Quality of life, anxiety, depression in patients with inflammatory bowel disease

From screening to the effect of a cognitive behavioural intervention

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CHAPTER 6

THE PATIENT SIMPLE CLINICAL COLITIS ACTIVITY INDEX (P-SCCAI) CAN DETECT ULCERATIVE COLITIS (UC) DISEASE ACTIVITY IN REMISSION: A COMPARISON OF THE P-SCCAI WITH CLINICIAN-BASED SCCAI AND BIOLOGICAL MARKERS

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ABSTRACT

Aim: To develop a patient-based Simple Clinical Colitis Activity Index (P-SCCAI) of ulcerative colitis (UC) activity and to compare it with the clinician-based SCCAI, C-reactive protein (CRP) and Physician's Global Assessment (PGA) of UC activity. Monitoring UC activity may give patients disease control and prevent unnecessary examinations.
Methods: Consecutive UC patients randomly completed the P-SCCAI either before or after consultation. Gastroenterologists assessed patients' UC activity on the same day. Overall agreement between SCCAI and P-SCCAI was calculated with Spearman's Rho(r_s) and Mann–Whitney U test. Agreement regarding active disease versus remission and agreement at domain level were calculated by percent agreement and kappa (κ).
Results: 149 (response rate 84.7%) UC patients participated. P-SCCAI and SCCAI showed a large correlation (r_s = 0.79). The medians (IQR) of the P-SCCAI (3.78; 0–15) tended to be higher than those of the SCCAI (2.86;0–13), although this difference did not reach statistical significance (z=1.71| p=0.088). In 77% of the cases the difference between clinicians' and patients' scores was not clinically different (i.e. ≤ 2). Percentage agreement between clinicians and patients, judging UC as active or in remission, was 87%, r_s=0.66, κ=0.66, indicating a substantial agreement. In general patients tended to report more physical symptoms than clinicians. C-Reactive protein (CRP) was found to have a significant association with both P-SCCAI and SCCAI (κ = 0.32, κ = 0.39 respectively) as was PGA (κ=0.73 for both indices).
Conclusions: The P-SCCAI is a promising tool given its substantial agreement with the SCCAI and its feasibility. Therefore, P-SCCAI can complement SCCAI in clinical care and research.

INTRODUCTION

Ulcerative colitis (UC) is one of the major types of inflammatory bowel diseases (IBD). UC is a chronic, relapsing condition that is manifested as inflammation in the rectum and sometimes in the rest of the colon.[1] UC is predominantly associated with symptoms such as abdominal pain, (bloody) diarrhea, weight loss, anemia, fatigue and fevers. Extracolonic features involving organs and systems such as joints, skin, liver, eye and mouth can also occur.[2] The course of the disease is unpredictable including frequent exacerbations and remissions.[3] Regardless of disease activity, UC has a negative impact on the quality of patients' lives.[4] Moreover, previous research shows that many UC patients suffer from anxiety and depressive symptoms compared to a reference group of the general population.[3,5–7]

In general, monitoring disease activity is of vital importance, as relapse is unpredictable and frequent, with a quarter to half of UC patients relapsing annually.[8] This underscores the need for a reliable clinical disease activity index. In daily clinical practice, no gold standard for the assessment of disease activity in UC exists.[9,10] The clinician can assess disease activity in UC patients using the Physician's Global Assessment (PGA). This assessment is based on judging the patient's symptoms during consultation together with additional examinations such as blood tests, endoscopy and C-reactive protein (CRP), when necessary.[11] Several clinical scoring indices such as the Simple Clinical Colitis Activity Index (SCCAI) are used by the clinicians to quantify UC disease activity.[9,12] These assessments require completion by the treating clinician, which makes them prone to bias, since the clinician gives an interpretation of the patient's response.

Alternatively, patient- based assessment of disease activity may have several advantages. It reduces invasive and uncomfortable examinations, laboratory tests and the number of visits to the gastroenterologist. This in turn might reduce not only patient's burden, but also health care costs. Finally, it may provide an easy means to early detection of imminent relapse.

To the best of our knowledge only three studies[13–15] have examined patient-based disease activity questionnaires. However, these studies suffer from several methodological and statistical shortcomings. Only one study compared the SCCAI as completed by the clinician with a questionnaire derived from the SCCAI as completed by the patient.[15] The findings showed a significant agreement between the clinicians' and patients' scores, despite, the small sample size (n = 63). This study is encouraging to constructively replicate and extend.

The first aim of the current study was to develop an easy to use patient-based SCCAI questionnaire to measure disease activity in a large sample of UC patients. We decided to use the SCCAI, because it is a well validated and reliable instrument that allows easy translation into a patient-based questionnaire (P-SCCAI). The SCCAI is also an adequate replacement for more objective disease activity measurements such as endoscopy and

blood tests.[12,16] The second aim was to assess agreement between the P-SCCAI and the original clinician-based SCCAI. The third aim was to compare the P-SCCAI and clinician-based SCCAI with the PGA and the biological marker C-reactive protein (CRP).

MATERIALS AND METHODS

Study population and procedure

Consecutive patients with confirmed UC attending the IBD outpatient clinic of the Academic Medical Centre (AMC) in Amsterdam, from April 2010 till November 2011, were invited to participate in the study. Patients with insufficient command of Dutch were excluded. Participants were asked to complete the patient-modified SCCAI in the hospital. To avoid order effects, a random half of the patients completed the questionnaire prior to the outpatient consultation, and the other half after the consultation. Four clinicians participated in the study, blinded for the patients' responses. They assessed UC activity during the outpatient consultation by completing the original SCCAI.

Clinician-based Simple Clinical Colitis Activity Index

The clinicians completed the Dutch version of the original SCCAI (see Appendix I). This questionnaire refers to disease symptoms during the previous week. It is composed of six domains: bowel frequency (during the day) ranging from 1 to > 9; bowel frequency (during the night) ranging from 0 to 6; urgency of defecation ranging from none to incontinence; blood in stool ranging from none to usually frank (> 50% of defecation); general well-being ranging from very well to terrible (1–10) and a number of defined extracolonic features of UC (i.e. arthritis, erythema nodosum, pyoderma gangrenosum, uveitis). The four latter questions have a 'yes' or 'no' option. After recoding (see Appendix I), the clinician-based SCCAI is able to categorize two types of patients: patients with inactive disease (SCCAI score < 5) and patients with active disease (SCCAI score ≥ 5).

Patient-based Simple Clinical Colitis Activity Index

For patients, the original SCCAI was translated into a patient-based questionnaire (see Appendix II). This patient- modified P-SCCAI was devised by two medical psychologists, one research assistant and one gastroenterologist. All items within the P-SCCAI refer to symptoms during the previous week and were translated into patients' comprehensible language. Medical terminology and disease symptoms were clarified. For example "uveitis" is described as "eye infection, which your specialist diagnosed as uveitis".

The domains 'bowel frequency (during the day)', 'bowel frequency (during the night)', blood in stool and 'general well-being' each consist of one item. The domain 'urgency of defecation' consists of three items. The domain 'extracolonic features' consists of four extracolonic features (erythema nodosum, arthritis, uveitis and pyoderma gangrenosum) and has a total of six items. For these items the response options for the patient were

threefold: 'yes', 'no' and 'I do not know'. This third response option was added, as patients may not know whether they have a specific manifestation or may be unfamiliar with its specific medical terminology, despite our explanation.

Piloting the P-SCCAI

We examined the comprehensibility of the patient-based questionnaire during a pilot study. Three patients completed the questionnaire and were then asked if they had experienced any difficulties while filling out the questions. In general, they reported that the questionnaire was easy and quick to complete and that the questions were clear. These results did not lead to changes.

Demographic, clinical characteristics, CRP and PGA

UC diagnosis, sex, date of birth, year of diagnosis, presence of a pouch (yes/no), number of operations associated with UC and presence (no versus ≥ 1) of co-morbidity unrelated to UC (i.e. twelve other illnesses) were measured by self-reports.

CRP and PGA were collected for each patient from the electronic patient database. These were only taken into account if they were collected within a time frame ranging from 4 weeks prior to and 4 weeks after the time of (P-) SCCAI administration. Laboratory values were considered to reflect remission (CRP ≤ 5) and active disease (CRP > 5).[17]

STATISTICAL ANALYSIS

Assuming that 35% of the patients have disease activity and that agreement is 0.22, which is higher than chance (kappa (κ) 0.62 versus 0.40) 148 patients were needed, with 80% power and a two sided α of 0.05. We used standard descriptive statistics to summarize the sociodemographic, clinical characteristics, CRP and PGA of included patients. We examined agreement between SCCAI scores of the clinician and patient on the total sum score, per domain, on CRP and PGA.

As previously indicated, the P-SCCAI had a third response option for 9 items, 'I do not know'.

We analyzed the patients' response 'I do not know' in three different manners, either by scoring it as 'no', as 'yes' or as missing. Differences between these three modes of analyses were negligible (data not shown). Therefore, we decided to consider 'I do not know' as 'no' for further analysis.

During consultation, biological markers (i.e. blood tests, CRP) might be discussed with the patient. Therefore, those patients who completed the questionnaire after the consultation could have prior knowledge of these biological markers. This might influence patients' self-reports of their disease activity. Consequently, in the analyses comparing the SCCAI and P-SCCAI with CRP, we only used the data of those patients who completed the questionnaire prior to consultation. Likewise, in the case of the clinicians we only used

laboratory values received from questionnaires that were completed without clinicians' prior knowledge of biological markers. If within one month before a consultation the clinicians received data on the biological markers of the patient in question, they were deemed to have prior knowledge. If blood tests and consultation with the patient occurred on the same day, we only used data from those cases where the blood tests were carried out after the consultation. Dates and times of consultations and blood test results were available in the electronic patient database.

Patients'–clinicians' agreement at domain level

Agreement between clinician and patient was calculated on domain level. For the items with categorical response options we used Cohen's kappa (κ) to measure agreement. The strength of the correlation between the total SCCAI score assessed by the clinician and by the patient was calculated using Spearman's Rho (r_s).

Patients' and clinicians' SCCAI scores compared with CRP and PGA

First, we assessed agreement of the presence of disease activity based on the SCCAI and P-SCCAI respectively, with CRP and the PGA. For CRP and PGA, disease activity was categorized as active or in remission. Agreement was examined using the kappa statistic.[18,19] Second, we tested if the total SCCAI scores assessed by clinicians and by patients were significantly associated with CRP and PGA using the Chi square test.

Ethical considerations

Since no ethical approval is required for the completion of non-intrusive self report questionnaires under Dutch law, the Medical Ethical Committee of the AMC exempted this project from formal approval.

RESULTS

Patient characteristics

From April 2010 until November 2011, 176 patients at the outpatient IBD clinic of the AMC were asked to complete the P-SCCAI. Twenty-seven patients refused to participate, 14 due to time constraints, 9 due to lack of motivation and 4 due to reading constraints. In total, 149 patients (response rate 84.7%) with UC participated in the study and completed the P-SCCAI (see Table 1). The median (IQR) age of participants was 48 years (37–59) and 50.3% was female. UC was diagnosed at a median (IQR) age of 30 years (22–43). At the moment of participation, the median (IQR) duration of UC was 12 years (6–20). In total 21 patients (14.0%) have undergone at least one operation for UC in their lifetime and 14 patients had a pouch (9.4%). 60 patients (40.3%) reported to have no co-morbidity, while 89 patients (59.7%) reported to have one or more co-morbid diseases.

Table 1. Socio-demographic and clinical patient characteristics.

	Ulcerative Colitis (N = 149)			
	N	%	Median	IQR
Demographic variables				
Age (median; range)	149		48.0	37-59
Sex				
Female	75	50.3		
Male	74	49.7		
Clinical characteristics				
Age at diagnosis	149		30.0	22-43
Disease at duration in years	149		12.0	6-20
Stoma	0	0		
Pouch	14	9.4		
Number of operations				
0 operations	128	86.0		
≥ 1 operations	21	14.0		
Co-morbidity				
No co-morbidity	60	40.3		
≥ 1 co-morbidities	89	59.7		

IQR indicates interquartile range.

CRP and PGA

CRP data were available in 74 patients and PGA in 46 patients. According to the CRP, disease activity in UC was found in 25 cases and UC in remission was found in 49 cases. According to the PGA, disease activity in UC was found in 21 cases and in 25 cases as in remission.

Comparison of SCCAI and P-SCCAI

To control for order effects, 73 patients (49.0%) received the P-SCCAI before the outpatient visit and 76 patients (51.0%) received the P-SCCAI after the outpatient visit. The scores of patients who received the P-SCCAI before versus after the outpatient visit were not statistically significantly different by Mann Whitney U test (z=0.434, p=0.664).

Total SCCAI score

First, Spearman's Rho (r_s) between SCCAI and P-SCCAI scores was 0.79, indicating a large correlation. Second, the medians (IQR) of the P-SCCAI (3.78; 0–15) tended to be higher than the total SCCAI (2.86; 0–13), although this difference did not reach statistical significance according to the Mann Whitney U test (z=1.71| p=0.088). Third, the difference between the total SCCAI and P-SCCAI scores was not clinically relevant (i.e. difference ≤ 2 points) in 114 (76.5%) cases. Fourth, the percentage agreement between clinician and patient, both judging UC as active or as in remission, was 87%. Cohen's Kappa (κ) yielded a score of 0.66 (substantial agreement) (see Table 2 and Fig. 1). In 12 cases (8.1%) the P-SCCAI classified disease activity as active, while clinicians scored the same disease activity as inactive. In 7 cases (4.6%) the P-SCCAI assessed disease activity as inactive, while clinicians considered the same disease activity as active. Positive and negative predictive values are shown in Table 2. Fifth, the statistically significant difference between patient and clinician total SCCAI scores was similar for patients with and without co-morbidity (data not shown).

Table 2. Clinician–patient association and agreement on SCCAI judged as in remission or as active.

N =149		Clinician assessment		
		Remission (<5)	Active (≥ 5)	
Patient assessment	Remission (<5) (= positive)	103	7	Positive predictive value = 0.94
	Active (≥ 5) (= negative)	12	27	Negative predictive value = 0.69
Agreement	87%	r_s = 0.66	$_{\kappa}$ = 0.66	

Note: SCCAI = Simple Clinical Colitis Activity Index, r_s = Spearman Rank correlation, κ = Kappa. Data is presented as frequencies unless stated otherwise.

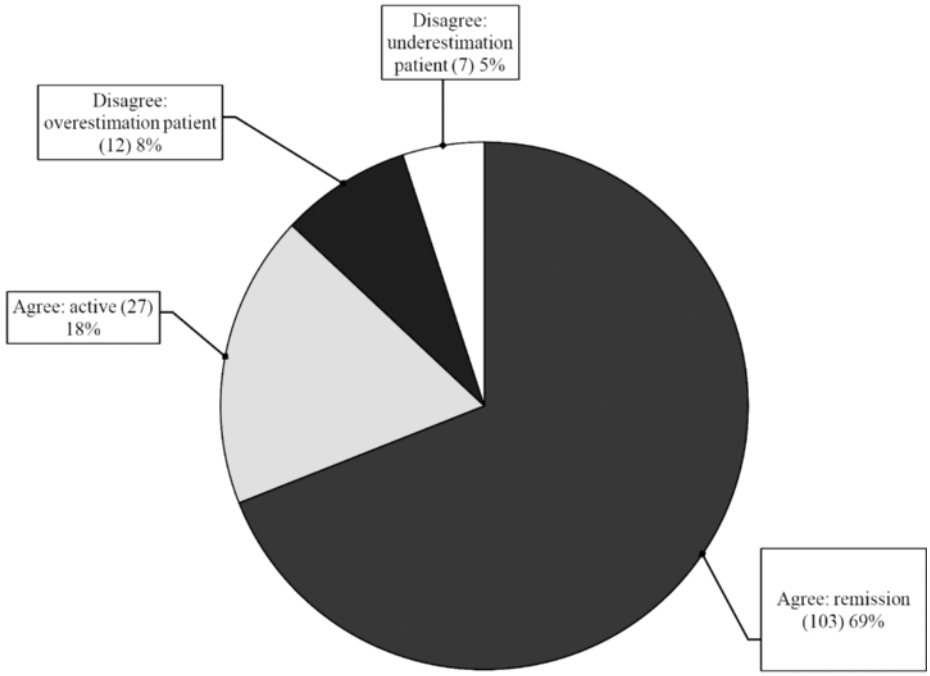

Figure 1. Proportion of (dis)agremeent regarding disease activity.

Domain-level SCCAI scores

On the first domain 'well-being', the P-SCCAI correlated highly (r_s = 0.75) with the SCCAI and yielded a moderate agreement (κ=0.49) (see Table 3). Both domains 'defecation frequency during the day' and 'defecation frequency during the night' showed a large correlation (respectively r_s = 0.71 and r_s = 0.67) and a substantial agreement (respectively κ = 0.62 and κ =0.67) between clinician and patient assessment. In 21 cases 'defecation frequency during the day' was scored higher by patients than clinicians, while 'defecation frequency during the day' was scored lower by patients in 12 cases. Compared to the SCCAI, the P-SCCAI scored higher on 'defecation frequency during the night' in 17 cases, while patients scored lower on 'defecation frequency during the night' in 4 cases. Also the domain 'Blood with defecation' had a large correlation (r_s = 0.88) and substantial agreement (κ = 0.63). In 18 cases patients scored 'Blood with defecation' higher than clinicians, while 'Blood with defecation' was scored lower by patients in 9 cases. A slight agreement (κ = 0.26) and large correlation (r_s = 0.52) have been found for the domain 'continence' (see Table 4). Agreement between the P-SCCAI and the SCCAI on frequent extracolonic features of UC varied from poor to a perfect agreement (see Table 5).

Table 3. Clinician–patient association and agreement on SCCAI domain 'Well-being' on a ten-point scale.

N = 149		Clinician assessment				
		<4	4	5	6	≥7
Patient assessment	<4	69	14	3	0	0
	4	6	18	4	0	1
	5	1	6	6	0	0
	6	0	4	1	3	0
	≥7	0	2	3	3	5
Agreement	68%	r_s = 0.75			κ=0.49	

Note: SCCAI = Simple Clinical Colitis Activity Index, r_s = Spearman Rank correlation, κ=Kappa. Data is presented as frequencies unless stated otherwise.

Table 4. Clinician–patient association and agreement on SCCAI domain 'Continence' on a three-point scale.

N = 149		Clinician assessment			
		0	1	2	3
Patient assessment	0 (continence)	79	2	3	0
	1 (can't delay)	10	2	6	0
	2 (toilets near)	16	1	6	0
	3 (incontinence)	8	1	12	3
Agreement	60%	r_s = 0.52			κ = 0.26

Note: SCCAI = Simple Clinical Colitis Activity Index, r_s = Spearman Rank correlation, κ = Kappa. Data is presented as frequencies unless stated otherwise.

Table 5. Clinician–patient agreement on SCCAI 'extracolonic features'.

	Well-known extracolonic features							
Patient/clinician association and agreement	n	n % total agreement	n 'no' agreement	n 'yes' agreement	n patient higher scores	n patient lower scores	r_s	κ
Erythema Nodosum	149	100	149	0	0	0	1	1
Arthritis	149	82	108	14	4	23	0.45	0.41
Uveïtis	149	99	148	0	0	1	–	–
Pyoderma	149	100	148	1	0	0	1	1

Note: SCCAI = Simple Clinical Colitis Activity Index, r_s = Spearman Rank correlation, κ = Kappa.
– Cannot be calculated.

CRP and PGA, versus SCCAI and P-SCCAI scores

In 54 assessments of the clinicians and in 74 assessments of the patients, clinicians and patients had no prior knowledge of CRP or PGA and were thus included in this analysis. Results are show in Table 6. The judgment of both the clinician and the patient on the presence of disease activity with the presence of disease activity according to CRP and PGA ranged from fair (κ = 0.32) to substantial (κ = 0.73). Moreover, judgment of both the clinician and the patient on the presence of disease activity was significantly associated with the presence of disease activity according to CRP and PGA.

Table 6. Comparison of the presence of disease activity according to the SCCAI, CRP and PGA in clinicians and patients.

	Clinician judgment ** N = 54				Patients' judgment ** N = 74		
	χ^2	p	κ		χ^2	p	κ
Disease activity according to CRP (N = 44)	6.80	0.009*	0.39	N = 37	4.20	0.040*	0.32
Disease activity according to PGA (N = 46)	26.5	<0.001*	0.73	N = 23	13.08	<0.001*	0.73

Note: χ^2 = Chi-square, κ = Kappa
* $p < 0.05$
** Clinicians and patients without prior knowledge.

DISCUSSION

This study evaluated the agreement between a patient-based P-SCCAI assessed by UC patients and the SCCAI assessed by their clinician, CRP and PGA.

Agreement between SCCAI and P-SCCAI

The P-SCCAI yielded a large correlation with the clinician derived SCCAI score. A substantial agreement between clinicians and patients in assessing UC as active or as in remission was found. Furthermore, the positive predictive value of P-SCCAI is noteworthy. When patients judge UC to be in remission, in nearly all of the cases (94%) clinicians will also judge the disease as in remission. On the other hand, the negative predictive value of UC is somewhat lower. When patients assessed their disease as active, about two-thirds (69%) of the clinicians agreed with the patient's judgment.

Agreement on domain-level SCCAI scores

The SCCAI and P-SCCAI scores on the domains 'well-being', 'defecation frequency during day and night' and 'blood with defecation' correlated highly, with a moderate to substan- tial agreement.

However, the domain 'continence' showed only a fair agreement between patients and clinicians. An explanation for this discrepancy could be that the domain 'continence' from the original SCCAI is divided into three sub-items in the patient version. Another explanation could be that patients are ashamed to discuss continence-related issues with the clinician and are, therefore, reluctant to report this during consultation.

In line with findings by Laugsand et al. [20] (n = 2294) we found several discrepancies between clinicians and patients on the P-SCCAI and SCCAI. In their study clinicians tended to underestimate cancer patients' symptom intensities based on a quality of life questionnaire (e.g. pain, fatigue, depression, constipation, diarrhoea). In our study, when the P-SCCAI and SCCAI differ, patients also report a higher disease activity than clinicians: more 'defecation frequency during the day and the night', more 'blood with defecation', more incontinence, more extracolonic features (i.e. arthritis). These results can be explained by patients' hesitation to be open about their physical symptoms to avoid a painful physical examination (e.g. endoscopy) or surgery. A large study by Lesage et al.[21] on quality of life in 2424 IBD patients, found that patients reported more symptoms and a larger impact of the disease on their lives than clinicians did. In contrast to these results, our findings on the domain 'well-being' do not demonstrate this discrepancy between patients and clinicians.

In general, extracolonic features were not very common among our patients, therefore no firm conclusion could be drawn. Only the item concerning arthritis indicated a moderate agreement between the SCCAI and P-SCCAI.

CRP and PGA, versus SCCAI and P-SCCAI

Significant associations between CRP, PGA and both SCCAI and P-SCCAI were found. Therefore, we can conclude that the P-SCCAI is a valid assessment of UC disease activity. CRP has proved to be a valuable biomarker of IBD activity but mainly for CD.[23–25] Previous studies have also found an association between elevated CRP, active disease in UC[26] and the SCCAI.[27] However, caution must be made since CRP does not sufficiently distinguish between inflammation in the intestinal tract and inflammation elsewhere in the body.[28]

Therefore, use of merely this one biological marker may be insufficient in identifying UC disease activity. Lacking a gold standard, many studies use the PGA to approximate various aspects of disease activity.[22] Two previous studies[13,14] compared patients' and clinicians' ratings of UC activity with biological markers. One study used the patient-based Pediatric UC Activity Index (PUCAI) for patients and the original PUCAI for clinicians.[14] In line with our findings, clinicians' and patients' scores correlated well with each other and with the biological markers (PGA, erythrocyte sedimentation rate (ESR) and CRP) of disease activity. However, results of the second study showed that the clinicians' disease activity scores corresponded better with biological markers (CRP, ESR, albumin, hemoglobin and PGA) of disease activity than the patients' scores did.[13] These results

may be explained by the fact that the authors used two different questionnaires (PUCAI and a bowel domain of IMPACT, a disease specific measure of health-related quality of life) for patients and clinicians.

Limitations

A number of limitations of this study merit attention. First, using the clinicians' global opinion in defining relapse or remission (i.e. PGA) is open to criticism because it lacks objectivity. The interpretation of such a subjective assessment might be dependent on clinician's experience and varies between clinicians. Future studies should confirm our findings in a larger set of clinicians with several levels of experience.

Second, only some of the UC symptoms that are important to patients are included in standard clinician-based indices, such as the SCCAI.[29] Recently, Joyce et al. found that UC disease activity indices do not include all of the relevant symptoms (e.g. stool mucus, tenesmus, fatigue). Validation of questions concerning these other symptoms should be under- taken in future longitudinal studies.[29]

Finally, although the recruitment of UC patients was performed in a tertiary referral center, severely ill UC patients were underrepresented. Most UC extracolonic features were not common among our sample of patients. Moreover, our study included patients with a median disease duration of 12 years. The experience of these patients with IBD may have impacted the results. Future research should replicate our study with a larger and more heterogeneous sample of patients including those patients with mild and severe UC, with and without UC extracolonic features and with different disease durations. Also, future research should further explore the reliability, validity and responsiveness of the P-SCCAI by prospectively comparing it to additional biological markers and endoscopy data of disease activity.

Strengths

This study has a number of strengths. First, this is one of the first studies that has developed a patient-based question- naire of the SCCAI, and has compared this questionnaire with a clinician-based assessment, using a sufficiently large sample size. The P-SCCAI was found to be feasible. It can easily be transformed into a web-based questionnaire or a mobile phone app, that can be used by patients without the presence of a clinician. Second, this study included measurements from CRP which is a more objective index of disease activity. By combining CRP with the clinical indices, a more comprehensive representation of disease activity is achieved. A third strength is that the patient- and clinician-based assessment of the SCCAI took place on the same day within a time span of an hour and consequently captured the same UC activity. Finally, in this study clinicians were blinded for patients' responses and it was controlled for order effects by means of randomization.

Clinical implications and recommendations for further research

Using a self report assessment is less demanding for patients in routine clinical care and will facilitate clinical research. For suspected UC patients, the P-SCCAI can be used to identify patients without UC activity and who can, therefore, abstain from further testing. If patients are diagnosed with UC, regular measurement of the P-SCCAI can be used to monitor disease course by non-specialist clinicians or by patients themselves. Moreover, the P-SCCAI might be used to identify patients who are most likely to respond to medical treatment or require additional treatment. Finally, the P-SCCAI can be used at follow-up to successfully examine UC activity.

As Lesage et al. suggest, listening better to patients can improve the clinicians' judgment of physical as well as emotional well-being.[21] In this study we found evidence that when UC is in remission the clinician's assessment can be replaced by the patient's assessment (P-SCCAI). Indeed, these results are promising. However, when the disease is active, two-thirds of the clinicians agreed with the patient's judgment. Therefore, measuring active disease using the P-SCCAI should be done with caution, since there is a slight risk of misinterpretation of disease activity.

As a gold standard for measuring UC disease activity is still unavailable,[10,16] some researchers prefer endoscopic examination,[30] others biological markers [27] or the PGA.[31,32] The current and several other studies suggest the complementary use of patients' assessments, clinicians' assessments and biological markers.[13,14,33]

CONCLUSION

The P-SCCAI is a promising tool given its substantial agreement with the original SCCAI and its feasibility. Therefore, P-SCCAI can complement SCCAI in clinical care and research. It may assist clinicians in preselecting patients for a clinical consultation. For patients with UC in remission according to P-SCCAI a clinical consultation may be postponed. Assessing UC activity without clinical consultations or additional examinations may improve the patient's quality of life and can potentially reduce health care costs. Nevertheless, additional examination is required when UC is active according to the P-SCCAI, in order to avoid undertreatment of patients. These patients should visit their clinician to be assessed according to the original SCCAI.

COMPETING INTERESTS

The authors declare that they have no competing interests. F. Bennebroek Evertsz' received an unrestricted research grant from Scheringh and Plough of 20.000 euro to study psychological factors in IBD.

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Appendix I. Clinician-based Simple Clinical Colitis Activity Index (SCCAI)

Variable	Description	Scoring	
1	Bowel frequency (day)	n (1 per occurrence)	
		0 – 3	(score 0)
		4 – 6	(score 1)
		7 – 9	(score 2)
		> 9	(score 3)
2	Bowel frequency (night)	0	(score 0)
		1 – 3	(score 1)
		4 – 6	(score 2)
3	Urgency of defecation	None	(score 0)
	a,b of c	a)Hurry	(score 1)
		b)Immediately (toilet nearby)	(score 2)
		c)Incontinence	(score 3)
4	Blood in stool	None	(score 0)
		Trace	(score 1)
		Occasionally frank (<50% of defecation)	(score 2)
		Usually frank (>50% of defecation)	(score 3)
5	General well-being	≥ 7 = very well	(score 0)
	(0 – 10)	6 = slightly below par	(score 1)
		5 = poor	(score 2)
		4 = very poor	(score 3)
		< 4 = terrible	(score 4)
	Extracolonic features	1 per manifestation:	
6	a,b of c	Arthritis	Yes = 1
			No = 0
7		Erythema nodosum	Yes = 1
			No = 0
8		Pyoderma gangrenosum	Yes = 1
			No = 0
9		Uveïtis	Yes = 1
			No = 0

Appendix II. Patient-modified SCCAI

The following questions concern your ulcerative colitis. These questions refer to your symptoms during the PREVIOUS WEEK.

1. On average per day (24 hours),how many times did you use the toilet for defecation during the previous week? Blood and slime discharge is also considered as defecation.
   - □ 0 to 3 times
   - □ 4 to 6 times
   - □ 7 to 9 times
   - □ More than 9 times

2. On average per night, how many times did you get out of bed to use the toilet for defecation during the previous week?
   - □ Never
   - □ 1 to 3 times
   - □ More than 3 times

3a. During the previous week, were you able to hold up your stool for 15 minutes or longer, when you felt the urge to use the toilet?
   - □ Yes
   - □ No
   - □ I do not know*

3b. During the previous week, did you have to make adjustments to your activities, to ensure that there was a toilet nearby?
   - □ Yes
   - □ No
   - □ I do not know*

3c. During the previous week, have you found stool in your underwear?
   - □ Yes
   - □ No
   - □ I do not know*

4. During the previous week, how many times did you see blood in your stool?
   - □ Never
   - □ Much less than half of the times
   - □ A little less than half of the times
   - □ More than half of the times

5. If you would have to rate your general well-being during the previous week by giving it a number, what number would you choose? (1 = very bad, 10 = perfect)

   1 2 3 4 5 6 7 8 9 10

6a. During the previous week, did you have joint pain which was worse at rest than after activity?
   - □ Yes
   - □ No
   - □ I do not know*

6b. During the previous week, were your joints red or swollen?
   - □ Yes
   - □ No
   - □ I do not know

6c. During the previous week, have you ever woken up from joint pain?
   - □ Yes
   - □ No
   - □ I do not know*

7. During the previous week, have you had askin disorder that has been diagnosed as erythema nodosum by your treating specialist?
   - □ Yes
   - □ No
   - □ I have a skin disorder but have not seen my specialist for it or do not know what the disorder is called.*

8. During the previous week, have you had a skin disorder that has been diagnosed as pyoderma by your treating specialist?
   - □ Yes
   - □ No
   - □ I have a skin disorder but have not seen my specialist for it or do not know what the disorder is called.*

9. Do you momentarily have an eye infection, that you have seen an eye-specialist for and which your treating specialist diagnosed as uveïtis?
   - □ Yes
   - □ No
   - □ I have an eye infection but have not seen an eye specialist for it or do not know what the infection is called.*

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