Efficacy of vedolizumab 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 vedolizumab (VDZ) in pCD

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

Methods

French multicentre and observational study (Bio-LAP)

All patients who received VDZ 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

151 patients

- Duration of CD: 15 years
- 2.4 prior perianal surgeries

- 149/151 (98.7%): exposed to at least 1 anti-TNF
- 143/151 (94.7%): exposed to immunomodulators
- 10/151 (6.6%): exposed to ustekinumab

102 patients: active pCD
- 61/102 (59.8%): seton

49 patients: inactive pCD

- Follow-up time: 86 weeks
- 98/151 (65%) discontinued VDZ
  Mean time: 284 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>Multiariate analysis OR (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of prior biologic agents (≥ 3)</td>
<td>0.18 (0.04-0.84)</td>
<td>0.029</td>
<td>0.13 (0.02-1.09)</td>
<td>0.018</td>
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<tr>
<td>Antibiotics at initiation (no)</td>
<td>4.78 (1.31-17.43)</td>
<td>0.018</td>
<td>4.12 (1.06-15.98)</td>
<td>0.024</td>
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<tr>
<td>Seton at initiation (no)</td>
<td>0.44 (0.16-1.24)</td>
<td>0.122</td>
<td>0.4 (0.13-1.21)</td>
<td>0.095</td>
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<tr>
<td>Fistula or abscess drainage prior VDZ initiation (no)</td>
<td>1.49 (0.57-3.92)</td>
<td>0.417</td>
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<tr>
<td>Number of prior anti-TNF (≥ 3)</td>
<td>0.35 (0.07-1.63)</td>
<td>0.18</td>
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<td>Optimisation (no)</td>
<td>0.81 (0.31-2.09)</td>
<td>0.66</td>
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<tr>
<td>Immunosuppressive treatment at initiation (no)</td>
<td>1.65 (0.63-4.34)</td>
<td>0.308</td>
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</tbody>
</table>
Results: Efficacy outcomes and predictive factors of success

Success: among patients with active pCD (102)
- Clinical success at 6 months
- No need for medical treatment for pCD
- No need for surgical treatment for pCD

Success: 23/102 (22.5%)
Follow-up time: 63 weeks
Seton ablation: 9/61 (15%)

Recurrence: among patients with inactive pCD (49)
- Occurrence of I, II or IIIary pCD
- Need for medical treatment for pCD
- Need for surgical treatment for pCD

Recurrence: 15/49 (30.6%)
Mean time: 26 weeks
Treatment for perianal disease: 11/49 (22.4%)
Conclusions

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

- 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

• Numerous treatment cessations (65%) and perianal disease recurrences (reccurrence 30.6%; success 22.5%): efficacy of anti-integrins at anal canal site?

• Prospective studies are needed to precise the role of VDZ for the management of refractory pCD
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