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Research Article

Use of Omeprazole in A Junction to Band-Ligation for Portal Hypertensive Patients in Al-Managel Hospital 2024, Sudan

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Abstract:

Portal hypertensive patients candidate for band ligation were administered omeprazole tab (proton pump Inhibitor) in Al-Managel Hospital to assess post-ligation ulcer healing and heartburn, dysphagia, and odynophagia symptoms following ligation. Forty-five patients were treated with omeprazole tab 20 mg twice daily for one week immediately after the ligation session and rechecked in the next session (3-4) weeks later. Healing of post-banding ulcers occurs naturally without significant association with using omeprazole, as examined by Qui Square and Fisher's exact test. Omeprazole is significantly associated with decreased heartburn and odynophagia symptoms as checked by an independent paired T-test. Adjunctive use of omeprazole with band ligation for portal hypertensive patients is recommended to improve post-ligation symptoms of heartburn and odynophagia.

Keywords: PPIs, EVL, Endoscopic variceal ligation, Esophageal ulcers, Heartburn, PBUB

Introduction

Up to 50 % of cirrhotic patients may suffer gastroesophageal varices, with a chance of 20% developing a life-threatening acute hemorrhage in advanced cases (1). Variceal band ligation is an effective, simple, and relatively safe technique for treating oesophageal varices in cirrhosis patients. For patients who are bled, intolerant, or contraindicated to β-blockers treatment, Endoscopic variceal ligation (EVL) is of utmost importance in preventing the recurrence of variceal rebleeding (2).

A superficial ulcer is formed after banding and usually heals in 2–3 weeks (Polski & Brunt, 2001). Variceal banding complications include dysphagia, pain, fever, bleeding during the procedure, and post-banding ulcer bleeding (PBUB). Incidence of PBUB is low (2.3%–7.3%) (Vanbiervliet et al., 2010), (da Rocha et al., 2009), (Sinclair et al., 2015), but it is difficult to manage and with high morbidity and mortality.

Proton pump inhibitors (PPIs) are the most potent pharmacological agents for gastric acid secretion inhibition. They improve the general conditions of upper gastrointestinal diseases through faster onset of action, greater symptom relief, and increased healing rates compared with ranitidine and placebo. PPIs are considered the first choice for treating gastric ulcers (3).

In a study evaluating the efficacy of endoscopic variceal ligation combined with proton pump inhibitors infusion (either omeprazole or pantoprazole) versus a combination of EVL (endoscopic variceal band ligation) with vasoconstrictor infusion after managing acute variceal bleeding, the PPI side is similar in terms of initial hemostasis, and rate of very early rebleeding with the benefit of fewer adverse events was the conclusion (Lo et al., 2013).

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Acid suppression therapy should be considered after EVL since it reduces the risk of treatment failure. The conclusion of a randomized, controlled trial performed on elective EVL patients assessing the efficacy of rabeprazole, a PPI, on treatment failure defined as either hemorrhage from varices or severe medical complications (Hidaka et al., 2012).

A meta-analysis assessed the association between PPI use in cirrhotic patients and spontaneous bacterial peritonitis SBP development. The observational studies included had inconsistent results, concluding that a potential association needs further studies to be clarified and that PPIs should be used only when clearly indicated (Trikudanathan et al., 2011).

A systematic review of 20 studies assessing the efficacy and safety of proton pump inhibitors (PPIs) in gastroesophageal varices (GEVs) encourages the use of a short course (10 days) of PPI post-EVL since it reduces ulcer size and discourages prolonged use and high-dose infusion till proven by evidenced data (7,8)

Another study investigating the general treatment of PPIs in cirrhotic patients related to overall survival found that PPI use is an independent risk factor for mortality, despite that, a causative role is not found (8,9).

In a study enrolling cirrhotic patients for primary prevention of variceal bleeding, elective EVL was done with the occurrence of bleeding post-EVL as the primary endpoint. A conclusion was that not starting PPI is the sole risk factor for post-EVL bleeding (9).

The objective of this study is to study the effect of omeprazole, one of the PPIs, as an adjunctive therapy on post-endoscopic variceal ligation ulcer healing and symptoms of Heartburn, Dysphagia, and Odynophagia.

Materials and Methods

A case-control study was conducted at Al-Managel Teaching Hospital, Endoscopic Section, from May 2024 to October 2024 for portal hypertensive patients undergoing endoscopic variceal ligation (EVL). We hypothesised that when subjects are treated with a proton pump inhibitor following ligation, they will have no post-banding ulcers and will experience less dysphagia, odynophagia, and heartburn symptoms. Video endoscopes (Pentax, Olympus, Evis Lucera) and band ligation sets (PENTA-GUN-INDIA) were used in the procedure. The coagulopathy profile, including prothrombin time and platelet counts as well as liver function test were done a few days before the procedure. Midazolam 2 mg and pethidine 25 mg were administered intravenously as premedication just before band ligation. After an overnight fasting, the procedure was performed on a day-case basis. The patients were then closely observed for two hours and discharged. They were advised to start oral feeding two hours after the procedure, continue on a fluid diet for two days, and then wean themselves onto solids. Patients on the case side were issued Omeprazole 20 mg twice daily for 7 days following the EVL session, while patients with the same baseline demographics as the case group had no intervention and were considered the control group. Forty-five (45) patients completed the study with a ratio of 3:1 for case to control, respectively. All patients had a (4-6 weeks) endoscopy checkup to detect the degree of esophageal ulcer healing. The degree of dysphagia, odynophagia, and heartburn symptoms following the EVL procedure was evaluated before and after the checkup period. Data was collected by using a pre-coded data collection tool. All subjects agreed to participate in the study by signing ethical consent. All participants met inclusion and exclusion criteria.

The data was analyzed by SPSS 25 software; the intervention and control groups were compared by using Chi-Square and Fisher's Exact test with the calculation of the p-value for significance. For assessing symptoms, an Independent Paired T-test was chosen to check for significant association by measuring the P-value.

Study Results

Data from 45portal hypertensive patients enrolled in Al-Managel Hospital for band ligation was analyzed using SPSS version 25 to assess the effect of omeprazole on post-banding ulcer healing and symptoms following the procedure like heartburn, dysphagia, and odynophagia. 34 of them were from the case study group (administered omeprazole), and 11 were from the control study group (administered nothing), with a ratio of 3:1. 31/45(69%) of patients were males and 14/45(31%) were females, as shown in Table (1)

Table (1) Sex distribution among the study subjects(n=45)

		Frequency	Percent	Cumulative Percent
Gender	F	14	31.1	31.1
	M	31	68.9	100.0
	Total	45	100.0	

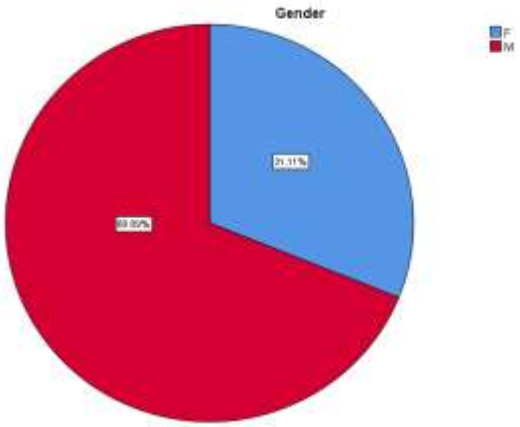

Figure (1) Pie chart showing sex distribution among the study subjects (n=45)

The data was normally distributed. The age range was from 18 to 80, with a minimum age of 22, a maximum age of 75, and a mean age of 53, as shown in Table (2) below.

Table (2) Age Distribution Among Study Subjects (n=45)

Age range	Frequency	Percent	Cumulative Percent
18_30	3	6.6	6.6
31_40	8	17.7	24.4
41_50	8	17.7	42.2
51_60	12	26.6	68.9
61_70	12	26.6	95.6
71_80	2	4.4	100.0
Total	45	100.0	

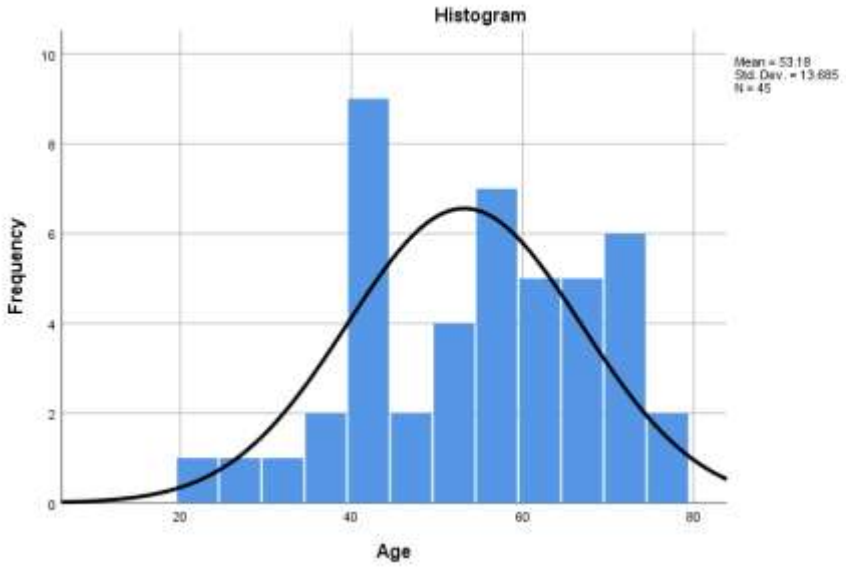

Fig (2) Age distribution among the participants (n=45)

About the occupation, most of the patients were farmers (45%). Concerning other jobs were shared by housekeepers, self-employed merchants, teachers, and medical assistants, as expressed in Table (3) below.

Table (3) Occupation among the study subjects(n=45)

Occupation	Frequency	Percent	Cumulative Percent
Farmer	21	46.7	46.7
Housekeeper	10	22.2	68.9
none	4	8.9	77.8
Self- Employment	4	8.9	86.7
Teacher	3	6.7	93.3
Merchant	2	4.4	97.8
Medical Assistant	1	2.2	100.0
Total	45	100.0	

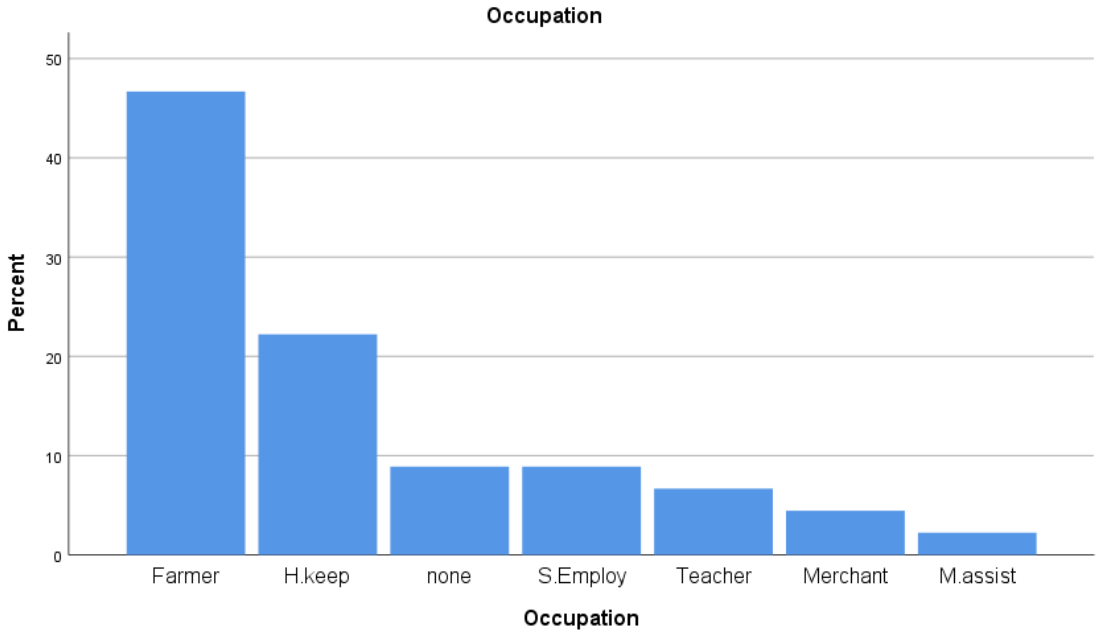

Fig (3) Age distribution among the subjects (n=45)

Concerning the presentation:55% of patients presented with hematemesis and Malena,20% had hematemesis,15% had Malena, and 9% had none of them, as shown in Table (4).

Table (4) Diversity of Presenting Symptoms among the study subjects (n=45)

Presenting symptoms	Frequency	Percent	Cumulative Percent
Hematemesis & Malena (Both)	25	55.6	55.6
Hematemesis	9	20.0	75.6
Malena	7	15.6	91.1
None	4	8.9	100.0
Total	45	100.0	

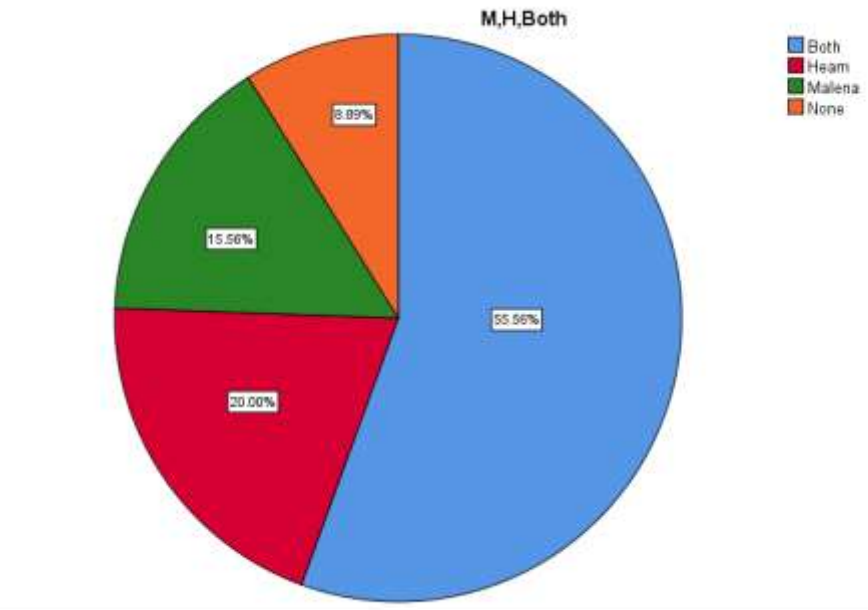

Fig (4) Presenting symptoms among the study subjects (n=45)

Most of the patients 36/45(80%), came with a compensated liver, while 9/45(20%) had a decompensated liver, as shown in Table (5)

Table (5) Liver compensation and decompensation among the study subjects (n=45)

Liver Compensation & Decompensation	Frequency	Percent	Cumulative Percent
Compensation	36	80.0	80.0
Decompensation	9	20.0	100.0
Total	45	100.0	

During examination34/45 (75%) of patients were anemic, 41/45 (91%) were found to have splenomegaly, 6/45 (13%) had ascites, 9/45 (20%) with lower limb edema, 1/45 (2%) had hepatomegaly and 4/45 (9%) had jaundice, as shown in Table (6)

Table (6) Signs of examination of the study subjects (n=45)

Symptoms	Frequency	Percent	Cumulative Percent
Splenomegaly	41	91.1	91.1
Anemia	34	75.6	75.6
Lower Limb Edema	9	20	20
Ascites	6	13.3	13.3
Jaundice	4	8.9	8.9
Hepatomegaly	1	2.2	2.2

Endoscopic sessions for patients who have undergone band ligation showed that most of them had grade 2,3 or 4 varices. More than 50% of patients had grade 3 varices. The number of bands needed for each band ligation session varied from 2 to 6, with the number 5 as the predominant one for 58% of patients, as shown in Table (7)

Table (7) Grades of Varices among study subjects (n=45)

Grades of Varices	Frequency	Percent	Cumulative Percent
2	8	17.8	17.8
3	25	55.6	73.3
4	12	26.7	100.0
Total	45	100.0	

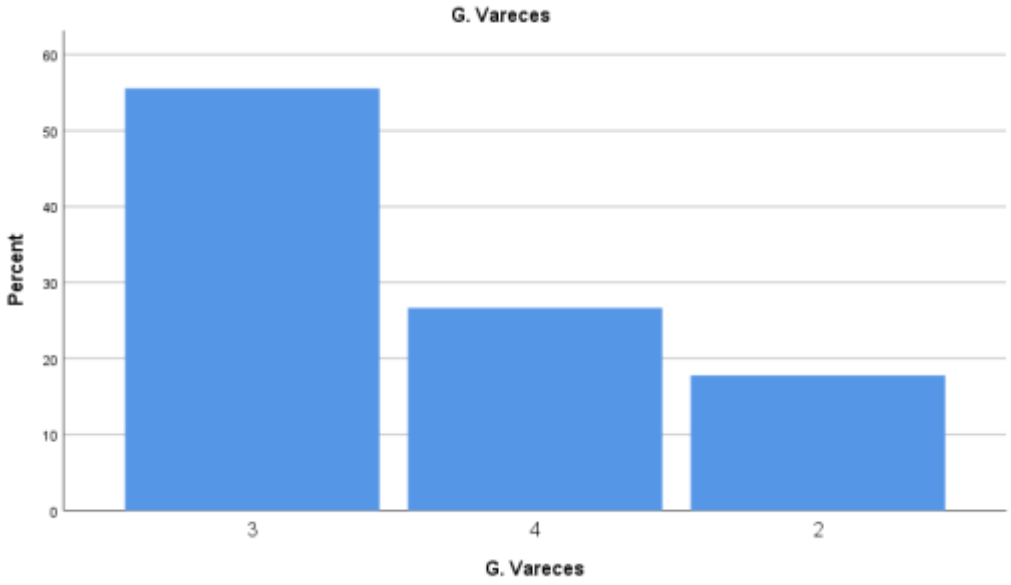

Fig (5) Grades of Varices among study subjects (n=45)

Table (8) Number of bands needed per session among study subjects (n=45)

Number of Bands	Frequency	Percent	Cumulative Percent
5	26	57.8	57.8
4	7	15.6	73.3
3	5	11.1	84.4
6	5	11.1	95.6
2	2	4.4	100.0
Total	45	100.0	

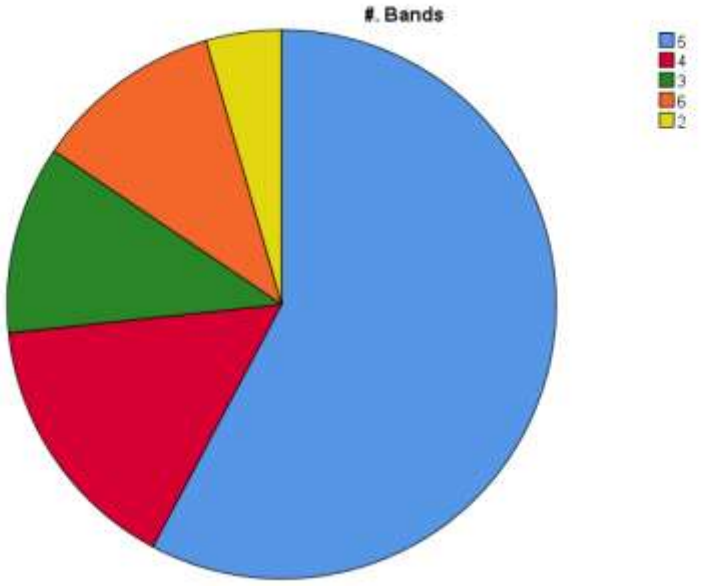

Fig (6) Number of bands needed for ligating study subjects (n=45)

No correlation was found between the grade of varices and the number of bands per session(*P*=0.895), e.g., patients with a high grade of varices did not need more bands, as shown in Table (9).

Table (9) Correlation of variceal grade to the number of bands per session (n=45)

Correlations

		Grade of Varices	Number of Bands
Grade of Varices	Pearson Correlation	1	.021
	Sig. (2-tailed)		.893
	N	45	45
Number of Bands	Pearson Correlation	.021	1
	Sig. (2-tailed)	.893	
	N	45	45

There was no duodenal ulcer among the participants. 37/45(82%) had mild gastropathy, 6/45(13%) had moderate gastropathy, and 2/45(4%) had severe gastropathy, as shown in Table (10).

Table (10) Distribution of gastropathy among the study subjects (n=45)

Gastropathy	Frequency	Percent	Cumulative Percent
Mild	37	82.2	82.2
Moderate	6	13.3	95.6
Sever	2	4.4	100.0
Total	45	100.0	

21/45(47%) of patients were using beta blockers (Propranolol) while 24/45(53%) of them were not, as shown in Table (11).

Table (11) Use of beta-blocker among the study subjects (n=45)

On Propranolol	Frequency	Percent	Cumulative Percent
No	24	53.3	53.3
Yes	21	46.7	100.0
Total	45	100.0	

Omeprazole (Proton pump Inhibitor)20 mg/ tablet was administered twice daily for a week to part of the patients (case group) immediately after the ligation session. In contrast, the second part (control group) was administered nothing. Complete post-ligation ulcer healing was observed in 40/45(89%) of all patients, while 5/45 (11%) had a partially healed ulcer, as shown in Table (12).

Table (12) Ulcer healing rate among the study subjects (n=45)

Healing of Ulcer	Frequency	Percent	Cumulative Percent
Completely healed	40	88.9	88.9
Partially healed	5	11.1	100.0
Total	45	100.0	

Qui square test for independence was applied to check if there was a significant association between

categories of healing (complete or partial) of post-ligation ulcers among the case and control groups. Since

some expected frequencies were less than 5, a **Fisher's Exact Test** was chosen instead. Fisher's Exact Test P-value was (0.31) is more than (0.05). That is why we accepted **the null hypothesis (H_0),** saying there is no association between the treatment status (Case (administered omeprazole) or Control) and the degree of

healing (Complete or Partial). There was no significant difference between the two categorical variables.

Having PPI added to ligation sessions had no specific relation to the ulcer healing effect, as shown in Table (12).

Table (12) A Chi-Square and Fisher's Exact Test Analysis

Chi-Square Tests

	Value	df	Asymptotic significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.820[a]	1	.177		
Continuity Correction[b]	.635	1	.425		
Likelihood Ratio	3.000	1	.083		
Fisher's Exact Test				.313	.228
N of Valid Cases	45				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 1.22.

b. Computed only for a 2x2 table

The effect of Omeprazole on Heartburn, Dysphagia and Odynophagia symptoms following ligation was checked by using an **Independent Paired t-test for significance**. The mean of odynophagia in the first session was 0.78 versus 0.16 in the last session. This suggests that there is a significant difference between the two means. The resulting p-value of (0.00) is less than (0.05), which assures that there was a statistically significant difference, as shown in tables (13) and (14). This means that omeprazole is recommended to decrease the degree of odynophagia in patients undergoing band ligation.

Table (13) Paired Samples Statistics for Odynophagia

Paired Samples Statistics

Odynophagia		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Session 1	.78	45	.823	.123
	Session 2	.16	45	.367	.055

Table (14) Paired Samples test for odynophagia

Paired Samples Test

Odynophagia		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	Session 1 - Session 2	.622	.860	.128	.364	.881	4.851	44	.000

The difference between the two means of heartburn sessions was large (1.07 and 0.11), showing they were not the same. A P-value of (0.00) assures that the difference was significant, as shown in Table (15 and 16) so omeprazole was recommended to decrease heartburn for patients candidates for the band ligation procedure.

Table (15) Paired Samples Statistics for Heartburn

Paired Samples Statistics

Heartburn		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Session 1	1.07	45	.986	.147
	Session 2	.11	45	.318	.047

Table (16) Paired Samples test for heartburn

Paired Samples Test

Heartburn		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	Session 1 – Session 2	.956	.952	.142	.669	1.242	6.730	44	.000

For dysphagia the difference between the two means was small (0.07 and 0.00) and the P-value of (0.18) is more than (0.05) ensuring there was no significant difference, as shown in Tables (17 and 18). There was no significant association between the use of omeprazole and the decrease in dysphagia for ligated patients.

Table (17) Paired Samples Statistics for Dysphagia

Paired Samples Statistics

Dysphagia		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Session 1	.07	45	.330	.049
	Session 2	.00	45	.000	.000

Table (18) Paired Samples test for dysphagia

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
					95% Confidence Interval of the Difference				
Dysphagia		Mean	Std. Deviation	Std. Error Mean	Lower	Upper			
Pair 1	Session 1 - Session 2	.067	.330	.049	-.033	.166	1.354	44	.183

Discussion and Recommendations

Portal hypertensive patients candidates for band ligation were tracked in Al-Managel Hospital for 6 months (from May 2024 to October 2024) to assess the effect of omeprazole as adjunctive therapy to ligation on post-banding ulcer healing and Heartburn, Dysphagia, and Odynophagia symptoms following the procedure. Out of Seventy-two (72) patients enrolled in the study, only Forty-five (45) patients completed the study, which may be due to civil war threatening Sudan recently.

Endoscopic variceal band ligation is generally a safe and effective procedure. A superficial ulcer is formed after banding and usually heals in 2–3 weeks (Polski & Brunt, 2001). Complete post-ligation ulcer healing was observed in 40/45(89%) of all patients, which may be due to a natural healing process versus 5/45 (11%) who had a partially healed ulcer with no specific association with Omeprazole treatment, a P-value > 0.05.

Concerning symptoms, the difference between the two means of heartburn sessions (1.07 versus 0.11) and Odynophagia sessions (0.78 versus 0.16) with a P-value of (0.00) <0.05 for both symptoms assures that there was a significant difference. Omeprazole was recommended to decrease Odynophagia and heartburn symptoms for patients candidates for the band ligation procedure. Omeprazole administration had no specific association with the decrease in the degree of dysphagia, a P-value > 0.05.

Conclusion

Omeprazole use as adjunctive to band-ligation has no specific association with ulcer healing, but it is recommended for improving symptoms of heartburn and odynophagia following the band-ligation procedure.

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