare no conflict of interest.

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