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Role of Sucralfate in Promoting Healing of Post Band Variceal Ulcer

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Abstract

Background: The role of Sucralfate to be slightly superior to placebo in accelerating the healing process of oesophageal ulcerations after sclerotherapy had been elicited. Currently, its role in the healing process of oesophageal ulcerations after ligation has not been clarified.

Objectives: to assess the use of sucralfate after variceal band ligation and to clarify its role in healing of post variceal band ligation ulcers.

Methods: Sixty two patients with oesophageal varices eligible for band ligation represented the population of the study. The patients were allocated into two groups: **Group I (study group):** Included 31 patients in whom endoscopic band ligation was done then received sucralfate 1 gm every 6 hours for 2 weeks. **Group II (control group):** Included 31 patients in whom endoscopic band ligation was done then received placebo every 6 hours for 2 weeks.

Results: During the follow up endoscopy, 2 weeks after band ligation we observed that: All post-banding ulcers in both groups were superficial, 12 patients (38.7%) in the study group developed post-band ulcers versus 23 patients (74.2%) in the control group with **a statistically significant difference (p-value, 0.005)**. Also, there was **a statistically significant difference** between both groups regarding the size of the post banding ulcers as the mean size of ulcers was **2.7 mm** ± 1.2 in study group whereas it was **3.8mm** ± 1.7 in control group with P value (0.043).

Conclusion: Sucralfate has a significant role in decreasing the rate of occurrence of variceal post-banding ulcers and as well their size.

Key words: Endoscopic variceal band ligation (EVL); Sucralfate; Clinical pharmacy

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INTRODUCTION

Portal hypertension is the pathophysiologic basis for the formation of oesophageal varices, which are present in 60-80% of patients with cirrhosis[1]. Bleeding from varices occurs in about 30% of patients with varices, and carries a mortality risk of 15%-30% per episode[2, 3].

Endoscopic band ligation of oesophageal varices has been developed and adapted for use with the flexible endoscope. Endoscopic variceal ligation (EVL) leads to mechanical obliteration of oesophageal varices, and therefore ulcers after EVL should behave differently than sclerosant induced ulcers[4].

The behavior of post-ligation ulcer appears benign because of the instrument design which sucks up mucosa and submucosa leading only to the formation of superficial ulcers. They heal by fibrosis, entrapping only the mucosa, and submucosal venous channels, leaving the muscle layer unaffected. These post-ligation ulcers are superficial with a lesser degree of esophagitis and they heal faster than post-sclerotherapy ulcers[5].

Sucralfate is a unique oral drug. Chemically, it's a complex of the disaccharide sugar, sucrose, combined with sulfate and aluminum; different actions are thought to be important for its beneficial effects (a) It binds to the

surface of ulcers (attaching to exposed proteins) and coats the ulcer, thus protecting the ulcer surface to some extent from further injury by acid and pepsin. (b) It directly inhibits pepsin in the presence of stomach acid. (c) It binds to bile salts coming from the liver. (d) It increases prostaglandin E2 production[6].

Sucralfate seems to be slightly superior to placebo in accelerating the healing process of oesophageal ulcerations after sclerotherapy as denoted by Roark, 1984[7].

To our knowledge, none of the investigators have assessed the role of sucralfate in the setting of post-band variceal ulcers.

AIM OF THE STUDY

The aim of the present work is to assess the use of sucralfate after variceal band ligation and to clarify its role in healing and prevention of post-variceal band ligation ulcers bleeding.

PATIENTS AND METHODS

Study Design

This study is a randomized double blinded placebo controlled study.

Study Setting and time; This study was conducted in Endoscopy Unit, department of Hepatology, Gastroenterology (Naser Institute), Emergency Haematemesis Unit and Central Gastrointestinal Endoscopy Unit (Ain Shams University Hospitals) in the period from December 2007 to August 2009.

Inclusion criteria

All patients were above age of 18 and below age of 65 years, with chronic liver disease (post schistosomal and/or post-viral hepatitis) and with oesophageal varices eligible for band ligation(post bleeding or non-bleeding high risk oesophageal varices with red mark signs)[8,9].

Exclusion criteria

Patients with other causes of liver diseases (autoimmune, metabolic, Budd Chiarri, etc.). Patients who had been subjected to injection sclerotherapy sessions or having endoscopically confirmed pre-existing oesophageal ulcers. Patient's ongoing therapy with sucralfate, H2 blockers or proton pump inhibitors. The presence of Barrett's metaplasia, isolated fundal varices or peptic ulcer disease previous anti-reflux procedures. Diabetic patients, pregnancy, patients with advanced systemic disease as heart failure renal failure or any depleting disease that might affect healing process and\or life expectancy and as well those with suspected malignancy. Allergy to sucralfate, and finally patients who refuse to participate in the trial.

The Recruited Patients were Allocated into Two Groups

Group I (study group): Included 31 patients in whom endoscopic band ligation was done then received sucralfate 1 gm every 6 hours for 2 weeks.

Group II (control group): Included 31 patients in whom endoscopic band ligation was done then received placebo every 6 hours for 2 weeks.

Ethical considerations; the objective of the study and the possible complications were explained to all patients who met the eligibility criteria and they were asked to sign a consent form. Approval of the local ethical Committee of the Faculty was also obtained.

All the Studied Cases were Subjected to the Following

- **Complete clinical evaluation**
- **Laboratory investigations:** [To detect the etiology of liver disease, to evaluate the liver function, and to detect the impact of liver disease and portal hypertension on kidney and blood elements].
- Patients were classified according to **Child-Turcotte Pugh** scoring system (A, B, C)[10]
- **Abdominal ultrasonography.**
- **Upper GI endoscopy (pentax EPM 3500 videoscope and Pentax EPM 3300 videoscope);** Esophagogastroduodenoscopy was done to all patients to evaluate the following points and then to conduct the process of oesophageal varices band ligation.

a- Oesophageal varcies:

o Number.

o Grading according to ***Westaby et al., 1982***[11].

Westaby et al. (1982) classified EV according to the size at the gastro-esophageal junction into four grades:

Grade I: Varix is flush with the wall of the esophagus.

Grade II: Protrusion of the varix, but not more than half way to the center of the lumen.

Grade III: Protrusion of the varix more than half way to the center of the lumen.

Grade IV: The varices are so large that they meet at the midline.

o Red colour signs (cherry red spots, hemocysts, red wale) according to ***Beppu et al., 1981***[9].

b- Portal hypertensive gastropathy (PHG):

It's classified, according to consensus statement of ***Baveno IV meeting into***[12]:

- Mild PHG: Mild mosaic pattern.
- Sever PHG: When mosic pattern is superimposed by any red signs (red point lesions, cherry red spots, black brown spots)

Endoscopic Band Ligation of Oesophageal Varices

The procedure of band ligation was conducted using Saeed multiband ligator shooter. Following band ligation, each patient was given one of the bottles containing either sucralfate suspension or placebo according to his

serial number. Both the patient and the operator were not aware of the type of the suspension, whether sucralfate or placebo, as this was handled by the assistant.

Preparation of sucralfate suspensions (by the clinical pharmacist);

Sucralfate suspension was prepared by crushing 1gm tablets in a sterilized porcelain mortar till become powder like then adding few drops of glycerin, and mixing it with 5 ml of water, drop by drop, till forming suspension form, then putting in glass bottle, the concentration of sucralfate in suspension is equal to 1gm/5ml.

Placebo; this is prepared by adding few drops of glycerin to 1gm of starch in a special container and mixing it with 5 ml of water to make a suspension form, then putting in glass bottle of the same shape and size of sucralfate bottle (figure 1). Each bottle was assigned a number by the assistant. The number of the bottle and the corresponding content were registered in a special sheet kept by the assistant. Patients were instructed to have 5ml every 6hrs. Patients were instructed to consume fluids and semisolid food for the next 7-10 days[13] and were requested to come in the predetermined dates of follow up:

- After 7 days.
- After 14 days.

Post-Procedure Follow up and Evaluation

After one week: A special questionnaire to inquire about compliance of the patients in taking the suspension and the possible complications: Post banding bleeding (haematemesis and/or melena), chest pain [mild, moderate and severe] and dysphagia [mild, moderate and severe][14].

After Two weeks;A same previous questionnaire in addition to upper GI endoscopy to assess: number of E.V., grade of E.V., number of post banding ulcers, size of ulcers regarding {depth (superficial, deep) and diameter (by graded catheter)} (figure 2)

STATISTICAL ANALYSIS

The data were processed and analyzed using the statistical package for social sciences (SPSS) program. Expression of data in the form of mean, S.D. (standard deviation) and range for quantitative variables, description of qualitative variables by frequency and percent, comparison between 2 groups' quantitative variables was carried out by student t-test; comparison of more than two groups' quantitative variables was carried out by one way ANOVA test. And chi-square test (Pearson chi-square) was used to compare between qualitative variables [A significant statistical finding is declared if p-value is less then or equal 0.05].

Results: This study was conducted on 62 patients eligible for elective band ligation. The study and control groups were matched for age & gender. It is apparent that the majority of patients in both groups were males in the 5th decade (table 1). Both groups were also matched regarding the aetiology of liver disease and child-pugh classification (table 1), as well as the prebanding status of oesophageal varices (table 5).

Table 1
Demographic Characteristics of the Study and Control Groups

Parameter	Study group (N=31)	Control group (N=31)	*P*-value
Age in years(mean ±SD)	44.4(±7.4)	47.0(±7.1)	<0.05
Gender:			
Male	25 (80.6%)	22 (71.0%)	<0.05
Female	6 (19.4%)	9 (29.0%)	
HBsAg +ve	3 (9.7%)	5 (16.1%)	<0.05
HCV Ab+ve	30 (96.8%)	28(90.3%)	<0.05
Mixed HCV& HBV	2 (6.5%)	2 (6.5%)	<0.05
Schistosomiasis (Mixed)	10 (32.3%)	7 (22.6%)	<0.05
Childs's score* (mean ±SD)	9.2 (±2.1)	9.9 (±2.0)	<0.05
Childs's class*			
A	5 (16.1%)	2 (6.5)	
B	11 (35.5%)	10 (32.3)	<0.05
C	15 (48.4%)	19 (61.3)	

N; number of patient
P<0.05; non significant
SD; standard deviation
*According to Child-Turcotte pugh (10)

Table 2
Relevant Clinical Data of Patients in the Study and Control Groups

Parameter	Study group (N=31)	Control group (N=31)	*P*-value
Pallor	22(71.0)	23(74.2)	<0.05
Jaundice	21(67.7)	23(74.2)	<0.05
Palmer erythema	27(87.1)	25(80.6)	<0.05
Lower limb odema	25(80.6)	26(83.9)	<0.05
spleen			
Palpable	26(83.9)	28(90.3)	<0.05
Not Palpable	2(6.45)	1(3.2)	<0.05
Surgically removed	3(9.7)	2(6.45)	<0.05
liver			
Palpable	6(19.4)	8(25.8)	<0.05
Not Palpable	25(80.6)	23(74.2)	<0.05
Ascites			
No ascites	5(16.1)	3(9.7)	<0.05
Moderate	16(51.6)	15(48.4)	<0.05
Tense ascites	10(32.25)	13(41.9)	<0.05

N; number of patient
P<0.05; non significant

All patients of both groups were re-evaluated clinically with good history taking 1st week and two weeks following band ligation to clarify the possible, expected minor complications of band ligation with special stress on chest pain, dysphagia and re-bleeding. The difference between the study & control groups regarding these complications (1st week and two weeks following band ligation) proved to be **statistically** insignificant (P-value >0.05). (Figure 3)

During the follow up endoscopy, 2 weeks after band ligation we observed that:

All post-banding ulcers in both groups were superficial. Twelve patients (38.7%) in the study group developed post-band ulcers versus 23 patients (74.2%) in the control group with a statistically significant difference (P-value, 0.005) (table 5).

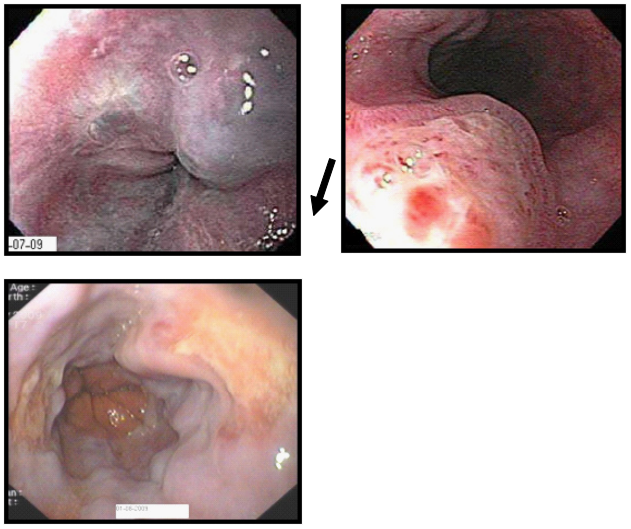
Also, we studied the number of post-banding ulcers in both groups as shown in table 5. In the study group, 7 patients (58.3%) had a single ulcer, 3 patients (25%) had two ulcers while 2 patients (16.7%) had three ulcers. However in control group, 9 patients (39.1%) had a single ulcer, 10 patients (43.5%) had two ulcers and 3 patients (13%) had three ulcers and only one patient (4.3%) had four ulcers, the difference between the study and control groups regarding the number of post-banding ulcers was statistically insignificant.

During the follow up endoscopy after two weeks we compared the two groups regarding the mean size of ulcers as shown in table 6. There was statistically significant difference in ulcers size between both groups; as the mean size of the post banding ulcers was 2.7 mm ± 1.2 in study group whereas it was 3.8mm ± 1.7 in control group with P- value (0.043).

We had studied the effect of band ligation on the grade of OV in both groups of patients. Both groups experienced more or less reduction in size of OV after EVL however it was statistically not significant between both groups (table 6).

The relation between the status of hepatic reserve (Child's Classification) and the development of post-banding ulcers was studied in both groups. However, this relation appeared to be statistically insignificant as had shown in table 7.

No side effects related to the use of sucralfate were recorded in this study.



A: Post banding OV with small superficial ulcer (2x2 mm) (black arrow).
B: Post banding OV showing superficial ulcer (6x6 mm).
C: Post banding OV showing two large superficial ulcers (6x6 mm and 5x5 mm).

Table 3
Laboratory Data of Patients in the Study and Control Groups

Parameter	Study group (N=31)	Control group (N=31)	*P*-value
Liver profile (Mean ±SD)			
AST Up to (40 IU/L)	55.9 (±21.3)	54.4 (±22.5)	>0.05
ALT Up to (37 IU/L)	55.9(±25.7)	57.5 (±26.8)	>0.05
Bilirubin (Total) Up to (1.2mg/dl)	1.8 (±0.8)	2.4 (±1.0)	0.013*
Bilirubin (Direct)(0.3mg/dl))	0.93 (±0.4)	1.43 (±0.8)	0.003*
Albumin(3.5-5mg/dl)	2.8 (±0.5)	2 .5(±0.4)	0.019*
PT in Conc.% (70-100%)	61.0(±9.8)	56.9 (±12.9)	>0.05
Complete Blood Picture (Mean ±SD)			
Hemoglobin (12-16g/dl)	10.3 (±0.9)	9.9 (±1.5)	>0.05
WBCs x 1000 (411cells/mm3)	6.0 (±3.2)	5.1 (±2.7)	>0.05
Platelets x 1000 (150 - 400/mm3)	74.8 (±18.3)	81.2 (±33.2)	>0.05

N; number of patient
p>0.05;non significant
p<0.05; significant

Table 4
Endoscopic Status of Oesophageal Varices in Patients of the Study and Control Groups at the First Presentation (Pre-Band Ligation Endoscopy) and the Number of Applied Bands

Oesophageal varices	Study group (N=31)	Control group (N=31)	*P*-value
No. of Columns			
• Two	1 (3.2%)	3 (9.7%)	
• Three	11 (35.5%)	6 (21.4%)	>0.05
• Four	19 (61.3%)	22 (78.6%)	
Grade *			
• II1	(3.2%)	-	
• II-III	16 (51.6%)	7 (22.6%)	
• III	3 (9.7%)	4 (12.9%)	>0.05
• III-IV	7 (22.6%)	12 (38.7%)	
• IV	4 (12.9%)	8 (25.8%)	
Red Markings	31(100.0%)	31 (100.0%)	>0.05
No of bands (Mean± SD)	4.3(±0.9)	4.4(±1.0)	>0.05

N;number of the patients
P>0.05; Non significant
SD; Standard Deviation
*According to *Westaby et al*. (1982)[11]

Table 5
The Number of Patients with Post-Banding Ulcers & Number of Ulcers Per Patient as well as Mean Size of the Post Banding Ulcers in Both Groups

Parameter	Study group (N=31)	Control group (N=31)	*P*-value
Number of patients with post-band ulcers	12(38.7%)	23(74.2%)	0.005*
Number of ulcers/ patients			
• One	7(58.3%)	9(39.1%)	
• Two	3(25.0%)	10(43.5%)	>0.05
• Three	2(16.7%)	3(13.0%)	
• Four	-	1(4.3%)	
Mean Size of Ulcers (mm)(Mean± SD)	2.7(±1.2)	3.8(±1.7)	0.043*

N; number of patients
P>0.05; non significant
P <0.05; significant

Table 6
Relation Between Pre-Banding OV Grade and Development of Post-Banding Ulcers in the Study and Control Groups

Variceal grade	Study Group(N=31)				Control Group (N=31)			
	Ulcer (+ve) N=12		Ulcer(–ve) N=19		Ulcer (+ve) N=23		Ulcer (–ve) N=8	
	N	%	N	%	N	%	N	%
•II	1	(8.3)	-	-	-	-	-	-
•II-III	5	(41.7)	11	(57.9)	5	(21.7)	2	(25.0)
•III	1	(8.3)	2	(10.5)	3	(13.0)	1	(12.5)
•III-IV	2	(16.7)	5	(26.3)	9	(39.1)	3	(37.5)
•IV	3	(25.0)	1	(5.3)	6	(26.1)	2	(25.0)
P-value	>0.05				>0.05			

N; number of patients
P >0.05; non significant

Table 7
Effect of Child's Classification (Child-Turcotte Pugh) (10) on Development of Ulcers in the Study and Control Group

Child Class	Study Group(N=31)				Control Group (N=31)			
	Ulcer (+ve)		Ulcer(–ve)		Ulcer (+ve)		Ulcer (–ve)	
	N=12	(%)	N=19	(%)	N=23	(%)	N=8	(%)
A	1	(8.3)	4	(21.1)	1	(4.3)	1	(12.5)
B	4	(33.3)	7	(36.8)	6	(26.1)	4	(50.0)
C	7	(58.3)	8	(42.1)	16	(69.6)	3	(37.5)
P-value	>0.05		>0.05		>0.05		>0.05	

N; number of patients
P>0.05; non significant

A B

Figure 1
A- Glass Bottles Containing the Drug (sacralfate -suspension form). B- Glass Bottle Containing Placebo (suspension form)

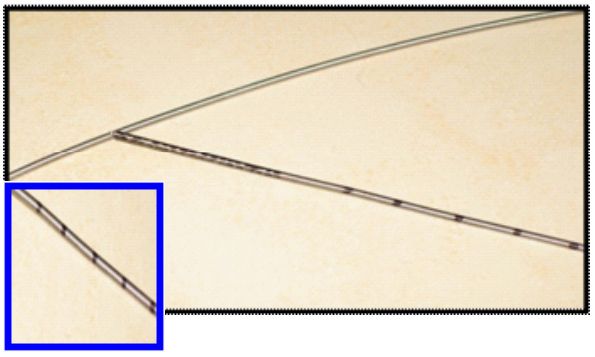


Figure 2
Graded Catheter

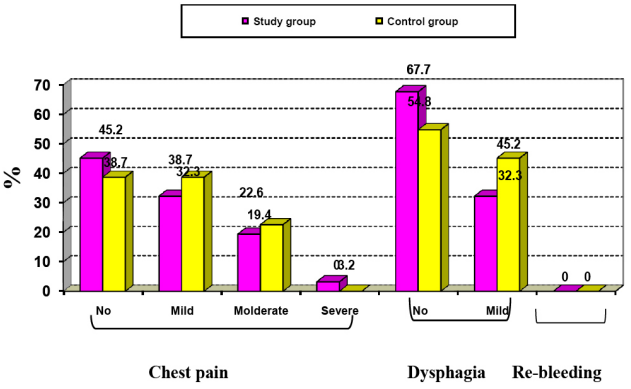


Figure 3
Complications Detected at the First Visit of Follow Up (one week after band ligation) in the Study & Control Groups

DISCUSSION

Variceal band-ligation is a common clinical practice performed with the intent of decreasing subsequent variceal hemorrhage[15]. Variceal band ligation is associated with side effects of its own which can be classified as those resulting from elastic band ligation itself and its tissue effects and those from use of the overtube (in the old technique). Postligation ulcers are necessary accompaniment of EVL, similar to postsclerotherapy ulcers, they heal by time as follows; by the end of the third day, nearly one half of the varices will have overlying ulcers, after one week, all ligated varices will be replaced by superficial ulcers of the same size; more than one half of them will have been healed within two weeks, and all of them will have been completely healed by the end of the third week[4]. These ulcers carry a potential risk of upper gastrointestinal bleeding (in very deep ulcers). In view of their rapid spontaneous healing, it is unclear whether the presence of post-band ulceration requires specific therapy to accelerate the healing process or not. Treatment of post-band ulcers has been mostly empirical with drugs used for peptic ulcer diseases with very few data existing regarding their beneficial effect[16].

In order to assess proton pump inhibitors in post-banding ulcers, *Elsayed et al., 2007*[17] conducted a randomized controlled trial which showed no statistically significant difference regarding the size and number of post-banding ulcers between PPI- treated group and placebo group.

In 1984 *Roark* and his colleagues[7] reported the first successful treatment of post-sclerotherapy oesophageal ulcers with sucralfate, which had been shown to enhance healing in a randomized controlled trial of 45 patients[5]. On the contrary, a randomized controlled trial of **proton pump** inhibitors was unable to demonstrate a beneficial effect of omeprazole on post-sclerotherapy ulcers[18].

Sucralfate, the aluminum salt of sucrose, is a well-tolerated drug for peptic ulcer disease, including duodenal and gastric ulcer and reflux esophagitis. Its mode of action is different from alkalinizing agents such as antacids or histamine-2 receptor blockers and also proton pump inhibitors. It can be described as mucosa-protective because it strengths the natural defense mechanisms of GI tract and also because it protects the ulcerated area against attack by acid and pepsin[19]. Specific hypotheses were that patients treated with sucralfate following band ligation would have fewer and smaller post banding ulcers and they would experience less chest pain, dysphagia and rebleeding.

In the current study, the underlying aetiology of liver disease did not differ significantly between the study and control groups. **Hepatitis C** virus infection was on the top of the list in both groups being incriminated in 96.8% of patients of the study group and 90.3% of the control group, **shistosomiasis** contribute in the aetiology in10 patients (32.3%) in the study group and 7 patients (22.6%) in control group. **Hepatitis B** virus infection was documented in a limited number of patients either in study group 3 patients (9.7%) or the control group 5 patients (16.1%).

Many Egyptian investigators had studied the prevalence of different etiological factors of chronic liver disease in our country, *Mohammed, 2007*[20] reported that HCV is behind most of the cases of chronic liver disease (96.2%). The contribution of shistosomiasis ranges between 61-65%, while HBV was incriminated in only 11-15% of the cases. Hepatitis C virus genotype 4 (HCV-4) is the most common variant of the hepatitis C virus (HCV) in the Middle East and Africa, particularly Egypt. This region has the highest prevalence of HCV worldwide, with more than 90% of infections due to genotype 4[21]. Egypt has the highest prevalence of HCV in the world (13%)[22]. A recent study conducted 20 years later screened 55,922 potentially healthy asymptomatic blood donors for HBsAg. The cumulative seroprevalence of HBV infection was 1.3% with decline in the annual seroprevalence throughout the study period from 2.3% to 0.9%[23]. The significant decline in HBV rates indicates the effectiveness of the universal hepatitis B virus immunization of infants that was initiated in 1991[24].

As regards the beneficial effect of band ligation on decreasing the size and hence grading of oesophageal varices, the present study revealed that there was a satisfactory reduction in grading of OV in each group after EVL, however it was statistically **not significant** between both groups. The results of the current study support the statement that have been reported by many authors that band ligation is the most suitable option for variceal eradication[15, 25].

The current study showed that there was **no statistically significant** relation between the pre-banding variceal size (grading) and the occurrence of post-banding ulcers in both groups (p>0.05). This was in agreement with *Mohamed*, 2007[20] who reported a non significant impact of variceal size (grading) on the development of post-banding ulcers.

The current study revealed that the use of sucralfate has a beneficial effect in decreasing the rate of occurrence of post-banding ulcers, as the percentage of patients who developed ulcers were higher in the control group compared to the study group (74.2% and 38.7% respectively) with a statistically significant difference **(P < 0.05).**

In contrast, Elsayed,* 2007**[17] in a similar study using PPI demonstrated a non significant difference between the study and control groups regarding the rate of occurrence of post banding ulcers being 68.4% and 75%, respectively, showed **no significant** difference between both groups. *Mohamed*, 2007[20], demonstrated that the number of patients who developed post banding ulcers showed no statistically significant difference between both groups, as 25 patients (96.1%) in PPI group developed post banding ulcer compared to 26 patients (100%) in placebo group. *Similarly* ***Nicholas., 2005[16] demonstrated **no significant** difference between pantoprazole and control groups regarding the number of patients who developed post-banding ulcers and as well the numbers of ulcers.

Moreover, the present study revealed that there was a significant difference in post-banding ulcer's size, as the mean size of post-banding ulcers was larger in the control group compared to the study group [3.8mm ± 1.7 and 2.7mm ± 1.2 respectively] (P<0.05).

Our findings were in agreement with *Abd El-Monem*., 2008 (26), in a randomized controlled trial (for assessing of PPI after EVL) who demonstrated **statistically significant** difference of ulcer's size between PPI group & placebo group. The mean size of ulcers of PPI group was (4.2mm) compared to (6.5mm) in the placebo group **(*P*-value 0.010)**. Similar findings were documented by other authors, 4.9 mm compared to 6.5mm as reported by ***Mohammed in 2007***[20] and 3.7 mm compared to 8.2 mm as repoted by ***Nicholos in 2005***[16].

However Elsayed., 2007[17], in randomized controlled trial (for assessing of PPI after EVL) conducted on 46 patients, showed no statistically significant difference in

post banding ulcer's size between both groups. The mean size of ulcers of drug group was 4.8 mm compared to 5.4 mm in the control group.

The current study revealed that the mean number of ulcers per patient did not differ significantly between both groups (P>0.05), Similarly *Nicholas*., 2005[16] demonstrated no significant difference between pantoprazole and control groups regarding the number of ulcers.

The current study revealed that all the ulcers that developed in both groups were superficial and hence the difference regarding the depth of ulcers could not be evaluated statistically. This finding is consistent with *Elsayed*. , 2007[17] who revealed, in a randomized controlled trial (for assessing PPI after EVL), that all the ulcers that developed were superficial. It is also supported by *Abd El-Monem*. , 2008[26] who used PPI.

The post-banding complications encountered in the current study (either after one week or two weeks) were minor including chest pain & transient dysphagia and the affected patients suffered from the mild to moderate form of these complications. Moreover, the difference between both groups was statistically insignificant.

The present study agreed with *Abd El-monem*., 2008[26] who demonstrated that there was **no statistically significant** difference between the study group and the control group as regards post-banding complications in a randomized controlled trial which was conducted to asses PPI after EVL on 60 patients from Emergency Haematemesis Unit and Central Gastrointestinal Endoscopy Unit (Ain Shams University Hospitals). Similar results were reported by other investigators who tried the PPI[17, 20]

It is worth mentioning that none of the patients in our series experienced post-banding re-bleeding. Our results are similar to the study conducted by *Mohamed,* 2007[20] although their trial was on PPI, not sucralfate.

However, *Ferrari*., 2005[27] in a study comparing EVS Vs EVL found that the rate of re-bleeding after oesophageal band-ligation was 8.7% and in similar study *Kuran et al*. , 2006[28] found that the rate of post banding re-bleeding was 6.1%.

CONCLUSIONS

Endoscopic variceal band ligation (EVL) is a safe and effective therapeutic and prophylactic method in managing oesophageal varices. -Although EVL has some complications, yet these complications are minor and transient.-Post-banding ulcers are expected, however, they are superficial and rarely bleed.-The rate of occurrence of post-banding ulcers is not significantly affected by smoking, size of varices or hepatic reserve (Child-Turcotte Pugh classification). -Sucralfate is a safe drug. It has a significant role in decreasing the rate of occurrence of post-banding ulcers and as well their size.

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