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

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CROHN'S COLITIS CURE

INTRODUCTION & AIM:

- Infliximab (IFX) is a monoclonal antibody targeting TNF-α
- Some people with IBD on standard dosing of IFX therapy have persistent disease activity, necessitating dose escalation (DE).
- Globally, pharmaceutical funding schemes variably fund escalated doses of drug, making access to adequate dosing insecure.
- Aim: to evaluate the extent of IFX DE and patient outcomes in a 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 from CCCare flow across to a de-identified clinical quality registry, which was interrogated in November 2023.
- DE for IFX was defined as dosing **interval <8 weeks and/or dosing >5mg/kg.**

RESULTS:

- Across 14 private and public IBD care centres, **1725** people were receiving IFX, of whom **44.2%** were on DE therapy.
- Of the entire IFX cohort, 65% had Crohn's Disease, 33% had ulcerative colitis, and 2% were IBD-unclassified.
- Even gender distribution (**52.5%** male)

RESULTS *(CONT.):*

In the DE cohort (n=762):

- Median age: **37 years** (IQR 27-49)
- Median age at diagnosis: **23 years** (IQR 16-32)
- Median disease duration: **11.6 years** (IQR 5.8-17.3).
- DE and standard dose cohorts did not differ by IBD diagnosis, gender, disease duration, age or age at diagnosis.

Outcome Measure (%)	Pre-DE	12 months post-DE	p-value
Faecal Calprotectin Remission (<250ug/g)	50.8	69.6	<0.001
Endoscopic Remission	23	39.2	0.047
Radiologic Remission	73.2	69.5	0.512
PRO2 Remission	70.5	78.1	0.015
Systemic Steroid Therapy	5	2.1	0.002

RESULTS *(CONT.):*

- Median drug level was higher 12-months post DE **(8.16μg/ml vs 3.65 μg/ml).**
- **Faecal calprotectin (FCP)** remission rate (FCP <250μg/g) was higher 12 months post DE, as was **endoscopic remission** rate and **patient reported outcome remission** (Table 1).
- The rate of **systemic corticosteroid use** was lower 12 months post-DE than pre-DE.
- In the DE-IFX cohort, measures of healthcare utilisation were lower 12-months post-DE; hospitalisation **(56 vs 146; p<0.001)**, surgical interventions **(41 vs 61; p=0.040),** endoscopic procedures **(210 vs 397, p<0.001)** and radiological investigations **(243 vs 343; p<0.001).**

CONCLUSIONS:

These prospectively collected data from large Australian and New Zealand IBD treatment centres show:

- A considerable proportion of people receiving IFX required DE, which appeared to be effective.
- DE IFX was associated with improved measures of remission *and* a reduction in several measures of healthcare utilisation.
- Further analysis can be performed to determine price points at which DE is cost-effective; additional data on quality of life and indirect healthcare costs would allow for a robust, holistic assessment of value in care.