

Dose escalated vedolizumab in Inflammatory Bowel Disease –Crohn’s Colitis Cure (CCC) Data Insights Program

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INTRODUCTION & AIM:

- Vedolizumab is a gut specific integrin antagonist with established efficacy in inflammatory bowel disease (IBD).
- Standard dosing of vedolizumab can result in insufficient effectiveness, necessitating dose escalation (DE).
- **Aim:** to explore the need for DE and subsequent outcomes in a large real-world cohort.

METHODS:

- Crohn’s Colitis Care is a cloud-based IBD-specific electronic medical record (EMR) used at IBD centres across Australasia since 2018.
- Data was interrogated in October 2023.
- DE: maintenance dosing > 108mg SC fortnightly, > 300mg IV Q8weekly and/or additional induction doses.
- Data were examined prior to and at 12 months post-DE.

RESULTS:

- **919** people with IBD received Vedolizumab, with **28%** (n=261) receiving DE.
- Median age for DE was **40 years** (IQR 29-56) with median at age diagnosis **26 years** (IQR 19-39).
- Median age, age at diagnosis, disease duration and BMI did not vary significantly between DE & standard cohorts.

RESULTS (CONT.):

- The DE cohort: **60%** had Crohn’s, **38%** ulcerative colitis and **2%** IBDU with an even gender distribution (49.8% female) and median time to DE 6 months.
- Median drug level increased from 10.3mg/L pre-DE to 19.8mg/L post DE

	Pre DE	12 months post DE	P value
Faecal Calprotectin Remission (<250) (%)	32.5	49.6	.007
PRO2 Remission (%)	50.2	60.6	.034
Radiological Remission (%)	63.6	70.0	.217
Endoscopy Remission (%)	11.6	22.9	.016
Systemic Steroid Use (%)	16.1	6.1	.001

Abbreviations: DE, dose escalation; PRO2, patient-reported outcomes

- **FCP remission** (FCP < 250ug/g) **increased** 12 months post DE as did **PRO2 and endoscopic remission** (see table above).
- Improved remission rates coincided with **decreased systemic steroid** requirements which fell by **>50%** at 12 months post DE.

RESULTS (CONT.):

- Hospital admissions and radiological investigations did not change; need for **endoscopic assessment decreased** 12 months post DE (see table below)

(n=919)	Pre DE	12 months post DE	P value
Hospital Admissions (n)	33	28	.514
Clinical Assessments (n)	676	741	.001
Endoscopies (n)	216	156	.001
Radiology (n)	106	128	.123
HealthLine Calls (n)	607	729	.001

Abbreviations: DE, dose escalation;

- DE cohort had increased encounters with healthcare providers 12 months post escalation, with more clinical assessments and HealthLine calls.

CONCLUSIONS:

These prospectively collected data from large Australasian IBD treatment centres show:

- Over a quarter of individuals receiving Vedolizumab therapy required DE, which correlated with improved endoscopic, PRO2 and FCP remission rates at 12 months with reduced steroid use
- As biosimilars reduce the cost of DE therapy, further research beyond 12 months examining remission rates, healthcare utilisation and cost analysis is needed