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.

<table>
<thead>
<tr>
<th>UC Patients</th>
<th>TREAT</th>
<th>Remicade®</th>
<th>SWITCH</th>
<th>Remsima®</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Infliximab</td>
<td>Biosimilar</td>
<td>Mar-Jun 2015</td>
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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.

RESULTS

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 True-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 effectiveness and / or safety in patient with UC.
Long term assessment of these patients is guaranteed to confirm these results.