# A pilot study using point of care testing for infliximab and fecal calprotectin in inflammatory bowel patients with a secondary loss of response

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## BACKGROUND AND OBJECTIVES

- Therapeutic drug monitoring (TDM) and fecal calprotectin (FCP) testing, in IBD patients with a secondary loss of response (LOR) to infliximab (IFX), help guide clinicians to the most appropriate intervention to recapture response.
- However, TDM and FCP result reporting can be delayed, hampering immediate treatment optimization.
- **We investigated the clinical utility of TDM, FCP and resultant early dose optimization, using rapid point of care (POC) testing.**

## METHODS

- We prospectively included adult IBD patients (February to November 2017) accessed for a secondary clinical LOR to IFX, defined as worsening of symptoms with a Harvey Bradshaw index (HBI) ≥ 5 for Crohn's disease (CD) and partial Mayo score (pMS) ≥ 3 for ulcerative colitis (UC).
- Results of testing for IFX through levels (TL) and FCP, measured by a POC device (BÜHLMANN device Quantum Blue®), were compared to standard IFX TL, anti-IFX antibodies (ELISA, Progenika) and FCP (ELISA, ALPCO), measured through a central laboratory.
- Based on POC results, an algorithmic approach to TDM/FCP results was implemented (Table 1).
- The primary endpoint was the proportion of patients in clinical remission (HBI < 5, pMS < 2) at week 12, in those patients that underwent early treatment optimization.

| Point of Care Results | Proposed Appropriate Action |
|---|---|
| Low TL and High FCP | Optimize treatment (dose escalate/change treatment) |
| Adequate TL, High FCP | Change biologic class |
| Adequate TL and Low FCP | Verify disease activity |

**Table 1. Algorithmic approach to POC testing**

## RESULTS

- Overall, 17 patients were included (65% female, mean age: 37.1 +/-17.4 years), CD n=9 (53%) with mean HBI 6.33+/-1.5; UC n=8 (47%) with mean partial Mayo 4.5+/-2.1.
- Mean duration of prior biological treatment was 28.1 months +/- 36.1. Mean IFX TL with POC testing was 14.5 +/-6.6 and with standard testing was 16.8 +/-7.9 (Pearson R=0.8, p=0.001). Mean FCP level with POC testing was 472+/-332.7 and with standard testing was 489.9+/-630.5 (Pearson R=0.53, p=0.04). 7/17 (41%) patients had low TL and high FC, 4/17 (24%) patients had adequate TL and high FCP and 6/17 (35%) patients had adequate TL and low FCP.
- In the 7 patients with low IFX trough and elevated FCP, treatment was modified (dose escalation/change therapy) in 5 (71%) and 4 out of 6 (67%) patients with available follow-up data from this group were in clinical remission at week 4 and 12.
- Using an algorithmic approach with POC TDM and FCP suggests that immediate dose optimization would have resulted in an inappropriate management in 10/17 (59%) patients.
- Overall, clinical remission data at week 12 were available in 13 patients and 10 (77%) were in clinical remission (see Table 2 for available follow-up).

| Clinical Loss of Response (n=17) | Early treatment modification | Remission at week 12 (available data n=13) |
|---|---|---|
| **1. Low TL, High FCP (n=7)** | 5/7 (71%) | 4/6 (67%) |
| **2. Adequate TL, High FCP (n=4)** | 1/4 (25%) | 2/2 (100%) |
| **3. Adequate TL and Low FCP (n=6)** | 0/6 (0%) | 4/5 (80%) |

**Table 2. Clinical outcomes**

## CONCLUSION

**Using POC testing for IFX patients with a secondary LOR is clinically useful, correlates well with standardized testing, allows for immediate appropriate management of patients with low IFX trough and high FCP and results in a rapid clinical remission**