

## Simple Clinical Colitis Activity Index (SCCAI) and future patient-centered telemedical care of Ulcerative Colitis patients

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### Abstract

Ulcerative Colitis (UC) is a chronic inflammatory disease of the colon of increasing prevalence characterised by periods of remission and activity. Compared to Crohn's Disease (CD) symptom-based disease activity indices correlate fairly well with endoscopic and biometric grading of activity<sup>1, 2, 3, 4</sup>

We review the mounting number of studies that show that the "Simple Clinical Colitis Activity Index" (SCCAI), originally developed as a physician-completed tool, is the most robust disease activity index when completed by the patient themselves<sup>5</sup>. With the expansion of telemedicine there is increasing evidence to support the novel use of web-based applications to improve outcomes in UC<sup>6</sup>. An example of this is the mobile-phone application "IBDSmart<sup>TM</sup>", which is currently being piloted in Auckland, New Zealand<sup>7</sup>.

**Keywords:** inflammatory Bowel Disease; ulcerative colitis; simple colitis activity index

## **1. Development of the Simple Clinical Colitis Activity Index (SCCAI)**

The SCCAI was devised from a panel of symptoms in Ulcerative Colitis patients from 2 major teaching centres in the UK. The aim was to devise an accurate, easily calculated index of disease activity using only a small number of purely clinical criteria, negating the need for physical examination, sigmoidoscopic evaluation or laboratory indices. This would allow its completion by non-specialist carers, such as general practitioners or inflammatory Bowel Disease (IBD) nurses<sup>2</sup>. The resultant clinically-based index was then compared with a well-established index (the Powell-Tuck Index)<sup>8</sup> and a complex scoring system (the SEO index)<sup>4</sup> and objective laboratory markers. The newly devised SCCAI showed a highly significant correlation with the Powell-Tuck Index ( $r=0.959$ ,  $p<0.0001$ ) as well as the complex index ( $r=0.924$ ,  $p<0.0001$ ) and all laboratory markers ( $p=0.0003$  to  $p<0.0001$ )<sup>2</sup>.

### **1.1. The validity of SCCAI as a simple, patient-completed clinical index in UC**

The first study to assess the validity of the patient-completed score was that of Jowett et al in 2001. The study combined this with a number of other indices and a physician's global assessment to determine the relapse-defining score. Patients and their physicians (who were blinded to the scoring process), completed the same questionnaires. There was excellent correlation between the scores obtained by the patient and the physician (mean difference of 0.38, 95% CI 0.10 - 0.65). An SCCAI score of 5 or more defined relapse with 92% sensitivity, 91% specificity, 85% positive predictive value (PPV) and 89% negative predictive value (NPV)<sup>9</sup>.

### **1.2. The SCCAI as a marker of response to steroid treatment**

The correlation between SCCAI, faecal calprotectin (FC), and blood biochemical markers in UC during high-dose steroid treatment was studied by Theede et al. In this prospective observational study FC, C-reactive protein (CRP), leukocytes, haemoglobin, albumin and SCCAI were assessed prior to initiating treatment and on days 2, 6, 13 & 27. All patients had significant decreasing levels of FC ( $-1014$  mg/kg,  $p<0.0061$ ), CRP ( $-10$ mmol/L,  $p=0.0313$ ) and SCCAI ( $-3$ ,  $p=0.0002$ ) during the first 4 days of high-dose steroid treatment. A significant correlation between the changes in CRP and SCCAI was shown ( $r_s = 0.65$ ,  $p=0.03$ ), but not between FC and SCCAI ( $r_s = -0.06$ ,  $p = 0.83$ ). Overall, significant correlations between absolute levels of FC and CRP ( $r_s = 0.46$ ,  $p=0.0001$ ), between FC and SCCAI ( $r_s = 0.36$ ,  $p = 0.001$ ), and between CRP and SCCAI ( $r_s = 0.28$ ,  $p = 0.01$ ). FC, CRP and SCCAI seem to be reliable markers of treatment response during steroid treatment<sup>10</sup>.

### **1.3. The patient-reported SCCAI is an accurate measure of clinical remission**

The SCCAI has been shown to have robust discriminative and construct validity, as well as test-retest reliability and responsiveness to change<sup>11, 12</sup>. The full 6 point MAYO score that includes an endoscopic aspect is still, however, the most commonly used disease activity index in randomised controlled trials of Ulcerative Colitis. In a cross-sectional study, by Bewtra et al, the 6-point Mayo score was compared with the SCCAI. The full Mayo score correlated well with the SCCAI ( $p<0.0001$ ) and patient-reported disease activity ( $p<0.0001$ ). At a score of 1.5, the 6-point Mayo score had 83% sensitivity and

72% specificity for patient-defined remission, whereas at a score of  $<2.5$ <sup>11, 12</sup> the SCCAI gave a sensitivity of 89% and specificity of 67%. The authors noted that the addition of the SCCAI's general well-being question to the Mayo score improved the predictive ability for patient-defined remission. The study concluded that the patient-reported SCCAI score accurately measured clinical disease activity without activity without requiring direct physician contact<sup>13</sup>.

#### **1.4. The correlation of SCCAI and mucosal healing**

The discriminative ability of four clinical indices to identify Ulcerative Colitis patients with endoscopic mucosal healing was investigated by Pagnini et al, who also analysed the possible prognostic indication for disease course in 1 year of follow-up. The clinical indices (Seo' activity index<sup>4</sup>, SCCAI<sup>2</sup>, Partial Mayo score<sup>14</sup> and Endoscopic-Clinical Correlation Index<sup>15</sup>) were calculated and their correlation to endoscopic and histological activity and to CRP increment was assessed by means of Spearman's rank correlation. All clinical indices displayed a good correlation with endoscopic activity (Mayo:  $r = 0.77$ , SCCAI:  $r = 0.75$ , ECCI:  $r = 0.77$ , SEO:  $r = 0.64$ ;  $p < 0.0001$ )<sup>16</sup>. Their correlation with the histological score was poor (Mayo:  $r = 0.35$ , SCCAI:  $r = 0.33$ , ECCI:  $r = 0.36$ , SEO:  $r = 0.36$ ;  $p < 0.005$ ). With regards to the CRP increment, the correlation with the indices was fair (Mayo:  $r = 0.54$ , SCCAI:  $r = 0.55$ , ECCI:  $r = 0.55$ , SEO:  $r = 0.57$ ;  $p < 0.0001$ )<sup>16</sup>. Authors conclude that SCCAI showed the better results among the tested indices and may be of help in clinical practice in accurately identifying patients with mucosal healing<sup>16</sup>.

## **2. Online completion of SCCAI**

The validity of online completion of the SCCAI compared to that of in-clinic gastroenterologist-assessed SCCAI was investigated in the CRONICA-UC study<sup>5</sup>. The initial recruitment assessment was performed in clinic. At 3 and 6 months, patients completed the SCCAI online. A gastroenterologist, blinded to the patients' score, then completed the in-clinic SCCAI within 48 hours. SCCAI scores were dichotomised to remission (SCCAI scores of  $\leq 2$ ) or active disease (SCCAI score  $> 2$ ). Then, disease activity changes from month 3 to 6 were classed as worsening (increase in SCCAI score  $\geq 3$ ), stable (SCCAI score variations not exceeding 2 points) or improving (decrease in SCCAI score  $\geq 3$ ). Correlation of SCCAI scores by patients and physicians was good (Spearman's  $p = 0.79$ ), with 85% agreement for remission or activity (95% CI: 80.8-88.6,  $k = 0.66$ ). The negative predictive value (NPV) for active disease was 94.5% (91.4-96.6) with a positive predictive value (PPV) of 68.0% (58.8-69.2)<sup>5</sup>. Cases in which patients and physicians disagreed were mainly due to lower activity reported by the physician. Underestimation of specific patients' symptoms by the physician may be one reason to explain the discrepancy suggesting that patients are in fact more likely to report intimate clinical details when self-completing the SCCAI<sup>5</sup>.

The high NPV for disease activity (94.5%) suggest that those scoring as in remission on the online SCCAI will be very unlikely to have active disease. The clinical implication might be that a more flexible follow-up of these patients, reducing the number of clinic visits, for example, may be possible.

### **2.1. Web-guided use of SCCAI in individualising patient care**

The implementation of new communication technologies which can enable better patient-physician communication has been set as a priority by the European Commission<sup>17</sup>. An EU grant was used to fund a prospective, open-label, web-guided study with mesalazine therapy in mild-to-moderate UC. Patients entered their modified SCCAI scores and registered a point-of-care Faecal Calprotectin (FC) result on a web application. A traffic light system was used to guide patient's therapy of mesalazine. 86% of patients were adherent to 3 months of web-guided therapy. From week 0 to 12, patients experienced a significant reduction in SCCAI (4.6 vs 1.6,  $p < 0.001$ ) and mean FC (437 vs 195,  $p < 0.001$ ). The study concluded that web-guided therapy with mesalazine in mild-to-moderate UC helps to individualise the dose and improve adherence<sup>18</sup>.

## **3. Telemedicine and e-health technologies**

Telemedicine is the use of medical information exchanged from one site to another through electronic communications with the goal of improving a person's health status. It has potential uses in effectively and promptly reporting patient symptoms to healthcare professionals (HCP) in order to make accurate clinical assessments.

### **3.1. Benefits of telemedicine**

The landscape of clinical practice is changing and the era of telemedicine is upon us. Telemedicine is growing at a rapid rate because of 4 fundamental benefits which are:

- Improved quality – probably as good as in-person consultations

- Cost efficiencies – reduced travel times, streamlined staffing and shorter hospital stays
- Improved access – incredible capacity to deliver services to patients beyond health professionals' own locations
- Patient demand – empowers patient to better understand their condition and, therefore, adhere to clinical practices

Telemedicine and other e-health technologies allow for unique research opportunities creating a unique resource to study patient reported outcomes and changes in management over time<sup>9, 19, 20, 21</sup>.

### **3.2. Limitations of telemedicine**

While telemedicine has clear potential for improving patient management, there remains a paucity of robust evidence from peer-reviewed studies to show whether they really can improve patient outcomes and enhanced communication with medical professionals<sup>22</sup>.

A review in June 2016 found trials testing the utility of mHealth apps in the areas of alcohol use, asthma, diabetes, cardiovascular disease, and lifestyle factors such as smoking and weight loss<sup>23</sup>. One study using phone-app communication to monitor post-operative recovery found a high satisfaction among both Breast reconstruction patients of 3.7 (on a scale of 1 [poor] to 4 [excellent] and orthopaedic patients (3.7)<sup>24</sup>. It is plausible, therefore, that similar care could be utilised after resection, colectomy or ileal pouch construction in IBD patients.

Self-managed web-based eHealth treatment approaches in IBD have been shown to optimize maintenance therapy, adherence with medication and disease course in UC<sup>21</sup>. Pederson et al conducted a

prospective, open-label, web-guided study with a total of 95 patients in Copenhagen. The study aimed to assess the efficacy of self-managed, web-based treatment with a 5-ASA in patients with mild-to-moderate UC who were non-adherent or insufficient responders to previous 5-ASA therapy in improving adherence and inducing remission<sup>6</sup>. Patients completed the SCCAI and registered a Faecal Calprotectin (FC) on the web application: [www.meza.constant-care.dk](http://www.meza.constant-care.dk). SCCAI and FC were summed to give a total inflammatory burden score (TIBS). Deep remission was defined as  $SCCAI \leq 2$ ,  $FC = 0$  and  $TIBS \leq 1$ . Patients were initially allocated 4.8g Mesalazine per day. 82 (86%) patients were adherent to web therapy, completing 3 months of web-guided therapy. From weeks 0 to 12, patients experienced a significant reduction in mean SCCAI (4.6 vs 1.6,  $p < 0.001$ ), mean FC (437 vs 195,  $p < 0.001$ ) and mean TIBS (6.7 vs 2.4,  $p < 0.0001$ ). Based on TIBS values ( $\leq 1$ ) the mesalazine dose was reduced to 2.4g in 25% of patients at week 3, in 50% of subjects at week 5 and in 88% at week 12. The authors conclude therefore that web-guided therapy with mesalazine in mild-to-moderate UC helps to individualise the dose and improve adherence to therapy<sup>18</sup>.

#### 4. IBD Smartphone Apps

Hand-held computing devices offer increased convenience of communication for patients. McCombie et al conducted a systemic review of IBD smartphone apps available for inflammatory bowel disease symptom monitoring and communication with Healthcare professionals (HCP). No apps were peer-reviewed in clinical studies. Only one used a validated symptom index. Only 4 of the apps had obvious pharmaceutical and/or HCP input in their development. Therefore, it was known whether these apps are really useful in terms of improving the medical care of the patient.

The review suggested that the SCCAI could be effectively used in apps for UC<sup>25</sup>.

An ideal IBD app would use a validated clinical index, enable electronic communication between patients and their HCP and allow patients to urgently report disease flares in an electronic manner<sup>25</sup>.

#### 4.1. IBDSmart™

The University of Otago (Dunedin, New Zealand) has developed and piloted a smart-phone app, aptly called IBDSmart™<sup>26</sup> that uses patient-completed IBD indices to allow rapid communication between IBD patients and their clinical team. The patient can complete not only the SCCAI, but also the Dudley Intestinal Symptom Questionnaire (DISQ)<sup>27</sup> and, in the case of Crohn's disease patients, the shortened Crohn's Disease Activity Index<sup>28</sup> and a modified (not yet validated) Harvey Bradshaw Index<sup>29</sup>.

"Help" function provides video and photographic guidance on how to complete the questionnaires and describes the appearance of extraintestinal manifestations. In the case of SCCAI this is based on the Guide to Self Completion which was developed in conjunction with the Crohn's & Colitis New Zealand patient group, and is appended in this article (Appendix 1). The App is now being trialed to assess its function in routine clinical outpatient care, in conjunction with point-of-care Faecal Calprotectin smart phone app developed by Bulmann (IBDoc™)<sup>30</sup>

#### 5. Summary

The SCCAI is proven to be the most robust validated clinical index in assessing disease activity in UC and response to treatment. Patient-directed application of the SCCAI correlates extremely well with physician-directed use of the same score.

Novel telemedical technologies are shown to improve patient-physician communication allowing for effective remote monitoring of UC patients, which may increase patient adherence to clinical management and reduce hospital visits. While several IBD smartphone apps have been developed, none have been tested using randomised control trials. However, “IBDsmart” is an app which is a great move forwards, using validated clinical

indices and enabling electronic communication between patient and healthcare professionals. It is currently being piloted in New Zealand with promising results. It warrants further research to investigate whether this app can be used to replace face-to-face outpatient consultations, enhance quality of life, reduce flares and improve other clinical outcomes.

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## APPENDIX

# How to complete your own Simple Clinical Colitis Activity Index.

## A guide for patients with Ulcerative Colitis.



**Ulcerative Colitis (UC)** is a chronic illness. This means that although it may not be active, it is always with you.

UC mainly causes inflammation of the colon, but other organs can be affected including the joints, eyes and skin.

### **Specific symptoms.**

Inflammation of the lining of the colon will cause you a mixture of symptoms.

- You will empty your bowels more frequently.
- You may have little warning (i.e. urgency).
- You may pass blood.

Depending on how much of the colon is affected you might also experience tiredness, weight loss, fever, tummy cramps or pain.

Some patients also experience symptoms in other parts of their body.

- Inflammation of the eyes may cause, redness, blurred vision or pain.
- The skin may show rashes which could be red or purple in colour and can be painful.
- The joints can also be affected causing swelling and pain. This most often occurs in the knees, but can also affect other joints such as the elbows, hands and ankles.

### **Treatment.**

Medicines are very effective in treating Ulcerative Colitis and keep 75% of patients symptom-free.

A wide variety of types of medicines can be used to control the inflammation. Some are tablets, some are enemas and some are injections under the skin or into a vein.

Surgery is also necessary in some cases.

Treatment of relapse of your symptoms (called a 'flare') may differ from that used to keep your colon in good health.

Early and correct treatment has been shown to shorten flare-ups and be better for you in the long term.

### **How to measure the activity of Ulcerative Colitis.**

We can get information about how active your condition is in a number of ways.

Your doctor may examine you, do blood tests, stool tests, x-rays or look inside at the lining of your colon (called a sigmoidoscopy or colonoscopy).

In addition your doctor will ask a set of questions to get a detailed idea of how your condition is. These set of questions have been put together to make the *Simple Clinical Colitis Activity Index*, which is an internationally recognized measure of Ulcerative Colitis.

### **What can you do?**

It will help both you and your doctor if you use the answers to the same questions to monitor your condition. That way the best treatment can be started at the right time.

An explanation of how to complete these questions is set out on the next few pages.

We suggest you complete the Simple Clinical Colitis Activity Index if;

- you think your condition is getting worse (a 'flare')
- before your next appointment with your medical team.

### The Simple Clinical Colitis Activity Index.

This next section takes you through the 5 questions that make up the Simple Clinical Colitis Activity Index.

Answer according to the symptoms you have over the *past 3 days*.

1. (a).

**How many bowel motions have you been passing during the daytime**, i.e. from waking up till going to bed to sleep for the last 3 days?

- |           |                                   |
|-----------|-----------------------------------|
| 1-3 times | <input type="checkbox"/> 0 points |
| 4-6 times | <input type="checkbox"/> 1 point  |
| 7-9 times | <input type="checkbox"/> 2 points |
| > 9 times | <input type="checkbox"/> 3 points |

1. (b).

**How many bowel motions have you been passing during night time**, i.e. after going to bed, for the last 3 nights?

- |           |                                   |
|-----------|-----------------------------------|
| 1-3 times | <input type="checkbox"/> 1 point  |
| 4-6 times | <input type="checkbox"/> 2 points |

**2. What degree of Urgency of defecation do you experience?**

i.e. When you feel the need to open your bowel, how quickly do you need to go?

- |  |                                   |
|--|-----------------------------------|
| I have no urgency at all (i.e. just as normal)                       | <input type="checkbox"/> 0 points |
| I have to hurry to the toilet  | <input type="checkbox"/> 1 point  |
| I have to go immediately   | <input type="checkbox"/> 2 points |
| I have incontinence (unable to control the urge and had an accident) | <input type="checkbox"/> 3 points |

**3. How much blood has been in your stool?**

- |   |                                   |
|---|-----------------------------------|
| None                                      | <input type="checkbox"/> 0 Point  |
| Trace – (a hint or a tiny amount)         | <input type="checkbox"/> 1 point  |
| Moderate (occasional obvious/frank blood) | <input type="checkbox"/> 2 points |
| Severe (Usually obvious/frank blood)      | <input type="checkbox"/> 3 points |

**4. General well being** – How do you feel about your general health?

- |                    |                                   |
|--------------------|-----------------------------------|
| Very well          | <input type="checkbox"/> 0 point  |
| Slightly below par | <input type="checkbox"/> 1 point  |
| Poor               | <input type="checkbox"/> 2 points |
| Very poor          | <input type="checkbox"/> 3 points |
| Terrible           | <input type="checkbox"/> 4 points |

**5. Do you have any of the following symptoms apart from your bowels?**

(a). **Joint problems;** have you had painful, red or swollen joints?

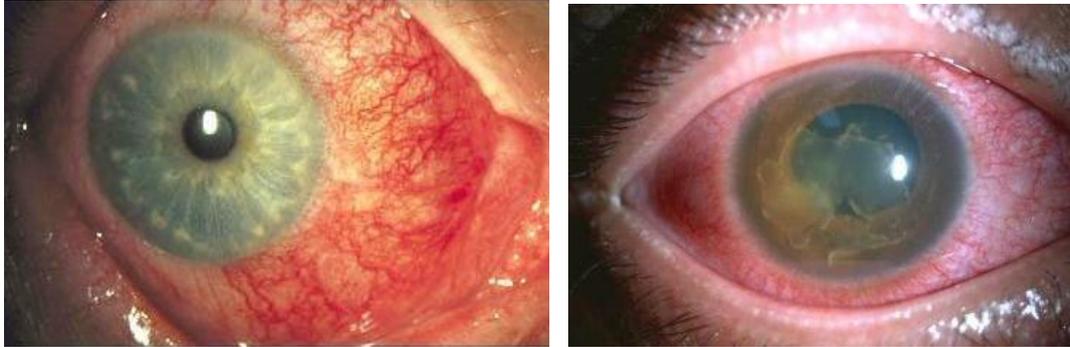
The most common joints affected are the knees, ankles or toes.

1 point

(b). **Eye problems;** have you had sore, red and swollen eyes?.

Other symptoms include blurry vision, sensitivity to light, floaters or increased tear production?

\*



1 point

**Note:** If you have a **painful red eye** or if you have been diagnosed with **uveitis, episcleritis** or **scleritis** and recognize a flare of your symptoms. **Seek medical help urgently.**

(c). **Mouth problems;** The most common problems are round or oval mouth ulcers which usually appear as round yellowish elevated spots surrounded by a red halo.

\*\*



1 point

**(d). Skin problems:**

**Do you have any deep, purple ulcers, often painful, which usually develop suddenly ?**

\*\*\*



\*\*



1 point

**Do you have any tender, hot and red bumps which most often affect the skin on the shins, arms and legs ?**

\*\*



1 point

**(e). Perianal problems.**

**Do you have any tears or breakdown (crack/ cleft) in the skin of the anus or tender lumps (abscesses) surrounding it?**

1 point

**Your Simple Clinical Colitis Activity Index Score is the sum of all the points added together.**

• Your **Total Score** : \_\_\_\_\_

**Contact numbers and useful links:**

Your IBD specialist nurse;

Tel:.....

Fax:.....

Email:.....

Your specialist doctor;

Tel:.....

Fax:.....

Email:.....

**Acknowledgments,**

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SMOG score 14.5 (<http://www.niace.org.uk/misc/SMOG-calcula>)