PROACTIVE TDM IS SUPERIOR TO CONVENTIONAL MANAGEMENT IN IBD


Centro Hospitalar Universitário de Lisboa Norte, Portugal

Copenhagen, 8th March 2019
CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare
Therapeutic drug monitoring (TDM) of anti-TNF therapies is recommended upon secondary loss of response to guide clinical decision-making. 1-2

There is insufficient data supporting the use of proactive TDM in IBD. 3-4

Aims of the study

To evaluate the clinical and endoscopic outcomes of a proactive TDM strategy

METHODS

• Prospective comparative single center study
• **Inclusion criteria:** Patients completing Infliximab induction (3 doses)

**Proactive cohort (pTDM)**

• Bf 4th infusion and every 2 infusions:
  • Trough levels and anti-drug antibodies
  • Proactive escalation

**Comparative cohort (noTDM)**

• **Inclusion:** 2000-2014
• No therapeutic drug monitoring

<table>
<thead>
<tr>
<th>Crohn’s disease</th>
<th>3-7 ug/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ulcerative colitis</td>
<td>5-10 ug/ml</td>
</tr>
</tbody>
</table>

*Theradiag®, Lisa Tracker*

<table>
<thead>
<tr>
<th>Outcomes: 2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
</tr>
<tr>
<td>Tx discontinuation</td>
</tr>
<tr>
<td>Hospital admission</td>
</tr>
<tr>
<td>Mucosal healing</td>
</tr>
</tbody>
</table>
Total cohort n=240  no TDM n=183  Proactive TDM n=57

Median age, years
37 (17-70) 38 (17-70) 37 (18-70) 0.56

Median CRP at start of anti-TNF, mg/L
4.6 (0.1-231) 6.5 (0.1-175) 3.4 (0.3-321) 0.19

Male gender (%)
118 (49.2) 88 (48.1) 30 (52.6) 0.33

Previous surgery CD (%)
56 (30.9) 49 (32.9) 7 (20.0) 0.16

IBD type (%)
• CD 185 (77.1) 150 (82.0) 35 (61.4) 0.002
• UC 55 (22.9) 33 (18.0) 22 (38.6)

UC Extension (%)
• E2 16 (29.1) 7 (21.2) 9 (40.9) 0.10
• E3 39 (70.9) 26 (78.8) 13 (59.1)

CD location (%)
• L1 48 (25.9) 35 (23.3) 13 (37.1) 0.20
• L2 24 (13.0) 19 (12.7) 5 (14.3)
• L3 113 (61.1) 96 (64.0) 17 (48.6)
• L4 32 (17.3) 27 (18.0) 5 (14.3) 0.80

CD behavior (%)
• B1 76 (41.1) 62 (41.3) 14 (40.0) 0.19
• B2 64 (34.6) 48 (32.0) 16 (45.7)
• B3 45 (24.3) 40 (26.7) 5 (14.3)

Perianal disease (%)
69 (37.3) 61 (40.7) 8 (22.9) 0.04

Anti-TNF naive (%)
214 (89.2) 166 (90.7) 48 (84.2) 0.13

Immunomodulator (%)
165 (68.8) 124 (67.8) 41 (71.9) 0.34

RESULTS
Crohn's disease
Ulcerative colitis
## RESULTS

### Regression analysis

<table>
<thead>
<tr>
<th>Multivariate analysis</th>
<th>Odds ratio [95% CI]</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mucosal healing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunomodulator use</td>
<td>2.291 [1.287-4.080]</td>
<td>0.005</td>
</tr>
<tr>
<td>TDM strategy</td>
<td>3.173 [1.642-6.129]</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>Surgery</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TDM strategy</td>
<td>0.355 [0.133-0.949]</td>
<td>0.039</td>
</tr>
<tr>
<td><strong>Any unfavorable outcome</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunomodulator use</td>
<td>0.502 [0.277-0.910]</td>
<td>0.023</td>
</tr>
<tr>
<td>TDM strategy</td>
<td>0.394 [0.213-0.728]</td>
<td>0.003</td>
</tr>
</tbody>
</table>

**Other variables:**

Gender, age, IBD type, prior anti-TNF
CONCLUSION

✓ Up to 25% of patients with CD and almost 50% with UC presented infra-therapeutic trough levels;

✓ Patients with proactive TDM had lower rates of surgery and unfavorable outcomes and higher rates of mucosal healing than patients under conventional management.