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Efficacy and safety of adalimumab in children with active Crohn’s disease: a prospective, open-label, single-centre trial
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Adalimumab (ADA) (HUMIRA, Abbott®), a fully human IgG1 anti-TNFα monoclonal antibody, is effective in inducing and maintaining remission in adult patients (pts) with active Crohn’s Disease (CD), regardless of previous experience with anti-TNFα therapy. There are only few data on its use in pediatric pts with CD.

Aim: To prospectively evaluate efficacy and safety of ADA in pediatric pts with moderate to severe CD.

Patients and Methods: 23 CD pts, median age 16.1 years (range 9–20), naive to (9 pts) or who had failed prior Infliximab (IFX) therapy (14 pts) received ADA. The induction schedule at week (wk) 0 and 2 was 160 mg/80 mg in 13 pts, 80 mg/40 mg in 8 pts, followed respectively by 80 mg or 40 mg every other week (ew) during the 44 wks maintenance phase. Two pts received an induction dose of 120 mg/80 mg, followed by 80 mg ewo.

Primary outcomes were: clinical remission (PCDAI score ⩽10), clinical response (decrease in PCDAI score of >50% versus baseline), safety of the therapeutic course at wk 2, 4, 12, 24 and 48. ITT analysis including all pts who received at least 1 dose of ADA was performed.

Results: mean disease duration at the beginning of ADA course was 52.2±42.5 months (mts). Fourteen pts had previously received IFX therapy (9.2±8.2 doses), discontinued due to loss of efficacy (11 pts) or intolerance (3 pts). Mean time between the last IFX dose and the beginning of ADA was 19.2±15.5 mts. At baseline 13 pts were receiving concomitant immunomodulators (IM); only 2 pts at wk 48. Mean oral corticosteroids dose (mg/kg/day) was 0.9±0.2 mg at the beginning of the trial, 0.07±0.1 at wk 48 (p<0.001).

The mean PCDAI, ESR, CRP values at each study point are shown in the table. Rates of remission at wk 2, 4, 12, 24 and 48 were: 36.3%; 60.8%; 30.5%; 50% and 65.2%. Rates of response were respectively: 54.5%; 34.8%; 39.1%; 40.9%; 30.4%. During the maintenance phase 5/8 pts receiving 40 mg ewo had to increase ADA dose to 80 mg ewo in order to maintain clinical remission; 6/13 pts receiving 80 mg ewo were able to shift to 40 mg ewo without CD exacerbation. Only 2 pts presented a serious adverse event requiring temporary cessation of ADA: 1 within wk 24 (abdominal abscess), 1 through wk 48 (severe cutaneous infection).

<table>
<thead>
<tr>
<th>Wks</th>
<th>0</th>
<th>2</th>
<th>4</th>
<th>12</th>
<th>24</th>
<th>48</th>
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<tr>
<td>PCDAI</td>
<td>36.5</td>
<td>14.7</td>
<td>11.5</td>
<td>16.6</td>
<td>13.7</td>
<td>9.9</td>
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<td></td>
<td>±5.7</td>
<td>±5.05*</td>
<td>±2.38*</td>
<td>±4.7*</td>
<td>±6.4*</td>
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<td>ESR (mm/h)</td>
<td>54</td>
<td>22</td>
<td>27.0</td>
<td>27.0</td>
<td>20</td>
<td>13.1</td>
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<td>±36</td>
<td>±11.1**</td>
<td>±19**</td>
<td>±14**</td>
<td>±14.8**</td>
<td>±4.4**</td>
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<tr>
<td>CRP (mg/L)</td>
<td>31.2</td>
<td>6.5</td>
<td>7.3</td>
<td>11.2</td>
<td>8.8</td>
<td>2.7</td>
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<tr>
<td></td>
<td>±24²</td>
<td>±5.8*</td>
<td>±6.2*</td>
<td>±5.6*</td>
<td>±4.8*</td>
<td>±1.3*</td>
</tr>
</tbody>
</table>

*p<0.01 vs baseline, **p<0.05 vs baseline.

Conclusions: Our data suggest that ADA is an effective and well tolerated therapeutic option in rapidly inducing and maintaining clinical remission in pediatric pts with refractory CD, irrespective of prior IFX therapy. ADA maintenance dose can easily and efficiently be modulated over time according to disease activity.

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Functional results of IPAA for ulcerative colitis after postoperative pelvic complications
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Background: Proctocolectomy with ileal pouch-anal anastomosis (IPAA) has become the procedure of choice for surgical treatment of intractable ulcerative colitis (UC). Complications developing early postoperatively may compromise long-term functional outcome. Aim of this study was to evaluate long-term functional outcome and quality of life (QoL) after IPAA in patients who developed early complications compared with not complicated controls.

Methods: We prospectively evaluated 118 patients with IPAA (55 male) operated for UC in our institution between 1987 and 2002. Median age at the time of surgery was 38 (12–62) years. Data regarding diagnosis, surgical procedure, postoperative complications, pouchitis, functional results and failure rate were prospectively collected. Every complication developed after surgery, such as early (within 3 months) or late, was recorded. Standard FU intervals were at 3, 6 and 12 months during the first year, and every year thereafter for at least 5 years (range 5–14 ys). Patients answered a questionnaire about bowel function, need for medications, pad usage, day and night continence, urinary dysfunction, sexual activity and overall satisfaction with surgery 1 year and again 5 years after ileostomy closure.

Results: 117 patients completed the early FU. Nine patients (2 W and 7 J-pouch) developed early pelvic sepsis (7.69%): 3 abscess (1W) formations without fistula, 5 leakages of pouch-anal anastomosis (1W) and 1 low pouch-vaginal fistula (~2cm from the dentate line). Treatment was conservative in 3 cases (1 requiring antibiotic therapy and 2 CT-guided drainage) and surgical with pouch salvage procedure in 6. Salvage surgery provided 2 trans-anal procedures (1 pelvic sepsis and 1 pouch-vaginal fistula) under anesthesia and 4 major surgery interventions. In about 33.3% of cases more than one procedure has been necessary. Eighty-eight patients (38 male) median age 44 years (17–68) completed the 5 years FU, completely answered the questionnaire and were available for functional evaluation. Patients who developed early sepsis (n=9) showed worse long-term functional results compared to controls (n=79): stool frequency: 9.1 (5.15) vs 4.2 (1–9) movements/day p=0.0001; pts with night evacuation: 8 (88.8%) vs. 13 (16.4%) p=0.0001; pts achieving perfect continence during day: 3 (33.3%) vs. 63 (79.7%); pts achieving perfect continence during night: 1 (11.1%) vs. 48 (60.7%); pts needing anti diarrhoeals: 7 (77.7%) vs. 15 (19%) p=0.0001; pad: 5 (55.5%) vs. 11 (13.9%) p=0.002; pts with sexual dysfunction: 2 (22.2%) vs. 3 (3.8%) p=0.024. QoL and satisfaction after surgery were good in all patients. This observation did not correlate with function.

Conclusions: IPAA is the procedure of choice for surgical treatment of intractable ulcerative colitis. Functional outcome may be influenced by septic early complications. Overall QoL and satisfaction with surgery are comparable to those of controls.