

TECHNICAL NOTE

Technical report: an ePRO patient reported outcome program for the evaluation of patients with irritable bowel syndrome

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Key Messages

- Irritable bowel syndrome patients are amenable, via a specially designed ePRO program, to evaluation away from the office in a manner that enhances understanding of their progress over time.
- This study was designed to determine the feasibility of a novel ePRO program that required patients to complete questionnaires at regular intervals at home over a six month time period.
- Software was designed so questionnaires, completed by patients on their own computers, were automatically summed and placed on a time-line graph for review during medical visits.
- Results demonstrated that this method allowed measures to be recorded at about twice the frequency of office visits, doubling the data points tracking clinical progress. It was positively experienced by the patients and facilitated and clarified their progress, leading to improved collaboration between physician and patient.

Abstract

Background Patient reported outcome (PRO) is an important healthcare concept that describes patient's participation in their care by self-evaluation, usually in the form of questionnaires. This report describes an unique computerized technique, electronic PRO (ePRO), for following the progress of patients with irritable bowel syndrome (IBS). **Methods** Patients first completed a series of questionnaires, including questions about their illness history, symptom severity, and, in this application, psychological and relationship issues. The symptom severity and psychological

questionnaires were then completed at intervals by the patients on their own computers. The ePRO was constructed to allow scores to be automatically summed and placed on a time-line graph for review at the time of the next office visit. **Key Results** Of the 32 patients who completed the initial set of questionnaires, 20 maintained participation in the program for a 6-month period. Of those 20 patients, median number of submissions was 7.0; median interval between questionnaire submissions was 3.0 weeks, whereas median interval between office visits was 5.9 weeks. On average, questionnaire completion took less than 5 min and was positively experienced by the patients. **Conclusions & Inferences** The ePRO program proved to be technically feasible, clinically useful, and positively experienced by the patients. It provides a focus on a collaborative conversation between physician and patient. It has significant potential as a technique for evaluating outcome in response to various therapies.

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Abbreviations: ePRO, electronic patient reported outcome; IBS, irritable bowel syndrome; SSS, symptom severity scale.

Patient reported outcome (PRO) describes direct patient participation in their health care, by means of self-evaluation, usually with the use of questionnaires. In this report, a unique computerized electronic PRO (ePRO) method is described, wherein patients with irritable bowel syndrome (IBS) completed questionnaires on their own computers in a manner that allowed scores to be automatically graphed for review in a physician’s office. The purpose was to improve assessment of a patient’s clinical course, to empower patients, and to provide insight concerning a patient’s progress, or lack of, to patient and physician.

MATERIALS AND METHODS

New patients who met Rome III criteria¹ were offered the opportunity to participate. The only requirement was computer access. Patients were told that their willingness to participate had no bearing on their continuing care. This project has been approved by Mount Sinai Hospital’s Institutional Review Board.

If the patient agreed, he or she entered their log-in and password on a computer in the office, in order to establish their own secure page. Patients then answered a series of questions regarding their IBS history (Table 1) and two questionnaires, the IBS symptom severity scale (SSS)² and a Psycho-Social Questionnaire created for this ePRO (Table 2). Scoring of the psychosocial questionnaire is divided into two parts. The first two questions represent the effect of symptoms on the patient’s psychological experience, and the last two represent the effect of psychological experience on symptoms. Maximum score for each is 20 points.

Every 2–3 weeks, patients were sent e-mail reminders asking them to answer the questionnaires. When no response was received, reminders were sent again at the same intervals twice more. If patients did not respond, no further reminders were sent.

The main advantage of the computer program is the automatic summing and graphic representation of questionnaire scores. The second advantage is the ability to ascertain a patient’s progress while they are away from the office. At office visits, changes in scores, and the relationship between the three graphs, are reviewed. At the bottom of each patient’s secure page, notes can be entered at each visit.

The administrator’s page has a list of all patient participants, with a search option, a record of number of data entries for each patient, last entry date, and a reminder button which sends an e-mail to the patient with the desired questionnaires. The ePRO is programmed to record when the patient last entered his/her questionnaire and stops him/her from completing a new questionnaire if the last questionnaire had been filled within 14 days. Entering a patient’s site provides easy access to all of their questionnaires as completed and previous notes. An excel data program keeps track of dates when questionnaires have been filled out and dates when reminders have been sent.

Table 1 IBS history

IBS HISTORY:

Number of Years with IBS Symptoms: _____

Number of Gastroenterologists already seen: _____

Family History of IBS: _____

Current Medications:

Prescription (including psychiatric medication):

Over The Counter: _____

Current psychotherapy (How Long; Kind of Therapy):

Past psychotherapy (How Long; Kind of Therapy):

Acupuncture and other forms of Complementary Treatment:

Prior gastro-intestinal evaluation:

Colonoscopy: _____

Gastroscopy: _____

Capsule endoscopy: _____

CT scan of the abdomen: _____

Abdominal surgery: _____

Technical aspects

The PRO portal uses state of the art technology called Ruby on Rails (http://en.wikipedia.org/wiki/Ruby_on_Rails), which is more powerful and robust than traditional technologies. This new technology wraps in HTML5 and CSS3, both of which are new technologies, to display the content on the website’s pages. These new technologies are compatible and goes hand in hand with all latest browsers such as Firefox, Chrome, and Internet Explorer 10 to name a few. The portal also uses MySQL (<http://en.wikipedia.org/wiki/MySQL>) as the primary data store, which again plugs in well with Ruby on Rails. The portal puts very little load on the browser so any computer with bare minimum configurations can run the portal.

The portal is currently hosted on a cloud server at Heroku (<http://heroku.com>) that provides MySQL databases for the portal as well. The portal is built on robust software architecture platform, which enables any software engineer to add more features with ease. An app is currently being developed for this ePRO to enhance patient compliance.

RESULTS

A total of 32 patients completed the initial questionnaires and 20 patients sustained participation through

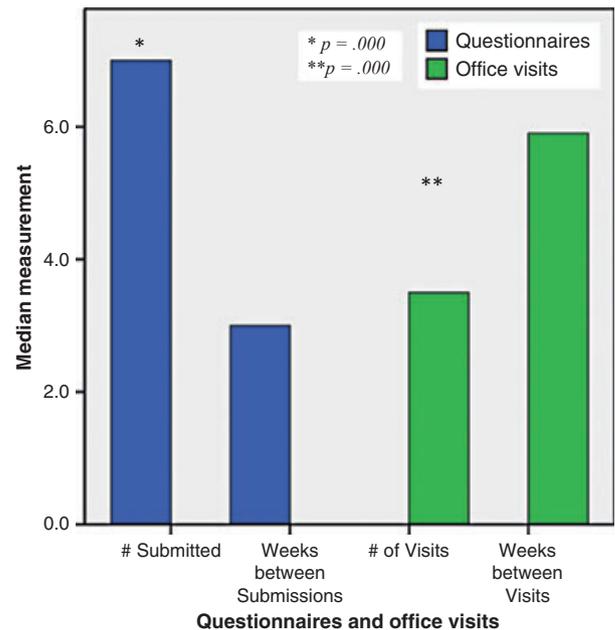
Table 2 Psycho-social questionnaire

Psycho-Social Inventory						
Respond to each question by indicating how much you agree or disagree with it using the following scale						
	1	2	3	4	5	
	Strongly disagree	Disagree	Neutral/mixed	Agree	Agree strongly	
1. How much did your symptoms interfere with your quality of life this month?						
Social Life:		1	2	3	4	5
Work Life:		1	2	3	4	5
Family life (if relevant):		1	2	3	4	5
2. How well do you think you coped with your IBS symptoms this past month? Rate your effectiveness:						
		1	2	3	4	5
3. Did you feel supported in your illness this past month? Rate how supported you felt, by:						
Intimates:		1	2	3	4	5
Co-workers and boss:		1	2	3	4	5
Family members:		1	2	3	4	5

6 months. All patients who had stopped returning questionnaires had also stopped making office appointments. For the 20 patients who completed the 6 months, the number of entries ranged from 4 to 10. The median interval between entries was 3.0 weeks. This is in contrast to the median interval between office visits (5.9 weeks). The ratio of questionnaire completions to office visits was 2:1 (Fig. 1).

Results for the IBS symptom severity scale typically showed a wide fluctuation of scores over time rather than a steady slope. The two psycho-social graphs varied over time but generally mirrored each other, supporting the concept of circularity between psyche and soma.³ Variations in the IBS SSS were usually reflected in one or both psycho-social questionnaires. Figure 2 shows an example of a patient's graphically represented record with all three scales superimposed. In the office, the three graphs are seen separately.

The results were useful in a number of ways. Patients' evaluations were assessed by interview (nine patients) and questionnaire (11 patients) with a simple Likert scale. Responses were almost uniformly positive. Patient interviews yielded comments such as increased awareness of change over time and of life circumstances that affected symptoms. One patient wrote: 'The PRO questionnaires and follow-up discussions helped me focus on how the symptoms were

**Figure 1** Median interval and number of questionnaires completed vs office visits.

affecting my life and gave me some sense of how I was progressing. Very helpful'. The physician found the process had therapeutic value. In reviewing the patient's graph with them, documentation of improvement served to reinforce hopefulness about symptom reduction whereas worsening of scores sometimes rendered the patient more amenable to a change in treatment. For example, one patient agreed to psychological referral after seeing her scores worsen despite medical treatment. Patients also felt that variations in their symptoms over time were fairly accurately represented by the fluctuation patterns of their graphs.

DISCUSSION

This report describes ePRO as a useful adjunct in assessing the clinical progress of IBS patients. It is based on sequential completion of questionnaires by patients on their computers with graphic display of data for review in the office. While notes in a patient's office chart may be helpful in the assessment of progress, it may be difficult to compare a patient's clinical status over time. The ePRO allows assessment of symptoms between office visits, resulting in a significant increase in data points, about twice as many as the number of office visits, in this study. This program can also be used as an efficient way to record questionnaires at the time of a patient's log-in as

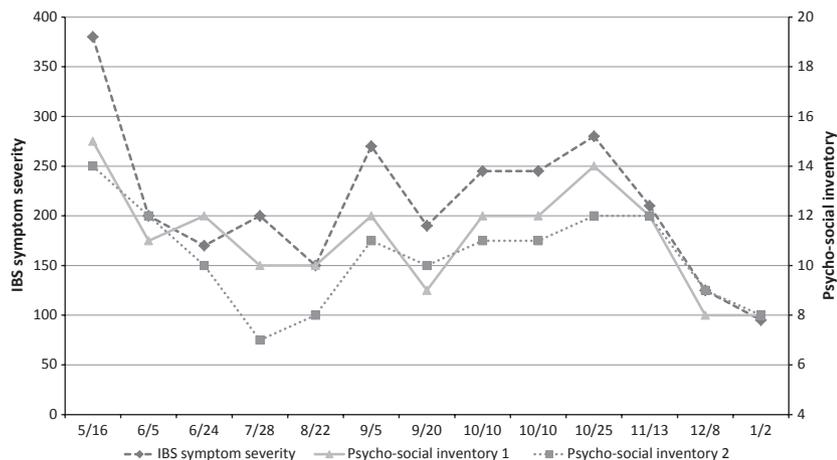


Figure 2 Graph representing a patient's symptom severity scale and psycho-social scores.

potential outcome predictors of various treatments. The ePRO proved to be technically feasible, user friendly, and clinically useful.

In this ePRO model, emotional and psychological aspects of the IBS experience were tracked. These dimensions are crucial in the course of IBS, but the physician may not have the time to fully inquire about them. Electronic patient reported outcome offers an alternative to the traditional hierarchical relationship between physician and patient.⁴ Patients directly contributing to their assessment create a sense of mastery over symptoms and help the patient feel less victimized by the unpredictability of IBS symptomatology. While the psycho-social scale was not a validated measure, patients affirmed, in their medical visits, that the graphs represented their illness experience. The main purpose of this project was to create an ePRO that could incorporate any questionnaire of interest, rather than validation of this particular questionnaire.

The use of home computers for gathering patient information has been used very effectively.⁵⁻⁸ The International Foundation for Functional Gastrointestinal Disorders with their large pool of IBS patients has surveyed large numbers of subjects.⁵ The patient reported outcome measurement information system (PROMIS), under the aegis of NIH, provides guidance in the use of PRO's.⁶ Patient reported outcome can be useful as a record of treatment effectiveness and drug side-effects in IBS.^{3,7-9}

However, there are few publications describing the quantitative tracking of patients over time.¹⁰ The most successful use of ePRO to do this is at the Dartmouth Spine Center.¹¹ Basch (2007) has utilized ePRO for tracking side-effects of chemotherapy in cancer patients.¹²

Choice of questionnaires in PRO allows great flexibility. We chose the IBS-SSS as it is the most widely used measure of symptom severity. There are obvious pitfalls in a recall system like this. Palsson, *et al.* recently published a work describing stool consistency in IBS patients over a 90-day period, as recorded with daily diaries, using a pocket diary.¹³ They concluded that daily diary records are more accurate than retrospective questionnaires such as the SSS which asks the patient to record symptoms over the previous 10 days. Lackner *et al.*¹⁴ compared daily symptom recording to weekly recall and found significant agreement for the aggregate patient population but not for each patient.

There are some limitations in this study. About one-third of subjects dropped out of the project during the 6-month observation period. These were invariably patients who had returned to the care of their referring gastroenterologists. The ePRO played no role in their decision to stop coming to our center. It is not clear whether patients were more inclined to complete their questionnaires when symptoms were better or worse. While an occasional patient described submitting the measures when their symptoms worsened, the IBS SS improved significantly over the 6-month period for the entire group, and thus it is unlikely that intensified symptomatology affected submission. For the most part patients reported that they delayed submitting questionnaires when their daily living tasks were too numerous. We assume that conversion to a handheld app will make the process easier for patients. There is evidence that distraction from symptoms is useful in terms of pain perception.¹⁵ It may seem counter-intuitive that focusing on symptoms would be helpful to patients but many patients reported that reflecting on overall patterns made them more hopeful and less confused by their symptom course.

The psycho-social questionnaire created for this project focused on issues deemed important by the authors. The clinical importance of psychological status in IBS patients has been well documented.¹⁶ Chang¹⁷ has emphasized the importance of incorporating psychological measures along with symptom severity in a PRO designed for IBS patients. It proved useful by helping patients recognize the importance of their emotional state and the importance of having their illness understood by others.

Irritable bowel syndrome is an ideal candidate for ePRO assessment as it lacks objective markers. Other chronic conditions such as inflammatory bowel disease might benefit from an ePRO program but validated measures would have to be created that were based on symptoms that a patient could quantify. Our goal was to develop a method for enhancing patient care in IBS. We believe our program serves that purpose.

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DISCLOSURE

None for each author.

AUTHOR CONTRIBUTION

CG conceived the project, collected and analyzed the data, helped draft the manuscript; MJG conceived the project, analyzed the data, helped draft the manuscript.

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