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Research Article

**A RANDOMIZED DOUBLE-BLIND TRIAL TO KNOW ABOUT  
THE EFFICACY OF ZINC SULPHATE FOR THE TREATMENT  
OF PEPTIC ULCER DISEASE**<sup>1</sup>Dr. Rania Hidayat, <sup>2</sup>Kainat Akram Chishti, <sup>2</sup>Hafiz Muhammad Salman Javed<sup>1</sup>Medical officer in Gastroenterology and Hepatology ward, Ayub Teaching Hospital  
Abbottabad.<sup>2</sup>Mayo Hospital Lahore**Abstract:****Objective:** The study to investigate the zinc sulfate effect on peptic ulcer disease healing process.**Study Design:** A randomized double-blind trial.**Place and Duration:** The Study was held for the period of one year from February 2016 to February 2017 in the Gastroenterology Department of Services Hospital, Lahore.**Methodology:** It is clinical trial involving patients referred to the Gastroenterology Department. Patients were selected randomly in the control group (n = 58) and interventional group (n = 46). All patients were given standard ulcer therapy containing Metronidazole, Amoxicillin, Bismuth and Omeprazole. For group of intervention, for the treatment zinc sulphate capsules (220 mg) was added to regimen (on an alternate day one capsule was given). The endoscopy was repeated after four weeks. Data were analyzed with  $\chi^2$  software, SPSS, T test and Fisher exact test were used for analysis.**Findings:** There were no significant differences between the control group and intervention group, such as consumption of tobacco, alcohol, consumption of NSAIDs, and ulcer size. The mean size of the interposed ulcers and pre-treatment control group were 25.0 ( $\pm$  18.0) mm and 23.05 ( $\pm$  21.02) mm, respectively. The mean decrease in ulcer size per treatment line in the control group and intervention was 93 ( $\pm$  15), 89.4 ( $\pm$  16.4) without significant difference. groups.**Conclusion:** In this study it is proven that zinc sulfate does not have a significant effect on the recovery of peptic ulcer at a daily dose of 220 mg. More studies should be done to evaluate the effectiveness of zinc sulphate with higher doses.**Key Words:** zinc sulphate, peptic ulcer, RCT.**\* Corresponding author:****Dr. Rania Hidayat,**

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**INTRODUCTION:**

Peptic ulcer or duodenum mucosa membrane is changed which cause local defects and active inflammation. In the United States, acid-pepsin change is common. And every year it houses about 400,0000 people. The peptic ulcer prevalence is 12% approximately in males and in females it is 10%. The factors predisposing to cause peptic and duodenal ulcer were prolonged use of NSAIDs, H. pylori infection, and increase acidity. Other factors include personality type, stress, diet tobacco and alcohol. In peptic ulcer one of the disadvantage is ulcers healing that can reduce complications. Zinc is important for growth, body metabolism, gastric acid secretion activation of about 300 enzymes and healing of tissues, but the zinc effect on healing of tissues is not fully understood. Some clinical studies and trials on animal have demonstrated the efficacy of zinc components in the prevention and treatment of peptic ulcer disease. Zinc levels in peptic ulcers patients were low than in the normal population, while zinc in the stomach mucosa was higher due to zinc accumulation in the injured mucus. Zinc deficiency (gastric and duodenal) on the surface of serum and peptide may have pathological effects on the ulcer, but this is not clear still. However, studies on humans and animals have shown the zinc cytoprotective effects. This study was performed to know the effects of zinc sulphate on the healing of peptic ulcer disease.

**METHODOLOGY:**

This randomized double-blind trial Study was held in the Gastroenterology Department of Services Hospital, Lahore for the period of one year from

February 2016 to February 2017 .104 patients from 164 patients met the participation criteria and were identified as randomized-block control group (n = 58) and intervention (n = 46). In the past four weeks, inclusion criteria, patient satisfaction, peptic ulcer and peptic ulcer treatment confirmed by endoscopy. For each person, an endoscopic questionnaire was completed. Critical discrimination The exclusion criteria included evidence of malignancy of the ulcer as a consequence of the pathology, and the patients were not willing to re-endoscopy. The drug was administered endoscopically and the procedure started with four drugs: metronidazole 400mg TDS, amoxicillin 500 mg QID, bismuth 240 mg TDS and omeprazole 20 mg / day for every patient. A nurse randomly assigned patients or placebo to a blockade method in the intervention group and applied 220 mg zinc sulfate capsule (daily) for the group of interventional. 4 weeks later, all the patients completed the questionnaire form again and the endoscopy was done again. The study was open for illness and the participants informed consent was obtained. The Department's Ethics Committee have given approved for this work. Data were analyzed with SPSS 11.5, T-test and Fisher was used to analyze the data.

**RESULTS:**

Of the patients, 104 (44.2%) were in the intervention group and 58 (55.8%) were in the control group. Four intervention patients, six patients and a control group not allow for a follow-up endoscopy. Patients history and demographic characteristics and are shown in Table-I.

Table-I: Comparison of Characteristics in two groups

Variables	Groups		Significance
	Intervention	Control	
Age (years)	44.24±10.06	48.12±16.73	NS*
Sex			
Male	23 (50%)	26 (44%)	NS
Female	23 (50%)	32 (55.2%)	NS
Epigastric pain (week)	8.02±9.65	13.07±25.99	NS
Distention (week)	17.14±41.73	11.61±19.15	NS
Nausea (week)	10.77±18.55	8.06±8.93	NS
Epigastric burn (week)	18.73±43.41	17.61±23.58	NS
Smoker	13 (23.8%)	13 (22.4%)	NS
Alcohol consumption	4 (8.7%)	3 (5.2%)	NS
NSAID consumption	5 (10.9%)	4 (8.7%)	NS

\*NS: Not Significant

The small 30 mm ulcer size in the intervention group noted in 32 (69.6%) and 30 mm 15 (31.4%). Ulcers in the control group noted in (74.1%) of cases were below than 30 mm in 43 cases and 30 mm in 15 cases (25.9%);

Between the two groups there was no significant difference ( $p > 0.05$ ). Ulcer of pyloric antrum and fourth part of duodenum were found in 29 (27.9%), 75 (72.1%), 4 (3.8%) and 16 (4.3%) duodenum in the second part and duodenum in the second part (4.8% (67.3%), mean size of the ulcers in the first and intervention and control groups was not significantly different before treatment, ie, mm (21.2  $\pm$ ) mm and 22.5 (17.7  $\pm$ ) 24.6 intervention after a mean decrease in the percentage of ulcer and control groups (16.4  $\pm$ ) 93 ( $\pm$  15) and 90.4, respectively.

Table-II: Comparison of ulcer size before and after treatment in two groups

Ulcer size	Group	N	Mean (mm)	SD (mm)	P-Value
Pre treatment	Intervention	46	24.65	17.72	NS*
	Control	58	22.51	21.22	
After treatment	Intervention	42	3.88	7.32	NS
	Control	52	5.79	10.83	

\*NS: Not Significant

There was no difference significantly between the ulcer mean size in the control and intervention group after and before the treatment (Table II).

### DISCUSSION:

Zinc is important for growth, metabolism and healing of tissues, but the effect of zinc on tissue healing and its mechanism is not entirely clear. Some laboratory and clinical studies have proven that zinc components are effective in the prevention of gastric ulcers and its affective treatment. In one study, patients with peptic ulcer disease may cause zinc accumulation in the serum level of the injured mucus, which is higher in normal and gastric mucosal zinc levels. Our results shows reduction in the mean number of ulcers in percentage 92.03% in the intervention group higher than the control group (89.42%), but there were significant statistically differences. Maybe a low dose of zinc sulphate (220 mg / day). In Hong Kong, a laboratory study proved that the healing of ulcers in rats was increased significantly; This process was associated with the dose. They were using 88 mg / kg zinc, which is high than our dose. In one more study, 220 mg of zinc and wood were used daily, and as a result, in the intervention group the number of ulcers was 3 times higher than the control group. In a study on an animals, zinc had a protective effect on the ulcer at a dose of 20 mg / kg. In a study in Spain, a dose of 600 mg / kg was shown to be more effective than 40 mg / kg / day of Famotidine in the recovery of duodenal ulcer. Compared to other studies, this study is lower in zinc than in others. This is due to the disapproval of the medical ethics committee for the use of high doses. In our intervention group, nausea increased only relatively. For this reason, zinc sulfate can be used at higher doses in subsequent studies. On the other hand, we did not detect serum zinc level before work, so we had a defect in our work. The zinc effect mechanism is not fully known in vitro study in the United States. The gastric juice probably confirmed the effect of zinc sulfate and acetylcysteine effects of sulphydryl compounds and a reduction in the basal secretion of gastric acid. In

other study, some drugs have been proposed, such as mecadanol, zinc sulfate, dipyridamole, propranolol, which have a cytoprotective effect on animal studies. In one study, alcohol-induced ulcers and gastric mucosa glands zinc sulfate and PGE2 levels were assessed and changes in histamine-scavenging rats were assessed for indo-methacin effects. Alcohol reduces histamine levels while indo-methacin reduces PGE2 in gastric mucus glands. Alcohol also increases histamine in the stomach secretions. Zinc sulphate has no effect on the reduction of PGE2, which is caused by histamine alcohols and secretion levels but is caused by indomethacin, as opposed to mucosal changes.

### CONCLUSION:

This study has shown that at a daily dose of 220 mg / day of zinc sulfate accelerates the recovery of peptic ulcer.

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