RESEARCH

A qualitative study of the impact of Crohn's disease from a patient's perspective

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Received 4 January 2016
Revised 12 April 2016
Accepted 15 April 2016
Published Online First
12 May 2016

To cite: Wilburn J, Twiss J, Kemp K, *et al. Frontline Gastroenterology* 2017;**8**:68–73.

ABSTRACT

Objective To understand how the lives of people with Crohn's disease (CD) are affected. Most research in CD has focused on symptoms and functioning rather than on how these outcomes influence quality of life (QoL).

Design As part of a study to develop a CD-specific patient-reported outcome measure, qualitative interviews were conducted with patients from Manchester Royal Infirmary to determine how CD affects QoL. The needs-based model was adopted for the study. The interviews, which took the form of focused conversations covering all aspects of the impact of CD and its treatment, were audio-recorded. Theoretical thematic analysis of the transcripts identified needs affected by CD.

Results Thirty patients (60% female) aged 25–68 years were interviewed. Participants had experienced CD for between 2 and 40 years. Nearly 1300 statements relating to the impact of CD were identified. Thirteen main need themes were identified: nutrition, hygiene, continence, freedom from infection, security, self-esteem, role, attractiveness, relationships, intimacy, clear-mindedness, pleasure and autonomy.

Conclusions The findings from the interviews indicate that CD has a major impact on need-fulfilment. Such issues should be addressed in CD audit, clinical trials and when evaluating clinical practice.

INTRODUCTION

There is increasing interest in the impact of chronic diseases such as Crohn's disease (CD) on patients. Furthermore, the introduction of outcomes-based commissioning and reimbursement requires the availability of outcome measures that are patient-centric, reliable and valid. To develop such measures, it is first necessary to obtain a clear idea of how a disease affects patients.

CD is a challenging disease for the healthcare services to manage.[1,2] As there is no cure for the condition, the main aims of treatment are disease control and maximising quality of life (QoL).[3] Given these aims, it is surprising that relatively little work has been conducted on the impact of CD on the QoL of patients.

Several small-scale studies have investigated how CD affects different aspects of patients' experiences. However, these have focused on a wide range of different outcomes. For example, Burkhalter *et al*[4] explored patients' clinical needs, Norton *et al*[5] compared experiences of patients receiving adalimumab with a group of biologic naïve patients and Dür *et al*[6] focused on what they termed the determinants of health. The overall focus of these studies was on how patients dealt with the burdens of symptoms and associated limitations in functioning resulting from CD. Samples included in these qualitative studies ranged from 3 to 11.

Many studies did not distinguish between CD and ulcerative colitis (UC), employing samples including both types of patients.[3–4,7–8] However, these two types of inflammatory bowel disease (IBD) have marked differences in clinical presentation, underlying genetic factors, response to treatment and complications.[9,10]

None of the reviewed studies reported a clear theoretical basis of the outcome measured. Several stated that CD affects QoL,[4,6,11] but none of the studies had assessed that outcome.[12–15] Where they had used outcome measures, these were standardised measures of health-related quality of life (HRQL), such as the IBDQ.[16] QoL and HRQL are very different outcomes. HRQL focuses on symptoms and a patient's ability to function,[17] information that is helpful for diagnosis and treatment. In contrast, QoL provides a holistic picture of the impact of disease and treatment on a patient's life. Rather than aid diagnosis, QoL assesses patient value—the benefit gained from interventions.

The most widely applied model of QoL in health research is the needs-based model.[18] This argues that life gains its quality from the ability and capacity of the individual to satisfy his or her needs (either inborn or learned during socialisation processes).[18 19] Functions such as employment, hobbies and socialisation are important only insofar as they provide the means by which needs are fulfilled. QoL is high when most needs are fulfilled. The model grew out of research undertaken to develop the Quality of Life in Depression Scale (QLDS)[18] and has now been applied successfully in 20 disease-specific QoL measures.[20 21] The needs-based model formed the basis of this study.

The aim of the study was to understand how the lives of individuals with CD are affected. A secondary aim was to generate a pool of potential items for the Crohn's Life Impact Questionnaire (CLIQ).[22]

METHODS

The design of the study differed in a number of ways from previous research (see box 1).

A descriptive phenomenological approach was adopted for the study. Unstructured in-depth qualitative interviews were conducted to determine the impact of CD on the lives of patients. The needs-based model of QoL was selected as the basis for the thematic interview analyses. Where interviewees reported symptoms or functional limitations, they were asked to explain how their needs are affected as a result of these limitations.

Patients

Approval for the study was granted by National Research Ethics Service Committee North West (11/NW/0171). Participants were recruited from the Crohn's registry at the Manchester Royal Infirmary Hospital. Participants were eligible to take part if they were 18 years of age or older, spoke English and were able to provide written informed consent. Patients were excluded if they were recovering from IBD-related surgery or if they had comorbidities (including cancer, heart disease or severe psychiatric morbidity) judged by their clinician as likely to affect their QoL significantly. Patients with major comorbidities were omitted from the study, as its purpose was to identify those issues directly related to CD. All patients consented to their interviews being audio-recorded. Any identifying information was omitted from the transcripts to ensure patient anonymity and confidentiality. Given the sensitive nature of the topic, interviewees were informed that they were free to stop the interview at any point without giving a reason.

Forty-eight patients were invited to participate by post, with the aim of recruiting 30 patients for interview. This number has been shown to provide saturation of information in similar studies.[23 24]

The interviews were conducted by highly experienced qualitative researchers in private rooms in the gastroenterology department of the hospital. Interviews started with a series of demographic and disease questions about the interviewee (see table 1). The interviews explored the impact of CD on the patient's life and, in particular, the ways in which CD prevented fulfilment of interviewees' needs. Participants were encouraged to talk freely about any aspect of their experience that they felt relevant. The interviews were concluded when both the interviewer and interviewee agreed that all important aspects of their experience had been covered.

Box 1 Differences between current and previous research

The study had a theoretical basis; the needs-based model of QoL.

Only patients with Crohn's disease were included.

A relatively large sample size was employed allowing common issues to appear.

The study focused on patient value rather than symptoms and functional limitations.

Table 1 Demographic and disease information (n=30)

Age in years		
Mean (SD)	**47.9 (14.3)**	
Gender	**n**	**Per cent**
Female	18	60.0
Marital status		
Married/living as married	20	66.7
Work status		
Full-time or part-time	16	53.3
Patient perceived general health		
Very good/good	15	50.0
Patient perceived CD severity		
Mild	13	43.3
Moderate	15	50.0
Quite severe	1	3.3
Very severe	1	3.3
Currently treated	26	86.7
Disease duration in years		
Mean (SD)	14.3 (13.4)	

CD, Crohn's disease.

Data analysis

Transcriptions were produced from the recorded interviews. Theoretical thematic analysis[25 26] was used in the analyses as the QoL model already existed and had been validated in several previous studies. Themes identified were at the latent level as the concern was whether or not statements made by interviewees indicated an absence of need-fulfilment.

At least two researchers analysed each transcript independently. Relevant statements were identified and a comprehensive list produced. The statements were reviewed by the whole research team. A senior gastroenterology nurse worked closely with the researchers to ensure that important impacts of the condition had not been missed and that CD was likely to be the cause of those issues identified.

RESULTS

Sample

Demographic characteristics of the interviewees are presented in table 1. The sample consisted of 30 patients with CD (18 female) with a mean age of 47.9 years. Interviews lasted between 15 and 60 min. Interviewees reported the process to be enjoyable and that it was easy to explain how their lives had been affected by CD.

Interview findings

Over 1300 statements about the impact of CD on the lives of patients were generated from the transcripts. From these, 13 need themes were identified. These are shown in box 2 and described in more detail with illustrative quotations.

Nutrition

An ambivalent relationship with food was described by interviewees. They revealed how diets had become restricted with large meals replaced by small portions. Food choices were also limited. Dairy products and spicy foods were commonly identified as triggers. Interviewees described being unable to enjoy the food they did eat, as they worried about potential after-effects.

> every now and again I'll [think] what harm can one sandwich do, and as soon as I've put the last bit in my mouth I can feel my stomach going, I think why did I do that? (female, 67)

Box 2 Needs affected by Crohn's disease

Nutrition
Hygiene
Continence
Freedom from infection
Security
Self-esteem
Role
Attractiveness
Relationships
Intimacy
Clear-mindedness
Pleasure
Autonomy

Hygiene

Interviewees reported concerns over hygiene. It was common for them to carry deodorants, spare clothes and wipes:

> it makes me feel dirty (female, 61)

> I'm constantly worried that I might smell or that the house smells (female, 33)

Continence

For many, CD meant that their life had to be planned around the location of toilets. Seeking out the nearest public toilets became the first thing to do on arrival anywhere unfamiliar:

> I plan my life around where the next toilet is (male, 46)

There was constant worry about not making it to the toilet in time:

> I hope there's not a queue, what if there is, what if I can't wait, the fear's there, what if I make a mess … the fear of not getting to the toilet, really I think that most affects your quality of life (female, 61)

Interviewees reported the need to make preparations before leaving the house, including not eating anything:

> I have to make sure if we're doing anything in a morning or I'm going anywhere the following day … I have to make sure that I'm up in time to have been to the loo three, four, five times before I go (female, 60)

Freedom from infection

Individuals reported feeling constantly ill and recovering slowly from minor illness. Consequently, they avoided people who appeared unwell:

> if someone's like stinking ill I'll stay away from them 'cos I know that you are, you know, susceptible to it (female, 32)

Security

Interviewees reported feeling vulnerable as a result of their illness:

> I just seemed to be feeling an awful lot weaker than I did before (female, 67)

Self-esteem

Negative self-evaluations were expressed in the interviews:

> I doubted myself, I doubted my value, I doubted my worth, I doubted my capability (female, 41)

The intimate nature of CD meant that interviewees were frequently unwilling to discuss their illness with friends and relations:

> kinda had to shut myself off and spent a lot of time at home (female, 41)

Role

Interviewees discussed how their role in life had altered as a result of CD:

> I'm unable to provide for myself and my partner (male, 35)

> I feel really upset within myself because I had to rely on an eight-year-old and a four-year-old to help me (female, 33)

Attractiveness

Participants discussed feeling conscious of their appearance. They tried to cover up with loose-fitting clothes:

> I'll be really conscious of my stomach…I'll sit and wrap my coat around me and stuff… I'm conscious during a flare up that people are looking at my tummy thinking that I'm pregnant (female, age 31)

> very self-conscious about my appearance… you can't wear the clothes you would normally wear, you'd have to wear loose clothes…my appearance is important to me (male, age 46)

Relationships

Interviewees reported being cautious about becoming emotionally close to people, as they did not want to talk about CD, and found it difficult to initiate relationships. CD also placed a strain on existing relationships with partners, family and friends and described:

> I don't really hang about with many people at the minute because if I'm not feeling great then I can snap at people far too easily (male, 35)

It was not unusual for planned arrangements with family and friends to be cancelled due to bowel-related issues. This contributed to feeling that they were letting people down and neglecting those close to them:

> I had made arrangements to go out with my sister…by the time we got to the evening I was not able to walk —never mind go out 'oh she's let us down again' (female, 67)

Meals out were viewed as bothersome rather than enjoyable:

> I couldn't go anywhere, I couldn't go out for anything to eat, I couldn't stay over at anybody's house (female, 30)

Tiredness was another factor affecting ability and willingness to socialise:

> cos you feel tired at the end of the day and you don't always want to go out and sort of socialise (female, 42)

Intimacy

CD affected interviewees' intimacy, and some described experiencing a loss of interest in sex:

> …not having any energy, feeling very tired, not wanting sex erm not necessarily wanting to go out, so it had a real huge knock on effect (female, 42)

Clear-mindedness

Interviewees described having an overwhelming sense of preoccupation with their condition, stating that it was always in the back of their mind:

> you're consumed by the fact that your whole life is thinking about going to the toilet, being in pain and are you gonna make it through the rest of the day (female, 30)

Pleasure

Interviewees explained that CD took away their pleasure in life:

> there's times where I think I'd be having more fun if I wasn't feeling this way (male, 27)

Fatigue led to interviewees having to give up hobbies and activities:

> I was tired all the time so didn't really want to do too many outside interests (female, 32)

Participants described being unable to go on holidays. This was largely explained by fear of having an accident on public transport or in public places:

> Holidays, days out, things like that, that I used to enjoy we've not been able to do you know so it does change your life (female, 61)

Maintaining a sense of humour was difficult:

> My sense of humour has taken a wallop (male, 35)

Autonomy

Autonomy was an important issue for interviewees. In common with other chronic diseases, feeling in control of the condition and being independent are important needs affected by CD:

> you can feel very alone and because it's something that is so personal … the embarrassment of thinking that you may not have this control over your bowel is always there (female, 61)

Feelings of dependency were commonly described by interviewees:

> my relationship with my fiancée is one of dependence at the minute… I'm utterly dependent on her (male, 35).

DISCUSSION

The qualitative interviews identified directly from patients how CD affected their lives. Qualitative studies can provide powerful and scientifically rigorous research findings[27] and have been used widely to investigate the impact of chronic illness from the patient's perspective.[28 29]

Previous research has identified symptoms and functional impairments resulting from CD but not how QoL or need-fulfilment is affected. HRQL measures such as the IBDQ[16] have been frequently used in IBD studies. Such measures focus on clinically relevant outcomes rather than on issues that are of particular concern to patients.

Some of the themes that emerged from this study confirmed a meta-analysis of qualitative articles in IBD.[30] These included autonomy, fear of incontinence and social isolation. In addition, Pihl-Lesnovska *et al*[31] reported that attractiveness and intimacy are important issues for patients with CD, and Greveson *et al*[32] reported that travelling distances, including foreign travel, were affected by IBD. However, the present study identified far more patient-centric impacts. Furthermore, the current findings fit clearly into a meaningful outcome model and are specific to CD.

Most of the samples rated their CD severity as mild or moderate. This may result from the sample being recruited from a hospital registry. While they may represent a more severe section of the CD population, it is likely that their condition was clinically well controlled.

CONCLUSIONS

The needs-based model of QoL has been validated by the development of several patient-reported outcome (PRO) measures specific to different diseases. These measures have proved effective in evaluating clinical[33 34] and non-clinical interventions.[35–37] The same qualitative methodology was applied to determine the impact of CD on the lives of patients. CD clearly has a major impact on need-fulfilment and, consequently, the QoL of patients. The insights gained from this study should help direct potential interventions towards producing the greatest value for patients. With the current moves towards outcomes-based commissioning and reimbursement, the onus falls on health services to demonstrate how patients' lives improve as a result of their care.

The original intention had been to replicate this study with patients with UC to explore differences in impact of the two conditions. It is hoped that such work will be possible in the near future. The availability of outcome measures specific to CD and to UC would allow direct comparisons to be made about the effectiveness of interventions for the two diseases.[38]

The need themes identified in this study formed the basis of the CLIQ.[22]

Key messages

What is already known on this topic

- Crohn's disease (CD) has a major impact on patients' lives; yet, there is little information on its true impact on patients.
- Existing research focuses primarily on symptoms and functioning rather than quality of life.
- Generic patient-reported outcome measures are currently used in clinical studies and trials.
- There is currently nothing in the literature that is specific to CD.

What this study adds

- The true impact of the disease on patients is reflected in limitations on need-fulfilment.
- The key need themes influenced by CD are identified.

How might it impact on clinical practice in the foreseeable future

- With the move to outcome-based commissioning, more attention should be paid to the ability of interventions to improve need-fulfilment in patients with CD.
- As a result of this fundamental work, a patient-centric outcome measure specific to CD that assesses need-fulfilment was developed (the CLIQ).
- Such a measure can be used in routine clinical practice and patient's annual review, clinical trials and studies and in audit. Examples of use include evaluation of the use of biologics and the impact of changing to a biosimilar.

Acknowledgements The authors would like to thank all the patients who contributed to the qualitative interviews. The study was part-funded by Crohn's and Colitis UK; the authors would like to thank them for their support. The authors acknowledge the support of The National Institute for Health Research/Wellcome Trust Clinical Research Facility at Central Manchester University Hospitals NHS Foundation Trust. The authors also acknowledge Alice Heaney for her administrative assistance.

Contributors JW, SPM and JT were involved with the conception and design of the study, acquisition of data, interpretation of data and writing of the manuscript. KK was involved in the recruitment of participants, interpretation of data, and contributed to and reviewed the manuscript. All authors read and approved the final manuscript.

Funding Crohn's and Colitis UK part-funded the study.

Competing interests KK has received fees for consultancy work from Abbvie, MSD, Takeda, Actavis, Dr Faulk and Vifor.

Ethics approval National Research Ethics Service Committee North West.

Provenance and peer review Not commissioned; externally peer reviewed.

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