



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

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Disclosures:

Conflict of interest: None



Background

Gap in pCD therapy

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



Perianal
Crohn's
disease: A
THERAPEUTIC
CHALLENGE



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

Recurrence among inactive pCD

Predictive factors of success

Clinical success at 6 months

- + No need for medical treatment for pCD
- + No need for surgical treatment for pCD

Occurrence of pCD

- +/- Need for medical treatment for pCD
- +/- Need for surgical treatment for pCD

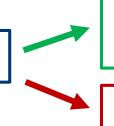
Logistic regression Univariate analysis (p<0,20) Multivariate analysis (p<0,05)

*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

Predictors of success	Univariate analysis OR (95% CI)	р	Multiariate analysis OR (95% CI)	р
Optimisation (no)	2.45 (1.14-5.26)	0.021	2.52 (1.15-5.56)	0.018
Fistula or abscess drainage prior UST initiation (no)	0.59 (0.3-1.15)	0.123	0.52 (0.26-1.05)	0.066
Seton at initiation (no)	0.88 (0.45-1.72)	0.703		
Number of prior anti-TNF (≥ 3)	0.42 (0.16-1.11)	0.081	0.45 (0.17-1.25)	0.111
Number of prior biologic agents (≥ 3)	0.71 (0.36-1.4)	0.576		
Immunosuppressive treatment at initiation (no)	1.6 (0.82-3.16)	0.171		
Antibiotics at initiation (no)	0.76 (0.39-1.47)	0.412		



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%)

Recurrence: among patients with inactive pCD (59)

Occurrence of I, II or IIIary pCD

Need for medical treatment for pCD

Need for surgical treatment for pCD

Recurrence: 13/59 (22%)

Mean time: 25 weeks

Treatment for perianal disease: 8/59 (13.6%)



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
- 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







BOURGOGNE FRANCHE-COMTE

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