

However, it is largely unknown to which degree the abundance of *F. prausnitzii* correlates with the inflammatory activity, and few studies have addressed this from a longitudinal perspective.²

Methods: Faecal samples ($n = 59$) were collected subsequently every third month from CD patients ($n = 9$). A qPCR assay was applied to quantify the relative abundance of *F. prausnitzii* in relation to the total amount of bacteria. To assess the total capacity of gut microbiota to produce butyrate, we measured the gene copy numbers of the Butyryl-CoA: acetate-CoA transferase gene using qPCR. The concentration of faecal calprotectin (ELISA EK-CAL, Bühlmann Laboratories) was used as a proxy of the inflammatory activity.

Results: No significant correlations between *F. prausnitzii* or the Butyryl-CoA: acetate-CoA transferase gene and f-calprotectin were observed in the total sample set. By analysing alterations between consecutive samples, we observed a negative correlation between the abundance of *F. prausnitzii* and the concentration of f-calprotectin (Figure 1; $R = 0.38$; $p = 0.01$). The difference in abundance of *F. prausnitzii* between two subsequent samples accounted for 14% of f-calprotectin variation ($R^2 = 0.14$). There was no significant association between the microbiota's total capacity to produce butyrate and f-calprotectin ($R = 0.12$; $p = 0.42$) when alterations between consecutive samples were assessed.

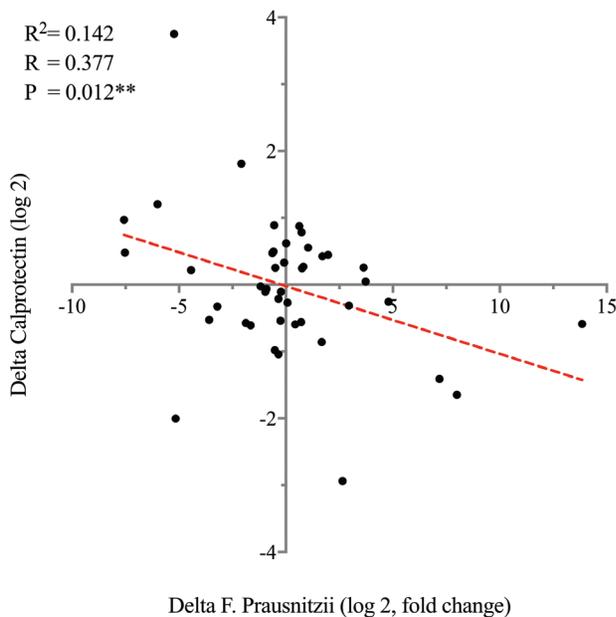


Figure 1 Changes in abundance of *F. prausnitzii* between two consecutive measurements vs. changes in faecal Calprotectin.

Conclusions: Temporal changes in the abundance of *F. prausnitzii* are inversely correlated to changes in f-calprotectin, indicating that *F. prausnitzii* may have an impact on the inflammatory activity in CD. Considering that the gene copy numbers of the Butyryl-CoA: acetate-CoA transferase gene did not correlate with inflammatory activity, we propose that *F. prausnitzii* may primarily inhibit inflammation by non-butyrate dependent mechanisms.

References

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P708

Home-based infusion therapy for biologic agent administration as a therapeutic option for patients with inflammatory bowel disease

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Background: Chemo@Home is a home-based infusion service based in Western Australia. This study aims to assess the safety of Chemo@Home for infliximab and vedolizumab infusions in inflammatory bowel disease (IBD) patients, the cost of delivery and the level of patient satisfaction.

Methods: IBD patients receiving infliximab and vedolizumab with Chemo@Home were assessed and any adverse effects noted. The cost of infusion by Chemo@Home was compared with private hospital administration and the activity-based funding in public hospitals. A patient satisfaction questionnaire assessed overall experience, infusion time and attitudes towards safety and accessibility. Safety was noted, with infusion reactions classified as minor, moderate or severe and managed according to treatment protocols.

Results: This retrospective study evaluated 162 infliximab (29 patients, 19 patient-years) and 155 vedolizumab infusions (27 patients, 16 patient-years) with Chemo@Home from August 2014 to April 2017. There were six acute infusion reactions with infliximab (3.7%) in four patients. One of these was classified as a moderate reaction (0.62%) managed by IV hydrocortisone and an antihistamine, which resulted in the infusion not completed. The rest were minor reactions and all infusions were completed. Three acute infusion reactions occurred with vedolizumab (1.9%) and all were minor with all infusions completed. There were no episodes of anaphylaxis, no reactions requiring a doctor to attend and no hospital transfers. The price per infusion by Chemo@Home (\$400–726AUS) was equivalent to the public (\$527AUS) and overall cheaper than private hospitals (\$316–\$1793AUS). Patient satisfaction was higher with Chemo@Home compared with infusions in a private hospital ($p < 0.0001$), infusion times were shorter ($p < 0.0001$) with less parking issues ($p < 0.0001$) and work or family life disruption ($p < 0.021$). Analysis of the public hospital data is underway.

Conclusions: Chemo@Home is safe with acute infusion reaction rates similar to previous studies. Costs are comparable to, or better than, the public and private hospitals. The service offers greater convenience and patient satisfaction to IBD patients receiving infliximab and vedolizumab.

P709

Is there a difference in adalimumab drug levels according to pen vs. syringe use: An international, multi-centre retrospective analysis

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Background: In an intensive pharmacokinetic study of adalimumab (ADA) in Crohn's disease (CD), trough drug levels were significantly higher in syringe compared with pen users.¹ Further data addressing the impact of delivery device on ADA drug level are lacking.

Methods: Retrospective observational study of adult CD patients receiving 40 mg ADA fortnightly (for >14 weeks) across five centres. Therapeutic drug monitoring (TDM) was performed with the following ELISA kits: Shikari (Matriks) at Alfred Health, St Vincent's Hospital, Monash Health and 54% of samples from Liverpool Hospital, Australia; LISA Tracker (Theradiag) at CHU Saint-Étienne, France; Promonitor (Grifols) for 46% of samples from Liverpool Hospital. The first recorded drug level (independent of indication), markers of disease activity including Harvey Bradshaw Index (HBI), C-reactive protein (CRP) and faecal calprotectin (FCP), and patient/disease demographics were collected. Drug levels >4.9 µg/ml were considered therapeutic, active disease was defined as CRP >5 mg/l or FCP >150 µg/g.

Results: A total of 218 patients were included. 52% of patients were male, mean age 39 years, 60% received concomitant immunomodulation. Mean FCP was 283 µg/g and CRP 10.2 mg/l at TDM. Pens were used by 64% of the cohort. Syringe users had a higher albumin, lower HBI and higher rates of concomitant immunomodulation than pen users (40 vs. 38 g/l, $p = 0.016$; 2.2 vs. 3.4, $p = 0.017$; 71 vs. 54%, $p = 0.014$). No significant differences in disease activity (CRP or FCP), duration or patient demographics between delivery device were observed. Considering all patients, there was no difference in drug levels in pen vs. syringe (5.3 vs. 5.2 µg/ml, $p = 0.442$, Figure 1a). Furthermore, drug levels did not differ between pen vs. syringe when controlling for disease activity (CRP or FCP). On subgroup analyses by centre, syringe users at Alfred Health had significantly higher drug levels than pen users (6.1 vs. 4.5 µg/ml, $p = 0.039$; Figure 1b) and a greater proportion were therapeutic (75 vs. 44%, $p = 0.045$). In contrast, a higher proportion of pen users from CHU Saint-Étienne had therapeutic ADA level (79 vs. 42%, $p = 0.027$), yet no significant difference in absolute drug level (7.9 vs. 4.5 µg/ml, $p = 0.119$). No differences between delivery device were seen at the remaining sites.

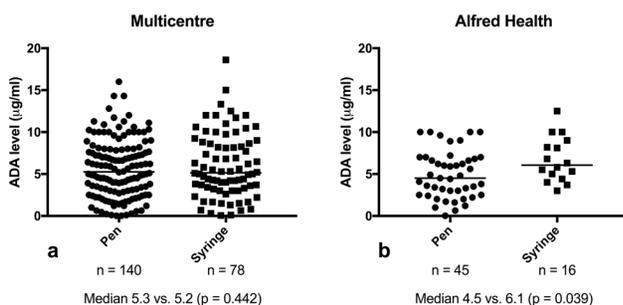


Figure 1. Drug level according to pen and syringe use at all participating sites (a) and at Alfred Health (b)

Conclusions: Drug delivery device does not appear to significantly affect ADA drug levels. Nevertheless, given site-specific differences between pen and syringe, further prospective controlled studies which include patient administration training are warranted.

References

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P710

Efficacy of therapeutic intervention for ulcerative colitis patients with the Mayo Endoscopic Score of 1

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Background: Mayo endoscopic score (MES) is widely used in the evaluation of ulcerative colitis (UC) activity. Both MES of 0 and 1 are considered as mucosal healing. However, recent study reported that UC patients with the MES of 1 had the worse outcome than those with the MES of 0. Furthermore, it is not clear whether therapeutic intervention for UC patients with the MES of 1 alters clinical outcome. Therefore, we aimed to investigate the efficacy of therapeutic intervention for UC patients with the MES of 1 in this study.

Methods: UC patients who had the MES of 1 and the partial Mayo score (pMayo) ≤2 were included in this study. Among them, participants who did not undergo CS after 1 year were excluded. Patients were followed up within 1 year after the initial colonoscopy. Risk factors for relapse (defined as clinical relapse or endoscopic aggravation) were assessed. Clinical relapse was defined as the case that needed any therapeutic intervention for 1 year after first CS. Endoscopic aggravation was evaluated at 1 year after enrollment.

Results: Among 1523 UC patients who underwent CS, 235 patients had MES of 1 with clinical remission (pMayo ≤2) at the enrollment. Even among patients with the MES of 1, 52 (22.1%) patients received additional treatment according to the initial endoscopic findings (the addition of topical treatment 43, 5-ASA escalation 17, thiopurine escalation 4, and the addition of corticosteroid 1). Univariate analysis indicated that therapeutic intervention just after first CS ($p = 0.004$), UCEIS vascular pattern score ($p = 0.012$), UCEIS erosion/ulcer score ($p = 0.017$), pMayo ($p = 0.033$), and CRP ($p = 0.049$) were risk factors for clinical relapse. Multivariable analysis indicated that non-therapeutic intervention ($p = 0.001$, OR 5.36, 95% CI: 2.18–13.1) and higher UCEIS vascular pattern score ($p = 0.002$, OR 3.18, 95% CI: 1.53–6.57) were the risk factors for relapse. Relapse rate in patients with therapeutic intervention (30.8%) was significantly lower than that patients without therapeutic intervention (57.4%) during the follow-up period ($p = 0.004$).

Conclusions: Therapeutic intervention for UC patients with the MES of 1 might prevented disease relapse. Among patients with the MES of 1, the items of UCEIS vascular pattern is also associated with relapse for UC.

P711

A pilot study using point of care testing for infliximab and faecal calprotectin in IBD patients with a secondary loss of response

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