Efficacy of ustekinumab in perianal Crohn’s disease (pCD): the BioLAP multicentre observational study


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Disclosures:

Conflict of interest: None
Background

Perianal Crohn’s disease: A THERAPEUTIC CHALLENGE

Gap in pCD therapy

✓ Sustained remission: 26-50% (1)
✓ Anti-TNF primary non response (2)
✓ Anti-TNF loss of response (3)
✓ Anti-TNF intolerance (4)

New therapeutic options needed

✓ Alternative mode of action (5)
✓ No dedicated study with a large sample has evaluated the efficacy of ustekinumab (UST) in pCD

Assess the efficacy of UST in pCD in the French GETAID multicentre cohort

Methods

French multicentre and observational study (Bio-LAP)

All patients who received UST with either active or inactive* pCD

Success among active pCD

Clinical success at 6 months
+ No need for medical treatment for pCD
+ No need for surgical treatment for pCD

Recurrence among inactive pCD

Occurrence of pCD
+/− Need for medical treatment for pCD
+/− Need for surgical treatment for pCD

Predictive factors of success

Logistic regression
Univariate analysis (p<0,20)
Multivariate analysis (p<0,05)

*inactive pCD but with history of fistulizing and drained perianal lesion over the past 10 years
Results: Baseline population and treatment characteristics

207 patients

148 patients: active pCD
- 88/148 (59.5%): seton

59 patients: inactive pCD

- Duration of CD: 14.3 years
- 2.8 prior perianal surgeries
- 205/207 (99%): exposed to at least 1 anti-TNF
- 197/207 (95.2%): exposed to immunomodulators
- 58/207 (28%): exposed to vedolizumab

Follow-up time: 66 weeks

56/207 (27%) discontinued UST
Mean time: 363 days
## Results: Efficacy outcomes and predictive factors of success

### Predictive factors of success: among patients with active pCD

<table>
<thead>
<tr>
<th>Predictors of success</th>
<th>Univariate analysis OR (95% CI)</th>
<th>p</th>
<th>Multivariate analysis OR (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimisation (no)</td>
<td>2.45 (1.14-5.26)</td>
<td>0.021</td>
<td>2.52 (1.15-5.56)</td>
<td>0.018</td>
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<td>Fistula or abscess drainage prior UST initiation (no)</td>
<td>0.59 (0.3-1.15)</td>
<td>0.123</td>
<td>0.52 (0.26-1.05)</td>
<td>0.066</td>
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<tr>
<td>Seton at initiation (no)</td>
<td>0.88 (0.45-1.72)</td>
<td>0.703</td>
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<td>Number of prior anti-TNF (≥ 3)</td>
<td>0.42 (0.16-1.11)</td>
<td>0.081</td>
<td>0.45 (0.17-1.25)</td>
<td>0.111</td>
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<tr>
<td>Number of prior biologic agents (≥ 3)</td>
<td>0.71 (0.36-1.4)</td>
<td>0.576</td>
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<tr>
<td>Immunosuppressive treatment at initiation (no)</td>
<td>1.6 (0.82-3.16)</td>
<td>0.171</td>
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<tr>
<td>Antibiotics at initiation (no)</td>
<td>0.76 (0.39-1.47)</td>
<td>0.412</td>
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</tbody>
</table>
## Results: Efficacy outcomes and predictive factors of success

### Success: among patients with active pCD (148)
- Clinical success at 6 months: +
- No need for medical treatment for pCD: +
- No need for surgical treatment for pCD: +

**Success:** 56/148 (37.8%)

**Follow-up time:** 58 weeks

**Seton ablation:** 29/88 (33%)
Conclusions

- Robust sample size
- 1st study to evaluate perianal disease recurrence
- Multi-centre and exhaustive register
- Long duration follow-up (> 1 year)
- Severe and refractory pCD = real-world

- Retrospective register
- No standardised criteria (clinical and radiological)
- No biological data
- Heterogeneity in the cohort (simple vs complex fistula)

- Encouraging results (success 37.8%; recurrence 22%): potential effective treatment option in perianal CD?

- Prospective studies are needed to precise the role of UST for the management of refractory pCD
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