

Abstract OWE-03 Table 1

Characteristic	Combined clinical-biochemical remission (n=24)	Not in combined clinical-biochemical remission (n=22)	p
Gender, male:female	18:6	9:13	0.035
Median age (years)	33	36	0.75
Concomitant immunomodulator	18 (75%)	17 (77%)	>0.99
Prior anti-TNF experience	0 (0%)	2 (9%)	0.22
Maintenance dose, 50 mg:100 mg	12:12	10:12	0.78
Median body mass index	23.5	25.0	0.37
Disease activity			
Median SCCAI	0	5	<0.0001
Median PRO2	0	2.5	<0.0001
Median Calprotectin (ug/g)	17	419	<0.0001
Median CRP (mg/L)	1	1	0.17
Median Albumin (g/L)	47	46	0.042
Quality of life			
Median IBD-Control-8	16	6	<0.0001
Median IBD-Control-Visual Analogue Scale	92	49	<0.0001
Golimumab Measurement			
Median Serum Golimumab Concentration (ug/ml)	3.0	2.0	0.031

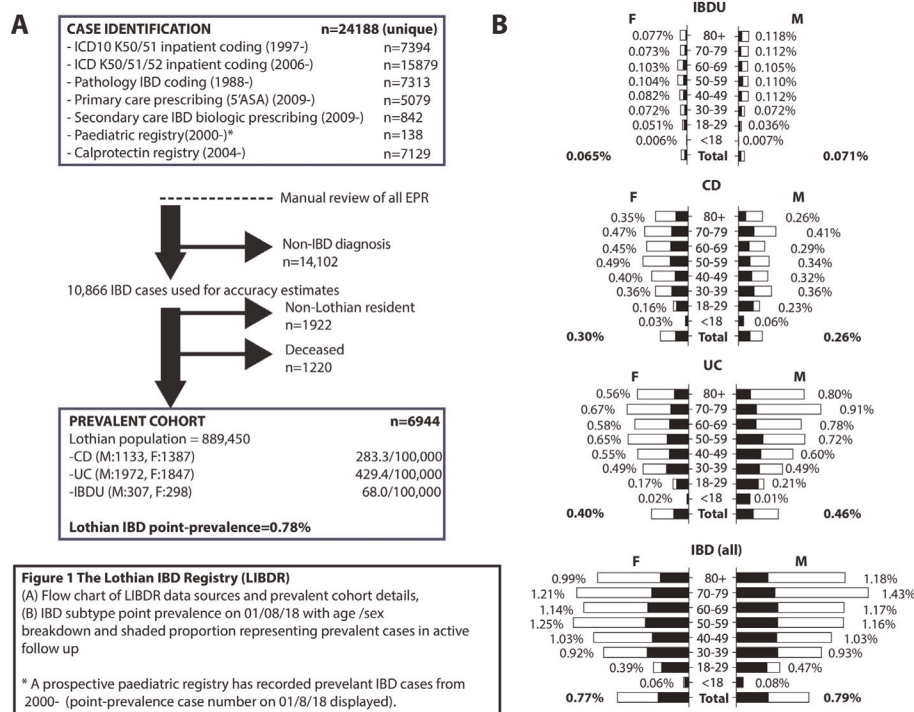
threshold to achieve combined remission (sensitivity 0.75, specificity 0.59, AUC 0.69). No AGA were detected.

Conclusions The GO-LEVEL maintenance cohort offers further evidence of the exposure-response relationship with golimumab, particularly when using a combined definition of remission that includes an objective marker of disease activity (FC). Clinicians may consider using therapeutic drug monitoring to optimise golimumab dosing aiming to achieve our suggested SGC therapeutic threshold of 2.1ug/ml.

OWE-04 A CAPTURE-RECAPTURE STUDY OF ALL-AGE IBD POINT PREVALENCE IN SCOTLAND

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10.1136/gutjnl-2019-BSGAbstracts.125



Abstract OWE-04 Figure 1

Background A recent systematic review reports an overall prevalence for IBD of 0.3% in Western countries¹ but there are no UK estimates since 2003. We aimed to report current all-age prevalence, healthcare usage and forecast 2028 case-load, for IBD in Lothian.

Methods We conducted an extensive capture-recapture search strategy, manually confirming all diagnoses through electronic patient record (EPR) review, to provide point prevalence estimates for Lothian, Scotland (Population 889,450). Patients were identified from inpatient IBD codes (K50/51/52), IBD pathology codes, IBD biologic prescriptions, primary care mesalazine prescriptions, an existing calprotectin database and a paediatric IBD registry to identify 'possible' IBD cases to 31/08/18.

Eight IBD physicians then manually screened the EPR for all possible cases to identify true cases as per Lennard-Jones/Porto criteria. Prevalence was calculated using postcode, date of diagnosis/death and population estimates from National Records Scotland. We then assessed our IBD cohort for attendance at secondary care, IBD-related admission, IBD-drug usage and projected 2028 Lothian IBD prevalence using autoregressive integrated moving average (ARIMA) modelling.

Results 24,188 possible IBD case records were manually reviewed to exclude non-IBD cases, leaving 10,866 true positives (figure 1A). The point prevalence of IBD in Lothian on 31/8/18 was 0.78% (figure 1A).

43.8% of prevalent cases attended out-patient clinic over the preceding 3 years which was inversely correlated with increasing age (Mean age 46.7±0.3 in follow up versus 54.9±0.3 not in follow up, p<0.0001)(figure 1B). Follow-up was significantly associated with IBD-related admission (OR 5.7 {4.6–6.9}, p<0.0001) and IBD-related admission duration was positively correlated with increasing age (R²=0.02, slope=0.12 {0.09–0.15}, p<0.0001).

ARIMA modelling projects a point prevalence on 01/08/28 of 0.99% (0.94–1.04%) affecting 1.6% (1.5–1.7%) of the >50s who will account for 59% of prevalent IBD.

Conclusions The prevalence of IBD in the UK is 0.78% (1 in 125 individuals). This is much higher than previously reported, and will continue to rise due to compound prevalence, reaching >1.0% by the end of 2028.

REFERENCE

1. Siew Ng, et al. Worldwide incidence and prevalence of inflammatory bowel disease in the 21st century: a systematic review of population-based studies. *Lancet* 2018;390:pp2769–2778.

OWE-05 INTERIM LONG-TERM SAFETY/EFFICACY OF RISANKIZUMAB TREATMENT IN CROHN'S DISEASE PATIENTS FROM THE OPEN-LABEL EXTENSION STUDY

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10.1136/gutjnl-2019-BSGAbstracts.126

Introduction Adults with moderate-to-severe Crohn's disease (CD) who responded to risankizumab (RZB) in the phase 2 induction and maintenance study (Feagan, 2017) could enroll in an open-label extension (OLE) study. Interim efficacy and

safety of RZB maintenance treatment from the OLE, up to 2 years, are reported.

Methods Patients (pts) achieving clinical response (decrease from baseline [BL] in CD Activity Index [CDAI] ≥100) without remission (CDAI <150) after wk 26 or clinical response and/or remission after wk 52 of the preceding study received 180 mg s.c. RZB every 8 wks for up to 216 weeks. Pts losing clinical response or remission after completing the preceding study were re-induced with 600 mg i.v. RZB at wk 0, 4, 8. Pts received subsequent 180 mg s.c. RZB maintenance treatment only if they achieved response or remission following re-induction treatment. Ileocolonoscopy was performed yearly. Efficacy data (clinical remission and endoscopic remission [CD Endoscopic Index of Severity (CDEIS) ≤4 or CDEIS ≤2 for pts with initial isolated ileitis]) are reported up to wk 48. Non-responder imputation (NRI) was used for missing data.

Results A total of 65 pts were enrolled (including 4 who were re-induced). Mean (standard deviation) exposure to RZB was 657.2 (190.73) days. At the data cut-off, 14 (21.5%) pts have discontinued the study. Up to wk 48, clinical remission rates were sustained and the proportion of pts with endoscopic remission increased from BL (table 1). Adverse events (AEs) were reported for 58 (89.2%) pts; 18(27.7%) pts had serious AEs. AEs occurring in >10% of pts were nasopharyngitis (26.2%), fatigue (16.9%), arthralgia and worsening CD (15.4% each). Four serious infections in 5 pts were perianal abscess (n=1), *Campylobacter* (n=1), viral gastroenteritis (n=2), and peritonitis (n=2). No events of tuberculosis, malignancies or deaths occurred.

Conclusions In this interim analysis, clinical remission and endoscopic remission were sustained in CD pts receiving long-term RZB treatment. The safety profile of RZB was consistent with previously published data (Feagan, 2017).

Abstract OWE-05 Table 1 Pts in the OLE achieving clinical remission and endoscopic remission by visit

	Clinical remission n (%) ^a	Endoscopic remission ^b n (%) ^a
Wk 0 ^c	48 (73.8)	27 (41.5)
Wk 8	47 (72.3)	
Wk 16	46 (70.8)	
Wk 32	48 (73.8)	
Wk 48	45 (69.2)	35 (53.8)

All pts had ≥48 wks observation at the data cut-off ^aN=65 ^bData from central reading ^cVisits in OLE

REFERENCES

1. Feagan BG, et al. *Lancet* 2017;29;389(10080):1699–1709.
2. Feagan BG, et al. *Gastroenterology* 2017;152(5):S1310.

OWE-37 CD4 T-CELL HLA-U PSEUDOGENE AT BASELINE PREDICTS CLINICAL REMISSION TO ANTI-TNF AGENTS IN ULCERATIVE COLITIS

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10.1136/gutjnl-2019-BSGAbstracts.127

Introduction Anti-tumour necrosis factor (TNF) agents are used to treat UC but response is variable. Apart from