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.

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-Etienne, France; Promonitor (Grijsols) 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 28 μg/ml 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-Etienne 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.

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

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 addition 43, 5-ASA escalation 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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Background: In a pilot study using point of care testing for infliximab and faecal calprotectin in IBD patients with a secondary loss of response (IndiaGastro 2017) 64% of patients were lost to follow up, we aimed to study the feasibility and the accuracy of point of care testing in patients with IBD who had a secondary loss of response (SLOR).

Methods: A pilot study was conducted from November 2017 to April 2018. A total of 25 patients were included in the study. The patients were considered to have had a secondary loss of response if they received infliximab and a failed to maintain clinical remission (pMayo ≤2). Serum infliximab and faecal calprotectin were measured at baseline and 4 weeks after the first dose in an attempt to identify a cut-off value for each parameter to help in identifying responders to this therapy.

Results: The study included 25 patients (19 females, 6 males; age range 18–85 yrs) with a mean age of 46 yrs. All patients were on infliximab and 72% were also on thiopurines. Baseline infliximab levels were above the cut-off in 18 patients, 6 patients had levels below the cut-off and 1 patient had undetectable levels. Baseline faecal calprotectin levels were above the cut-off in 12 patients, 6 patients had levels below the cut-off and 7 patients had undetectable levels. Four weeks after the first dose, 12 patients had levels above the cut-off for both infliximab and faecal calprotectin, 7 patients had levels above the cut-off for infliximab and below the cut-off for faecal calprotectin, 2 patients had levels below the cut-off for both infliximab and faecal calprotectin, 2 patients had levels below the cut-off for infliximab and above the cut-off for faecal calprotectin, and 2 patients had levels below the cut-off for both infliximab and faecal calprotectin.

Conclusions: Point of care testing for infliximab and faecal calprotectin in IBD patients with a secondary loss of response could be a feasible and accurate alternative to blood and stool testing for monitoring response to therapy.