Result We identified 4069 cases of UC over the study period. There were 1678 never smokers (41%), 329 smokers (8%), 1541 ex-smokers (38%) and 521 patients whose follow-up smoking status changed (13%). Multivariate regression analysis, adjusting for all covariates listed in table 1, demonstrated smokers had a significantly lower risk of thiopurine use compared to both never smokers (HR 0.52, 95% CI 0.27–0.97, p=0.04) and ex-smokers (HR 0.51, 95% CI 0.27–0.98, p=0.04). In contrast there was no difference in corticosteroid dependency (OR 0.83, 95% CI 0.44–1.75) or rates of colectomy (HR 0.4, 95% CI 0.53–3.02) in a multivariate analysis.

Conclusions Smoking is associated with a decreased requirement for thiopurines however it does not impact on the risk of corticosteroid dependency or colectomy. The risks associated with smoking outweigh any benefits and smoking cessation should be encouraged.

**PWE-007 A SYSTEMATIC REVIEW OF OUTCOMES AND ADVERSE EVENTS FOR RANDOMISED CONTROLLED TRIALS IN CROHN’S DISEASE**

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Introduction Despite major progress in drug development for Crohn’s disease (CD) and advances in trial methodology, there is no internationally recognised core outcome set (COS). Poor standardisation in outcome reporting may impact negatively on translation of trials into practice. The suitability of traditional disease activity indices as primary end-points has been challenged, with growing interest in objective measures of inflammation. We undertook a systematic review to explore heterogeneity and time trends in the reporting of efficacy and safety outcomes in placebo-controlled randomised controlled trials (RCTs) of patients with CD.

Methods We searched MEDLINE, EMBASE, CINAHL and Cochrane Library from their inception to November 2015, for RCTs of adult CD patients with treated with medical or surgical therapies. We extracted information on efficacy and safety outcomes, definitions of end-points, and measurement instruments. To explore temporal trends studies were stratified by publication date (pre-2009 and 2009-onwards).

Results 181 RCTs comprising 23 850 patients. Trial focus: Induction of remission, 110 trials (60.8%), 104 medical and 6 surgical interventions. Maintenance of remission, 71 trials (39.2%). Biologics were intervention of interest in 33.7%, as either monotherapy or part of a combination therapy. 92.3% of trials reported clinical efficacy outcomes as a primary or secondary endpoint. CDAI was the dominant index, used to determine clinical response or remission in 63.5% of trials. However, there was heterogeneity, with 35 definitions of response or remission. CDAI <150 was the commonest end-point, but reporting reduced between periods (46.4% to 41.1% of trials), whilst CDAI100 reporting increased (16.8% to 30.4%). Reporting of objective measures of inflammation increased over time, but with lack of standardisation. Reporting of both histologic and endoscopic outcomes increased, from 3.2% to 12.5% and from 14.4% to 30.4% of RCTs, respectively. Biomarker reporting increased from 33.3% to 40.6% of trials. Patient-reported outcome measures (PROMs) were reported in 41.4% of trials with growth in reporting from 39.2% to 46.4%. Safety outcomes were reported explicitly in 35.4% of trials and reporting increased from 32.8% to 41.1%.

Conclusions As expected, the CDAI was the dominant composite index reported but there was significant variation in the selection and definition of clinical trial end-points in RCTs for CD between studies, and over time. Despite growth in reporting of objective measures of inflammation and in PROMs, there is much heterogeneity and lack of standardisation. This highlights the need for international researchers and clinicians to develop a COS for comparative effectiveness research in CD.