Double-blind controlled trial of amylopectin sulphate (Depepsen) in the symptomatic treatment of duodenal ulcer

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SUMMARY In a double-blind controlled trial amylopectin sulphate (Depepsen) had no significant advantage over placebo in the symptomatic treatment of duodenal ulcer.

Most treatments of duodenal ulcer have attempted to neutralise or diminish acid output or to increase mucosal resistance; little attention has been given to pepsin. Amylopectin sulphate (Depepsen, Searle) has been reported to be effective in both gastric and duodenal ulcer (Cayer and Ruffin, 1967; Zimmon, et al., 1969; Sun and Ryan, 1970), though a negative study has also appeared (Cocking, 1972). We report here a double-blind trial of this agent in the asymptomatic treatment of duodenal ulcer.

Methods

Patients studied were men with radiological evidence of duodenal ulcer crater or deformity obtained within the previous two years. They had a history of six months to five years typical of duodenal ulcer, with pain on three or more days in the seven days before admission to the trial. There were no restrictions to entry into the trial because of age, cardiorespiratory or renal disease, but those with known gastric ulcer, hiatus hernia, gallstones, or irritable bowel syndrome, and those receiving anticholinergics, carbenoxolone, Caved-S, or gefarnate for their present relapse were excluded. Informed consent was obtained.

The patients were given their customary antacids and either amylopectin sulphate 500 mg to be chewed and swallowed with a drink two hourly for six daily doses, or an identical appearing placebo tablet containing dextrose 500 mg in place of the amylo-

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Table  Mean number of days and nights of ulcer pain and antacid tablets consumed during trial period

<table>
<thead>
<tr>
<th>Week of trial</th>
<th>Mean number of nights with pain/patient</th>
<th>Mean number of days with pain/patient</th>
<th>Mean number of antacid tablets/Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Active</td>
<td>Placebo</td>
<td>Active</td>
</tr>
<tr>
<td>1</td>
<td>3-6</td>
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</tr>
<tr>
<td>4</td>
<td>2-0</td>
<td>2-9</td>
<td>3-3</td>
</tr>
<tr>
<td>5</td>
<td>1-5</td>
<td>1-7</td>
<td>2-9</td>
</tr>
<tr>
<td>6</td>
<td>2-1</td>
<td>1-3</td>
<td>3-1</td>
</tr>
</tbody>
</table>

either of these two criteria, nor was there any difference in the severity of pain. No side-effects were noted with either amyllopectin or placebo tablets. The active and placebo groups were comparable in age, sex, and length of history.

Discussion

These observations show no advantage for amyllopectin sulphate compared with placebo in the treatment of symptoms of duodenal ulceration. In both treatment groups daytime and nocturnal pain and antacid consumption decreased during the six weeks of the trial—the decrease presumably representing the spontaneous symptomatic remission in duodenal ulcer.

These results differ from the significant benefit with amyllopectin sulphate 250 mg two hourly reported by Sun and Ryan (1970) and Sun (1974). However, in a trial using amyllopectin sulphate and propantheline, Cocking (1972) could show no advantage for amyllopectin sulphate 500 mg every three hours over a placebo, and in a recent endoscopically controlled eight week trial Landecker et al. (1976) also found no advantage for amyllopectin.

Although amyllopectin sulphate has been shown to inhibit gastric pepsin activity in man (Sun, 1967), it did not, in the dose range used in the present trial, produce significant relief of symptoms in patients with duodenal ulceration.

We wish to thank Searle and Co. Ltd., for supplying the active and placebo tablets.

References


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