

PWE-049

ASSESSMENT OF ADHERENCE TO MESALAZINE MAINTENANCE THERAPY OVER 1 YEAR USING MEMSCAPS MONITORING SYSTEM: A SUBSTUDY OF THE CODA TRIAL COMPARING ONCE- VERSUS THREE TIMES DAILY ASACOL IN ULCERATIVE COLITIS (UC)

doi:10.1136/gut.2011.239301.312

A B Hawthorne,^{1,*} R Stenson,¹ D Gillespie,² K Kapur,³ K Hood,² C S Probert⁴ ¹*Medicine, University Hospital of Wales, Wales, UK;* ²*SE Wales Trials Unit, School of Medicine, Cardiff University, Cardiff, UK;* ³*Gastroenterology, Barnsley District General Hospital, Barnsley, UK;* ⁴*Clinical Science at S Bristol, Bristol Royal Infirmary, Bristol, UK*

Introduction The Colitis Once Daily Asacol (CODA) study assessed the efficacy and safety of once daily dosing with Asacol 2.4 g (3 × 800 mg tablets) (OD) versus three times daily. Emerging evidence suggests OD mesalazine is as effective as divided doses. This has been attributed to better adherence, but detailed measures of adherence were lacking in previous studies. The Medication Event Monitoring System (MEMS) based in a bottle cap records the time each time the bottle is opened, giving detailed adherence data.

Methods 213 UC patients were followed for 1 year or until relapse. A subgroup used the MEMS bottle caps to record treatment adherence. Bottle opening (dosage event) was assumed to equate to tablet consumption. Analysis was performed on the complete case population (CCP). Daily adherence was defined for OD as one dosage event within 24 h, and for three times daily as three dosage events, (separated each by >1 h). Cofactors including treatment group, age, sex, employment status, and relapse/non-relapse were explored. Factors affecting relapse were explored in a multivariable regression model.

Results 58 entered the substudy, and used the MEMS system (OD 28, three times daily 30). In 49, complete data was collected (1 year or to relapse) and 9 had partial data. For the CCP 3/27 (11.1%) of the OD group relapsed, versus 13/29 (44.8%) of three times daily group (difference in relapse rates -34% (95% CI -55% to -12%). The % days adherent (median (IQR)) was 94.6% (90.8-96.7%) for OD, and 53.2% (32.0-80.8%) for three times daily (p<0.001). % days adherent did not differ between relapsers/non-relapsers. For OD group relapsers were 96.2% (90.8-96.5%) adherent versus non-relapsers 94.6% (90.8-96.8%); for three times daily group relapsers 42.4% (40.0-84.6%) adherent versus non-relapsers 57.1% (32.0-80.5%). In multivariable regression model of relapse, three times daily dosing affected risk of relapse: OR 6.5 (95% CI 1.3 to 3.5), p=0.024, but % adherence did not (OR 1.0 (95% CI 0.79 to 1.27), p=0.99).

There was a strong relation between both perceived adherence and ease of taking medication reported by patients, and measured adherence. Age, sex, centre and employment status did not affect adherence significantly.

Conclusion Adherence is significantly greater in OD versus three times daily dosing. In this small subgroup of the CODA population, the significantly reduced relapse rates in the OD group are not explained entirely by the improved treatment adherence.

Competing interests A. Hawthorne Grant/Research Support from: This work was supported by an unrestricted educational grant from Warner Chilcot, R. Stenson: None Declared, D. Gillespie: None Declared, K. Kapur: None Declared, K. Hood: None Declared, C. Probert: None Declared.

Keywords Adherence, clinical trial, Maintenance of remission, ULCERATIVE COLITIS.