

Neu!

ab 1. Juli 2001

Zum 1.7.2001 wird für die Berechnung der Urheberrechtsabgaben an die VG Wort die Nutzergruppe „Privatpersonen“ eingeführt.

Das Entgelt beträgt 5,- DM plus 7% MwSt. Es wird zusätzlich zu den Kosten der Dokumentlieferung erhoben und an die VG Wort abgeführt.

Zu Information beachten Sie bitte auch die nachfolgenden Hinweise:

Die Deutsche Zentralbibliothek für Medizin ist gehalten, gemäß des zwischen der Kommission "Bibliothekstantieme" der Kultusministerkonferenz und der Verwertungsgesellschaft Wort (VG Wort) geschlossenen Vertrages zur Abgeltung urheberrechtlicher Ansprüche beim Direktversand von Kopien pro Aufsatzkopie eine festgelegte Vergütung an die VG Wort abzuführen.

Dieser Vertrag gilt ab 1. September 2000.

Die an die VG Wort abzuführenden Entgelte gestalten sich wie folgt:

Nutzergruppe 1

Schüler, Auszubildende, Studierende, Angehörige bzw. Mitglieder von Hochschulen bzw. von überwiegend aus öffentlichen Mitteln finanzierten Wissenschafts- und Forschungseinrichtungen sowie juristische Personen des öffentlichen Rechts

2,- DM für jede Bestellung zuzüglich 7% Umsatzsteuer

Nutzergruppe 2

Privatpersonen

5,- DM für jede Bestellung zuzüglich 7% Umsatzsteuer

Nutzergruppe 3

Selbständige und kommerzielle Besteller

10,- DM für jede Bestellung zuzüglich 7% Umsatzsteuer

Die ZBMed muß ihren Kunden diese Entgelte zusätzlich zu den Gebühren für die Dokumentlieferung in Rechnung stellen.

Ihre ZBMed
21.6.2001

Impaired Health-Related Quality of Life in Inflammatory Bowel Diseases

Psychosocial Impact and Coping Styles in a National German Sample

F. Petrak, J. Hardt, T. Clement, N. Börner, U. T. Egle & S. O. Hoffmann

Clinic for Psychosomatic Medicine and Psychotherapy, University of Mainz and Practice for Gastroenterology, Mainz, Germany

Petrak F, Hardt J, Clement T, Börner N, Egle UT, Hoffmann SO. Impaired health-related quality of life in inflammatory bowel diseases: psychosocial impact and coping styles in a national German sample. *Scand J Gastroenterol* 2001;36:375–382.

Background: The purpose of this study is to give a detailed survey of the disease-specific and generic quality of life (HRQOL) of adult patients suffering from inflammatory bowel disease (IBD) in Germany. **Methods:** 1322 patients suffering from IBD were examined in a cross-sectional study. A questionnaire assessing disease-specific and generic quality of life, coping, and hopelessness was sent to members of the German Crohn/Colitis association. **Results:** Compared to the general population, the generic HRQOL in IBD patients is significantly reduced. Active coping has a negative influence on patients' generic physical HRQOL during an active phase ($\beta = -0.31$), while this association is not present in the case of patients in remission ($\beta = -0.02$, interaction: $P = 0.0003$). Depressive coping is strongly and negatively associated with assessment of the physical ($\beta = -0.39$, $P < 0.0001$) and mental ($\beta = -0.66$, $P < 0.0001$) HRQOL. Disease-specific burdens are mainly reported in the physical dimension. **Conclusion:** The pattern of psychosocial impact of disease in German IBD patients is largely congruent with the one observed in the USA and Canada, but shows some specific differences. The a priori unexpected finding that active coping was associated with poor HRQOL in active IBD status illustrates the importance of considering different determinants of HRQOL in terms of their mutual interaction.

Key words: Adaptation, psychologic; bowel diseases, inflammatory; colitis, ulcerative; Crohn disease; quality of life

Frank Petrak, Dipl.-Psych., Clinic for Psychosomatic Medicine and Psychotherapy, University of Mainz, Untere Zahlbacher Str. 8, 55131 Mainz, Germany (fax. +496131 176688, e-mail. petrak@psychosomatik.klinik.uni-mainz.de)

Psychosocial variables reflecting disease-specific and generic quality of life (HRQOL; used in the sense of generic HRQOL, which is divided into physical and mental components) are, in addition to somatic factors, considered important outcome parameters in the evaluation of medicinal and surgical therapies (1, 2).

The most extensive study so far assessing the health-related and psychosocial status of patients with inflammatory bowel diseases (IBDs) was conducted in the USA and involved 997 participants (3). In combination with numerous other studies, a relatively clear picture emerges, primarily in the USA and Canada, of the disease-specific and generic HRQOL of IBD patients. The results show that, in particular, the perceived social and interactional consequences of IBD constitute significant determinants of HRQOL (e.g. being a burden on others, feelings of loneliness and discrimination, occupational disadvantages, anxiety about losing bowel control, sexual problems). The majority of those affected are in relatively good physical health, although pain, exhaustion, and stress due to medical interventions lead to a significantly impaired HRQOL. Patients suffering from Crohn disease (CD) seem to

be exposed to more stress than those with ulcerative colitis (UC). In summary, there is evidence that the subjectively perceived HRQOL in IBD patients is impaired compared to the general population. In contrast, with regard to objective data such as educational level, occupational and marital status, they do not differ significantly from the general population (3–9).

In accordance with the recommendation to collect data on disease-specific indicators of HRQOL, in addition to general indicators (10), various questionnaires have been developed that survey HRQOL and the stress factors in IBD patients. Thus, the 'Rating Form of IBD Patient Concerns' (RFIPC) (11) surveys 'physical symptoms, general emotional and social functioning' and the 'Inflammatory Bowel Disease Questionnaire' (IBDQ) covers 'functional/economic or social/recreational aspects, general impact of IBD and medical symptoms' (12). These two most frequently utilized questionnaires were developed and evaluated in the USA and Canada at the beginning of the 1990s. Since then they have been translated and validated in several countries. At present this includes Korea (13), Holland (14), Sweden (15), France

Table 1. Sociodemographic and medical characteristics of the sample

Age (in years, \bar{x} SD)		39.6	11.2
Sex	Male	47.8%	(631/1319)
	Female	52.2%	(688/1319)
Marital status	Single	29.0%	(381/1315)
	Married	61.6%	(810/1315)
	Divorced/separated/widowed	7.6%	(124/1315)
Years of formal education	<10	25.3%	(333/1316)
	<14	55.7%	(733/1316)
	>14	19.0%	(250/1316)
Occupation	Unemployed	3.9%	(48/1230)
	Blue-collar worker	7.2%	(88/1230)
	White-collar worker/Civil servant	54.6%	(676/1230)
	Self-employed	6.4%	(79/1230)
	Housewife	9.8%	(121/1230)
	Pensioner/Early pensioner	10.5%	(139/1230)
	Pupil/student/trainee	6.5%	(79/1230)
Diagnosis	Crohn disease	47.3%	(619/1310)
	Ulcerative colitis	49.1%	(649/1310)
	IBD of unclear attribution	3.2%	(42/1310)
Characteristics of disease	Duration of disease (in years)	11.3 \bar{x}	(SD = 7.03)
	Partial intestinal resection	31.6%	(410/1296)
	Stoma bag	6.4%	(83/1288)
	Fistulae	21.1%	(270/1282)
IBD status	Inactive disease	60.4%	(783/1297)
	Active disease	12.3%	(160/1297)
	Chronically active	13.4%	(174/1297)
	Unclear ('I don't know')	13.9%	(180/1297)

Note: $n = 1322$. Differences in the indicated n result from missing data. For nominally scaled variables, percentage, frequencies, and reference values are indicated (in parentheses), for variables on proportional scale level, means and standard deviations are indicated.

(4), Germany (16), and Great Britain (17). The results of these studies confirm the reliability and validity of the questionnaires. This means that some disease-specific stress factors are obviously stable in IBD patients, transcending national and cultural boundaries. The question remains open as to what extent the structure of the questionnaire reflects the broad range of possible additional burden of disease in the respective countries. Knowledge of the stress factors affecting IBD patients leads us to ask which factors determine the HRQOL. From the aspect of medical variables, it is remarkable that the connection between severity of the disease and HRQOL is usually moderate (11, 15). It has been observed in several studies that patients with UC experience better HRQOL than those with CD (e.g. 12, 18, 19). As for the psychological variables, the correlation between coping styles and HRQOL has frequently been investigated (e.g. 3, 20–22). These studies have shown that emotion-focused and avoidant coping is associated with a low HRQOL. In some studies, active, problem-oriented coping correlated positively with psychosocial and medical outcome parameters. It can be concluded that the determination of HRQOL is based on multiple factors where variables from different areas probably interact together.

The present study pursues two aims: 1) to sketch a detailed picture of the disease-specific and generic HRQOL of adult

IBD patients in Germany and 2) to develop a statistical model for predicting the HRQOL in IBD on the basis of selected sociodemographic, medical, and psychological variables.

Methods

Sample recruitment

The study was conducted in cooperation with the German Morbus Crohn/Colitis Ulcerosa Association (Deutsche Morbus Crohn/Colitis Ulcerosa Vereinigung DCCV), the largest patient association for IBD in Germany, numbering around 12,000 members. The collection of data was carried out by mail between December 1996 and May 1997. The criterion for including the participants was the existence of a chronic IBD. The only exclusionary criterion was being under 18 years of age. A computer-generated random selection of 3000 members was made (stratified according to sex and CU versus CD). To increase the participation rate, every participant was offered a personal test evaluation. In order to minimize answers biased by social desirability, the study was conducted 'blind'. The association acted as mediator between its members and the headquarters of the study. In view of the exclusively observational character of the study, informed consent was attained by informing the participants of the aims of the study and about the procedure as to how they would be

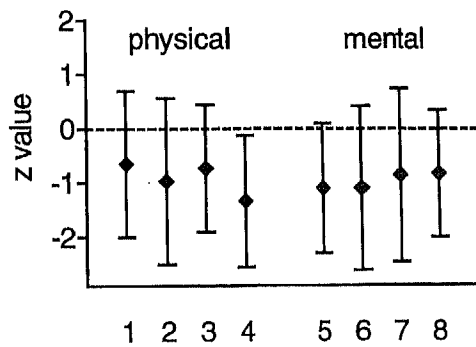


Fig. 1. Health-related quality of life (SF-36, z values, \bar{x} and s) in 1322 inflammatory bowel disease patients. 1. Physical functioning; 2. role limitations—physical; 3. bodily pain; 4. general health perceptions; 5. vitality (energy/fatigue); 6. social functioning; 7. role limitations—emotional; 8. emotional well-being.

notified of the results. To control for selection biases, the response rates of the four strata were compared.

Instruments: Diagnosis of IBD, its specification (UC versus CD), and the current status of inflammation were gathered on the basis of the participants' self-reports ('I am currently experiencing an acute attack of the illness' = active disease; 'My illness has been classified by my physician as being "chronically active"' = chronically active disease; 'Currently I am in remission (no current attack of illness)' = inactive disease; 'I don't know whether I am actually experiencing an attack or whether I am in remission' = unclear) (for results, see Table I). This procedure has proved to be highly valid at least for the distinction between UC versus CD (23).

Quality of life (QOL) specific to the disease was assessed by a list of 77 items. Participants were asked to indicate their specific amount of stress for each item. Answers were coded on a scale from 1 to 6, with 6 being the highest level of stress. The selection of items was made according to a multistep procedure comprising an assessment of the state of research, a hearing of experts, interviews with patients, and two pilot studies ($n = 67$ and $n = 300$).

HRQOL was assessed by the SF-36, a 36-item self-rating questionnaire developed by the Medical Outcome Trust (24) to investigate certain primary aspects of QOL. The first four subscales refer to physical aspects, the last psychosocial aspects (see Fig. 2). Subscores were computed according to the German manual (25). The resulting individual values were compared to means and standard deviations (s) of age- and sex-matched reference groups (total $n = 2914$, 55% female, mean age 47.7 years) out of the German normal population (taken from the manual). The results of the SF-36 were computed as z values $((x_i - \bar{x})/s)$. A z value of zero means it is identical to the population mean; a value of -1 is 1 s below, etc. This transformation was done for two reasons. Firstly, it is known that in some aspects the HRQOL decreases differently with age and differently in men and women. Secondly, reference values are at different levels for the different subscores (25). Total values were computed for the physical

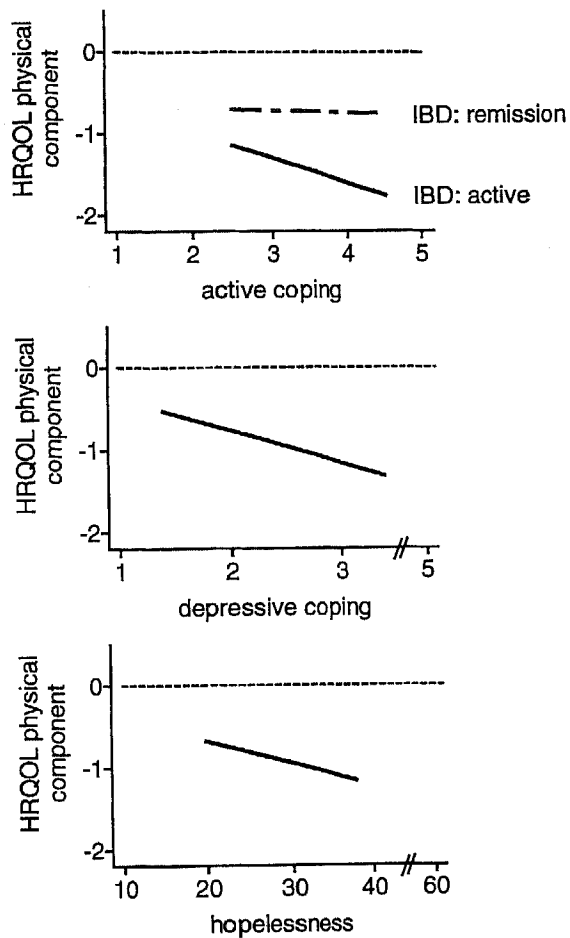


Fig. 2. Estimated HRQOL physical component (SF-36) predicted by multiple regression analysis.

and mental components of HRQOL by averaging the eight weighted subscales using the coefficients generated by Hays et al. in the MOS study (26). Ways of coping with the disease were assessed using the Freiburger Fragebogen zur Krankheitsverarbeitung FKV-LIS (27), a German questionnaire adapted from the items of the Ways-of-Coping Checklist (28). It consists of five coping dimensions: 1) active coping, 2) depressive coping, 3) religiousness, 4) self-affirmation/distraction, and 5) trivializing. Three items (13, 17, 18) on the self-affirmation/distraction scale were eliminated because of low specificity ($r_{it} < 0.25$ or higher item correlations to dimensions other than self-affirmation/distraction). In terms of content, the remaining scale only represents the aspect of distraction. One item on the trivializing scale was eliminated because of a high correlation to the dimension depressive coping ($R = 0.50$). Religiousness did not have sufficient internal consistency (Cronbach's $\alpha = 0.51$) and was not considered in the further analysis. The reliability coefficients of the remaining four subscales indicated moderate to satisfactory internal consistency (Cronbach's α between 0.67 and 0.76). Scores represent the mean item values ranging

from 1 to 5. Hopelessness was measured on the Scale for the Assessment of Hopelessness (H-RB-Skala) (28), a German-language adaptation of the American Hopelessness Scale (29). This was done to record the negative expectations of a person referring to himself, to his environment, or his future life. The score of the H-RB was computed by taking the sum of the individual items. The possible range covers the area 10–60. Reliability of the scale was good (Cronbach's $\alpha = 0.80$).

Hypotheses

1. *Disease-specific QOL.* Physical complaints, social consequences of IBD as well as disease-related worries are perceived as being most stressful (77 items stress list).

2. *Health-related QOL.* Compared with the general population, HRQOL is reduced significantly and to a clinically meaningful extent (SF-36).

3. The mutual interaction of the following variables leads to a clinically relevant and statistically significant *prediction model* for the physical and mental components of HRQOL. In particular, it is expected that these effects are also significant when the following background variables are controlled: (a) sociodemographic: sex, age, marital status; (b) medical: diagnosis (CD versus UC), duration of illness, status of inflammation; c) psychological: coping styles, hopelessness.

Statistical analysis

Results concerning hypothesis 1 were reported by a percentage-ranking of the items. The 2nd hypothesis was tested by *t* tests. The 3rd hypothesis was tested via multiple, non-linear regression analysis for mental and physical HRQOL (30). Variable selection in the regression analysis for the mental and physical health components followed a stepwise procedure. A backward selection of the main effects of all possible explanatory variables was performed first. All quadratic and interaction terms were offered to the resulting model, the one with the highest absolute *t* value was tested (including the underlying main effects, if not already in the model). The term was added only if the model change and the *t* value for the quadratic or interaction term were highly significant, i.e. $P < 0.001$. Otherwise, the next significant term was tested. The procedure was repeated until all *P*-values were > 0.001 . According to the observational design, the significance level was set very conservatively to $\alpha < 0.001$ for each statistical test. In addition, no effects explaining less than 1% of variance were interpreted, as they were regarded as clinically irrelevant. No Bonferroni correction was performed. In a sample at the given size, effects explaining about 1% of the variance (e.g. correlation coefficients of $R \approx 0.11$) would be detected with a statistical power of 80% at the chosen significance level of $\alpha < 0.001$. Statistics were performed using SPSS for Windows (Version 8.0) and Simcalc (Version 0.9) and PC-Size.

Results

Sample

Out of 3000 DCCV members who received the questionnaire, 1322 answered. This is a participation rate of 44.1%. The rate of missing data with regard to the 'raw values' was low, ranging from 0.4% to 1.8%. Table I presents an overview of the sociodemographic and medical characteristics of the sample. Participants show a higher rate of academic degrees and a lower rate of unemployment compared to the general population. In the chi-square test, the differences between the expected and the actual outcome of the sex and illness distributions were not significant (CD, UC, IBD of unclear attribution) ($\chi^2 = 0.912$, $df = 2$, $P = 0.634$). This means that meaningful selection effects regarding these two variables can be ruled out. On the whole, the sample seems to be comparable to the general population with regard to sociodemographic characteristics. As far as the medical characteristics are concerned, there is a predominance of patients in remission. The sample spans a broad spectrum of severity and duration of illness.

Disease-specific quality of life

The ranking of psychosocial stress intensity shows that the patient's severest stress is of a physical nature. The majority of those affected report being distinctly impaired by medical measures, symptoms and complications of IBD, and by thoughts that the disease might worsen. Anxiety about losing bowel control, worries about different areas of activity, impairment of mood and occupational problems are described as moderately stressful on average. Interactional consequences of IBD in a narrower sense, such as sexual and marital problems or low self-esteem towards others, are predominantly perceived as minor stress. The majority of the participants deny stress resulting from a lack of social support or from aspects of the doctor-patient interaction. Table II gives an excerpt of the most important stress factors (a complete list of all 77 variables can be requested from the first author).

HRQOL

Compared to the general population, HRQOL is statistically significantly reduced on all subscales of SF-36. This reduction can be regarded as clinically meaningful. Most pronounced are the differences in the general health perception and the four mental components of HRQOL (see Fig. 1).

Prediction model for HRQOL

The results of the multiple regression analyses for the physical and mental components of HRQOL are given in Table III. As to the physical component of HRQOL a model emerges consisting of 6 predictors that jointly explain 31% of the variance. Active coping shows an interaction with status of the disease on the physical component of HRQOL. It has a negative influence in patients experiencing an active phase

Table II. Disease specific quality of life in IBD

Considerable stress	\bar{x}	s
Laxative measures prior to medical examinations	4.2	1.8
Enteroscopies	4.1	1.8
Operations ¹	3.8	1.9
Fistulae, stenoses, abscesses ²	3.8	1.7
Weakness and exhaustion	3.8	1.7
Imperative diarrhea	3.6	1.9
Thoughts about possible worsening of disease	3.5	1.6
Moderate stress		
Anxiety about embarrassing loss of bowel control	3.4	1.9
Anxiety about developing cancer	3.3	1.8
Suffering from 'brooding thoughts'	3.3	1.8
Irritable mood	3.2	1.7
Exaggerated worries about various areas of life	3.2	1.8
Fear of burdening family with IBD	3.1	1.8
Poor chances of getting new job due to IBD	3.1	2.0
Worries that own children will become ill with IBD	3.0	2.0
Abdominal pain	3.0	1.7
Stress at work exacerbates physical complaints	3.0	1.8
Constantly looking out for available toilets	3.0	1.9
Agitation	3.0	1.7
Constant use of medication	2.9	1.8
Depressive mood	2.9	1.7
Limited ability to cope with pressure at work due to IBD	2.9	1.8
Pain in joints	2.9	1.8
Side effects of medication	2.9	1.9
Mood swings	2.7	1.7
X-ray examinations	2.6	1.8
Thoughts about future episodes of illness	2.6	1.6
Poor general physical health	2.6	1.6
Worries about shape and weight	2.6	1.8
Limited advancement in occupation due to IBD	2.5	1.9
Avoidance of public appearances due to imperative diarrhea	2.5	1.8
Light stress		
Less sexual intercourse since IBD	2.4	1.8
Impression of being less attractive due to IBD	2.4	1.7
Harm to marriage/partnership from IBD	2.4	1.6
Self-assessment is being 'handicapped'	2.3	1.6
Attempt to hide IBD from others	1.0	1.0-3.0*
Anxiety about losing partner	1.0	1.0-3.0*
No stress to light stress		
Fecal incontinence	1.0	1.0-2.0*
Lacking social support	1.0	1.0-2.0*
Insufficient medical information about IBD	1.0	1.0-2.0*
Lack of confidence in physician	1.0	1.0-2.0*

Note: $n = 1307-1320$ differences result from missing data. * In non-normally distributed variables, median and interquartile ranges are given. ¹Only patients with operation ($n = 410$), ²Only patients with fistulae ($n = 270$)

($P = 0.0003$; cf. Fig. 2). This association does not appear among patients in remission. Active coping has a mean value of $\bar{x} = 3.68$ ($s = 0.72$) in the former and a mean value of $\bar{x} = 3.53$ ($s = 0.77$, $P = 0.002$) in the latter. In addition, there are significant differences in main effects: patients in remission report a higher physical HRQOL than patients

during an active phase. Depressive coping is negatively associated with physical HRQOL ($\beta = -0.394$, $P < 0.0001$). The mean value for depressive coping during the active phase is $\bar{x} = 2.57$ ($s = 0.73$) and for patients in remission $\bar{x} = 2.35$ ($s = 0.76$, $P < 0.000$). With growing hopelessness, a lower physical HRQOL is reported ($\beta = -0.027$, $P < 0.0001$). Hopelessness has a mean value of $\bar{x} = 28.90$ ($s = 7.1$) in remission and of $\bar{x} = 30.26$ ($s = 7.9$, $P = 0.005$) during the active phase. Furthermore, we see effects for the diagnosis group and age which explain less than 1% of the variance. Fig. 2 shows the estimated relationships between HRQOL physical and active coping, depressive coping and hopelessness.

With regard to the mental components of HRQOL, three parameters show significant influences in the regression model (cf. Table III). Together they explain 43% of the variance. Depressive coping has a strong negative influence on the mental HRQOL ($\beta = -0.617$, $P < 0.0001$, cf. Fig. 3). The simple correlation between these two variables is $R = -0.57$. In addition to the other two predictors, depressive coping explains 16% of the variance of the mental HRQOL. Hopelessness also has a negative influence ($\beta = -0.036$, $P < 0.0001$) on the mental components of HRQOL. Patients in an acute IBD state report better values than patients in remission ($\beta = -0.541$, $P < 0.0001$).

Discussion

This study shows that German IBD patients suffer from a wide spectrum of psychosocial stress related to the disease. The perceived stress resulting from physical complaints and diagnostic or therapeutic measures predominates. This is followed by various worries and anxiety about losing bowel control in public. Moderate problems are reported in the area of work. This, however, is not reflected in the objective sample data (low rate of unemployment and high rate of white-collar workers). In the general social or interpersonal field, no particular stress among IBD patients in Germany is apparent. The extent of social support and the quality of doctor-patient interaction is mostly assessed positively. Compared to the general population, the HRQOL overall is clearly reduced, the mental aspects being particularly predominant. Most of the results agree with the findings in the USA and Canada (11, 31). As for sexual problems (32), occupational impairment (5, 33) and interactional problems, no particular stress could be replicated in this study.

With regard to the meaning of coping strategies and hopelessness, the clearest finding is a strong association between depressive coping styles and HRQOL. We should note that depressive coping, as assessed in FKV-LIS, and hopelessness, as measured on the H-RB scale, are not identical to depression in the clinical sense. Depressive coping is characterized by social withdrawal and irritable behaviour towards others as well as brooding, self-pitying, and pessimistic thinking. Typical aspects of hopelessness are,

Table III. Determinants of HRQOL

Response	Explanatory variables	R^1	Contribution when variable(s) added last			Parameter estimates			
			Proportion of variance %	DF	F	β^2	95% Confidence interval	t	P
Physical	Active coping ³	-0.02				-0.024	na	-0.63	0.5275
	IBD status ³	-0.36				0.275	na	0.95	0.3422
	Active coping \times IBD status ⁴		11.1	3	67.05	-0.282	-0.435 to -0.130	-3.63	0.0003
	Depressive coping	-0.40	6.3	1	114.16	-0.394	-0.466 to -0.21	-10.69	<0.0001
	Hopelessness	-0.29	2.5	1	45.75	-0.027	-0.035 to -0.019	-6.76	<0.0001
	Age	0.11	0.9	1	16.37	0.010	0.005 to 0.015	4.05	0.0001
	Diagnosis	-0.07	0.6	1	11.44	-0.170	-0.268 to -0.071	-3.38	<0.0007
	Constant					0.796	0.409 to 1.18		
Model			$R^2 = 0.31$				df = 7; 1257 ⁵	F = 79.52	$P < 0.0001$
Variables not in the equation, P -value if added next									
Physical	Distraction coping					-0.08			0.010
	Trivializing coping					-0.10			0.918
	Sex					-0.02			0.115
	Marital status								0.107
	Disease duration					0.06			0.050
Mental	Depressive coping	-0.57	16.0	1	352.01	-0.617	-0.681 to -0.552	-18.76	<0.0001
	Hopelessness	-0.45	4.9	1	107.73	-0.036	-0.042 to -0.029	-10.38	<0.0001
	IBD status	-0.28	4.8	1	105.19	-0.541	-0.644 to -0.437	-10.26	<0.0001
	Constant					1.735	1.536 to 1.935		
Model			$R^2 = 0.43$				df = 3; 1261 ⁵	F = 311.05	$P < 0.0001$
Variables not in the equation, β , P -value if added next									
Mental	Active coping					0.05			0.747
	Distraction coping					-0.05			0.305
	Trivializing coping					-0.17			0.400
	Diagnosis					-0.04			0.006
	Age					0.03			0.270
	Sex					-0.07			0.002
	Marital status ⁴								0.087
Disease duration					0.05			0.009	

¹ Pearson correlations. ² Unstandardized β s. ³ No main effects or CIs were reported when the interaction was significant. df and F see interaction Act. Coping \times IBD Status. ⁴ No Pearson correlation and β s can be computed. ⁵ $n = 1265$; 42 patients were excluded because of IBD of unclear attribution (see Table I) and others due to missing data. ⁶ Significant interaction between IBD diagnosis and gender was not included because its ΔR^2 was <1%.

for instance, beliefs that the future is dark and uncertain or that life will bring more bad times than good. The results of the prediction model for HRQOL show that it is particularly important to view the various determinants in terms of their mutual interaction. If we were only to analyse simple correlations, we would risk overlooking important factors. This is most evident with regard to the meaning of the inflammatory status: in general, the results show that patients in an active inflammatory phase have an impaired HRQOL. This is not surprising. Furthermore, if we consider the simple correlation between active coping and HRQOL, no association could be observed. However, considering the influence of the inflammatory status leads to an interesting result: During an active inflammatory phase patients who have an active coping style experience much more stress in terms of their HRQOL than patients who do not utilize active coping. In practical terms this means that confronting the illness head-on, actively seeking information and actively undertaking

efforts to solve problems during the acute phase of IBD lead to reduced physical HRQOL in patients. During remission, however, this behavior exerts little influence on the HRQOL. In our opinion, a plausible interpretation for this fact could be that in phases where the physical effects of the illness dominate, it is not advantageous to 'waste' energy through 'activism'. In this phase it seems more profitable to adhere to medical options and to accept that one's own possibilities of influencing the disease are fairly limited. Of course these results require replication prior to becoming generalized recommendations for medical and psychological care. However, the results are clear and may help, in direct doctor-patient interaction, to identify inappropriate 'overactive' coping styles.

In view of the randomized sample drawing and its size we can assume that the sample is representative for German IBD patients. However, it remains possible that the membership in a patient association constitutes a systematic bias. Likewise,

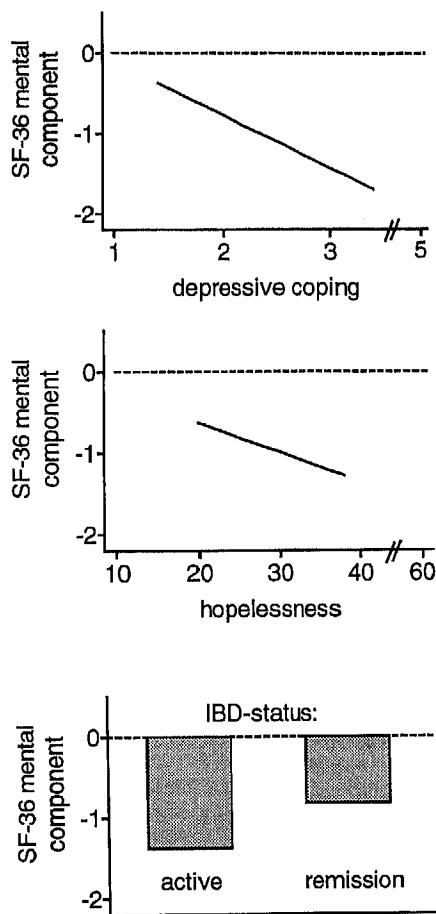


Fig. 3. Estimated HRQOL mental component (SF-36) predicted by multiple regression analysis.

the participation rate of 44% is seen as a limiting factor for generalizability of the results. But in comparing our participation rate with those of other studies, one must keep in mind that calculation of participation rates sometimes differs. In a study comparable in terms of aims and sample size to the present one, Drossmann et al. (1991) calculated the participation rate on the basis of subjects who had stated suffering from IBD and who had given consent to participation in the study in an initial phase. To calculate the participation rate in our study we established as the reference group the 3000 IBD patients who were contacted by mail without previously having been asked about their willingness to participate in a study. The participation rate of 44.1% (1322 participants) attained on this basis can be considered tenable against this background. In studies based on self-reports by the subjects it is generally impossible, due to reasons of data protection alone, to collect all of the potentially confounding variables about persons who refuse to participate in the study. Through the randomized sample selection and stratification according to sex and diagnosis, we were largely able to control those variables we deemed essential. Meaningful selection effects

regarding those two variables are not present. With regard to other sociodemographic or medical variables, selection biases cannot be completely excluded. However, the demographic data of the sample (see Table I) determine which patients the results can be applied to.

The cross-sectional design of the study constitutes a further fundamental limitation, as this does not enable us to derive causalities. On the other hand, some possible disadvantages of a mail survey could be avoided in this study. The low rate of missing values is an indicator of the high motivation of the participants. We can therefore assume that the data we obtained are valid. This is most likely the effect of a reward being offered in the form of an individual report on the outcome. We made an effort to avoid any semblance of 'data dredging' or overestimation of insignificant findings, as these are always critical points inherent to such large samples. By establishing a priori hypotheses and setting the significance level very conservatively at $P < 0.001$, we reduced the likelihood of overrated results. Furthermore, all psychometric questionnaires were checked with regard to their psychometric characteristic.

The following conclusions can be drawn for a use in clinical practice: The impairment of IBD patients is pronounced and consists predominantly of perceived stress due to physical complaints, medical measures, and concerns about the future. Stress is experienced in clearly defined day-to-day situations. An example of this is the phobic anxiety of losing bowel control in public, even during the remission phase. Objective data such as education level, occupational status, marital status, etc., allow us to conclude from an 'external perspective' that the surveyed population is largely not exposed to stress factors. However, there is the risk of underestimating actual patient stress when concentrating on objective data, laboratory parameters, and activity indices alone (1). Therefore, in medical consultations, specific questions concerning subjective impairment should routinely be asked in the examination of IBD patients. The question as to how to deal with the disease at work and in private life is essential for understanding the situation of the patient. This facilitates the identification of patients who are externally well adapted, yet internally are highly stressed with unfavorable coping styles and excessively pessimistic attitudes.

Further research should clarify the issue of systematic bias caused by membership in a patients' association and examine additional determinants in their interaction. At the beginning of the 1990s, a request was made for prospective studies on HRQOL (18). A decade later, there is still a considerable gap in research in this field. Existing results show a strong need for controlled studies on therapies that aim to change depressive coping styles and pessimistic attitudes.

Acknowledgements

We thank the German Morbus Crohn/Colitis Ulcerosa Association e.V. and those of its members who participated

in this study as well as the Dr. Falk Pharma GmbH for their support.

References

- Garrett JW, Drossman DA. Health status in inflammatory bowel disease. Biological and behavioural considerations. *Gastroenterology* 1990;99:90-6.
- Drossman DA. Presidential address: gastrointestinal illness and the biopsychosocial model. *Psychosom Med* 1998;60:258-67.
- Drossman DA, Leserman J, Mitchell M, Li Z, Zagami EA, Patrick DL. Health status and health care use in persons with inflammatory bowel disease. A national sample. *Dig Dis Sci* 1991;36:1746-55.
- Colombel JF, Yazdanpanah Y, Laurent F, Houcke P, Delas N, Marquis P. Quality of life in chronic inflammatory bowel diseases. Validation of a questionnaire and first French data. *Gastroenterol Clin Biol* 1996;20:1071-7.
- Frenzer A, Binek J, Hammer B. Physician-patient relations and stress caused by colonoscopy in patients with chronic inflammatory bowel disease. *Schweiz Med Wochenschr Suppl* 1996;79:94-6.
- Dudley BS. Living with ulcerative colitis. *Gastroenterol Nurs* 1996;19:60-4.
- Faller H, Kraus MR. Der Einfluß somatischer und psychosozialer Faktoren auf Entstehung und Verlauf chronisch-entzündlicher Darmerkrankungen. *Psychotherapeut* 1996;41:339-54.
- Friebel V. Morbus Crohn. Psyche einer Krankheit. Göttingen: Verlag für Angewandte Psychologie; 1995.
- Maunder RG, deRooy EC, Toner BB, Greenberg GR, Steinhart AH, McLeod RS, et al. Health-related concerns of people who receive psychological support for inflammatory bowel disease. *Can J Gastroenterol* 1997;11:681-5.
- Guyatt GH, Naylor D, Juniper E, Heyland, DK, Jaeschke R, Cook DJ. for the Evidence-based Medicine Working Group. Users' guide to the medical literature. XII. How to use articles about health-related quality of life. *JAMA* 1997;16:1232-7.
- Drossman DA, Patrick DL, Mitchell CM, Zagami EA, Appellaum MI. Health-related quality of life in inflammatory bowel disease. Functional status and patient worries and concerns. *Dig Dis Sci* 1989;34:1379-86.
- Guyatt G, Mitchell A, Irvine EJ, Singer J, Williams N, Goodacre R, et al. A new measure of health status for clinical trials in inflammatory bowel disease. *Gastroenterology* 1989;96:804-10.
- Kim WH, Cho YS, Yoo HM, Park IS, Park EC, Lim JG. Quality of life in Korean patients with inflammatory bowel diseases: ulcerative colitis, Crohn's disease and intestinal Behcet's disease. *Int J Colorectal Dis* 1999;14:52-7.
- Russel MG, Pastoor CJ, Brandon S, Rijken J, Engels LG, van der Heijde DM, et al. Validation of the Dutch translation of the Inflammatory Bowel Disease Questionnaire (IBDQ): a health-related quality of life questionnaire in inflammatory bowel disease. *Digestion* 1997;58:282-8.
- Hjortswang H, Strom M, Almeida RT, Almer S. Evaluation of the RFIPC, a disease-specific health-related quality of life questionnaire, in Swedish patients with ulcerative colitis. *Scand J Gastroenterol* 1997;32:1235-40.
- Krebs H, Kachel F, Faller H. Der Fragebogen zur Erfassung der Sorgen von Patienten mit chronisch-entzündlichen Darmerkrankungen (IBD Patient Concerns): Ergebnisse zur Reliabilität und Validität einer deutschen Version. *Praxis Klinische Verhaltensmedizin und Rehabilitation* 1998;11:50-5.
- Han SW, McColl E, Steen N, Barton JR, Welfare MR. The inflammatory bowel disease questionnaire: a valid and reliable measure in ulcerative colitis patients in the North East of England. *Scand J Gastroenterol* 1998;33:961-6.
- Drossman DA, Leserman J, Li Z, Mitchell CM, Zagami EA, Patrick DL. The rating form of IBD patient concerns: a new measure of health status. *Psychosom Med* 1991;53:701-12.
- Farmer RG, Easley KA, Farmer JM. Quality of life assessment by patients with inflammatory bowel disease. *Cleve Clin J Med* 1992;59:35-42.
- Alberts MS, Lyons JS, Anderson RH. Relation of coping style and illness variable in ulcerative colitis. *Psychol Rep* 1988;62:71-9.
- Kinash RG, Fisher DG, Lukie BE, Carr TL. Inflammatory bowel disease impact and patient characteristics. *Society of Gastroenterology Nurses and Associates*; 1993. p. 147-55.
- Normann D, Kordy H. Coping bei Morbus Crohn-Patienten unter differentieller Perspektive: Ein Beitrag zur Spezifitätsdiskussion. *Psychother Psychosom Med Psychol* 1991;41:11-21.
- Baird DD, Narendranathan M, Sandler RS. Increased risk of preterm birth for women with inflammatory bowel disease. *Gastroenterology* 1990;99:987-94.
- Ware JR, Snow KK, Kosinski M, Gandek B. SF-36 health survey: manual and interpretation guide. Boston: New England Medical Center, The Health Institute; 1993.
- Bullinger M, Kirchberger I. SF-36 Fragebogen zum Gesundheitszustand. Göttingen: Hogrefe; 1998.
- Hays RD, Marshall GN, Wang EYI, Sherbourne CD. Four year cross-lagged associations between physical and mental health in the medical outcome study. *J Consult Clin Psychol* 1994;62:441-9.
- Muthny FA. Freiburger Fragebogen zur Krankheitsverarbeitung. Göttingen: Hogrefe; 1989.
- Krampen G. Skalen zur Erfassung von Hoffnungslosigkeit (H-Skalen). Göttingen: Hogrefe; 1994.
- Beck AT, Weisman A, Lester D, Trexler L. The measurement of pessimism: the hopelessness scale. *J Consult Clin Psychol* 1974;42:861-5.
- Cox DR, Wermuth N. Multivariate dependencies: models, analysis and interpretation. London: Chapman and Hall; 1996.
- Maunder RG, deRooy EC, Toner BB, Moskovitz D. Health-related concerns of people who receive psychological support for inflammatory bowel disease. *Can J Gastroenterol* 1997;11:681-5.
- Moody GA, Mayberry JF. Perceived sexual dysfunction amongst patients with inflammatory bowel disease. *Digestion* 1993;54:256-60.
- Brevinge H, Berglund B, Bosaeus I, Tolli J, Nordgren S, Lundholm K. Exercise capacity in patients undergoing proctocolectomy and small bowel resection for Crohn's disease. *Br J Surg* 1995;82:1040-5.

Received 26 June 2000

Accepted 20 September 2000