

Evaluating the Safety Profile of Propofol Sedation in Patients Undergoing Endoscopic Variceal Band Ligation: A Comprehensive Analysis

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Abstract

Objective: To find out the incidence of complications of Endoscopic Variceal Band Ligation, when done under Propofol sedation.

Methods: This was a retrospective observational study, which was conducted in the Gastroenterology department, PAF Hospital. From 1st Feb 2019 to 30th June 2023. Patients who underwent Endoscopic Variceal Band Ligation were included in the study. Anesthesia was provided using Propofol and Midazolam. Endoscopic variceal band ligation was carried out by a consultant gastroenterologist. Incidence of complications during the procedure and within 48 hours was noted.

Results: Out of 385 patients included in the study, re-bleeding was reported in 8 patients (2.1%), bacteremia in 8 patients (2.1%), hypotension in 77 patients (20%), and hypoxia in 56 patients (14.5%). The rest of the complications such as perforation, Mallory-Weis tear, cardiac arrhythmias, and myocardial infarction were not observed in any patient.

Conclusion: Propofol is a safe drug for deep sedation during Endoscopic Variceal Band Ligation associated with reduced complication risk.

MeSH Keywords: Propofol, Endoscopy, Bacteremia, hypoxia.

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1. Introduction

Gastro-esophageal varices are present in about 50% of patients with liver cirrhosis. A high risk of mortality and morbidity is associated with variceal bleeding (15–20% mortality rate in 6 weeks with each episode). The management involves pharmacological, endoscopic, and radiological interventions. The three stages of management include primary prophylaxis, active bleeding, and secondary prophylaxis. Prevention of variceal bleeding includes primary and secondary prophylaxis. Being a medical emergency active variceal bleeding requires immediate intervention to control bleeding and establish long-term hemostasis.¹

Upper gastrointestinal endoscopy is the gold standard method for diagnosing and treating variceal bleeding.² Endoscopic Variceal band ligation should be performed within 12 hours of bleeding diagnosis.³ Levels of sedation that can be provided during an Upper GI Endoscopy are minimal sedation, moderate sedation (*conscious sedation*), deep sedation, and general Anesthesia.⁴

There has been an increase in anaesthesia involvement during endoscopic procedures since 2000 due to its numerous benefits that involve pain-free procedures,

increased cooperation, and willingness of patients to re-undergo the procedure.⁵

Complications that may arise during or following an upper GI endoscopy under moderate sedation include bacteremia (4%), delayed bleeding (3.6–5.8%), perforation (0.1%), Mallory-Weis Tear (less than 0.1%), and aspiration.^{6–8}

Propofol (2, 6-di-isopropyl phenol) is an ultra-short-acting drug with effects such as sedation, amnesia, and hypnosis with no analgesic properties. Propofol can rapidly cross the blood-brain barrier and cause a depressed consciousness that is probably related to potentiation of the gamma-aminobutyric acid. It provides deep sedation. Propofol is preferred due to its Rapid onset, favourable pharmacodynamics, mild antiemetic properties, potentially more effective, rapid termination of effect, and expedited recovery.⁹

In Pakistan, the majority of Gastroenterologists perform Upper GI Endoscopy without sedation or under moderate sedation. The purpose of the study was to assess the Safety of Propofol as a sedative in patients undergoing Upper GI Endoscopy and the relative incidence of complications occurring during Endoscopic Variceal Band Ligation when performed under deep sedation.



2. Materials & Methods

It is a retrospective observational study conducted at the Gastroenterology Department of PAF Hospital, Islamabad for 53 months (1st Feb 2019 to 30th June 2023). Approval from the Institutional Ethical Committee was obtained. A total of 385 patients were selected through a convenient sampling technique. The sample size was calculated using an online sample size calculator.

Patients 40 - 70 years of age who were diagnosed with Bleeding Gastroesophageal varices and underwent Endoscopic Variceal Band Ligation were included in the study. Patients with heart failure (Ejection fraction below 45%), deranged vital signs, and those who are allergic to propofol were not included in the study.

Patients presenting with symptoms of upper GI bleed were scheduled for Endoscopy. To achieve durable hemostasis Infusion Octreotide 15µg/hour, Infusion Omeprazole 8µg/hour, Injection Ceftriaxone 1gm q12hr, Injection Vitamin-K, blood or blood products were administered:

Anesthesia fitness was carried out by the anaesthesia team. Clinical examinations were performed. Monitors were attached. Vital signs, electrocardiograms, and capnograms were obtained. Deep sedation was provided with Propofol (30-80mg) and Midazolam (2-3mg) as per requirements by the anaesthesia team. Upper GI Endoscopy with Variceal Band Ligation was carried out by a consultant Gastroenterologist, using an Olympus endoscope. The duration of the procedure ranged from 15-30 minutes. Patients' symptoms, vital signs, electrocardiograms, and capnograms were continuously monitored during and till one hour after the procedure. The patients were either admitted to the inpatient or were followed up on an outpatient basis. Any abnormal changes in general condition, symptoms, and laboratory investigations, within 48 hours, were noted. Data is displayed in the form of tables and figures as appropriate. Quantitative data is presented as mean and standard deviation and qualitative data as numbers and percentages. Data was analyzed using Statistical Package for Social Sciences (SPSS) version 20 with a 0.05 level of significance. Comparisons were made by applying paired t-test and Fischer test.

3. Results

In our study population, out of 385 patients, there were 195 males (50.6%) and 190 females (49.4%). Most of the participants 332 (86%) were 40-69 years of age as shown in Table 1.

Table 1: Demographic Variable

Variables	Number(n)	Percentage(%)
Age		
40-49	26	6.8
50-59	163	42.3
60-69	169	43.9
70-75	27	7.0
Sex		
Male	196	50.6
Female	190	49.4

In our research, we found out that the most common causes of Portal Hypertension for which they are undergoing the procedure of EVBL are Hepatitis C chronic liver disease (60.3%), Portal Vein Thrombosis (19.2%) and Non-alcoholic steatohepatitis (7.8%) as shown in Figure 1.

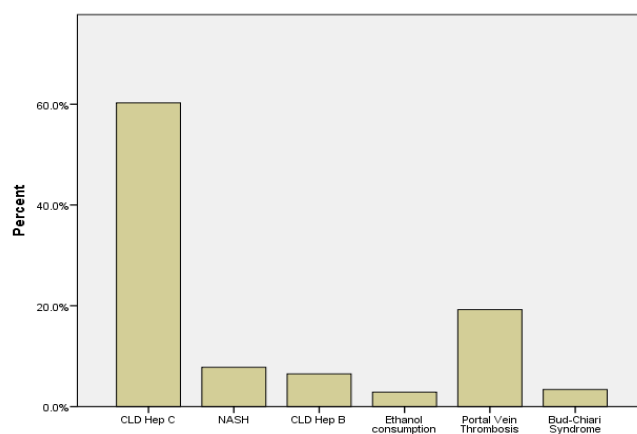


Figure 1: Underlying Cause of Portal Hypertension

Among the 385 patients who underwent endoscopic variceal band ligation, 8 patients (2.1%) suffered from re-bleeding, 8 patients (2.1%) suffered from bacteremia, 56 patients (14.5%) suffered from hypoxia, and 77 patients (20%) suffered from hypotension. 236 patients (61%) of the patients faced no complications as shown in Figure 2. The rest of the complications such as perforation, Mallory-Weis tear, cardiac arrhythmias, and myocardial infarction were not observed in any patient. The mean systolic blood pressure fall after the procedure was 108.56 ±13.92 mm of Hg, the mean pulse rate was 86.34 ±9.78 and the mean O₂ saturation was 93.90 ±3.010 as shown in Table 2.

Table 2: Changing in vital signs before and after EVBL

Variables	Before Procedure	After Procedure
Systolic Blood Pressure	116.88±16.52	108.56±13.92
Pulse Rate	83.24±14.11	86.34±17.78
SpO ₂	95.00±2.562	93.90±3.010

The EVBL lead to a significant increase in all inflammatory markers (p value<0.05) as shown in Table 3.

Table 3: Comparison between inflammatory markers before and after intervention

Variables	Before EVBL	After EVBL	P-value
1 st hour ESR	12.800±6.624	30.000±28.256	0.002
2 nd hour ESR	18.568±8.386	44.927±27.179	0.001
CRP	2.380±1.841	7.934±3.789	0.002
TLC	5.369±1.764	6.416±3.011	0.004

*p-value based on paired t-test. Statistical significance at $p < 0.05$

The incidence rate of bacterial infection among patients who had EVBL was 2.1% using blood culture. Out of 8 patients who developed bacteremia 5 were male and 3 were female. 5 patients who developed bacteremia, underwent EVBL procedure due to portal vein thrombosis (p -value 0.049) as shown in table 4.

Table 4: Association between bacterial infection after EVBL with gender and underlying aetiology for which they underwent EVBL

Clinical Characteristic	Bacterial infection by culture		P value
	Absent (n=377)	Present (n=8)	
Gender			
Male	190(50.4)	5(62.5)	0.190*
Female	187(49.6)	3(37.5)	
Underlying aetiology			
Portal Vein Thrombosis	69	5(62.5)	0.049*
CLD Hep C	230	2(25)	0.070*
CLD Hep B	24	1(12.5)	0.178*
NASH	30	0(0)	0.645*
Budd Chiari Syndrome	13	0(0)	0.289*
Ethanol Consumption	11	0(0)	0.397*

*p-values are based on Fischer's exact test. Statistical significance at $p < 0.05$

4. Discussion

In our study, the incidence of rebleeding following the EVBL was 2.1%. This is significantly low as compared to the incidence of re-bleeding during a moderately sedated EVBL (9.7%) as Sohaib et al (20%). This variation may be because they selected only those patients who have cirrhosis for EVBL, while in our study patients who underwent variceal banding have many underlying pathophysiology.¹⁰

The study published by Deaf M *et al* revealed the incidence of bacteremia in moderately sedated endoscopy to be 4%. In our study of sedated endoscopy, the incidence was comparatively lower (2.1%).⁶

In our study, the incidence of hypoxia was 14.5%. This was comparable to the study of Pasquale *et al* (2%), who recorded the safety of deep sedation with propofol in patients undergoing endoscopic retrograde cholangiopancreatography.¹¹ However, this complication can be significantly reduced by providing high-flow O₂ at 2L/minute to the patient 1 minute before the procedure, according to research published by Hyunil *et al*.¹²

In our study, 20% of the patients suffered from hypotension (systolic blood pressure ≤ 90 mmHg). This was comparable with the research published by J. Robert et al (36%).¹³ However, his research consisted of the incidence of hypotension during Propofol sedated colonoscopy. His research is used for comparison as the literature on the incidence of hypoxia in sedated endoscopies is inadequate. There was no incidence of rest of the complications; perforation, Mallory-Weiss's tear, myocardial infarction, cardiac arrhythmias, and hypertension, during our study. Our study limitations include data collection from a single hospital, absence of a control group, restriction to individuals aged 40 and 70, and limited follow-up after 48 hours of EVBL.

5. Conclusion

Our study highlights the importance of careful patient selection and continual vital monitoring both during and after the procedure. Studies contribute to the evidence that Propofol is a safe drug to provide deep sedation in patients with bleeding esophageal varices undergoing endoscopic variceal band ligation and it will help the clinicians to make more informed decisions when managing the patients undergoing endoscopic variceal band ligation, ultimately improving quality of care.

INSTITUTIONAL REVIEW BOARD

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Contributions:

A.S - Conception of study

- Experimentation/Study Conduction

A.S, M.R, M.B.S - Analysis/Interpretation/Discussion

M.R, M.T, M.Z.T - Manuscript Writing

M.S.M - Critical Review

All authors approved the final version to be published & agreed to be accountable for all aspects of the work.

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