Inflammatory Bowel Disease and Pregnancy: Lack of Knowledge is Associated with Negative Patient Views

Introduction
Enabling women with inflammatory bowel diseases (IBD) to have a successful pregnancy requires complex decisions. This study aimed to assess patients’ views on IBD and pregnancy and to correlate them with knowledge.

Methods
Female IBD patients aged 18–45 years were recruited from Australian gastroenterology clinics and private offices. Data were collected on demographics, disease specifics and previous pregnancies. General attitudes were assessed on fertility, medication use, mode of delivery and pregnancy outcomes. Attitudes regarding their personal situation were assessed in participants who had not given birth since their diagnosis of IBD. Agreement was rated on 5 Point Likert scales and knowledge of pregnancy related issues in IBD was assessed by the recently validated Crohn’s and Colitis Pregnancy Knowledge Score “CCPKnow”. Statistical analysis was performed using Student t test and ANOVA.

Results
Of 145 women (median age 32 years, 70% married) 45% had Crohn’s disease, 45% ulcerative colitis and 10% IBD-unclassified. 49 women had successfully delivered children after their diagnosis of IBD. General attitudes: Only 51% agreed that IBD medication should be continued prior to conception. 68% agreed with the need for medical therapy for flares during pregnancy, but 24% felt it more important to tolerate symptoms rather than to have medicines. 36% of participants believed that any IBD medication is “bad” for unborn children. Patients believed that women with IBD are likely to have a vaginal delivery (87%) or a healthy baby (68%), but 37% expected a difficult pregnancy. 70% thought that women on IBD medication should not breastfeed. Personal attitudes: Of 96 nulliparous women after IBD diagnosis, 46% were worried about infertility, passing IBD to offspring (75%) and 30% considered not having children because of IBD. 90% worried about the effect of IBD on pregnancy and 91% about the effects of pregnancy on IBD. Correlation of attitudes and knowledge: General attitudes that “medication should be stopped prior to conception” (p<0.001), “pregnant women should avoid all IBD drugs” (p<0.001), and “put up with symptoms” (p<0.001) were all associated with significantly lower knowledge. Personal attitudes were not associated with knowledge.

Conclusion
A significant minority of women felt that IBD medication is harmful to unborn children and women should put up with symptoms. Fear of infertility and concerns about inheritance may explain the extremely high rate of women considering not having children because of IBD. Views contrary to medical evidence were associated with significantly lower knowledge; education and personal counselling should be offered to young women with IBD, particularly those with a low CCPKnw score.

Competing interests
None declared.

Conveying Medication Benefits to Ulcerative Colitis Patients: What Thresholds for Adherence Are Applied?

Introduction
Although inflammatory bowel disease (IBD)-related knowledge empowers patients, it may engender anxiety and impair quality of life (QoL). We aimed to identify predictors of anxiety in IBD and the association with knowledge and disease-related QoL.

Methods
Ambulatory IBD patients were recruited from two Australian tertiary hospital clinics and office-based gastroenterologists. Self-administered questionnaire data were collected on demographics and details of IBD, including Crohn’s Colitis Association membership status. Disease-related knowledge was assessed using the validated Crohn’s and Colitis Knowledge Score (CCKnw) and disease related QoL using the short IBD questionnaire (SIBDQ). Anxiety (HADS-A) and depression (HADS-D) were assessed with the Hospital Anxiety and Depression Scores with significance defined as HADS-D<10 and probable disorder as HADS-D>10. Statistical analysis was performed using Student t test and ANOVA.

Results
258 patients (53.9% female, median age 47 years) were included. 50 patients (19.4%) had clinically significant anxiety and 58 (22.4%) had probable anxiety. Age, marital status, highest level of education, employment status, household income, diagnosis (Crohn’s vs ulcerative colitis) and duration of disease were all unassociated with higher anxiety levels. Female patients (HADS-A 7.5 vs 6.0 [males], p=0.003), hospital outpatients (7.8 vs 6.3 [from office based doctors], p=0.014) and non-Caucasian patients (7.9 vs 6.4 [Caucasians], p=0.037) had significantly higher anxiety levels, while Crohn’s Colitis Association members had marginally higher levels of anxiety (7.7 vs 6.5 [non-members], p=0.07). Disease related patient knowledge was higher in females (CCKnw 11.3 vs 8.4 [males], p<0.001), but was not influenced by diagnosis or ethnicity. Anxiety (HADS-D>8) was associated with significantly better patient knowledge (CCKnw 10.8 vs 9.3, p=0.016) and increased depression (HADS-D>3.1, p<0.001). Disease related quality of life was significantly lower in patients with anxiety (SIBDQ 44.8 vs 57.4, p<0.001).

Conclusion
Better patient knowledge is associated with higher anxiety levels. Educating patients about their disease and associated risks of surgery, cancer, infertility, etc might trigger anxiety. On the other hand anxious patients might seek out disease related information and hence acquire better knowledge. Our results suggest that an educational intervention may not be suitable to reduce anxiety. Anxiety is common in IBD patients and is associated with depression and significantly impaired quality of life. It may develop as the consequence of diminished quality of life from active IBD, but anxiety itself may lead to impaired quality of life.

Competing interests
None declared.
patients; the thresholds of benefit that would produce adherence were also assessed.

Methods Four methods of displaying information about the benefits of maintenance therapy in remission were explained to UC patients in remission, during face to face structured interviews. These were largely conventional numerical approaches: relative risk reduction (RR), absolute risk reduction (AR), number needed to treat (NNT). The fourth was an optical representation via Cates plot (CP).

Patients understanding and preference for each approach were recorded. Patients were asked to state the minimum thresholds required to adhere to a hypothetical medication (with 5-ASA like properties) for the benefits of relapse and cancer reduction respectively. Thresholds were determined for each method of display.

Results Of 50 participants (mean age 50 years; 58% male) 48% preferred data presentation by RR over CP (28%), AR (20%) and NNT (4%). 94% found RR easy to understand, better than CP (74%), AR (58%) or NNT (48%). Thresholds required for adherence also differed between methods. For bowel cancer prevention, 94% indicated adherence for benefit levels of 61% RR or lower but only 57% would adhere when presented with the corresponding CP (p<0.001). For relapse prevention, 78% of patients chose a threshold of 40% or lower but only 43% chose the corresponding CP (p<0.001). When presented with RR, adherence minimum thresholds equivalent or lower to the actual 5-ASA benefits were applied by 98% of patients for cancer reduction and 78% for flare reduction.

Conclusion Ulcerative colitis patients prefer RR and CP as methods to display medication benefit. NNT is poorly understood and unpopular. Patients apply significantly higher thresholds for adherence when presented with CP in comparison to RR. Presented with information in this way, most patients would choose to adhere to 5-ASA medication when offered the actual benefit profile. Reduction of cancer risk may be a stronger motivator than maintenance of remission. Interventions to improve 5-ASA adherence should use RR and convey benefits for cancer and flare prevention.


Results 194/200 returned baseline surveys (CD, n=107; UC, n=87). Study population (CD, UC): Age (mean): 41; 48 yrs. Disease duration (mean): 10.5; 10.7 yrs. Prev. Surgery (%): 50%; 3.4%. Immunosuppressants (%): 49.5%; 27.6%. Biologics (%): 22.4%; 8.0%. Disease activity (mean [SD] HBI; SCCAI): 5 [5]; 4 [3].

Measurement properties of IBD-Control: Completion time (mean [SD]): 1 min 15 s [25s]; Internal consistency: Cronbach’s α for all 15 items: 0.838; for sub-group of 8 questions (IBD-Control-8): 0.841. Strong correlation between IBD-Control-8 sub-score and IBD-Control-VAS (r=0.79). Test-retest reliability for stable patients (Baseline vs 2 week repeat, no change): IBD-Control-8, 15.8 vs 15.6; p=0.73; IBD-Control-VAS, 65.5 vs 68.0, p=0.33. Validity: Moderate-to-strong correlations between IBD-Control-8 subscore and IBD-Control-VAS vs disease activity, UK-IBD-Q and global health state (utility) with r values 0.56 to 0.84. Discriminant validity (mean scores for remission, mild, moderate, severe): ANOVA p<0.01. Sensitivity to change: (analysis of first 53 follow-ups): No significant changes for stable patients; moderate-to-large responsiveness statistics for IBD-Control-8 and IBD-Control-VAS: (Effect sizes: 0.4–1.6).

Conclusion The IBD-Control shows promise as a rapid (<2 min), reliable, valid and sensitive instrument for measuring overall disease control from the patient perspectives. Unlike existing PROMS, its ease-of-use and generic applicability make it a candidate for use in routine practice as a decision-support tool for patients and clinicians.

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THE IBD-CONTROL QUESTIONNAIRE: DEVELOPMENT AND PSYCHOMETRIC VALIDATION OF A TOOL FOR CAPTURING DISEASE CONTROL FROM THE PATIENT PERSPECTIVE USING ROUTINE CARE

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C Ormerod, 1D Shackcloth, 1M Harrison, 1E Brown, 1K Bodger. 1Digestive Diseases Centre, Aintree University Hospital, Liverpool, UK; 2Department of Gastroenterology, Institute of Translational Medicine, University of Liverpool, Liverpool, UK

Introduction Although a range of disease activity measures and QoL questionnaires is available for IBD, none has found a place in routine clinical practice. This project aimed to develop a tool for capturing disease control from the patient’s perspective with measurement properties appropriate for routine clinical practice.

Methods Phase I: Systematic review of existing PROMs, patient focus groups and a steering group to define domains and items for the ‘IBD-Control’. Instrument comprises 13 questions items plus a visual analogue scale (VAS, 0–100) for overall control. Phase II: Prospective validation, patient completion of IBD-Control, QoL questionnaire (UK-IBD-Q), EuroQol (EQ5D), Hospital Anxiety & Depression Scale (HADS); clinician assessment (blinded to questionnaire) recording disease activity (Harvey Bradshaw Index, HBI); or Simple Clinical Colitis Activity Index, SCCAI); global clinician assessment (remission; mild; moderate; severe), Montreal Classification, treatment history. Ongoing longitudinal survey (serial questionnaires).

Results 38 patients with IBD/other organic bowel disease (mean 56 yrs, range 15–49) and 24 patients with IBS (mean 56 yrs, range 20–45) were sampled. Sensitivity and specificity for active IBD vs IBS using manufacturers’ cut-offs of 50 μg/g were: Buhlmann EK-CAL 86% (95% CI 42 to 99) and 60% (95% CI 83% to 83%), PPV 50% (95% CI 22 to 78%), NPV 90% (95% CI 54% to 99%); PhiCal 78% (95% CI 40% to 96%) and 92% (95% CI 60 to 100%), PPV 88% (95% CI 47% to 97%) and NPV 86% (95% CI 56% to 97%). Correlation across full range of results were PhiCal vs EK-CAL, R²=0.48; PhiCal vs PhiCal, R²=0.54. However for results <100 μg/g by PhiCal, correlations improved that is, R²=0.64 and R²=0.83 respectively. Intra-batch imprecision of the whole process,

Fecal calprotectin analysis: does the method matter?

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C Tomkins, 1Z Zeino, 1C NWokolo, 1S C Smith, 2R Arasaradnam. 1Biochemistry, University Hospitals of Coventry and Warwickshire, Coventry, UK; 2Gastroenterology, University Hospitals of Coventry and Warwickshire, Coventry, UK

Introduction Fecal calprotectin (FC) is a sensitive marker of intestinal inflammation and is useful to help distinguish between organic and non-organic (functional) disease. The increasing popularity of this test, with various analytical methods available, potentially leads to confusion in interpreting results. The aim of this study was to technically evaluate FC measured by different ELISA methods in secondary/tertiary care.

Methods 62 stool samples were collected from sequential outpatients presenting with chronic diarrhoea. All participants had a colonoscopy with biopsy, to which FC results were compared. FC was measured by ELISA assays: Immundiagnostik PhiCal (version 1) and Buhlmann EK-CAL. Subsets were also measured by PhiCal (version 2). Stool was weighed and extracted, and ELISAs performed manually.

Results 58 patients with IBD/other organic bowel disease (mean 56 yrs, range 15–49) and 24 patients with IBS (mean 56 yrs, range 20–48) were sampled. Sensitivity and specificity for active IBD vs IBS using manufacturers’ cut-offs of 50 μg/g were: Buhlmann EK-CAL 86% (95% CI 42 to 99) and 60% (95% CI 83% to 83%), PPV 50% (95% CI 22 to 78%), NPV 90% (95% CI 54% to 99%); PhiCal 78% (95% CI 40% to 96%) and 92% (95% CI 60 to 100%), PPV 88% (95% CI 47% to 97%) and NPV 86% (95% CI 56% to 97%). Correlation across full range of results were PhiCal vs EK-CAL, R²=0.48; PhiCal vs PhiCal, R²=0.54. However for results <100 μg/g by PhiCal, correlations improved that is, R²=0.64 and R²=0.83 respectively. Intra-batch imprecision of the whole process,