# Measurement of Pain in Irritable Bowel Syndrome

Subjects: Allergy

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Irritable bowel syndrome (IBS) affects a significant number of people. It is characterized by abdominal pain, bloating and an irregular bowel habit, varying from constipation to diarrhea. It can affect up to 8.8% of people worldwide and, in all countries, it affects women more often than men with a ratio of 1.4:1.

pain measurement irritable bowel syndrome patient outcomes

## 1. Introduction

Pain and issues with constipation or diarrhea can affect patients two thirds of the time, with pain being commoner and present half of the time [1]. Indeed, antispasmodics for pain relief are the commonest drug prescribed for people with IBS [2]. However, the therapeutic approach adopted for the management of IBS needs to include effective regularization of bowel habit and control of the elusive symptom of bloatedness. Bloating is a cause of distress to many patients, but its definition is problematic and its role as a symptom varies across cultures and ethnic groups.

The diagnosis of IBS has always been problematic, and this is reflected in the range of names under which it has been described, including spastic colon and mucous colitis. However, it was not until the 1970s that there were attempts to establish clear diagnostic criteria for IBS by means of a questionnaire [3]. Chronic abdominal pain was identified as a major diagnostic feature of IBS following on from this study. Relief of pain with a bowel movement, and more frequent and looser stools at the onset of pain were also identified as significant features. An international movement towards developing a standardized definition of IBS emerged [4]. The Rome Foundation, based in Raleigh, USA, supports work on disorders in which there is a Gut Brain interaction. Between 1989 and 2016 it has published four updates on diagnostic criteria for such functional gastrointestinal disorders. The current criteria embodied in Rome IV are stricter than earlier versions and for IBS require:

“Recurrent abdominal pain, on average, at least 1 day/week in the last 3 months, associated with two or more of the following criteria:

- Related to defecation;
- Associated with a change in frequency of stool;
- Associated with a change in form (appearance) of stool.”

These symptoms need to be present for at least three months with an initial onset at least six months earlier [4]. In essence, they are now little different to the original criteria proposed by Manning et al. [3] with pain as the dominant feature. A central problem has now become how best to measure such pain in a reliable, reproducible and robust format.

## 2. Measurement of Pain in IBS

Despite the importance of pain to patients with IBS, clear questions have not been developed for use in IBS trials. Terms such as “relief of your IBS symptoms” have been used to measure efficacy, but they are not an objective end-point [5]. Regulatory agencies have been generally dissatisfied with such soft end-points which generate a simple “Yes” or “No” [6]. Such requirements have acted as stimuli to the development of reliable and reproducible tools with more nuanced outcome measures. Lackner et al. [7] have shown that, although recall of specific symptoms, such as worst pain or stool frequency, is reasonably accurate, this is not the case for typical pain, which is vulnerable to distortion. Consequently, tools need to be used contemporaneously throughout the period of treatment. As a result of such requirements, the number of validated IBS specific tools is limited. Those that exist tend not to be pain specific but evaluate a range of other symptoms.

In 1997, Francis et al. [8] developed the Irritable Bowel Severity Scoring System (IBS-SSS). It was the first simple method of monitoring the progress of the disease and its treatment. The questionnaire evolved and was simplified over a number of years, rather than being developed from formal patient involvement. It has nine stem questions of which three concern abdominal pain or discomfort. Five questions have scores of between 0 and 100 each, based on visual analogue scales. A score below 75 is seen in healthy people or those in remission, whilst 75–175 indicates mild disease, 175–300 moderate disease and over 300 severe disease.

IBS-SSS is frequently used in clinical trials to monitor the progress of the disease and treatment effect. However, there are several concerns regarding its use. It is an unwieldy 4-page document and when its readability is scored with on-line software, such as that provided by https://readabilityformulas.com/ (accessed on 26 July 2021), the Flesch Reading Ease Score is 64.5, which is generally considered suitable for a person with an average reading age, ref. [9] whilst the Gunning Fog Index is 11.1 indicating that it would be considered a “Hard Read” [10]. Both indices are of American origin and consider sentence length and word complexity, but have been generally accepted as useful tools in assessing healthcare literature [11]. Such scores mean that a significant number of people in the UK will have difficulties understanding the text [12]. It is possibly for these reasons that in clinical practice, and in many research protocols, only the first part of the document, which consists of five simple and quick questions is used.

The Irritable Bowel Syndrome Quality of Life (IBS-QOL) instrument measures quality of life [13]. The development of this questionnaire and its translation was driven by Novartis Pharmaceuticals Corporation and its agents [14]. It is easier to read and faster to complete than the IBS-SSS, with a Flesch Reading Ease Score of 76.6 (“Fairly easy to read”) and a Gunning Fog Index of 5.1 (“Easy to read”). It measures psychological well-being, rather than function, and has been translated into several languages. It has 34 items with a 5-point response scale. Although many of the 34 items could be affected by pain, it is not specifically mentioned and so is of limited value in the specific assessment of this symptom.

International concerns about the need to have adequate tools to measure outcomes led to the Food & Drug Administration issuing Patient Reported Outcomes. (PROs) in 2009 [6]. They consider that good PROs and their appropriateness require no intervention or interpretation by clinicians or anyone else. In clinical trials good PROs can be used to measure the effects of an intervention on a single symptom or group of symptoms, or on daily functioning or the severity of a disease. They thus meet the basic requirements for the lived experience of patients. Therefore, in IBS, it will be necessary to define whether pain relief is the main desired outcome or a global improvement in pain, bloating, defecation habit and ability to live a normal life are the desired endpoints.

An important aspect in the development of a PRO, which was flagged up in the FDA advice, was the way in which it originated. Patients are crucial. Through mechanisms, such as interviews and focus groups, PROs can be designed to capture what matters to patients and so are valid. For such reasons, the FDA recommended that when individual scores are added together to give a single overall score it is important that the score represents a recognizable domain rather than being an artificial entity [6]. Kitzinger [15] confirmed the need to ensure focus groups represented a cross section of society, either through use of multiple groups or, less favorably, one group with a widespread membership. However, the Gastrointestinal Pain Pointer, which is an electronic tool developed with the help of patient and control groups representative of Caucasians, African Americans and Asians is the only instrument where this has been attempted [16]. There have been no studies where it has been used in clinical trials of treatment. A further issue has been that in a number of studies, there has been a failure to recognise that an instrument cannot be simply translated and used in a new culture. Failure to validate the translation means that the result of such a study cannot be relied on.

## 3. Perceptions of Pain in IBS

The issue of how patients of different ethnicities view pain and bloating is an important aspect of their assessment, which has received little attention in the field of gastroenterology. Others, who have considered the issue, have often stereotyped communities. For example, as recently as 1985 Wolff [17] wrote: “Scandinavians are tough and stoic with a high tolerance to pain; the British are more sensitive but, in view of their ingrained “stiff upper lip”, do not complain when in pain; Italians and other Mediterranean people are emotional and overreact to pain and Jews both overreact to pain and are preoccupied with pain and suffering as well as physical health”. However, extensive clinical and laboratory pain research has confirmed that ethnic groups differ considerably in their response to and expression of pain [18].

Wise et al. [19] have shown that women report lower thresholds and tolerance compared to men and endure pain for less time and are more willing to report pain. Pain also appears to have different meanings for men and women [20]. In a survey, conducted by the United States National Center for Health Statistics, men and women reported differing symptomatology, different pain levels and different analgesic usage associated with the same disease process [21][22]. In a study of startle reactions male patients had reduced sensorimotor gating, suggesting a decreased ability to filter information; in contrast, female IBS patients had enhanced prepulse inhibition, possibly related to increased vigilance and greater attention to threat [23]. However, this difference was abolished by the oral contraceptive pill or the menopause. In a related study Chang et al. [24] was able to demonstrate that premenopausal women with IBS had a lower threshold of response to noxious rectal stimuli than men.

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