European Crohn's and Colitis Organisation

GETAID
Groupe d'Étude Thérapeutique des Affections Inflammatoires du Tube Digestif

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

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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

(1) Gecze KB et *al.* Gut 2014 (2) Bouguen G et *al.* Gastroenterol Hepatol 2013 (3) Haennig A et *al.* Colorectal Dis 2015
(4) Lichtenstein L et *al.* JCC 2015 (5) Feagan BG et *al.* NEJM 2016

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

Predictors of success	Univariate analysis OR (95% CI)	p	Multiariate analysis OR (95% CI)	p
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

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