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Prospective validation study of the International Classification of Functioning, Disability and Health score in Crohn's disease and ulcerative colitis

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KEYWORDS

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Abstract

Background and aims: Inflammatory bowel diseases (IBD) may result in disability. We aim to validate a novel scoring system for the IBD disability index (IBD-DI), and identify predictors of disability and its correlation with work absenteeism.

Methods: This prospective IBD ambulatory clinic cohort study measured IBD-DI, Crohn's Disease Activity Index (CDAI) for Crohn's disease (CD) or partial Mayo score (pMayo) for ulcerative colitis (UC), IBDQ quality-of-life, and Work Productivity and Activity Impairment. Negative IBD-DI represented greater disability. Validation tests were performed and predictors and extent of work absenteeism were determined.

Results: 166 consecutive subjects were recruited (75 CD, 41 UC, 50 controls). IBD-DI correlated with CDAI ($r = -0.77$, $P < 0.001$), pMayo ($r = -0.82$, $P < 0.001$) and IBDQ ($r = 0.86$, $P < 0.001$). IBD-DI differentiated CD, and UC from controls (medians -7 , -4 , $+10$; $P < 0.001$) with a score of >3.5 identifying controls with 94% sensitivity and 83% specificity (area-under-curve 0.92). Stable patients had unchanged IBD-DI ($P = \text{ns}$) but not in those who relapsed ($P < 0.001$). Intraclass correlation was 0.89 and Cronbach's alpha of internal consistency was 0.94. Diagnosis age, sex, phenotype, perianal disease, prior surgery, steroid-use and disease duration did not influence the IBD-DI but active use of biological agents significantly reduced disability ($P = 0.03$). 21.6% of

Abbreviations: CD, Crohn's disease; CDAI, Crohn's disease activity index; IBD-DI, Inflammatory bowel disease disability index; IBDQ, Inflammatory Bowel Disease Questionnaire; ICF, International Classification of Functioning, Disability and Health; pMayo, partial Mayo score; UC, ulcerative colitis.

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IBD patients had moderate-severe disability equating to missing >25% of work hours in the previous week. Multivariate analysis identified that only IBD-DI to be predictive of unemployment status (OR: 0.94; 95% CI: 0.89–0.99).

Conclusions: The IBD-DI is a valid tool measuring disability in both CD and UC and correlates with workforce participation. It is a potential useful tool in the assessment of participation restriction and activity limitation. Trial registration: ACTRN12613000903785.

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1. Introduction

Disability is defined by the World Health Organization International Classification of Impairments, Disabilities and Handicaps (ICIDH) as “any restriction or lack (resulting from any impairment) of ability to perform an activity in the manner or within the range considered normal for a human being”.¹ Disability, therefore, more accurately reflects impairments, activity limitation and participation restriction which correlates with the lost work productivity and increased health resources utilization. Reversal of disability to minimize or eliminate such limitations and restrictions then becomes an important driving force of any intervention as a marker of successful treatment. This in turn allows the cost of newer treatments to be directly incorporated into the regulatory approval process as a trade-off for the reduction in disability. In contrast, “quality of life” is a patient-reportable outcome on their feeling of their limitations and restrictions. Quality of life is heavily subjective based upon inter-individual coping strategies.²

Inflammatory bowel diseases (IBD) are chronic incurable gastrointestinal diseases that typically affect the young working-age population. Active disease, progressive course with cumulative intestinal damage, development of complications, the presence of extra-intestinal manifestations and treatment adverse effects may result in disability. Functional assessment is an essential consideration in chronic illnesses; as such the World Health Organization (WHO) is currently revising the International Classification of Diseases to include functional properties for disabling conditions.³ The WHO developed the International Classification of Functioning, Disability and Health (ICF), a structured and complete framework that classifies body functions, structure, activity and participation.⁴ This framework has been endorsed for use as the international standard to describe and assess health and disability. Disability data can be correlated with medical and rehabilitative service requirements. Studies on rehabilitation and rheumatology have previously used the ICF as an outcome measure.^{5–9} The ICF Comprehensive and Brief Core Sets, with the latter termed the IBD disability index (IBD-DI), have recently been developed for IBD to measure its functional consequences and disease burden.^{10,11} The IBD-DI was developed following an extensive literature search and consensus pertaining to disability in IBD. This questionnaire, however, has not yet been tested clinically or validated to capture the full spectrum of issues in IBD. To date no scoring system has been designed for the IBD-DI, which ideally must reflect the fluctuating nature of both Crohn's disease (CD) and ulcerative colitis (UC), demonstrate reversibility following successful medical and surgical therapies, and capture the multi-dimensionality of IBD. This score should be objective, has

a sufficiently wide range to be useful, correlate with work absenteeism, and correlate with measures of quality of life and disease activity.

The primary objective of this study was to design and validate a numerical scoring system for the IBD-DI to measure IBD disability using standard statistical techniques. Secondary endpoints were to describe the extent of disability in IBD, correlate the disease index with work absenteeism, and identify significant exploratory predictors of employment status.

2. Materials and methods

2.1. Subjects

Consecutive ambulatory patients aged 16 to 80 years old with established CD and UC of at least 6 months were prospectively recruited from the IBD clinics of Concord and Bankstown Hospitals, which are tertiary IBD referral centers in Sydney, Australia. Subjects were excluded if they were unable to comprehend the questionnaire, have an active psychiatric disorder, significant symptomatic comorbidity that might influence disability, with stomas or ileoanal pouches were excluded. Age- and sex- group-matched controls without a gastrointestinal disorder or gastrointestinal symptoms in the preceding month were recruited to determine baseline function. They were recruited from the same catchment area as cases, typically hospital visitors and relatives of patients. The Australian unemployment rate at the time of the study was <5%.

2.2. Inflammatory bowel disease disability index (IBD-DI) score

The ICF IBD-DI consists of 19 items divided into 28 parts covering the 5 domains of Overall Health, Body Function, Body Structures, Activity Participation and Environmental Factors.¹⁰ The IBD-DI was specifically designed to exclude the use of any questions that examine patients' subjective coping and feelings. It explores the severity of disability and limitations in the areas of sleeping, mood, abdominal pain, bowel frequency, regulating defecation, participation in social events and work or school and exacerbating effects of medication, food, family and healthcare professionals. In line with other ICF scores, positive scores were proportional to the lack of difficulties and the alleviating effects of medication, food, family and healthcare professionals. A novel composite scoring system was designed and implemented to test the IBD-DI to represent the presence and

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