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REPORTE CORTO / SHORT REPORT

ORAL HUMAN RECOMBINANT EPIDERMAL GROWTH FACTOR IN PATIENTS WITH DUODENAL ULCER

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SUMMARY

The role of Epidermal Growth Factor (EGF) in the physiology of regeneration and protection of the digestive tract has been thoroughly studied. Oral EGF accelerates healing of gastroduodenal ulcers in animals. The rate of healed patients in the groups treated with EGF increased with time, lowering the difference as compared to cimetidine group. This may indicate that EGF has a long-term healing effect. To our knowledge, this is the first report on the oral use of EGF in humans.

INTRODUCTION
Peptic gastroduodenal ulcer is a recurrent disease with economic repercussion as it mainly affects adults during their productive years. The role of Epidermal Growth Factor (EGF) in the physiology of regeneration and protection of the digestive tract has been thoroughly studied. Oral EGF accelerates healing of gastroduodenal ulcers in animals (1, 2). However, there are no reports showing the effect of oral EGF in humans.

METHODOLOGY

An open, randomized, positively controlled trial was conducted. Inclusion criteria were: endoscopic diagnosis of duodenal ulcer, major diameter between 0.5 and 1.5 cm, age between 18 and 75 years, and written consent to participate. Patients with H2 blockers during the previous 2 weeks were excluded. Seventy five patients were randomly distributed in three groups to receive oral human recombinant EGF in 1% carboxymethyl cellulose at two different doses (450 mg or 600 mg/day), or cimetidine. Treatment was administered up to 6 weeks. The most important assessment criteria was the proportion of patients healed after 2, 4 and 6 weeks of treatment determined by endoscopy. Biopsies were taken from 30 patients at each evaluation. One patient, erroneously included because of actually having a pre-pyloric ulcer, was withdrawn.

RESULTS

Distribution of the patients characteristics in trial groups was homogeneous. More than 50% of the patients were between 35 and 54 years old, and a predominance of white males was observed. Similar clinical improvement ratios were obtained in the three groups after 6 weeks of treatment.

Healing ratios compared by chi square or Fishers exact tests showed a significant difference between group B and group C during the first 4 weeks of treatment, but differences after 6 weeks were not significant (table). Adverse reactions were not detected in any of the patients. Abnormal histological modifications were not found in any of the biopsies performed.

<table>
<thead>
<tr>
<th>Group</th>
<th>Patients with healed ulcer</th>
<th>Failures</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>-------</td>
<td>--------</td>
<td>--------</td>
<td>--------</td>
</tr>
<tr>
<td>A</td>
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<td>13</td>
<td>19</td>
</tr>
<tr>
<td>B</td>
<td>3</td>
<td>10</td>
<td>17</td>
</tr>
<tr>
<td>C</td>
<td>11</td>
<td>21</td>
<td>25</td>
</tr>
<tr>
<td>-------</td>
<td>--------</td>
<td>--------</td>
<td>--------</td>
</tr>
<tr>
<td>Total</td>
<td>19</td>
<td>44</td>
<td>62</td>
</tr>
</tbody>
</table>
DISCUSSION

The healing percent obtained with EGF was within the range reported for effective medications in the treatment of peptic ulcers, 70 to 90% after 6 to 8 weeks of treatment (3). The rate of healed patients in the groups treated with EGF increased with time, lowering the difference as compared to cimetidine group. This may indicate that EGF has a long-term healing effect. A similar finding has been reported by Olsen et al (1). Higher doses of EGF or a higher concentration of carboxymethyl cellulose could be more effective. Itoh et al. (4) proved effectiveness of EGF combined with 2% hydroxypropyl cellulose, as compared to EGF alone. To our knowledge, this is the first report on the oral use of EGF in humans.

REFERENCES


There is no charge for this document.