CROHN'S COLITIS CURE

P959: Dose escalated vedolizumab in Inflammatory Bowel Disease – Crohn's Colitis Cure (CCC) Data Insights Program

J. McNamara, B. Alshiwanna, W. Wilson, J.L. Pipicella, S. Ghaly, R. Gearry, J. Begun, W. Ng, K. Lynch, I. Lawrance, M. Schultz, G. Walker, G. Radford-Smith, J.M. Andrews, S.J. Connor

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BACKGROUND

- 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.
- 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.

RESULTS (CONT.)

- Median drug level increased from 10.3mg/L pre-DE to 19.8mg/L post DE
- FCP remission (FCP < 250ug/g) increased 12 months post DE as did PRO2 and endoscopic remission (see table 1).

	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

- Improved remission rates coincided with decreased systemic steroid requirements which fell by >50% at 12 months post DE.
- Hospital admissions and radiological investigations did not change; need for endoscopic assessment decreased 12 months post DE (see table 2)
- DE cohort had increased encounters with healthcare providers 12 months post escalation, with more clinical assessments and HealthLine calls.

Total Patients 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;

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