PWE-035

**ENDOSCOPY CAN BE AVOIDED IN THE ASSESSMENT
OF ULCERATIVE COLITIS IN CLINICAL TRIALS**

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Introduction Several indices exist for the scoring of disease activity in the context of ulcerative colitis (UC) intervention trials. These combine clinical symptoms with laboratory parameters or endoscopic findings. Recently the emphasis has been on achievement of mucosal healing and therefore subjects enrolled in trials require multiple endoscopic procedures (usually with unsedated proctosigmoidoscopy) at different time points. The need for sigmoidoscopy can adversely effect recruitment into trials. A reliable non-invasive index which is a surrogate marker for mucosal healing is required to improve patient acceptability in clinical trials of UC. We aimed to compare an invasive (Mayo score) and non-invasive (partial Mayo score) activity index with histological findings from a recent clinical trial.

Methods 149 subjects with moderate to severe UC enrolled in a multicentre clinical trial were assessed using total and partial (excluding the endoscopic subscore) Mayo scores at day 0, week 4 and week 8. As an optional substudy, histological evaluation of biopsies was performed in 69 subjects. Using week 4 data, a model was constructed to predict total Mayo score from partial Mayo score; the model was then tested using week 8 data. A Bland and Altman test of agreement was performed. Biopsies were assessed by a single blinded independent gastrointestinal histopathologist and scored using an index described by Riley *et al.*¹ The Mayo score was compared to histological score by linear regression.

Results There is a weak correlation between histology score and both partial Mayo score ($r=0.35$) and total Mayo score ($r=0.25$). There is poor correlation between endoscopic subscore and histology score ($r=0.10$). Using the partial Mayo score (where the score equals x) and applying a formula $(4/3)x + 0.2$ accurately predicts the total Mayo score at week 4 ($r=0.98$) and week 8 ($r=0.98$). The change in total Mayo score from week 4 to week 8 correlated well with the change in score predicted by the model based on partial Mayo score ($r=0.93$). The Bland and Altman test of agreement suggests good agreement to an accuracy of ± 1 point. While very accurate for mild and moderate disease there is insufficient data to validate it in severe disease.

Conclusion There is poor correlation between histology and Mayo scores. Addition of endoscopy subscore to the clinical domains of the Mayo score adds nothing. If researchers wish to measure mucosal healing then sigmoidoscopy alone is inadequate and histology is necessary until such time as non-invasive biomarkers (eg, white cell proteins) have been validated.

Competing interests None.

Keywords activity scoring index, clinical trials, Mayo score, ulcerative colitis.

REFERENCE

1. Riley SA, *et al.* Gut 1991;32:174–8.