

5. Identified the location of Crohn's pathologies from intersection with a set of GI anatomical locations
6. Linked the outputs to the ground truth reference data to determine sensitivity, specificity, positive and negative predictive values

### Results

**Conclusions** The evolution of the regular expressions for the phenotypic characterisation of Crohn's disease through repeated cycles of validation has yielded a powerful tool for the rapid and reliable interpretation of text in semi-structured MRE reports. We propose further refinement of the algorithm to compute (where possible) Montreal classification as well as location, extent and severity of Crohn's-related pathologies. We have previously demonstrated the potential for NLP to understand IBD concept in linked endoscopy and histopathology reports; the addition of radiographic data will further refine the automated characterisation of IBD cohorts from disparate information systems without human intervention.

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### REAL WORLD EFFECTIVENESS OF USTEKINUMAB FOR REFRACTORY CROHN'S DISEASE: A REGIONAL EXPERIENCE

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**Introduction** Ustekinumab, a monoclonal human antibody to IL12/23, offers an alternative option for a cohort of patients with treatment refractory Crohn's disease (CD). However, real world data for the effectiveness of ustekinumab in this challenging population is lacking. Here, we describe the outcomes of patients who have received ustekinumab at Oxford University Hospitals and Royal Berkshire Hospital NHS Foundation Trusts.

**Methods** A retrospective multicentre study of all patients commenced on ustekinumab for active CD prior to January 2019. All patient records were reviewed up until June 2019. Harvey-Bradshaw Index (HBI), CRP and other biomarkers of disease activity (Faecal calprotectin, Hb, Plts, albumin & ferritin) were evaluated at baseline and at week 12. The primary outcome measures were clinical and biochemical response/remission at week 12, as defined by HBI and CRP respectively. Definitions: Clinical response-a decrease in HBI of  $\geq 3$  points; Clinical remission-HBI  $\leq 3$ ; Biochemical response-decrease in CRP  $\geq 50\%$ ; Biochemical remission-CRP  $< 5$  mg/L. Secondary outcome measures included need for dose escalation, drug continuation and need for CD-related surgery.

**Results** 68 patients were commenced on ustekinumab prior to January 2019. Median disease duration of 14.8 years (IQR 10–18), 43/68 (63%) had ileocolonic disease, 31/68 (46%) had perianal involvement. 65/68 (96%) had received  $\geq 1$  prior biological while 49/68 (72%) had received  $\geq 2$  biologics. 66/68 (97%) underwent week 12 evaluation with HBI documented in 42/66 (62%) and CRP in all patients. At week 12, clinical remission was achieved in 26/42 (61%), and clinical response in an additional 8/42 (19%). Biochemical remission was achieved in 20/66 (31%) and biochemical response in an additional 9/66 (13%). Perianal disease, baseline albumin or CRP were not predictive of

biochemical non-response, although a trend was observed for male sex. 21/68 (31%) received dose escalation to Q8W dosing, and 3/68 (4%) underwent IV re-induction. All patients receiving re-induction achieved clinical response at follow up. Median time to drug failure/cessation was 274d (IQR 115–377). Clinical improvement, as defined by reduction in PGA, was achieved in 43% at 1-year. Adverse events were observed in 10/68 (15%) including CD-related surgery (n=4), malignancy (n=1). Rates of AEs did not correlate with higher dosing.

**Conclusions** Ustekinumab demonstrated both early clinical and biochemical efficacy in this complex real-world cohort, with no unexpected safety signals seen.

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### OUTCOMES OF USTEKINUMAB IN CROHN'S DISEASE: THE REAL-WORLD EXPERIENCE OF A TERTIARY IBD CENTRE

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**Introduction** Ustekinumab (UST) is a human monoclonal antibody which targets interleukin-12 and interleukin-23, thus acting as a cytokine inhibitor. UST is approved for use in patients with moderate to severe Crohn's disease in whom conventional or anti-TNF therapies have failed or are contraindicated. We retrospectively evaluated patients with Crohn's disease at our IBD tertiary referral centre to monitor real life response to, and side effects of, UST.

**Methods** We used a prospectively collated database held by the IBD team to identify patients with Crohn's disease who had commenced on UST between 1st January 2017 and 31st June 2019. Data was collected retrospectively using electronic case notes. The Harvey Bradshaw Index (HBI), faecal calprotectin, endoscopic investigations and cross sectional imaging results were collected at baseline, after 12 weeks of treatment and after 12 months of treatment. Response was defined as a decrease in HBI by 3 or more and/or an objective improvement in Crohn's disease activity on imaging or endoscopy. Clinical remission was defined as a HBI of  $< 3$ .

**Results** 51 patients with Crohn's disease were commenced on UST at our institute (22 males, median age 37 (18–79)). 48 patients had been on at least one biological agent previously, with 10 patients having been treated with 3 previous biologics. Median duration on UST was 9 months (one dose-32 months), with 27 patients on UST for  $> 12$  months and 7 patients on UST for  $> 2$  years. 40 patients had an HBI score calculated at baseline and at 12 weeks. Of these patients, 16/40 saw decrease in HBI by  $\geq 3$ . At 12 weeks, 10/40 had a HBI  $< 3$ , indicating remission. After 12 months of treatment, 19 patients had an HBI score calculated at both baseline and 12 months. 9/19 saw decrease in HBI by  $\geq 3$  at 12 months. Faecal calprotectin decreased by a mean of 96.3 in these patients. At 12 months, 7/19 had a HBI  $< 3$ .

Overall, of the 36 patients that had been on UST for at least 6 months, 30 had a subjective (HBI at 12 month review) or objective (abdominal imaging or endoscopy) measure of their disease activity. 15/30 showed an improvement in the severity of their disease,  $p = < 0.001$ .

10 patients stopped UST due to loss of response (6) or side effects (recurrent shingles (1), headaches (2), joint pain (1)). 6 patients required surgery due to an inadequate response to UST.