Efficacy of Vedolizumab as Induction Therapy for Inflammatory Bowel Disease in a « real-life » Study

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BACKGROUND (1/3)

IBD: Basic therapeutic strategies

- Surgery
- Biological agents
  - Azathioprine (Imuran®) and méthotrexate (Ledertrexate®)
- Corticosteroids (systemic)
- Corticosteroids (topical)
  - Budésonide (Entocort®) and béclométasone (Clipper®)
- 5-ASA
  - (Sulfasalazine and mésalazine (Colitofalk®, Pentasa®))
IBD: Basic therapeutic strategies

**Surgery**

**Biological agents**
- Azathioprine (Imuran®) and méthotrexate (Ledertrexate®)

**Corticosteroids (systemic)**

**Corticosteroids (topical)**
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**5-ASA**
- (Sulfasalazine and mésalazine (Colitofalk®, Pentasa®))

**BACKGROUND (1/3)**

<table>
<thead>
<tr>
<th>Anti-TNF</th>
<th>Biosimilars</th>
<th>Anti-integrine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remicade (infliximab)</td>
<td>Remsima (infliximab)</td>
<td>Entyvio (vedolizumab)</td>
</tr>
<tr>
<td>Humira (adalimumab)</td>
<td>Inflectra (infliximab)</td>
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<tr>
<td>Simponi (golimumab)</td>
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</tbody>
</table>
IBD: Basic therapeutic strategies

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**BACKGROUND (1/3)**
VEDOLIZUMAB – ENTYVIO®

- Humanized monoclonal antibody
- Gut-specific biological agent
- Available in Belgium since Septembre 1st 2015
- Cost: 1.757,59€/injection

Therapeutic indications:
- Moderate to severe IBD
- Failure of anti-TNF therapy or first-line biologic therapy
Inhibitor of leukocyte trafficking

**Pros**
- **Very selective** (MAdCAM-1)
- **No systemic immunosuppression**
- **Safety**

**Cons**
- **Very selective** (extraintestinal manifestations)
- **Slow onset** (CD > UC)

**UC**: Ulcerative Colitis, **CD**: Crohn’s disease
OUTCOMES

- **Primary Outcome**: How effective is Vedolizumab in « real life »?
  - Efficacy well demonstrated in RCTs (GEMINI Studies)
  - Must be confirmed in everyday clinical practice

- **Secondary Outcomes**: Safety
  - Efficacy in CD vs UC
MATERIALS AND METHODS

- Observational
- Bicentric:
  - Centres hospitaliers Jolimont
  - Clinique Saint-Pierre Ottignies

- Inclusion criteria: Every single patient treated with Vedolizumab since September 1\textsuperscript{st}, 2015
- Exclusion criteria: None!

- Efficacy: response and remission during induction therapy
  - Mayo Clinic Score (UC)
  - Harvey-Bradshaw Index (CD)
## Study Population (n=20)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age – y median (IQR)</td>
<td>47.5 (± 22.3)</td>
</tr>
<tr>
<td>Female Sex – no. (%)</td>
<td>14 (70%)</td>
</tr>
<tr>
<td>Current smoker – no. (%)</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>Site of disease – no. (%)</td>
<td></td>
</tr>
<tr>
<td>. Crohn’s ileitis</td>
<td>4 (20%)</td>
</tr>
<tr>
<td>. Crohn’s colitis</td>
<td>3 (15%)</td>
</tr>
<tr>
<td>. Crohn’s ileocolitis</td>
<td>3 (15%)</td>
</tr>
<tr>
<td>. Crohn’s disease</td>
<td>10 (50%)</td>
</tr>
<tr>
<td>. Ulcerative Colitis</td>
<td>9 (45%)</td>
</tr>
<tr>
<td>Duration of disease – y (IQR)</td>
<td>11.3 (± 10.3)</td>
</tr>
<tr>
<td>Surgery – no. (%)</td>
<td>8 (40%)</td>
</tr>
<tr>
<td>Fistula – no. (%)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>Abscess – no. (%)</td>
<td>4 (20%)</td>
</tr>
<tr>
<td>Extraintestinal manifestation – no. (%)</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>Prior anti-TNF therapy - no. (%)</td>
<td>16 (80%)</td>
</tr>
<tr>
<td>Failure of anti-TNF therapy</td>
<td></td>
</tr>
<tr>
<td>. Inadequate response or loss of response – no. (%)</td>
<td>10 (50%)</td>
</tr>
<tr>
<td>. Adverse event – no. (%)</td>
<td>8 (40%)</td>
</tr>
<tr>
<td>Concomitant glucocorticoids – no. (%)</td>
<td>7 (35%)</td>
</tr>
<tr>
<td>Mayo Clinic Score (UC) – median (IQR)</td>
<td>8.6 (± 2)</td>
</tr>
<tr>
<td>Harvey-Brashaw index (CD) – median (IQR)</td>
<td>7 (± 2.8)</td>
</tr>
</tbody>
</table>
RESULTS

- **20 patients enrolled**
  - 16 in CH Jolimont
  - 4 in Saint-Pierre Ottignies

- **Primary Outcome – Efficacy**
  - Response in 13 patients (65%)
  - Remission in 3 patients (15%)

- **Secondary Outcomes**
  - Safety: no major side effect
  - Efficacy in CD vs in UC: 
    *too few patients enrolled to be assessed*
STUDY LIMITATIONS

- **Lack of statistical power**

- **Methods**
  - Partly retrospective study
  - Efficacy evaluated solely on a clinical basis for 2 patients (stoma)
Efficacy similar to or even superior than in GEMINI
- Small study, low statistical power
- Major benefit at this time: anti-TNF refractory IBD!

No major side effect...
- ... But loss of activity on extraintestinal manifestations/associated diseases
- ... Higher risk of postoperative infection?
Many studies still ongoing on Vedolizumab

Vedolizumab ... already a « mab » from the past?

- Ustekinumab (Stelara®) (anti-IL 12 and anti-IL 23)
- Tofacitinib (anti-JAK 1 and JAK 3)
- Etrolizumab (anti-integrin α4β7 AND αEβ7)
- Mongersen (anti-SMAD-7)
- ...
CONCLUSION

- **Vedolizumab** = **effective** and **safe** treatment in **real life**

- **Indication:**
  - Moderate to severe IBD (resistant or intolerant to systemic immunosuppressive drugs (anti-TNF))
  - RCUH > Crohn

- **Place in the future?**