DI-077

EFFECTIVENESS AND SAFETY OF BIOSIMILAR INFLIXIMAB IN ULCERATIVE COLITIS

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INTRODUCTION

Infliximab is one of the most widely used alternatives in ulcerative colitis (UC).
The recent appearance of a biosimilar makes necessary to assess its use

PURPOSE

To assess the effectiveness and safety of biosimilar infliximab in patients with UC.

MATERIAL AND METHODS

Retrospective observational study in a tertiary hospital.

UC Patients → TREAT → **Remicade ®** → SWITCH (Mar-Jun 2015) → **Remsima ®**

The **effectiveness** and **safety** were assessed **3 months** after the switch.

Effectiveness (Before and three months after the switch)**:**
- True-Love-Witts scale
- Protein-C reactive(CRP) levels.

Safety: All adverse events.

Variables
- Age.
- Sex.
- Concomitant therapy.
- Disease classification: Montreal scale (severity and extention).
- Effectiveness.
- Adverse events.

RESULTS

25 patients → 52% women → X= 45 years (21-71)

Baseline moment:
- 23 patients had stabilized disease
- 2 had minor outbreaks

Treated concomitantly:
→20% corticosteroids
→36% azathioprine/mercaptopurine

Montreal scale :

Extension level:
- 72% E3
- 28% E2
- 0% E1

Severity level:
- 8% S0
- 32% S1
- 48% S2
- 12% S3

The effectiveness could be assessed in 12 patients
✓1 patient had a minor outbreak at the beginning.
✓8 maintained the same Tru-Love-Witts score
✓4 decreased it.
No clinical change happened after the use of the biosimilar.
No clinically relevant increased in CRP.

No adverse events were detected after the switch

CONCLUSIONS

Despite being a preliminary assessment with just a few patients, initial data show that the switch to an infliximab biosimilar does not represent a decrease in effectivenees and / or safety in patient with UC.
Long term assessment of these patients is guaranteed to confirm these results.