

Dose escalated Ustekinumab in Inflammatory Bowel Disease - Crohn's Colitis Cure (CCC) Data Insights Program

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INTRODUCTION & AIM:

- **Ustekinumab** is a human monoclonal antibody targeting interleukin-12 & 23 with established efficacy in Inflammatory Bowel Disease (IBD).
- Some people on standard dosing of ustekinumab have persistent disease activity, necessitating dose escalation (DE).
- Aim: to investigate the frequency and outcomes of escalated dosing regimens in a large Australasian 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 from CCCare flow across to a de-identified clinical quality registry, which was interrogated in November 2023.
- DE was defined as maintenance dosing **>90mg subcutaneously Q8 weekly** and/or additional induction doses.

RESULTS:

- Of the **790** people receiving ustekinumab, **43.4%** were on DE therapy.
- **86.1%** had Crohn's Disease, **11.3%** had Ulcerative Colitis, and **1.6%** were IBD-unclassified.
- Median age: **40 years (IQR 30-52)**

RESULTS (CONT.):

- Even gender distribution (**50.3%** female).
- Median age at diagnosis: **25 years** (IQR 18-38)
- Median time to DE: **6 months** (IQR 1-15).
- **84.5%** of those on DE ustekinumab continued on therapy beyond 12 months.

	Pre-DE	12 months post-DE	P value
Faecal Calprotectin Remission (<250ug/g) (%)	47.9	60.0	.034
Patient-Reported Outcome Remission (%)	75.5	85.0	.006
Radiological Remission (%)	77.7	72.3	.370
Endoscopy Remission (%)	22.6	46.3	.001
Systemic Steroid Use (%)	9.0	2.6	.001
Hospital Admissions (n)	43	31	.153
Endoscopies (n)	194	126	.001
Radiology (n)	266	170	.001

RESULTS (CONT.):

- Rates of **faecal calprotectin remission** (<250ug/g), **endoscopic remission** and **patient reported outcome (PRO2) remission** were higher 12 months post DE.
- **Systemic steroid requirements fell significantly** 12 months post DE.
- The number of **endoscopies and radiological investigations fell at 12 months** post DE, while the rates of hospital admissions did not significantly differ between the DE and standard cohorts.
- The number of **clinical assessments per person fell** from 1.2 pre-DE to 0.9 post DE.

CONCLUSIONS:

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

- Close to half of those receiving Ustekinumab required DE.
- DE led to reduced systemic steroid use and improved endoscopic, PRO2 and faecal calprotectin remission rates at 12 months.
- These data can be used to perform health economy analysis to determine the price points at which DE is cost effective.