Dietary Therapies Induce Rapid Response and Remission in Active Paediatric Crohn’s Disease

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Disclosures

• Speaker fees- Nestle Health Science and Takeda
• Consulting- Nestle Health Science
## Background

Medical therapies such as steroids and Anti-TNF agents induce rapid response within the first 2-4 weeks.

### Time to clinical response and remission for therapeutics in IBD

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Weeks since start of treatment</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Infliximab</td>
<td></td>
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<tr>
<td>Adalimumab</td>
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<tr>
<td>IV corticosteroids</td>
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<td>Oral corticosteroids</td>
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**Luminal CD**

*Abhinav Vasudevan et al. World J Gastroenterol 2017 September 21; 23(35): 6385-6402*
Objectives

- To evaluate the early response rate (drop of 12.5 or remission PCDAI ≤10) in response to two different dietary therapies (EEN or CDED+50% PEN) by week 3
- To assess whether response by week 3 was predictive of remission by week 6.

Inclusion criteria:

- Children 4-18 years of age
- Recent diagnosis of CD (<3 years)
- PCDAI ≥ 10
- CRP ≥ 0.6 OR ESR ≥ 20 mm/h OR Calprotectin > 200 mg
- Paris Location L1, L3, L4 or right sided L2, Behavior B1
- Informed Consent
Methods

Study design- RCT comparing EEN to CDED+PEN

78 patients mean age 14.2±2.7 years

<table>
<thead>
<tr>
<th>Variable</th>
<th>CDED+PEN (N=40)</th>
<th>EEN (N=34)</th>
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<tr>
<td>Mean Age (years)</td>
<td>13.8±2.8</td>
<td>14.5±2.6</td>
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<td>Gender (males)</td>
<td>26 (65%)</td>
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<td>Disease Duration (months)</td>
<td>2.4±6</td>
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<td>Median PCDAI (IQR)</td>
<td>25 (20-35)</td>
<td>27.5 (18.75-32.5)</td>
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<td>Median CRP (g/L)</td>
<td>23.6 (9-55)</td>
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<td>IMM (7.5%)</td>
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Disease location

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<td>1</td>
</tr>
<tr>
<td>L3</td>
<td>19</td>
<td>15</td>
</tr>
<tr>
<td>L4a</td>
<td>14</td>
<td>13</td>
</tr>
<tr>
<td>L4b</td>
<td>2</td>
<td>3</td>
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*Modulen will be given ORALLY

**Study Design Crohn’s Disease Exclusion Diet (CDED)**

- **Weeks 0-6**
  - CDED Phase 1 +50% Modulen*
  - Group 1: CDED + PEN
  - Randomization
  - Allowed to start IMM Wk 3
  - Primary Endpoint Wk 6
- **Weeks 6-12**
  - CDED Phase 2 +25% Modulen*
  - Group 2: EEN
  - 25% Modulen + Free Diet*

Notes:
- IMM: Immunosuppressants
- PCDAI: Pittsburgh Crohn's Disease Activity Index
- PGA: Physician Global Assessment
- Calprotectin: Calprotectin test
- Lactulose Mannitol Test: Lactulose Mannitol test
- Food diary: Food diary
- Adherence: Adherence

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Response & remission - week 3

- Response at week 3 obtained in 61/74 (82.4%) patients
- Remission at week 3 obtained in 51/74 (69%)
- Normal CRP & remission obtained in 38/74 (51.3%) by 3 weeks
- **No significant difference between both treatments**
Improvement in Median PCDAI & CRP From Entry to week 3

**Results**

**PCDAI**
- **CDED+PEN**
  - PCDAI week 0: 25
  - PCDAI week 3: 27.5
  - PCDAI week 6: 27.5

- **EEN**
  - PCDAI week 0: 23.6
  - PCDAI week 3: 24
  - PCDAI week 6: 24

- **Total**
  - PCDAI week 0: 23.6
  - PCDAI week 3: 24
  - PCDAI week 6: 24

**CRP; (Normal ≤ 5)**
- **CDED+PEN**
  - CRP week 0: 5
  - CRP week 3: 5
  - CRP week 6: 5

- **EEN**
  - CRP week 0: 5
  - CRP week 3: 4.1
  - CRP week 6: 5

- **Total**
  - CRP week 0: 5
  - CRP week 3: 4.1
  - CRP week 6: 5

All improvements are significant at P<0.001.
Responders by week 3 were more likely to obtain remission by week 6

Among patients in remission at week 6, 54/56 (96.4%) had obtained a good response and 48/56 (85.71%) had obtained remission to therapy by 3 weeks.

Results

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<th>Rate (%)</th>
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- **Total cohort**
  - **Response**
    - % Response week 3/ remission week 6: 96.43%
  - **Remission**
    - % Remission week 3/ remission week 6: 85.71%
Conclusion

- Dietary therapy caused a rapid clinical and biochemical improvement and response by week 3, which was equivalent with both diets.
- Patients who failed to respond by week 3 were unlikely to reach remission by week 6.
The C D E D trial - Israel & Canada

Dr. Johan Van Limbergen- Dalhousie University, Halifax, Canada
Dr. Eytan Wine- University of Alberta, Edmonton Canada
Dr. Shannan Grant- Mount Saint Vincent University, Halifax
Prof. Dan Turner, Gila Abitbol- Shaare Zedek Medical Center, Jerusalem
Dr. Ron Shaoul, Rambam Health care Campus, Haifa
Dr. Michal Kori, Kaplan Medical Center, Rehovot
Prof. Amit Assa- Schneider Medical Center, Petach Tikva

Dr. Sarit Peleg, Haemek Medical Center, Afula
Dr. Avi On, Poria, Tiberius
Dr. Peri Milman, Hadasa Medical Center, Jerusalem
Dr. Shlomi Cohen, Tel Aviv Medical Center, Tel Aviv
Dr. Hussain Shamaly, Nazeret Medical Center
Dr. Ziv Baran Tomer- Tel Aviv University
Prof. Arie Levine, Rotem Sigall Boneh, Lee Abrams- Wolfson Medical Center, Holon, Tel Aviv University

THANK YOU!