

# Comparison Of Two Sucralfate Dosages In Duodenal Ulcer Healing

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## SUMMARY

The effects of two regimens of sucralfate, 1 g twice a day (1 hour before lunch and at bedtime) and 2 g twice a day (30 minutes before breakfast and at bedtime) on ulcer healing in 58 patients with endoscopically proved duodenal ulcer were compared. Healing was defined as complete re-epithelization. Endoscopic assessments were performed after four weeks and, if complete healing was not achieved after four more weeks. After four weeks, the ulcer had healed in 15 of 20 patients (% 75) who received 2 g of sucralfate twice a day and 28 of 40 patients (73.7 percent) who received 1 g of sucralfate twice a day. The cumulative healing rates after eight weeks were 85 percent and 84.2 percent, respectively. These results suggest that sucralfate tablets in a dosage of 1 g twice daily are as effective as 2 g twice daily in the treatment of duodenal ulcer and could lead to better patient compliance.

**KeyWords:** Duodenal ulcer Sucralfate

## INTRODUCTION

Sucralfate a basic aluminium salt of sucrose octosulfate with unique ulcer coating and mucosal protective properties has been used for 20 years in the treatment of peptic ulcer (1,2). It promotes ulcer healing by forming a complex with proteins at the ulcer base directly inhibiting "the action of pepsin, binding bile salts and blocking the diffusion of gastric acid into the ulcer with a small buffering capacity (2,3,4,5).

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## ÖZET

**DUODENAL ÜLSER TEDAVİSİNDE İKİ SUCRALFA TE DOZUNUN KARŞILAŞTIRILMASI**

Endoskopik olarak duodenal ülser tespit edilen 58 hastada iki farklı dozda (öğle yemeğinden 1 saat önce ve yatarken 1 g veya kahvaltıdan yarım saat önce ve yatarken 2 g) uygulanan sucralfate tedavisinin etkileri karşılaştırıldı. Tam reepitelizasyon gelişmesi iyileşme olarak kabul edildi. Tedavinin dördüncü haftasında endoskopik değerlendirme yapıldı, eğer tam iyileşme sağlanmamışsa sekizinci haftada endoskopi tekrarlandı. Dördüncü hafta sonunda günde iki kez 2 g sucralfate alan 20 hastanın 15'inde (%75), günde iki kez 1 g sucralfate alan 40 hastanın 28'inde (% 73.7) ülser iyileşti. Sekizinci hafta sonunda toplam iyileşme oranları sırasıyla % 85 ve 84.2 idi. Bu sonuçlar günde iki kez 1 g'lık sucralfate dozunun duodenal ülser tedavisinde günde iki kez 2 g olarak uygulanan doz kadar etkili olduğunu ve daha iyi bir hasta uyumu sağlayacağını telkin etmektedir.

**Anahtar Kelimeler:** Duodenal ülser Sucralfate

There is also evidence that it stimulates prostaglandin synthesis in the mucosa (6,7). Sucralfate given in a dose of 4 g/d (1 g t.d.s before meals and at night) has been shown to be significantly better than placebo (8,9,10) and as effective as cimetidine (0,8-1,2 g/d) (11,12), or ranitidine (150 mg b.d.) (13) in healing duodenal and gastric ulcers. It has also been shown that sucralfate given in a dose of 2 g two times a day is as effective as the conventional 1 g.q.d.s. dose (1,14,15,16).

The aim of this study was ascertain whether a dosage regimen of 1 g two times a day might be as effective as the 2 g two times a day regimen in short-term duodenal ulcer healing.

Table 1. Patient Characteristics

Characteristics	Group A	Group B	Significance
Number	20		
Male	9	19	NS
Female	11	19	NS
Mean age (years)	32.90 ± 9.91	33.68 ± 10.34	NS
Tobacco users	0	17	NS
Alcohol users	0	1	NS
Ulcer history			
First episode	5	8	NS
Relapse	15	10	NS

NS: not significant

Table 2. Endoscopic Finding

Characteristics	Group A	Group B	Significance
Ulcer size			
5-10 mm	10	29	NS
10 mm	4	9	NS
Duodenal deformity	12	25	NS

Table 3. Healing Rates at Four Weeks

Endoscopic Aspect	Group A	%	Group B	%	Significance
Healed ulcers	15	75	28	73.7	NS
Unhealed ulcers	5	25	10	26.3	

Table 4. Healing Rates at Eight Weeks

Endoscopic Aspect	Group A	%	Group B	%	Significance
Healed ulcers	17	85	32	84.6	NS
Unhealed ulcers	3	15	6	15.4	NS

Table 5. Healing Rates in Smokers and Nonsmokers

	Healed	%	Unhealed	%	Significance
Smokers	17	73.9	6	26.1	NS
Nonsmokers	24	68.6	11	31.4	NS

## METHODS

The patients of this prospective study ambulatory 28 male and 30 female symptomatic outpatients with endoscopically documented duodenal ulcer, measuring at least 5 mm in diameter. Patients were excluded if they were younger than 18 or older than 75 years of age. Additional criteria for exclusion included previous upper gastrointestinal surgery, co-existent gastric ulcer, pyloric stenosis, grade II or III esophagitis, recent treatment with H<sub>2</sub>-blockers, ulcer bleeding during the previous 24 hours or treatment with steroids, salicylates, or other nonsteroidal anti-inflammatory drugs. The patients were randomly assigned to treatment with sucralfate tablets either 2 g two times a day (30 minutes before breakfast and at bedtime) for group A, or 1 g two times a day (1 hour before lunch and at bedtime) for group B. Sucralfate tablets were administered four weeks without any other anti-ulcer treatment. The patients were seen every 5 for clinical evaluation

Endoscopic examination was carried out on entry into the study, at the end of four weeks, and if the ulcer was unhealed, at the end of eight weeks by the same operator. The endoscopist was un-

aware of the treatment group of the patients. Healing was defined as complete reepithelization of the ulcer crater. The endoscopist recorded the location, size, shape, depth, number of ulcer(s) and the eventual presence of bulboduodenitis.

The significance of differences was analysed by Fisher's exact test.

## RESULTS

### Patient Characteristics

A total of 60 patients entered the study, 22 in the group A, and 38 in the group B. Two patients in group A were excluded because of insufficient compliance during the first two weeks of the study. The characteristics of the two groups are listed in Table 1. There were no significant differences between the two groups. The size of ulcer and the incidence of duodenal cap deformity were also similar in the two groups (Table 2).

### Healing Rates

Endoscopically documented healing rates after four weeks of treatment were very similar with 15 of 20 patients (75 percent) in group A, and 28 of 38 patients

(73,7 percent) in group B (Table 3). The pain scores decreased promptly in the both groups, and no difference between them was found. After eight weeks, the healing rates were 85 percent in the group A, and 84.2 percent in the group B. (Table 4). The difference between the two groups was not statistically significant ( $p>0.05$ ).

The healing rates in smokers and non smokers did not differ in either group (Table 5)

### Adverse Effects

There was no serious reaction seen in the either group. Side effects in the group A were nausea in two patients, constipation in one patient and transient rash in one patient. In the group B no adverse effect was seen.

### COMMENTS

The result of this study suggests that sucralfate, in a dosage of a 1 g two times a day, is as effective as the dosage of 2 g two times a day in the short-term healing of duodenal ulcer. At four weeks, there were no significant differences in healing rates between the two groups: 75 percent for the group A receiving 2 g two times a day, 73.7 percent for the group B receiving 1 g twice a day. Healing rates approached 85 percent in the group A, and 84.2 percent in the group B at eight weeks. Pain relief was similar in the both groups. The average healing rates were similar to that reported by other authors for the dosages of 1 g four times a day and 2 g two times a day (10,14,17).

There were a low incidence of side effects in the group B receiving 1 g of sucralfate two times a day.

In conclusion, the present study shows that the tablet form of sucralfate in a dosage of 1 g, 1 hour before lunch and at bedtime, without any other antiulcer drug, has as effective a duodenal ulcer healing rate as does 2 g two times a day. These data are important for better patient compliance to duodenal ulcer treatment.

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