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Prospective Comparison of Endoscopic and Pharmacological Therapy Outcomes in Peptic Ulcer Patients

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ABSTRACT

Background
Peptic ulcer disease continues to pose a significant clinical challenge, especially in patients at risk for complications such as gastrointestinal bleeding and recurrence. Both endoscopic and pharmacological treatments are commonly employed, yet their comparative effectiveness in routine care remains underexplored.

Objective
This study aimed to compare clinical outcomes between endoscopic and pharmacological treatment approaches in patients with gastric or duodenal ulcers.

Methods
A prospective cohort study was conducted at two tertiary care hospitals from January to June 2024. A total of 120 patients were enrolled, with 60 receiving endoscopic therapy and 60 managed pharmacologically. Demographic, clinical, and endoscopic data were collected. Key outcomes included ulcer healing at 4 weeks, rebleeding within 3 months, ulcer recurrence, hospital stay duration, need for surgery, and treatment-related adverse events. Data were analyzed using SPSS version 26. Appropriate statistical tests were applied based on data type and distribution, including logistic regression for adjusted outcome analysis.

Results
Ulcer healing at 4 weeks was significantly higher in the endoscopic group (93.3% vs. 65.0%, $p < 0.001$). Rebleeding and ulcer recurrence were significantly lower in the endoscopic group. Patients receiving endoscopic therapy also had shorter hospital stays and required fewer surgical interventions. Logistic regression confirmed the treatment group as an independent predictor of healing and recurrence.

Conclusion
Endoscopic therapy was associated with better clinical outcomes compared to pharmacological management in patients with peptic ulcer disease. These findings support the broader use of endoscopic treatment beyond emergency settings.

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INTRODUCTION:

Peptic ulcer disease (PUD) remains a significant global health concern, with millions affected annually despite advancements in diagnostics and treatment [1]. The condition is characterized by mucosal breaks in the stomach or duodenum due to an imbalance between aggressive factors like gastric acid and pepsin, and protective mechanisms such as mucosal blood flow and bicarbonate secretion. Common etiological factors include Helicobacter pylori infection, nonsteroidal anti-inflammatory drug (NSAID) use, stress, and smoking [2, 3].

In recent decades, the management of peptic ulcers has evolved substantially, particularly with the introduction of proton pump inhibitors (PPIs) and Helicobacter pylori eradication therapy [4]. Pharmacological treatment remains the cornerstone for uncomplicated ulcers, offering symptom relief and promoting mucosal healing. However, complications such as upper gastrointestinal bleeding still occur and are often life-threatening, necessitating more urgent and invasive interventions [5].

Endoscopic therapy has become the standard of care in managing bleeding ulcers. Techniques such as thermal coagulation, injection therapy, and hemoclips not only arrest bleeding but also reduce the risk of recurrence and need for surgical intervention. Numerous studies have demonstrated its superiority in acute settings, particularly for high-risk lesions, with some also suggesting benefits in long-term healing rates[6].

Despite the established roles of both treatment modalities, direct comparisons between endoscopic therapy and pharmacological management for broader outcomes such as ulcer healing rates, rebleeding, recurrence, hospital stay, and need for surgery are still limited. While prospective cohort studies have shown the benefit of combining endoscopic therapy with PPIs in bleeding ulcers, few have explored how these strategies compare as stand-alone options in real-world clinical settings, especially over a short- to mid-term follow-up.

Most available literature emphasizes acute bleeding control, often in emergency settings, and underrepresents outcomes like recurrence and long-term healing in non-emergency patients. Moreover, existing studies frequently rely on randomized designs that may not reflect typical clinical workflows where treatment decisions are often guided by clinician preference or institutional protocols. This gap limits generalizability to routine hospital settings, especially in low- to middle-income countries.

Objective

The primary objective of this study is to compare the clinical outcomes of endoscopic and pharmacological treatments in patients with gastric or duodenal ulcers. Specifically, it aims to evaluate differences in ulcer healing at 4 weeks, rebleeding within 3 months, ulcer recurrence, hospital stay, and need for surgical intervention. By providing data from a prospective cohort in a real-world context, the study hopes to guide clinical decision-making and highlight areas for future therapeutic optimization.

METHODOLOGY

This was a prospective cohort study conducted from February to July 2024 to compare the outcomes of endoscopic versus pharmacological treatment in adult patients with peptic ulcer disease. The study was conducted at two tertiary care hospitals in Pakistan: DHQ Teaching Hospital KDA Kohat and Bahria International Hospital, Rawalpindi, between January and JUNE 2024. Both institutions provided ethical clearance for the research protocol.

A non-random consecutive sampling technique was used. All eligible patients presenting during the study period were screened and included if they met the selection criteria. Written informed consent was obtained from each participant prior to enrollment.

Ethical approval for the study was obtained from two institutions. The first approval was granted by the Ethical Review Board of DHQ Teaching Hospital KDA Kohat (Approval No. 5360/K-17, dated 30/12/2023). A second submission and approval request were also processed at Bahria International Hospital, Rawalpindi (BIH/Ph-8/Administrator/54/2024, dated 05/02/2024), under the supervision of their ethical committee. Both approvals confirmed that the study protocol met ethical standards and posed no risk to participants.

The required sample size was calculated using the standard formula for comparing two independent proportions:

$$n = \frac{(Z\alpha/2 + Z\beta)^2}{(p1-p2)^2} \times [p1(1-p1)+p2(1-p2)]$$

Where: $Z\alpha/2=1.96$ for a 95% confidence level, $Z\beta=0.84$ for 80% power, $p1=0.04$ (expected rebleeding rate in the endoscopic group), $p2=0.23$ (expected rebleeding rate in the pharmacological group), based on a study by Lau et al [7].

Substituting these values yielded a sample size of approximately 47 participants per group. To accommodate potential dropouts and incomplete follow-up, a 10% inflation was applied, resulting in a final sample size of 104 participants. However, the study enrolled 120 patients (60 in each group) to further strengthen statistical reliability.

Inclusion criteria adults aged 18 years or older, endoscopically confirmed gastric or duodenal ulcer, eligible for either endoscopic or pharmacological treatment based on clinical assessment and provided informed written consent. Exclusion Criteria suspected or confirmed malignant ulcer, history of gastric surgery, coagulopathy or current anticoagulant therapy, pregnancy or breastfeeding, hemodynamic instability unresponsive to initial management and incomplete follow-up or refusal to participate

Patients were not randomized. Group assignment was based on initial clinical presentation and physician judgment following institutional protocol:

Patients with active bleeding, high-risk stigmata (Forrest Ia, Ib, IIa), large ulcers (>10 mm), or hemodynamic compromise were managed with endoscopic therapy (e.g., injection, coagulation, or clips). Patients who were clinically stable, without high-risk features or bleeding, received pharmacological treatment alone, primarily high-dose proton pump inhibitors.

This reflects real-life decision-making in tertiary care and allowed natural clinical assignment to treatment arms. Group comparability was statistically adjusted during analysis using multivariate methods.

Baseline demographic data (age, gender), clinical factors (smoking status, NSAID use, comorbidities), and ulcer characteristics (location, size, presence of bleeding, hemoglobin levels, and H. pylori status) were documented at admission. Patients were followed up at 4 weeks and 3 months to assess ulcer healing, rebleeding, recurrence, need for surgery, hospital stay duration, adverse events, and treatment adherence.

Upper gastrointestinal endoscopy was performed using standard video endoscopes under conscious sedation by experienced gastroenterologists. Ulcer size and location were noted during endoscopy; large ulcers were defined as >10 mm. Bleeding ulcers were classified using the Forrest classification. H. pylori infection was diagnosed using the rapid urease test or histopathology. Laboratory investigations included a complete blood count (CBC) to assess hemoglobin and detect anemia.

The data collection tool was pilot-tested on 10 patients (excluded from final analysis) to refine clinical forms and ensure clarity. All endoscopic procedures were supervised by senior consultants to reduce observer bias. Data were double-entered and cross-verified for accuracy. Standardized protocols for both interventions and follow-up ensured consistency and enhanced internal validity.

Data were entered and analyzed using IBM SPSS Statistics Version 26. Descriptive statistics were calculated for all study variables. Categorical variables were presented as frequencies and percentages, while continuous variables were expressed as means and standard deviations.

The Shapiro–Wilk test and visual methods (histograms, Q–Q plots) were used to assess the normality of continuous variables including age, BMI, hospital stay duration, and symptom duration. All variables were normally distributed ($p > 0.05$), and therefore, independent samples t-tests were used for comparison of continuous variables between the treatment groups.

Group comparisons for categorical variables such as gender, smoking status, NSAID use, comorbidities, ulcer type, ulcer size, H. pylori status, GI bleeding, hemoglobin levels, treatment completion, adverse events, and clinical outcomes were performed using the Chi-square test or Fisher's exact test as appropriate. The Cramér's V test was applied to assess the strength of association for significantly associated categorical variables.

To evaluate the independent effect of treatment group (endoscopic vs. pharmacological) on ulcer healing at 4 weeks, rebleeding within 3 months, and ulcer recurrence at 3 months, binary logistic regression analysis was conducted. The following potential confounding variables were included in the regression models based on clinical relevance and prior associations: For ulcer healing at 4 weeks: Group, age, BMI, ulcer type, presence of GI bleeding. For rebleeding within 3 months: Group, age, BMI, presence of GI bleeding, ulcer size >10 mm. For ulcer recurrence at 3 months: Group, age, BMI, H. pylori status, treatment completion status Adjusted odds ratios (AORs), 95% confidence intervals (CIs), and p-values were reported for each model. A p-value < 0.05 was considered statistically significant.

RESULT

Table 1 presents the baseline demographic data for the two treatment groups. Statistically significant differences were observed in mean age and BMI. Patients in the pharmacological group were older on average (52.0 ± 1.89 years) compared to those in the endoscopic group (47.7 ± 1.82 years), with a p-value < 0.001. Similarly, the endoscopic group had a higher mean BMI (25.6 ± 1.00 vs. 24.6 ± 1.04; $p < 0.001$). No significant differences were observed in gender distribution, smoking status, or comorbid conditions. However, NSAID use was significantly more prevalent in the pharmacological group (71.7%) than in the endoscopic group (48.3%), indicating a possible risk factor influencing ulcer development and response to treatment.

Table 1. Baseline Demographic Characteristics of Patients (n = 120)

Variable	Endoscopic Group (n = 60)	Pharmacological Group (n = 60)	p-value	Cramér's V	Association
Age (years, mean ± SD)	47.7 ± 1.82	52.0 ± 1.89	<0.001*	—	—
Gender (Male)	29 (48.3%)	27 (45.0%)	0.714	0.033	Not Significant
BMI (kg/m², mean ± SD)	25.6 ± 1.00	24.6 ± 1.04	<0.001*	—	—
Smoking status (Yes)	24 (40.0%)	23 (38.3%)	0.852	0.017	Not Significant
NSAID use (Yes)	29 (48.3%)	43 (71.7%)	0.009*	0.238	Significant
Comorbidities present (Yes)	36 (60.0%)	31 (51.7%)	0.358	0.084	Not Significant

* Statistically significant at $p < 0.05$ Cramér's V only applies to categorical variables; it measures the strength of association (range 0 to 1).

Table 2 compares ulcer-related clinical features between groups. Gastric ulcers were significantly more common in the pharmacological group (68.3%) than the endoscopic group (38.3%), with a strong association (Cramér's V = 0.301, p = 0.001). Ulcer size, H. pylori positivity, GI bleeding, and hemoglobin levels did not show statistically significant differences. However, patients in the pharmacological group had a longer duration of symptoms prior to presentation (8.48 ± 0.94 days) compared to the endoscopic group (7.55 ± 1.03 days), which was statistically significant ($p < 0.001$), suggesting delayed care or recognition.

Table 2. Clinical Features and Ulcer Characteristics of Patients

Variable	Endoscopic Group (n = 60)	Pharmacological Group (n = 60)	p-value	Cramér's V	Association
Gastric ulcer	23 (38.3%)	41 (68.3%)	0.001*	0.301	Significant
Ulcer size >10 mm	38 (63.3%)	31 (51.7%)	0.196	0.118	Not Significant
H. pylori positive	31 (51.7%)	35 (58.3%)	0.463	0.067	Not Significant

GI bleeding present	22 (36.7%)	13 (21.7%)	0.071	0.165	Not Significant
Hemoglobin <10 g/dL	21 (35.0%)	17 (28.3%)	0.432	0.072	Not Significant
Symptom duration (days)	7.55 ± 1.03	8.48 ± 0.94	<0.001 *	—	Significant (t-test)

* Statistically significant at $p < 0.05$ — Cramér's V applies to categorical variables only; t-test was used for continuous variable.

Table 3 outlines treatment outcomes and follow-up results. The endoscopic group demonstrated markedly better clinical outcomes. Ulcer healing at 4 weeks was significantly higher (93.3%) compared to the pharmacological group (65.0%), and no cases of rebleeding were recorded in the endoscopic group versus 21.7% in the pharmacological group—both with highly significant p-values (< 0.001). Additionally, the mean hospital stay was shorter for the endoscopic group (3.48 days vs. 5.32 days; $p < 0.001$). Although the need for surgery did not differ significantly, ulcer recurrence at 3 months was significantly lower in the endoscopic group (3.3% vs. 16.7%, $p = 0.015$).

Table 3. Treatment Outcomes and Follow-Up Results

Outcome	Endoscopic Group (n = 60)	Pharmacological Group (n = 60)	p-value	Cramér's V	Association
Ulcer healing at 4 weeks	56 (93.3%)	39 (65.0%)	<0.001*	0.349	Significant
Rebleeding episodes	0 (0.0%)	13 (21.7%)	<0.001*	0.349	Significant
Hospital stay (mean ± SD)	3.48 ± 0.53 days	5.32 ± 0.50 days	<0.001*	—	Significant (t-test)
Need for surgery	3 (5.0%)	7 (11.7%)	0.186	0.121	Not Significant
Ulcer recurrence at 3 months	2 (3.3%)	10 (16.7%)	0.015*	0.222	Significant

* Statistically significant at $p < 0.05$

Table 4 evaluates adverse events and treatment adherence. While a greater percentage of patients in the endoscopic group completed treatment as prescribed (95.0% vs. 86.7%), this difference was not statistically significant. Similarly, adverse events and the requirement for blood transfusion were not significantly different between the two groups, suggesting comparable safety profiles for both treatment approaches.

Table 4. Additional Clinical Indicators: Adverse Events and Treatment Completion (n = 120)

Variable	Endoscopic Group (n = 60)	Pharmacological Group (n = 60)	p-value	Cramér's V	Association
Treatment completed as prescribed	57 (95.0%)	52 (86.7%)	0.114	0.144	Not Significant
Reported adverse events	3 (5.0%)	7 (11.7%)	0.186	0.121	Not Significant
Required blood transfusion	7 (11.7%)	6 (10.0%)	0.769	0.027	Not Significant

Table 5 summarizes the logistic regression analysis adjusting for key confounders. Endoscopic treatment was associated with significantly greater odds of ulcer healing at 4 weeks (AOR = 11.63, $p = 0.008$), indicating its effectiveness independent of age, BMI, ulcer type, and GI bleeding. Furthermore, it significantly reduced the likelihood of rebleeding within 3 months (AOR = 0.19, $p = 0.041$). However, while the odds of ulcer recurrence were higher in the pharmacological group, the difference was not statistically significant (AOR = 6.80, $p = 0.118$), possibly due to the limited number of recurrence events or follow-up duration.

Table 5. Logistic Regression Analysis for Adjusted Outcomes

Outcome Variable	Adjusted Odds Ratio (AOR)	95% Confidence Interval	p-value
Ulcer healing at 4 weeks	11.63	1.89 – 71.43	0.008*
Rebleeding (within 3 months)	0.19	0.04 – 0.94	0.041*
Ulcer recurrence (3 months)	6.80	0.61 – 75.19	0.118

* Statistically significant at $p < 0.05$

This chart clearly illustrates the differences in outcomes between the two treatment groups. Patients who received endoscopic therapy had a markedly higher ulcer healing rate at 4 weeks (93.3%) compared to those treated pharmacologically (65%). Rebleeding episodes were absent in the endoscopic group, whereas 21.7% of patients in the pharmacological group experienced rebleeding. Similarly, endoscopic treatment led to a shorter average hospital stay (3.5 vs. 5.3 days). Although surgical intervention was needed in both groups, it was slightly more frequent among patients managed pharmacologically. Ulcer recurrence at 3 months was significantly lower in the endoscopic group (3.3%) compared to the pharmacological group (16.7%). These results suggest a consistent advantage of endoscopic management over pharmacological treatment for short-term ulcer control and complication reduction.

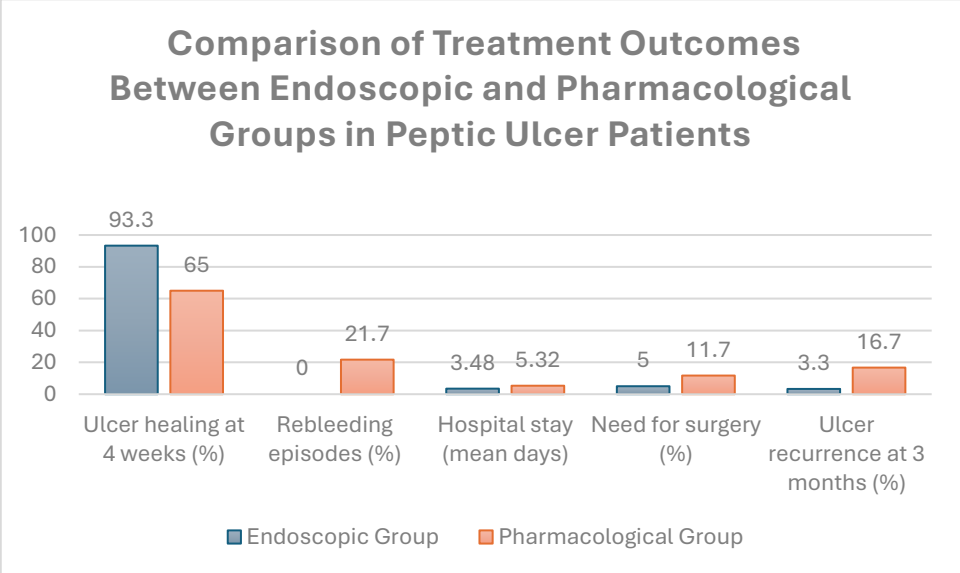

Figure 1
Bar chart comparing the clinical outcomes of endoscopic and pharmacological treatments among 120 peptic ulcer patients. The outcomes include ulcer healing at 4 weeks, rebleeding episodes, average hospital stay, need for surgery, and ulcer recurrence at 3 months.

DISCUSSION

This prospective cohort study investigated the effectiveness of endoscopic versus pharmacological treatment for peptic ulcer disease, focusing on ulcer healing at 4 weeks, rebleeding within 3 months, and ulcer recurrence at 3 months. Our findings indicate that endoscopic therapy significantly improves early ulcer healing and reduces rebleeding compared with pharmacological treatment. Although the odds of ulcer recurrence tended to be lower in the endoscopic group, this difference did not reach statistical significance after multivariate adjustment.

The superior healing observed with endoscopic therapy is consistent with recent work by A. M. M. Ibrahim et al. (2022), who demonstrated that endoscopic interventions combined with high-dose proton pump inhibitors significantly enhance ulcer healing rates [8]. Similarly, I. Braimakis et al. (2024) reported that rapid endoscopic hemostasis is associated with reduced complications and improved short-term outcomes in patients with peptic ulcer bleeding [9]. These studies support our finding that early mechanical intervention can accelerate mucosal recovery and decrease the likelihood of treatment failure.

Our results also revealed a markedly lower rebleeding rate in the endoscopic group. T. Kamada et al. (2021) found that prompt endoscopic management in high-risk ulcers minimizes rebleeding events [10], a finding further corroborated by F. Javed et al. (2024), who emphasized that achieving immediate hemostasis is crucial in reducing recurrent bleeding [11]. Moreover, the work by H.-H. Hsieh et al. (2021) highlighted ulcer size as a significant predictor of rebleeding a factor that was integrated into our regression model, with larger ulcers exhibiting higher risk [12]. In our analysis, endoscopic therapy was independently associated with a reduction in rebleeding (AOR = 0.19), which is in agreement with these recent observations [13].

While ulcer recurrence was lower in the endoscopic group, the adjusted association for recurrence was not statistically significant (AOR = 6.80, p = 0.118). E. M et al. (2024) demonstrated that successful eradication of Helicobacter pylori, along with patient compliance to therapy, is critical for minimizing

long-term recurrence [14]. In our study, factors such as H. pylori status and treatment completion were carefully monitored, yet the inherent variability among patients may have contributed to the wide confidence interval observed.

The influence of patient characteristics such as age and BMI on treatment outcomes was also notable. Recent research by A. Sachan, et al. (2021) and M. Li et al. (2022) has linked older age and elevated BMI with delayed healing and increased complications in peptic ulcer disease [15, 16]. Our findings, which adjusted for these confounders in the logistic regression models, reinforce the importance of considering individual patient profiles when planning treatment strategies.

Furthermore, studies by İ. E. Güven et al. (2023) and J. E. Tham et al. (2022) highlighted that endoscopic therapy is especially beneficial in patients presenting with active bleeding and high-risk ulcer features [17, 18]. Our real-world data, wherein clinical judgment guided group allocation, align with these recommendations and underscore the value of tailored, risk-stratified management. Although our study was limited by its non-randomized design and single-center setting, the results contribute to a growing body of evidence suggesting that endoscopic intervention should be considered the treatment of choice in clinically severe cases.

Future research should involve larger, multicenter studies with extended follow-up to better define the long-term outcomes of these treatment modalities. In addition, further exploration of adjunctive strategies such as Firth's penalized likelihood methods could help address issues of separation in logistic regression models when events are rare [8]. Emerging work by X. Xie et al. (2022) and E. Ahmed Ibrahim El Haweet and A. Muhammad Kamel Senosy
et al. (2023) also suggests that integrating real-time risk prediction models may optimize patient selection for endoscopic therapy and improve overall outcomes[19, 20].

In summary, our study supports the use of endoscopic therapy for peptic ulcer management, with significant benefits in ulcer healing and rebleeding reduction. Although ulcer recurrence did not differ significantly between groups, the trends observed warrant further investigation. Tailoring treatment based on patient risk factors remains paramount, and future studies should aim to refine these selection criteria to enhance clinical decision-making.

Limitations

This study, while valuable, has several limitations. First, the non-randomized design introduces potential selection bias, as treatment allocation was based on clinical judgment rather than random assignment. Second, the study was limited to two tertiary hospitals, which may affect the generalizability of the findings to other healthcare settings, particularly rural or lower-tier centers. Additionally, the follow-up period of three months may not fully capture long-term ulcer recurrence or delayed adverse outcomes. Finally, although multivariate adjustments were made, the influence of unmeasured confounding variables cannot be ruled out entirely.

Future Recommendations

Future research should consider larger, multicenter randomized controlled trials to validate these findings across diverse populations. Studies with extended follow-up are needed to assess long-term ulcer recurrence, treatment adherence, and cost-effectiveness. Moreover, integrating patient-reported outcomes and quality-of-life metrics may provide a more comprehensive understanding of treatment impact. Lastly, the role of combined endoscopic and pharmacological strategies in non-emergency ulcer care deserves further exploration.

CONCLUSION

In this prospective cohort study, endoscopic therapy demonstrated superior outcomes in ulcer healing, reduced rebleeding, and shorter hospital stays compared to pharmacological management. While both approaches are used in clinical practice, our findings support the broader application of endoscopic treatment, even beyond acute bleeding scenarios. Tailoring therapy based on patient risk factors and resource availability remains essential for optimal care in peptic ulcer disease.

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