Symptomatic GERD: double blind controlled study of intermittent
treatment with omeprazole or ranitidine

ESG investigators. BMJ 1999;318:502-7

Study Type: POEM

Purpose: Should omeprazole or ranitidine be used for intermittent treatment of GERD?

Study Duration: 1 year

Patients: 677 patients, mean age 55 years (18-75), 55/45-male/female, BMI = 27 (overweight), ~40% h.pylori +

Trial Design: Double-blinded, placebo-controlled, randomized, intention-to-treat, multicenter (56 Centers, 6 countries)

Drugs: omeprazole 10 mg qd
       omeprazole 20 mg gd
       ranitidine 150 mg bid

Protocol: patients were given either treatment for 2 weeks , if they remained symptomatic after 2 weeks, the dose was increased for another 2 weeks, except for those randomized to omeprazole 20 mg, any recurrence was retreated with initial drug. Maalox was provide for use prn.

Inclusion: patients with heartburn and mild endoscopy or mild erosive changes

Exclusion: those with grade D erosive changes.

Outcome Endpoint: the number of patients successfully completing the study on intermittent therapy

1. Are the results valid?
   * randomized? yes
   * double-blinded? yes
   * were groups similar? yes
   * all patients accounted for? yes

2. What were the results?

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>ranitidine</th>
<th>omeprazole 10 mg</th>
<th>omeprazole 20 mg</th>
<th>ARR*</th>
<th>P</th>
<th>NNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>asymptomatic at 2 weeks</td>
<td>26%</td>
<td>40%</td>
<td>55%</td>
<td>29%</td>
<td>.001</td>
<td>3.5</td>
</tr>
<tr>
<td>completed intermittent</td>
<td>47%</td>
<td>46%</td>
<td>48%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>transferred to maintenance</td>
<td>27%</td>
<td>22%</td>
<td>22%</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

   *omeprazole 20 mg vs ranitidine

3. Will the results help me?
   * long term outcome was not effective by initial treatment (~45% completed intermittent therapy)
   * ~ 50% do well with intermittent therapy and not need maintenance therapy
   * omeprazole 20 mg was the most effective
   * older patients and smokers have higher relapse rates
   * those who got response in the first 2 week trial had better outcomes with intermittent treatment
   * no matter what the done, 13% of patients stayed symptomatic
   * no correlation to sex, age, BMI or presence of h.pylori

For every 100 patients presenting with GERD, 55 patients will be asymptomatic at 2 weeks on omeprazole 20 mg, 29 extra patients would be asymptomatic over ranitidine. Approximately 48 patients will respond to intermittent therapy regardless of the drug used after a year.