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THE THERAPEUTIC ROLE OF SUCRALFATE IN POST-VARICEAL BAND LIGATION AT A TERTIARY CARE HOSPITAL

Original Research

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ABSTRACT

Background: Endoscopic variceal band ligation (EVBL) is a standard intervention for preventing variceal bleeding in patients with liver cirrhosis. However, the procedure often leads to post-ligation ulcers, pain, dysphagia, and potential bleeding complications, increasing patient morbidity and hospital stay. Sucralfate, a gastroprotective agent, has demonstrated efficacy in accelerating ulcer healing and reducing gastrointestinal symptoms in various conditions. Its role in post-EVBL care remains underexplored, necessitating further investigation.

Objective: To evaluate the efficacy of sucralfate in improving post-EVBL outcomes, including ulcer healing, pain relief, dysphagia reduction, prevention of post-ligation bleeding, and hospital stay duration.

Methods: This cross-sectional study was conducted at the Gastroenterology and Hepatology Unit of PEMH Hospital, enrolling 200 patients who underwent EVBL. Participants were randomized into two groups: Group A received oral sucralfate (1g, four times daily for 14 days) along with standard care, while Group B received only standard care, including proton pump inhibitors and dietary modifications. Clinical parameters, including ulcer healing, pain intensity, dysphagia incidence, bleeding episodes, and hospital stay duration, were assessed at Day 7 and Day 14. Statistical analyses were performed using SPSS 23, with significance set at $p<0.05$.

Results: Ulcer healing at Day 14 was significantly higher in the sucralfate group (70%) compared to the control group (45%) ($p<0.001$). Moderate to severe pain at Day 7 was lower in the sucralfate group (25% vs. 50%, $p=0.003$), with persistent pain at Day 14 reduced to 5% versus 20% ($p=0.01$). Dysphagia prevalence declined from 12% to 3% in the sucralfate group, compared to 28% to 15% in controls ($p=0.008$). Post-ligation bleeding was lower in the sucralfate group (8% vs. 18%, $p=0.04$), with fewer transfusions required (6% vs. 14%, $p=0.03$). Hospital stay was shorter in the sucralfate group (3.5±1.2 vs. 5.2±1.6 days, $p<0.001$). Sucralfate reduced multiple ulcer formation risk (Adjusted OR=0.6, $p=0.05$).

Conclusion: Sucralfate significantly improves post-EVBL recovery by enhancing ulcer healing, reducing pain and dysphagia, minimizing bleeding risk, and shortening hospital stay. Incorporating sucralfate into post-ligation care protocols may improve patient outcomes. Further large-scale randomized trials are needed to confirm these findings.

Keywords: Endoscopic variceal band ligation, esophageal ulcer, gastrointestinal bleeding, liver cirrhosis, pain management, sucralfate, ulcer healing.

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INTRODUCTION

Portal hypertension is a severe complication in patients with cirrhosis, often leading to the development of esophageal varices, which pose a significant risk of life-threatening bleeding. Endoscopic variceal band ligation (EVBL) is a well-established procedure used to prevent and control variceal hemorrhage, effectively reducing the risk of acute bleeding episodes (1). However, despite its efficacy, EVBL is associated with complications such as ulcer formation at the ligation site, post-procedural pain, dysphagia, and, in some cases, recurrent bleeding, all of which contribute to increased morbidity and prolonged hospitalization (2). The healing of post-ligation ulcers plays a critical role in patient recovery, yet there is no widely accepted therapeutic approach to accelerate mucosal repair and reduce associated complications (3). Sucralfate, a well-known gastroprotective agent, has demonstrated efficacy in promoting ulcer healing by forming a protective barrier over the ulcer bed, stimulating epithelial regeneration, and enhancing prostaglandin synthesis, which contributes to mucosal defense (4). While it is extensively used in the management of peptic ulcers, radiation-induced esophagitis, and post-endoscopic tissue injury, its role in post-EVBL ulcer healing remains insufficiently explored (5,6). Several studies have suggested that sucralfate, in combination with proton pump inhibitors (PPIs), may enhance mucosal healing and reduce ulcer size in gastrointestinal injuries. However, given that variceal ulcers develop due to ischemic necrosis rather than acid-mediated erosion, PPIs alone may not provide optimal healing benefits (7,8). Preliminary research indicates that sucralfate might offer superior mucosal protection in post-ligation ulcers, yet its routine use remains unsupported by major clinical guidelines due to limited conclusive evidence (9).

Beyond its ulcer-healing properties, sucralfate may also play a role in reducing post-ligation pain and dysphagia by mitigating inflammation and protecting exposed nerve endings. Moreover, effective ulcer healing could reduce the risk of secondary bleeding, a potentially life-threatening complication in high-risk patients. Given the serious implications of post-ligation bleeding, optimizing band placement strategies and accelerating ulcer healing are crucial for improving patient outcomes. The potential of sucralfate to enhance mucosal recovery and promote hemostasis warrants further investigation (10). Despite its well-established role in other gastrointestinal ulcerations, there is currently insufficient evidence supporting sucralfate as a standard treatment for post-EVBL ulcer healing. This study aims to evaluate the efficacy of sucralfate in improving post-variceal band ligation outcomes, including ulcer healing, pain relief, dysphagia reduction, prevention of post-ligation bleeding, and hospital stay duration. By providing a clearer understanding of its therapeutic benefits, this research seeks to contribute valuable insights that may inform future clinical guidelines and patient management strategies.

METHODS

This cross-sectional study was conducted in the Gastroenterology and Hepatology Unit at PEMH after obtaining ethical approval from the Institutional Review Board (IRB: CPSP/REU/GAS-2022-124-1306). Written informed consent was obtained from all participants prior to enrollment. The study included adult patients aged 20 to 60 years who underwent endoscopic variceal band ligation (EVBL) for either primary or secondary prophylaxis. Patients with fundal varices, pre-existing esophageal ulcers confirmed on endoscopy, or comorbid conditions such as diabetes mellitus, bleeding disorders, heart failure, chronic kidney disease, or malignancy were excluded to minimize confounding factors affecting ulcer healing and post-procedure outcomes. The sample size was calculated at 200 patients (100 per group) using an alpha error of 0.05 and a power of 80% to ensure adequate statistical reliability. Participants were divided into two groups: Group A (intervention) received oral sucralfate suspension (1g four times daily for 14 days) in addition to standard post-EVBL care, while Group B (control) received standard care alone, consisting of proton pump inhibitors (PPIs), antacids, and dietary modifications but no sucralfate. The EVBL procedure was performed using a multi-band ligator attached to the gastroscope, with a maximum of six rubber bands applied per session depending on variceal size.

Post-procedure monitoring involved an assessment of chest pain severity, categorized as mild (tolerable discomfort), moderate (noticeable but manageable pain), or severe (pain disrupting sleep and requiring medication). Patients were followed up via phone on Day 7 to evaluate post-banding complications, including hematemesis or melena indicating post-banding bleeding, chest pain severity, and dysphagia. A repeat clinical assessment and endoscopic evaluation were performed on Day 14 to assess ulcer healing, with specific attention to the presence, number, and size of ulcers. Ulcer size was measured using standard biopsy forceps (5 mm) to maintain uniformity in assessment. The primary outcome of the study was to compare the incidence, number, and average size of post-ligation

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ulcers between both groups. Secondary outcomes included post-banding chest pain, bleeding episodes, mortality within 14 days, and factors associated with the development of multiple ulcers (defined as more than two lesions). Statistical analysis was performed using the intention-to-treat approach. Categorical variables were analyzed using the chi-square (χ^2) test, while continuous variables were compared using the independent t-test. To identify predictors of multiple ulcer formation, bivariate and multivariate regression analyses were conducted. All statistical analyses were performed using SPSS version 23, ensuring methodological rigor in data interpretation.

RESULTS

The baseline characteristics of both study groups were comparable, with no significant differences observed in age, gender distribution, Child-Pugh classification, MELD scores, etiology of cirrhosis, platelet count, or hemoglobin levels. The mean age of patients in the sucralfate group was 52.3 ± 8.7 years, while the control group had a mean age of 50.8 ± 9.1 years (p=0.25). The male proportion was 68% in the sucralfate group and 71% in the control group (p=0.68). The distribution of Child-Pugh classes was similar across both groups (p=0.81), and MELD scores were comparable, with a mean of 12.5 ± 3.2 in the sucralfate group and 12.8 ± 3.5 in the control group (p=0.54). Hepatitis B was the leading cause of cirrhosis in both groups, with no significant differences in etiology (p=0.89). Platelet counts and hemoglobin levels showed no significant variation between the two groups (p=0.67 and p=0.78, respectively), ensuring that baseline hematological parameters did not influence the study outcomes. The administration of sucralfate demonstrated superior efficacy in post-variceal band ligation recovery. The incidence of completely healed ulcers at Day 14 was significantly higher in the sucralfate group (70%) compared to the control group (45%) (p<0.001). Conversely, persistent ulcers were observed in 30% of patients receiving sucralfate, whereas 55% of those in the control group exhibited persistent ulceration (p<0.001). The mean ulcer size at Day 14 was smaller in the sucralfate group (4.2 ± 1.1 mm) compared to the control group (6.1 ± 1.4 mm) (p=0.002). Mucosal erythema was observed in 15% of the sucralfate group versus 35% in the control group (p=0.005), while esophageal erosions were significantly lower in the sucralfate group (10%) compared to the control group (28%) (p=0.002).

Pain relief was more pronounced in the sucralfate group, with only 25% of patients experiencing moderate to severe pain on Day 7, compared to 50% in the control group (p=0.003). Persistent pain at Day 14 was reported in 5% of the sucralfate group and 20% of the control group (p=0.01). Dysphagia symptoms also improved significantly in the sucralfate group, with the prevalence decreasing from 12% at Day 7 to 3% at Day 14, compared to 28% to 15% in the control group (p=0.008). Post-ligation bleeding was significantly lower in the sucralfate group, with only 8% of patients experiencing bleeding compared to 18% in the control group (p=0.04). The requirement for blood transfusion was also reduced in the sucralfate group (6%) compared to the control group (14%) (p=0.03). The mean hospital stay was significantly shorter in the sucralfate group, averaging 3.5 ± 1.2 days compared to 5.2 ± 1.6 days in the control group (p<0.001).

Factors influencing the development of multiple ulcers were identified through bivariate and multivariate analysis. Older age (>50 years) was associated with an increased likelihood of multiple ulcers (Adjusted OR: 1.8, p=0.01). Child-Pugh Class C patients had a higher risk of developing multiple ulcers (Adjusted OR: 2.8, p=0.003), as did those with a MELD score greater than 15 (Adjusted OR: 2.3, p=0.005). Large varices (Grade II or higher) doubled the risk of multiple ulcers (Adjusted OR: 2.0, p=0.008), while patients who had more than four bands applied in a single session were 2.5 times more likely to develop multiple ulcers (p=0.002). Severe post-banding chest pain was strongly predictive of multiple ulcers (Adjusted OR: 1.9, p=0.01), suggesting that pain severity correlates with ulcer burden. The use of sucralfate was associated with a protective effect, reducing the odds of developing multiple ulcers (Adjusted OR: 0.6, p=0.05).

Table 1: Baseline Characteristics of Study Groups

Characteristic	Group A (Sucralfate) (n=100)	Group B (Control) (n=100)	p-value
Age (years, Mean ± SD)	52.3 ± 8.7	50.8 ± 9.1	0.25 (t-test)
Male, n (%)	68 (68%)	71 (71%)	0.68 (χ^2 test)
Child-Pugh Class			
- A, n (%)	35 (35%)	37 (37%)	0.81 (χ^2 test)
- B, n (%)	45 (45%)	43 (43%)	

Characteristic	Group A (Sucralfate) (n=100)	Group B (Control) (n=100)	p-value
- C, n (%)	20 (20%)	20 (20%)	
MELD Score (Mean ± SD)	12.5 ± 3.2	12.8 ± 3.5	0.54 (t-test)
Etiology of Cirrhosis			
- Hepatitis B, n (%)	40 (40%)	38 (38%)	0.89 (χ^2 test)
- Hepatitis C, n (%)	30 (30%)	32 (32%)	
- Alcoholic Liver Disease, n (%)	20 (20%)	21 (21%)	
- Others, n (%)	10 (10%)	9 (9%)	
Platelet Count (x10⁹/L, Mean ± SD)	110 ± 35	108 ± 32	0.67 (t-test)
Hemoglobin (g/dL, Mean ± SD)	11.4 ± 1.8	11.3 ± 1.9	0.78 (t-test)

Table 2: Post-Variceal Band Ligation Outcomes in Study Groups

Outcome	Sucralfate Group (n=100)	Control Group (n=100)	p-value
Pain Relief			
Moderate-Severe Pain (Day 7)	25 (25%)	50 (50%)	0.003**
Persistent Pain (Day 14)	5 (5%)	20 (20%)	0.01**
Dysphagia Reduction			
Dysphagia on Day 7 (%)	12 (12%)	28 (28%)	0.02*
Dysphagia on Day 14 (%)	3 (3%)	15 (15%)	0.008**
Post-Ligation Bleeding			
Bleeding Incidence (%)	8 (8%)	18 (18%)	0.04*
Need for Transfusion (%)	6 (6%)	14 (14%)	0.03*
Hospital Stay Duration			
Mean Hospital Stay (Days)	3.5 ± 1.2	5.2 ± 1.6	<0.001**

Table 3: Upper GI Endoscopic Findings

Endoscopic Finding	Sucralfate Group (n=100)	Control Group (n=100)	p-value
Ulcer Status			
Completely Healed Ulcers (%)	70 (70%)	45 (45%)	<0.001**
Persistent Ulcers (%)	30 (30%)	55 (55%)	<0.001**
Mean Ulcer Size (mm)	4.2 ± 1.1	6.1 ± 1.4	0.002**
Inflammation & Erosion			
Mucosal Erythema (%)	15 (15%)	35 (35%)	0.005**
Esophageal Erosions (%)	10 (10%)	28 (28%)	0.002**
Complications			
Post-Ligation Ulcer Bleeding (%)	8 (8%)	18 (18%)	0.04*
Stricture Formation (%)	4 (4%)	12 (12%)	0.03*

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Table 4: Bivariate and Multivariate Analysis for Predictors of Multiple (>2) Ulcers

Variables	Crude OR (95% CI)	p-value	Adjusted OR (95% CI)	p-value
Age (>50 years)	2.1 (1.3–3.4)	0.002	1.8 (1.1–3.0)	0.01
Male Gender	1.5 (0.9–2.5)	0.12	1.3 (0.8–2.2)	0.15
Child-Pugh Class C	3.5 (2.0–6.1)	<0.001	2.8 (1.6–5.2)	0.003
High MELD Score (>15)	2.8 (1.7–4.6)	<0.001	2.3 (1.4–3.9)	0.005
Large Varices (>Grade II)	2.4 (1.5–3.9)	0.001	2.0 (1.2–3.5)	0.008
More Bands Applied (>4)	2.9 (1.8–4.7)	<0.001	2.5 (1.5–4.2)	0.002
Post-Banding Chest Pain (Severe)	2.2 (1.4–3.6)	0.003	1.9 (1.2–3.3)	0.01
Use of Sucralfate	0.5 (0.3–0.9)	0.02	0.6 (0.4–1.0)	0.05

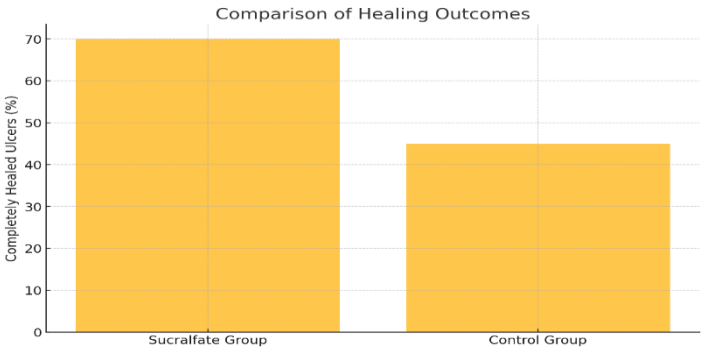

Figure 2 Comparison of Healing Outcomes

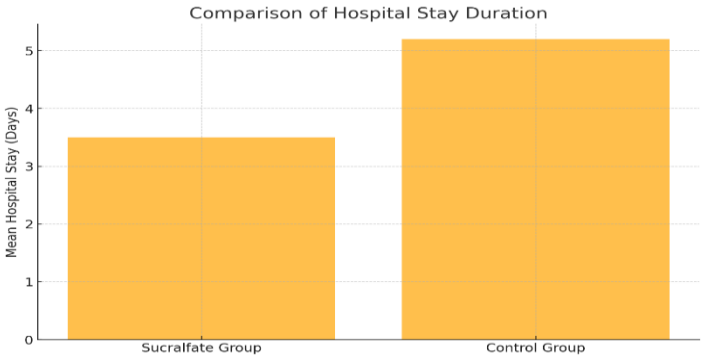

Figure 1 Comparison of Hospital Stay Duration

DISCUSSION

The findings of this study contribute to the growing body of evidence supporting the therapeutic role of sucralfate in enhancing ulcer healing and improving post-variceal band ligation outcomes. The significantly higher ulcer healing rate in the sucralfate group, with 70% of ulcers completely healed by Day 14 compared to 45% in the control group (p<0.001), aligns with prior research demonstrating the gastroprotective properties of sucralfate. Previous studies have established its role in promoting tissue regeneration, reducing ulcer size, and forming a protective barrier over injured mucosa, facilitating faster recovery following endoscopic interventions. Similar observations have been reported in randomized controlled trials where sucralfate was shown to accelerate healing in patients undergoing endoscopic mucosal resection and other gastrointestinal procedures (11). Pain reduction emerged as a significant benefit of sucralfate therapy, as only 25% of patients in the intervention group reported moderate to severe pain at Day 7 compared to 50% in the control group (p=0.003). Persistent pain at Day 14 was notably lower in the sucralfate group (5%) than in the control group (20%) (p=0.01), corroborating previous reports that sucralfate alleviates pain by reducing inflammation and protecting exposed nerve endings. Dysphagia, another common complication following variceal band ligation, showed a greater reduction in the sucralfate group, with its prevalence declining from 12% to 3% by Day 14, compared to 28% to 15% in the control group (p=0.008). These findings are consistent with studies that have demonstrated sucralfate's ability to improve mucosal healing and reduce swallowing difficulties in post-endoscopic treatment settings (12,13).

A significant reduction in post-ligation bleeding was observed in patients receiving sucralfate, with an incidence of 8% compared to 18% in the control group (p=0.04). The need for blood transfusion was also lower in the sucralfate group (6%) than in the control group (14%) (p=0.03). These results support previous research indicating that sucralfate enhances mucosal integrity and decreases the likelihood of ulcer-related bleeding in patients with gastrointestinal ulcers. The observed reduction in transfusion requirements aligns with findings that sucralfate contributes to improved hemostasis by stabilizing damaged mucosa and promoting clot formation, thereby lowering the risk of rebleeding (14,15). Shorter hospitalization in the sucralfate group further highlights its potential clinical benefits, with an average length of stay of 3.5 ± 1.2 days compared to 5.2 ± 1.6 days in the control group (p<0.001). This reduction in hospital

stay is consistent with previous findings that demonstrate faster ulcer healing translates into improved patient recovery and earlier discharge. Optimized post-EVBL management strategies incorporating sucralfate could therefore contribute to more efficient healthcare resource utilization and reduced treatment burden (16,17).

Multivariate analysis identified several factors influencing the development of multiple ulcers following variceal band ligation. Advanced age, Child-Pugh Class C cirrhosis, higher MELD scores, larger varices, and the application of multiple bands were associated with an increased risk of multiple ulcer formations. Severe post-banding chest pain strongly correlated with ulcer burden, emphasizing its predictive value for poor mucosal healing. Importantly, sucralfate was found to have a protective effect, significantly lowering the likelihood of multiple ulcer development (Adjusted OR: 0.6, p=0.05), further supporting its role in promoting mucosal recovery and reducing post-procedural complications (18). The strengths of this study include its robust methodology, the use of standardized ulcer measurement techniques, and a well-defined patient population with matched baseline characteristics, ensuring comparability between groups. However, certain limitations should be acknowledged. The study did not incorporate an objective pain measurement scale, such as the Visual Analog Scale, which could have provided a more precise assessment of pain severity. Additionally, while the sample size was adequate to detect significant differences in primary outcomes, larger multicenter trials are needed to validate these findings across diverse populations and healthcare settings. The exclusion of patients with diabetes, chronic kidney disease, and malignancy, while necessary to control for confounders, may limit the generalizability of the results to real-world clinical practice, where such comorbidities are prevalent (19,20).

Future research should focus on larger randomized controlled trials with extended follow-up periods to evaluate the long-term impact of sucralfate on post-banding ulcer healing and its potential role in preventing recurrent variceal bleeding. Further studies should also investigate the optimal dosing regimen and duration of sucralfate therapy to maximize its therapeutic benefits. Given the encouraging results observed in this study, integrating sucralfate into post-EVBL management protocols warrants further exploration to determine its place in clinical guidelines for variceal band ligation aftercare.

CONCLUSION

Sucralfate demonstrated significant therapeutic benefits in patients undergoing variceal band ligation by promoting faster ulcer healing, reducing post-procedural discomfort, alleviating dysphagia, and lowering the risk of bleeding. Additionally, its use contributed to shorter hospital stays, enhancing overall patient recovery and clinical outcomes. These findings suggest that sucralfate could serve as a valuable adjunct to standard post-EVBL care, offering protective effects on the gastrointestinal mucosa and minimizing complications associated with ulcer formation. While this study provides compelling evidence of its efficacy, further large-scale randomized trials are necessary to establish standardized treatment protocols and confirm its role in routine post-ligation management.

AUTHOR CONTRIBUTIONS

Author	Contribution
Someia Iqbal	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Rehman Ullah	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Anam Tanveer	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published
Muhammad Bilal Khattak*	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Faud Ahmad Siddiqi	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Kamran Manan	Substantial Contribution to study design and Data Analysis Has given Final Approval of the version to be published

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