

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

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Clinical Study

BACKGROUND (1/3)

IBD : Basic therapeutic strategies

Surgery

**Biological
agents**

**Azathioprine (Imuran®)
and méthotrexate
(Ledertrexate®)**

Corticosteroids (systemic)

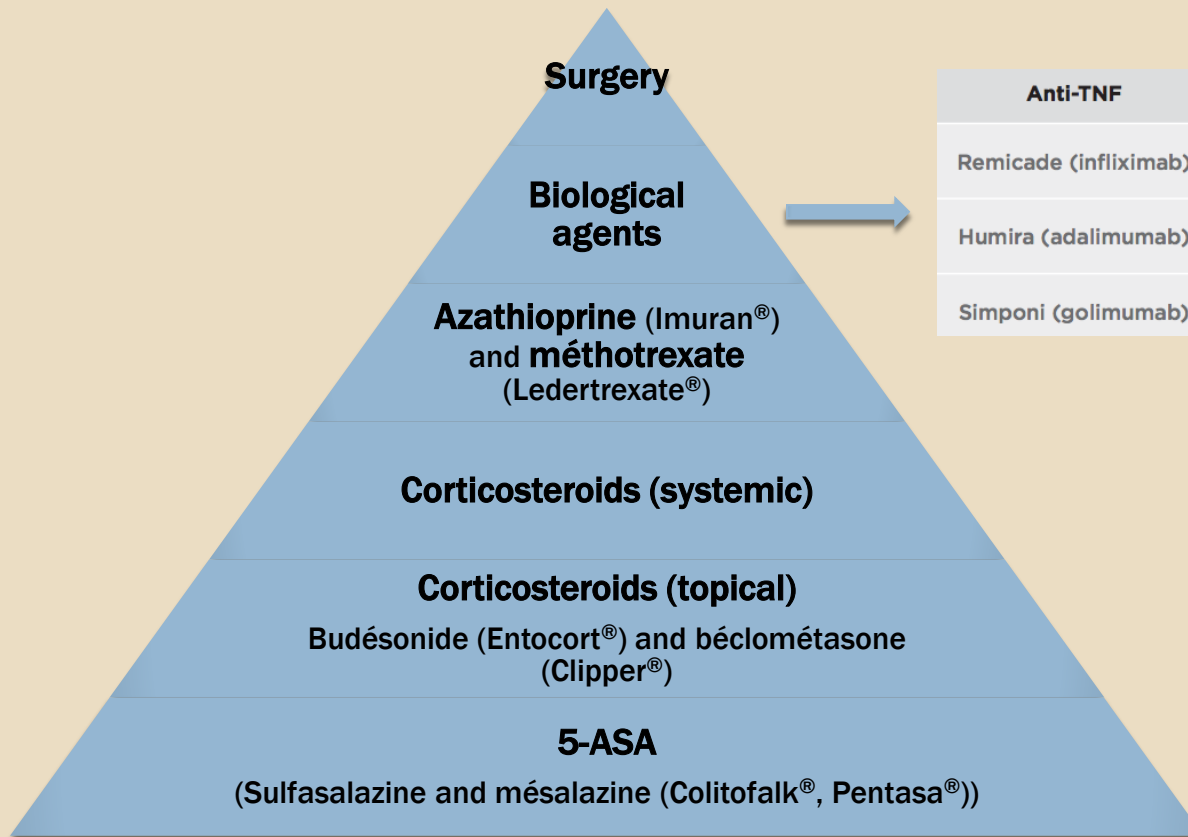
Corticosteroids (topical)
Budésónide (Entocort®) and béclométasone
(Clipper®)

5-ASA

(Sulfasalazine and mésalazine (Colitofalk®, Pentasa®))

BACKGROUND (1/3)

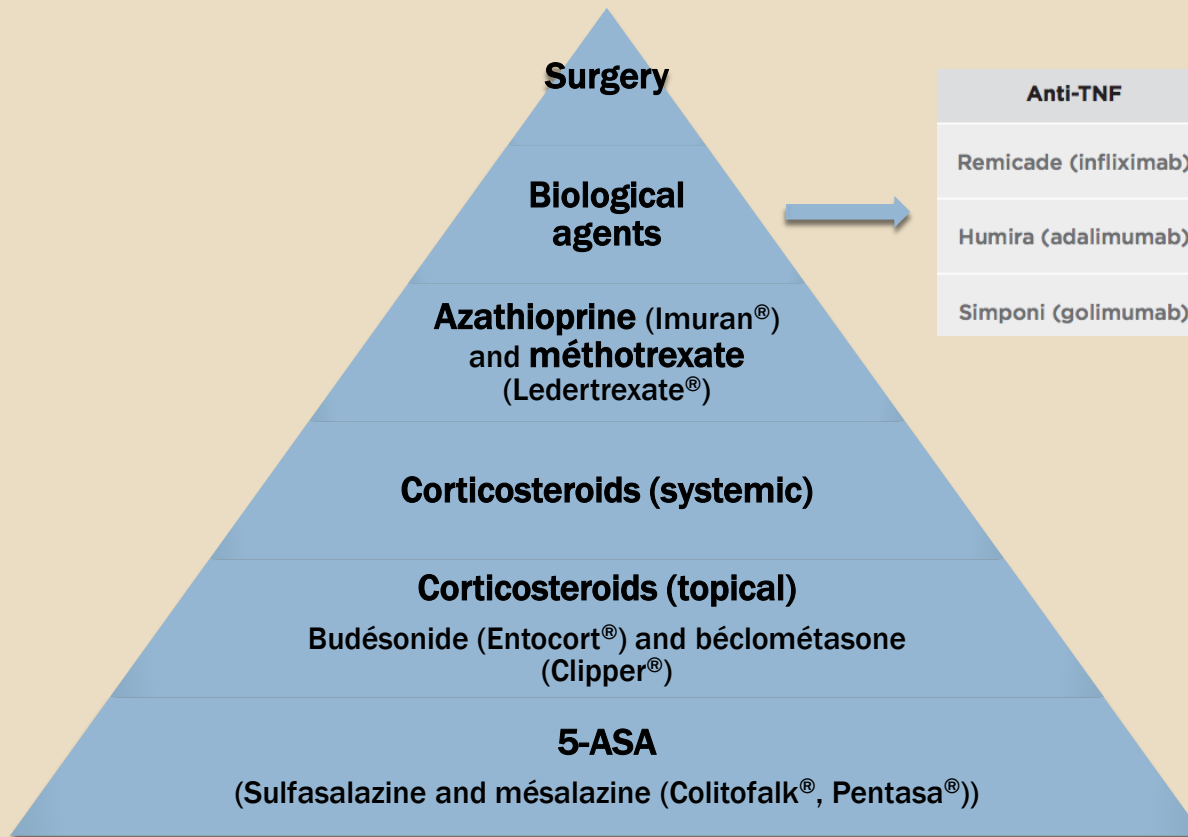
IBD : Basic therapeutic strategies



Anti-TNF	Biosimilars	Anti-integrine
Remicade (infliximab)	Remsima (infliximab)	Entyvio (vedolizumab)
Humira (adalimumab)	Inflectra (infliximab)	
Simponi (golimumab)		

BACKGROUND (1/3)

IBD : Basic therapeutic strategies



Anti-TNF	Biosimilars	Anti-integrine
Remicade (infliximab)	Remsima (infliximab)	Entyvio (vedolizumab)
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Simponi (golimumab)		



BACKGROUND (2/3)

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



BACKGROUND (3/3)

■ Inhibitor of leukocyte trafficking

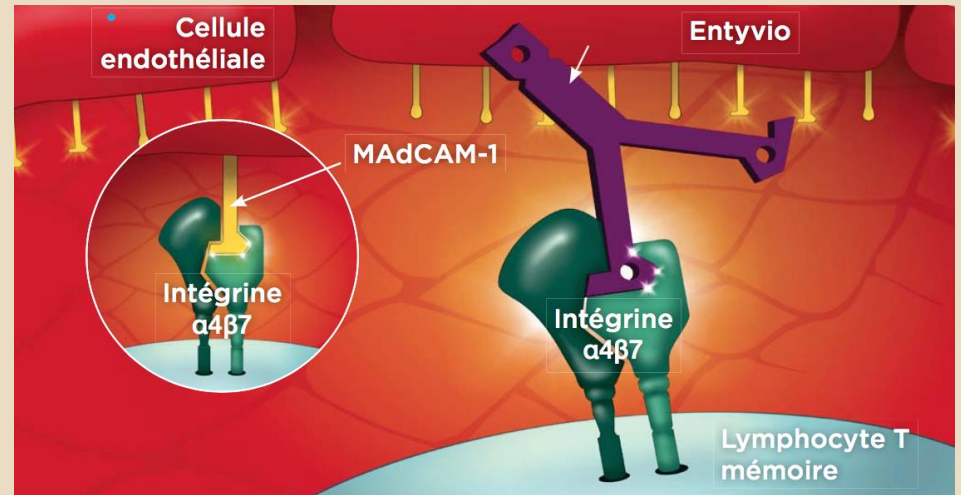
■ Pros

- 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

ORIGINAL ARTICLE

Vedolizumab as Induction and Maintenance
Therapy for Crohn's Disease

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Vedolizumab as Induction and Maintenance Therapy
for Ulcerative Colitis

- **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 1st, 2015

- **Exclusion criteria** : None !

- **Efficacy** : response and remission during induction therapy

- Mayo Clinic Score (UC)
- Harvey-Bradshaw Index (CD)

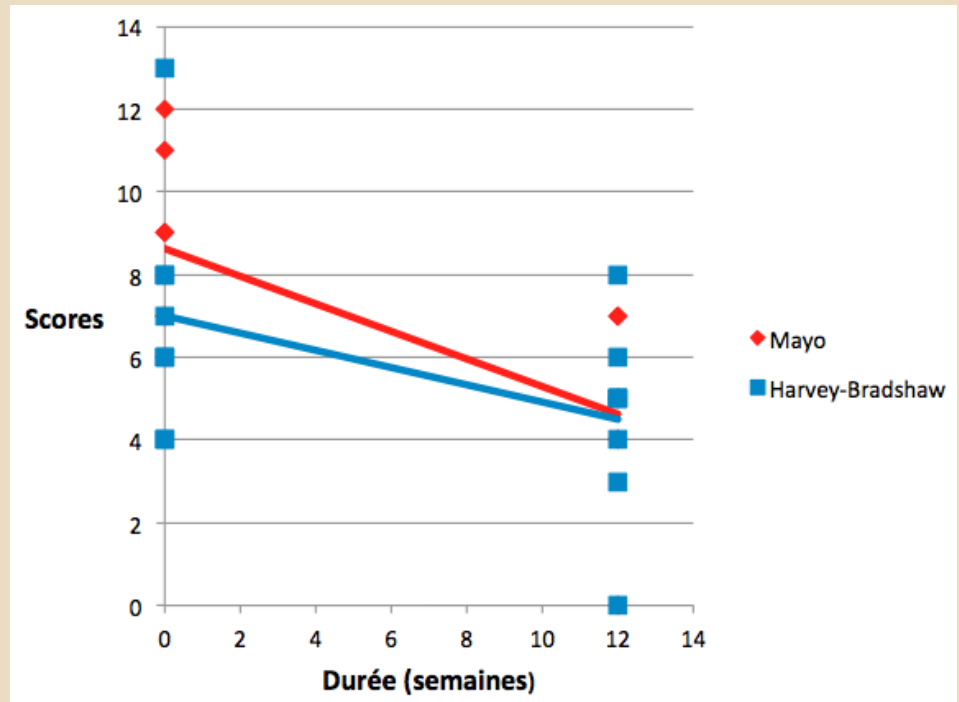
STUDY POPULATION (n=20)

Age – y median (IQR)	47,5 (± 22,3)
Female Sex – no. (%)	14 (70%)
Current smoker – no. (%)	2 (10%)
Site of disease – no. (%)	
. Crohn's ileitis	4 (20%)
. Crohn's colitis	3 (15%)
. Crohn's ileocolitis	3 (15%)
. Crohn's disease	10 (50%)
. Ulcerative Colitis	9 (45%)
Duration of disease – y (IQR)	11,3 (± 10,3)
Surgery – no. (%)	8 (40%)
Fistula – no. (%)	5 (25%)
Abscess – no. (%)	4 (20%)
Extraintestinal manifestation – no. (%)	2 (10%)
Prior anti-TNF therapy - no. (%)	16 (80%)
Failure of anti-TNF therapy	
. Inadequate response or loss of response – no. (%)	10 (50%)
. Adverse event – no. (%)	8 (40%)
Concomitant glucocorticoids – no. (%)	7 (35%)
Mayo Clinic Score (UC) – median (IQR)	8,6 (± 2)
Harvey-Brashaw index (CD) – median (IQR)	7 (± 2,8)

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)

DISCUSSION

- **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 ?

PERSPECTIVES

- 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 $\alpha 4\beta 7$ AND $\alpha E\beta 7$)
 - 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 ?**



A vintage-style film strip is centered on a light beige background. The film strip is dark with a yellowish glow in the center. It features several sprocket holes on both the left and right sides. The text "THE END" is printed in a bold, black, serif font in the middle of the strip. There are some small stains and imperfections on the film surface, giving it an aged appearance.

THE END