of patients with moderate CD; in this subgroup, high baseline CRP was associated with substantially higher remission rates. This analysis suggests that patients with moderate disease can be treated effectively with adalimumab, especially when there is evidence of inflammation. Prospective studies are warranted to confirm these findings.

Abstract PTU-108 Table 1  

<table>
<thead>
<tr>
<th>Placebo</th>
<th>ADA40/40</th>
<th>ADA160/80</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12% (9/74)</td>
<td>24% (18/75)</td>
<td>36% (27/76)*</td>
</tr>
<tr>
<td>CRP &gt;10 mg/l, % (n/N)</td>
<td>4% (1/28)</td>
<td>27% (9/33)*</td>
</tr>
<tr>
<td>CDAI ≤300, % (n/N)</td>
<td>17% (8/46)</td>
<td>29% (13/45)</td>
</tr>
<tr>
<td>CRP &gt;10 mg/l, CDAI ≤300, % (n/N)</td>
<td>7% (1/15)</td>
<td>26% (6/23)</td>
</tr>
<tr>
<td>CDAI &gt;300, % (n/N)</td>
<td>4% (1/28)</td>
<td>17% (5/30)</td>
</tr>
<tr>
<td>CRP &gt;10 mg/l, CDAI &gt;300, % (n/N)</td>
<td>0% (0/13)</td>
<td>30% (3/10)</td>
</tr>
</tbody>
</table>

*p<0.05 vs placebo.

†p<0.005 vs placebo.

Competing interests  


REFERENCE  

1. Hanauer SB. Gastroenterology 2006;130:323.

PTU-109  

EFFICACY AND SAFETY OF ADALIMUMAB IN MODERATE COMPARED WITH SEVERE CROHN’S DISEASE: POOLED DATA FROM THE CHARM AND EXTEND TRIALS

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Introduction  
The efficacy of adalimumab (ADA) in Crohn’s disease (CD) by disease duration has been explored, but efficacy and safety of ADA by disease severity have not been investigated. The CHARM1 and EXTEND3 trials assessed ADA treatment for the maintenance of remission in patients with moderate to severe CD. Results from CHARM and EXTEND in patients with moderate vs severe CD were pooled to assess efficacy and safety by disease severity.

Methods  
This analysis of pooled data was performed to assess clinical response and clinical remission at week 56 (CHARM) or 52 (EXTEND) in patients with moderate (CDAI ≤300) or severe (CDAI >300) CD, treated with blinded ADA every other week (eow) or placebo. In both trials, patients received open-label ADA induction (CHARM: 80 mg at week 0, 40 mg at week 2; EXTEND: 160 mg at week 0, 80 mg at week 2), followed by blinded treatment (ADA 40 mg eow or weekly, or placebo in CHARM, 40 mg eow or placebo in EXTEND) from weeks 4 to the end of the trial (week 56 in CHARM, week 52 in EXTEND). Data from the ADA 40 mg eow arm of CHARM was pooled with data from EXTEND; safety and efficacy (proportion of patients in clinical remission, defined as CDAI<150, or clinical response, defined as at least a 70 point decrease in CDAI [CR70]) at week 56/52 were assessed for patients who achieved CR70 at week 4, separated by baseline disease severity (moderate or severe).

Results  
A total of 485 patients were included in the pooled analysis: 187 with moderate CD (placebo: 92; ADA: 95) and 251 with severe CD (placebo: 126; ADA: 125). For both moderate and severe CD groups, a statistically significantly greater proportion of patients treated with ADA 40 mg eow achieved clinical response and clinical remission at week 56/52 compared with placebo treated patients (Abstract PTU-109 table 1). The safety profiles in the moderate and severe CD subgroups were similar.

Abstract PTU-109 Table 1  

Clinical response (CR70) and clinical remission at week 56/52, by baseline CDAI: pooled data from CHARM and EXTEND

<table>
<thead>
<tr>
<th>CDAI ≤300</th>
<th>CDAI &gt;300</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>ADA 40 mg eow</td>
</tr>
<tr>
<td>CR70 (%)</td>
<td>16 44 &lt;0.001</td>
</tr>
<tr>
<td>Clinical remission (%)</td>
<td>14 40 &lt;0.001</td>
</tr>
</tbody>
</table>

*ADA vs placebo.

Conclusion  
The analysis of the pooled data from CHARM and EXTEND suggests that ADA 40 mg eow is safe and effective for the treatment of either moderate or severe CD.

Competing interests  

REFERENCES  

PTU-110  

ELEVATED C REACTIVE PROTEIN IN ANTI-TNF-NAIVE PATIENTS IS ASSOCIATED WITH HIGHER REMISSION RATES

doi:10.1136/gutjnl-2012-302514c.110

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Introduction  
The CHARM trial demonstrated that adalimumab (ADA) was effective for the maintenance of remission in patients with moderate to severe Crohn’s disease (CD), and that remission rates are influenced by a patient’s baseline C reactive protein (CRP).
PTU-109 Efficacy and safety of adalimumab in moderate compared with severe Crohn's disease: pooled data from the charm and extend trials

J-F Colombel, W J Sandborn, M M Castillo, Q Zhou and R B Thakkar

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