# Outcomes after using Vedolizumab in paediatric inflammatory bowel disease in a tertiary centre, over a 3 year period.

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**Background;**
Vedolizumab has proven efficiency in adults but data in paediatric inflammatory bowel disease (pIBD) is limited. We present the outcome of treatment with vedolizumab in refractory pIBD cohort.

**Study Design;**
Retrospective and ongoing prospective review of all patients commenced on Vedolizumab following loss of response to anti-tumour necrosis factor [TNF] between Nov 2017 and Nov 2020.

**Aims and Objectives**;
Primary outcome;
- remission at Week 14 and last follow up (wPCDAI/PUCAI<10) from commencing vedolizumab.

Secondary outcomes;
- review trend of biochemical makers, surgical interventions, and adverse effects

**Table 1 showing patient demographics (n=11)**

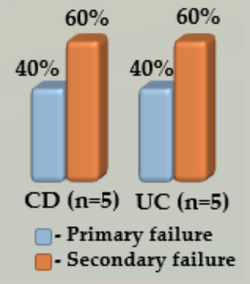
| | | |
|---|---|---|
| **Gender** | Male | 6 (54%) |
| | Female | 5 (46%) |
| **Diagnosis** | Crohn's disease (CD) | 6 (54%) |
| | Ulcerative colitis/IBD Unclassified (UC/IBDU) | 5 (46%) |
| **Mean age at time of diagnosis** | | 12.45 (8.34-15.48) |
| **Median (IQR) time from diagnosis** | | 2.68 (1.79-5.28) |
| **Baseline characteristics at $V_0$ ^** | Median age | 14.99 (13.0-17.6) |
| | faecal calprotectin(FC) | 2851 (92-6000) |
| | Hb | 114 (96-146) |
| | ESR | 22 (4-90) |
| | albumin | 39 (27-46) |
| | CRP | 16.7 (4-39.5) |

*^$V_0$- time of commencing vedolizumab*

## Results
Patient demographics are as shown in table 1. For CD all had colonic disease, 3/6 upper GI involvement and 3/6 perianal disease. 80% of UC children had pan-colitis. 4/11(36%) required surgery, three of whom had colectomy.

Outcome of previous anti-TNF treatemnet is shown in figure A. One child with UC and Bruton's agammaglobulinemia was anti-TNF naïve when commenced on vedolizumab. 8/11 remained on immunomodulators with vedolizumab. Transient raised transaminases and eczema was reported once and low mood with suboptimal response noted once. 6/11(54%) were in remission 14 weeks from commencing vedolizumab ($V_{14}$) and 4/11(36%) were excluded. At last follow up from commencing vedolizumab ($V_F$), median years 2.21(0.78-3.43), 3 remained in remission.

Figure A




In CD cohort, one child had a defunctioning ileostomy and remained in steroid free remission (SFR) at $V_{14}$ and $V_F$ (3.43 years) on vedolizumab monotherapy. One had colectomy (FC-3296 wPCDAI-60), steroid dependency compounded by methotrexate induced interstitial nephritis and vedolizumab was discontinued at $V_F$ (2.19 years). Two continue to have active disease at $V_{14}$ after commencing vedolizumab. One had SFR at $V_{14}$ and was transitioned at 2 years (FC-2585, wPCDAI-25) on vedolizumab. One with anti-TNF resistant disease, achieved clinical remission 9 months after starting vedolizumab (wPCDAI 2.5, FC 598) before being transitioned.

| Table 2 | | Chron's Disease | Ulcerative Colitis |
|---|---|---|---|
| **Completion of vedolizumab induction** | | 4/6 | 4/5 |
| **Median (IQR) follow-up years from $V_0$** | | 2.76 (0.04-3.43) | 2.06 (0.57-3.28) |
| **Remission at 14 weeks** | Total^ | 4 (100%) | 2 (66.6%) |
| **CD (n=4), UC (n=3)** | Steroid free* | 2 (50%) | 1 (33%) |
| **Remission at last follow up** | Total | 2 (50%) | 1 (33%) |
| **CD (n=4), UC (n=3)** | Steroid free | 2 (50%) | 1 (33%) |
| **PUCAI/PCDAI median (range)** | $V_0$ | 37.5 (0-67.5) | 40 (30-60) |
| | $V_{14}$ | 6.25 (5-10) | 5 (0-15) |
| | $V_F$ | 25 (0-60) | 22.5 (15-25) |
| **Calprotectin median (range)** | $V_0$ | 2214.5 (92-6000) | 3702 (143-5075) |
| | $V_{14}$ | 185 (30-4228) | 126 (8-244) |
| | $V_F$ | 2332 (31-6000) | 862.5 (366-6000) |
| **Weight centile median (range)** | $V_0$ | 30 (3-75) | 42 (31-99) |
| | $V_F$ | 41 (29-84) | 48.5 (54-99) |

^Total number of patients in remission, with or without concomitant steroid treatment
*Total number of patients in remission, without concomitant steroid treatment
$V_{14}$ - 14 weeks from time of commencing vedolizumab
$V_F$ - point of last follow up from starting vedolizumab

In UC cohort, two had vedolizumab primary non-response needing subtotal colectomy. One patient with PUCAI 5 at $V_{14}$ needed regime intensification for low vedolizumab levels but had active disease (PUCAI-25, FC-366) when transitioned at $V_F$ (2.06 years). One patient, who achieved remission whilst on steroid at $V_{14}$, remains in SFR at $V_F$ (0.58 years) on concomitant immunomodulation and optimal vedolizumab level at end of induction (>19). One who was lost to follow-up during COVID, was transitioned on 4 weekly vedolizumab regime.

## Conclusion
At $V_{14}$, 54% of patients achieved clinical remission and we see clinical improvement with PUCAI/PCDAI scores and faecal calprotectin in both UC and CD cohort. We are continuing this study over a longer period to achieve a larger cohort.