

A COMPARATIVE CLINICAL TRIAL OF SUCRALFATE AND CIMETIDINE IN DUODENAL ULCER HEALING

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SYNOPSIS

The ulcer healing rates with either cimetidine or sucralfate in endoscopically proven duodenal ulcers were compared. Fifty patients were randomised into two treatment groups; four grams of sucralfate a day or cimetidine one gram daily. Endoscopy was repeated at six weeks to assess healing and at eight weeks if not healed. Cimetidine-treated subjects had healing rates of seventy-nine percent compared with seventy-four percent in sucralfate-treated patients. There were no significant adverse reactions noted in either groups.

INTRODUCTION

Sucralfate has been in use in Japan for many years and even though it was introduced locally about four years ago it has not achieved as much impact as expected.

The local mode of action and the reported few side-effects with sucralfate has a lot of appeal (1, 2, 3).

This study compares the efficacy of initial duodenal ulcer healing of sucralfate compared with cimetidine.

MATERIAL AND METHOD

Fifty patients with endoscopically proven chronic duodenal ulcers (DU) were randomly assigned to either treatment groups:-

- (i) Sucralfate 1 gram three times a day and at bedtime.
- (ii) Cimetidine 200 milligrams three times a day and 400 milligrams at bedtime.

However patients who had evidence of upper gastro-intestinal tract bleeding within the last two weeks and who were on NSAID therapy were excluded. Patients were given supplemental antacids (Magnesium Trisilicate tablets) for additional symptom relief.

A physical examination, hemogram, electrolytes, serum creatinine and serum liver function tests were assessed before treatment, at two weeks and at the time of second endoscopy at six weeks. During these visits symptomatology in particular consumptions of antacids, was assessed. There were three dropouts from this cohort, none needed a change in medication. At the conclusion of the trial there were twenty-three patients in the sucralfate group and twenty-four in the cimetidine group.

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RESULTS

Efficacy of ulcer healing

The end point of ulcer healing was complete ulcer healing. (I) showed comparable and statistically insignificant differences in the ulcer healing efficacy of the two drugs. There are no further ulcer healing observed at eight weeks.

Symptom relief and antacid use

With antacids freely available to the patients, there were no significant differences in the amount of antacids consumed (Fig 1). Symptoms were more difficult to evaluate, however, the impression was that in both groups there was almost complete symptom relief after the second week of therapy in those who eventually had their ulcers healed and the impression was that relief was obtained faster with cimetidine. However, objective assessment was abandoned since the endoscopist had full knowledge of the treatment schedules.

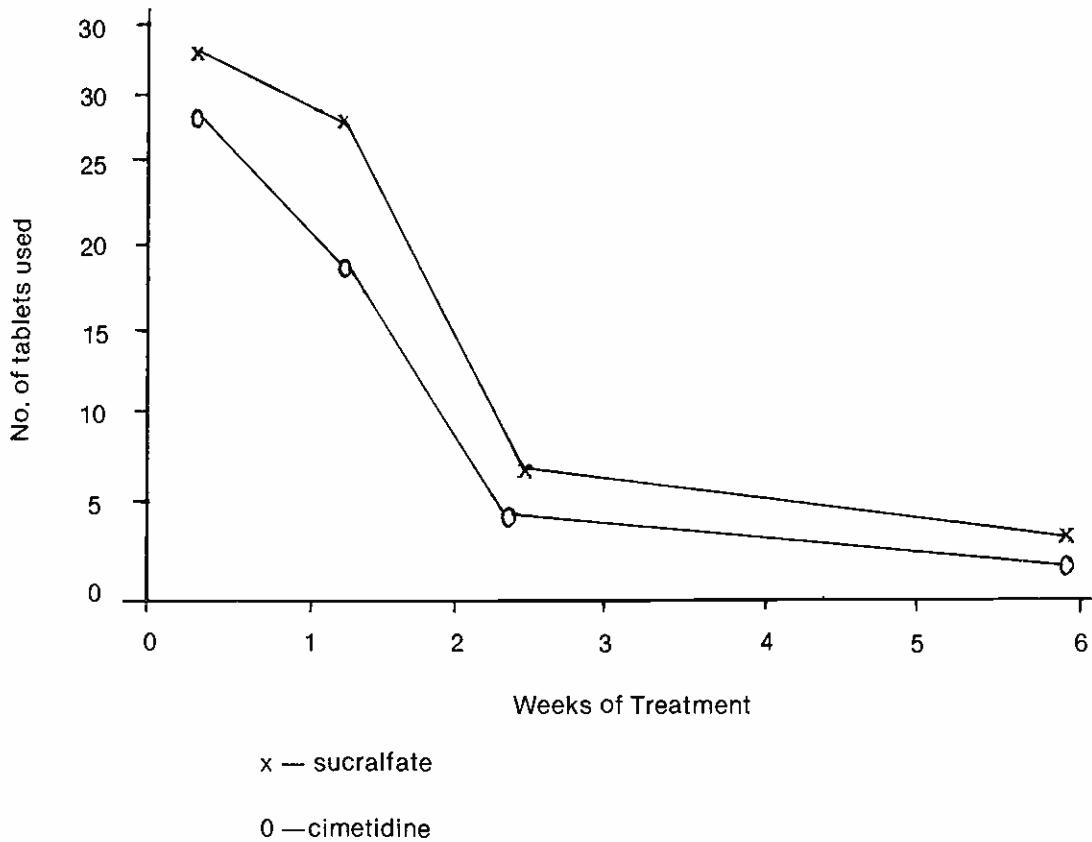
efficacy in duodenal ulcer healing with cimetidine and both treatments were relatively devoid of adverse effects (4).

With so many effective drugs available for duodenal ulcer healing it is obvious that the final choice of treatment will be influenced by the safety and side-effects of the drugs.

**TABLE 1
COMPLETE ULCER HEALING AFTER SIX WEEKS
OF THERAPY**

Medication	Healing	Non-healing	Percentage
Sucralfate	17	6	74
Cimetidine	19	5	79

FIGURE 1



Side-effects and laboratory results

There were no dropouts from side effects. In the sucralfate group four volunteered symptoms of constipation (seventeen percent). One patients on cimetidine complained of lack of concentration at work. There were no changes noted in the liver enzymes, serum creatinine or hemogram.

CONCLUSION

This study showed that sucralfare had comparable

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