Assessing patients’ satisfaction with anti-TNFα treatment in Crohn’s disease: qualitative steps of the development of a new questionnaire

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Purpose: To develop a self-administered questionnaire assessing patients’ satisfaction with treatments in Crohn’s disease for use in clinical research and epidemiological studies.

Patients and methods: Semi-directive interviews (16) were conducted with patients with severe Crohn’s disease treated with anti-tumor necrosis factor alpha (anti-TNFα). Transcripts were analyzed and concepts related to satisfaction with treatment were extracted and organized into a model. Items were generated using patients’ words. The resulting test version was tested for relevance and comprehension with 7 patients and revised accordingly; the new version was tested with 5 other patients and revised to provide the pilot version. A clinician advisory board was involved at each milestone of the development.

Results: The test questionnaire assessed treatment satisfaction through 67 items, organized into 5 sections: treatment efficacy, side-effects, convenience and constraints, overall impact, and satisfaction. Conceptual content of the questionnaire includes comparison with prior state and with expectations, satisfaction, acceptability, and intentions. The questionnaire was generally well accepted and understood by patients; few modifications were made in the structure and item formulation. After the second round of comprehension tests, the pilot version contained 62 items; the questionnaire was named Satisfaction of PaTients in Crohn’s diseasE (SPACE©).

Conclusion: The questionnaire is a unique tool to assess treatment satisfaction in patients with Crohn’s disease. A scoring and validation study is currently being performed to finalize and establish its scoring, as well as its psychometric properties.

Keywords: Crohn’s disease, anti-TNF treatment, questionnaire, patient satisfaction, patient-reported outcome

Introduction

Crohn’s disease (CD) is an idiopathic, chronic, inflammatory disease of the gastrointestinal tract characterized by intermittent flares. Typical manifestations of CD include diarrhea, abdominal pain, weight loss, rectal bleeding, and fever,1 and can lead to complications such as strictures, abscesses, and fistulae.2 The growing importance of this disease and its debilitating nature explain the need for efficient treatments to limit its impact on patients’ lives.

Conventional CD treatments include 5-aminosalicylates, corticosteroids, and immunosuppressant treatments,3 and more recently the anti-tumor necrosis factors alpha (anti-TNFα) such as infliximab or adalimumab.1 Anti-TNFα have shown good efficacy over the past years in the induction and maintenance of remission in CD.4,5 They represent a considerable advance in CD management,6 improving both the clinical aspects of the disease and the patients’ health-related quality of life (HRQL).4,7,8
Even though CD therapies have similar efficacy and safety profiles, they differ in terms of mode and constraints of administration, leading to different convenience profiles.

As the peak period for the onset of CD is in the second and third decades of life, many patients with CD are young adults. Perception of treatment and its constraints, as well as satisfaction with treatment, may thus play a particularly critical role in the management of CD. For example in a recent study, 40% of patients with CD aged 40 years on average described the treatment as moderate or bad.

To investigate patients’ satisfaction with their medication is of relevance in order to improve and adapt their pharmacological management, and to help to improve adherence to treatment. Patient perspective and more largely qualitative research are acknowledged and essential in the field of CD. Quality-of-life studies were performed in inflammatory bowel diseases in clinical trials, HRQL was used as a secondary endpoint. However, no study has assessed patients’ satisfaction in CD. A recent prospective study showed that despite the preference of CD patients for adalimumab versus infliximab for maintenance, a proportion of patients returned to infliximab due to intolerance, supporting the importance of patients’ outcomes in patients’ behavior towards CD’s therapeutics and their efficacy.

Satisfaction is defined as an emotive evaluation which enables the assessment of the appropriateness of the perceived quality of treatment with expectations. Satisfaction is different from HRQL, which covers physical, psychological, social functioning, and somatic sensations. For this reason, instruments developed to measure HRQL cannot be used to assess patients’ satisfaction with their treatment. Satisfaction with medication, as defined by Shikiar and Rentz, is “the patient’s evaluation of the process of taking the medication and the outcomes associated with the medication”. This is thus a specific subdimension of treatment satisfaction, which encompasses both medicinal and nonmedicinal aspects of treatment (eg, relationship with physician). In our work, we explored specifically satisfaction with medication.

To our knowledge, no specific instruments exist that assess patients’ satisfaction with anti-TNFα therapeutics. Those questionnaires used in the field of CD either do not evaluate satisfaction with anti-TNFα treatments specifically and are not designed to be used with severe CD condition, such as the Treatment Satisfaction Questionnaire for Crohn’s disease (TSQ-C); or are specific to CD treatments but assess HRQL rather than patients’ satisfaction, such as the Inflammatory Bowel Disease Questionnaire and the Rating Form of Inflammatory Bowel Disease Patient Concerns. Other available instruments such as the Treatment Satisfaction Questionnaire for Medication (TSQM) and the Treatment Satisfaction with Medicines Questionnaire (SATMED-Q) are generic satisfaction questionnaires.

Our aim was to develop a specific self-administered questionnaire to assess patients’ satisfaction with anti-TNFα treatments in CD for use in clinical research studies and epidemiological studies. This paper focuses on the qualitative steps of the questionnaire development with respect to the current methodological standards.

Materials and method
Clinical advisory board
A clinical advisory board composed of 7 clinicians experienced in the field of CD management, working either at hospital, in secondary care, or at university, was set up at the beginning of the study.

The role of the clinical advisory board was to provide clinical expertise throughout questionnaire development and to ensure its clinical relevance, to validate study documents and decisions made at each milestone, and to review the questionnaire.

Exploratory phase: literature review
A literature review was carried out to identify existing questionnaires assessing patient satisfaction with CD treatments or with anti-TNFα treatments. Search was conducted in biomedical databases (Embase, MEDLINE) from 2005 to 2008, the patient-reported outcomes and quality of life instruments database (ProQolid), as well as abstracts from patient-reported outcomes conferences (International Society for Quality of Life Research, International Society for Pharmacoeconomics and Outcomes Research) from 2005 to 2007 and from gastroenterology conferences (United European Gastroenterology Week 2006 and 2007, European Crohn’s disease and Colitis Organisation from 2006 to 2008). Abstracts were selected if they included information on patients treated with anti-TNFα treatments or if they involved patients with CD or inflammatory bowel disease reporting their satisfaction or preference.

Development of the conceptual model of the questionnaire
All the patients gave their informed consent to participate in the study.

In order to help define inclusion criteria and content for the second set of patient interviews, 3 patient interviews were performed to gather patients’ perception and experience of
anti-TNFα treatments in CD. Gastroenterologists recruited voluntary male and female patients diagnosed with CD and treated either with infliximab or adalimumab for at least 3 months. Interviews were conducted face-to-face using exploratory questions on treatment: expectations, satisfaction, perceived constraints, efficacy and side-effects, impacts of treatment.

Based on information retrieved during this first set of patient interviews, a specific interview guide was developed to carry out a second set of 13 exploratory patient interviews in order: 1) to gather information on patient experience with anti-TNFα treatments in CD and their impact on every day life; 2) to gather patients’ words to develop the items of the questionnaire. The second set of patients (n = 13) was recruited by 6 gastroenterologists. Patients had been diagnosed with CD for at least 2 years, having been treated either with infliximab or adalimumab for at least 6 months, and treated with corticosteroids at least once for their CD. A psychologist performed the exploratory face-to-face interviews using a semi-directive interview method. The aim of this approach was to offer speaking time to interviewees by means of open questions, to enable patients express their perception of the advantages and disadvantages of their anti-TNFα treatments.25

The 13 exploratory interviews were analyzed using a thematic approach. The significant elements of patients’ speech expressing concepts directly or indirectly related to patient satisfaction with their anti-TNFα treatments were extracted: experience related to satisfaction, comparison between previous expectations and real experience leading to satisfaction, satisfaction as such, or expressed in terms of acceptability or intentions. Concepts related to quality of life or disease impact were not extracted, as they were not related to satisfaction with medication. At this stage, a detailed conceptual model of patients’ satisfaction was developed and agreed on during a meeting with the clinical advisory board and patient-reported outcomes experts. Concepts to be measured in the future questionnaire were selected at that step, based on their clinical relevance (according to the clinical advisory board members), and their importance from a patient perspective (according to the team who participated in the patients’ interview conduct and analysis).

Development of the pilot version of the questionnaire

Item generation

Based on the identified concepts related to patients’ satisfaction that had to be assessed, the team involved in conducting and analyzing the exploratory phase and patient interviews generated items in French using patients’ own words to provide the first test version of the questionnaire.

Comprehension tests

The content validity of the questionnaire was tested during comprehension interviews to check the acceptability and relevance of the questionnaire for patients with CD. Ten patients were recruited by gastroenterologists according to the same inclusion criteria as for the second set of patient exploratory interviews; 2 other patients were recruited if they had been diagnosed with CD for at least 2 years, and if they were treated with corticosteroids. A psychologist conducted face-to-face interviews. Patients were asked to comment on their understanding of each item and to suggest alternative formulations in the case of problematic wording. The comprehension test methodology followed an iterative process: a first set of 7 patients was interviewed, modifications were made to the questionnaire according to the patients’ suggestions, and the resulting version was tested during interviews with 5 other patients, following the same methodology.

Pilot version

After analysis of the second set of interviews and last modifications made to the second test version, the pilot version of the questionnaire was issued in French.

Results

Exploratory phase: literature review

Four questionnaires assessing patient satisfaction with CD treatments or with anti-TNFα treatments were retrieved from the literature review: 1) a questionnaire developed by Chilton and Collett in 2008, assessing preferences of patients with rheumatoid arthritis (RA) with 3 treatment options;26 2) the Self-Injection Assessment Questionnaire (SIAQ), developed in 2007, assessing the perceived advantages of self-injection and potential limitations of self-injection in RA and CD;27 3) a specific questionnaire developed by Kivitz et al in 2006, assessing preference of patients with RA between 2 treatment devices;28 and 4) the TSQ-C developed in 2005, assessing the satisfaction with pharmacological therapy in patients with mild to moderate CD.29 However, none of them aimed at evaluating specifically patients’ satisfaction with anti-TNFα treatments in CD.

Development of the conceptual model of the questionnaire

The first 3 patient interviews confirmed the feasibility of the qualitative approach, as well as the relevance of the con-
cept of satisfaction to be explored. Their analysis identified areas of interest in severe CD treated with anti-TNFα. These themes were further explored with the second set of 13 patients: experience of both past and current treatments, ie, efficacy, side-effects, and perception of constraints of treatment, as well as impact of these treatments and overall satisfaction. Table 1 summarizes sociodemographic and clinical characteristics of the patients interviewed during the exploratory phase. Age and level of education of each group was represented through the 13 interviewed patients, and the majority were professionally active. The median disease duration was 6 years, and the majority of the patients were treated with infliximab (8 out of the 13; the remaining 5 were treated with adalimumab) (Table 1).

A total of 595 concepts and subconcepts were extracted from the patient interviews. Their thematic analysis revealed 6 main groups of concepts directly or indirectly related to patient satisfaction with anti-TNFα treatments: efficacy (eg “I feel much more better”), side-effects (eg “There is always an unpleasant effect”), convenience (eg “I can do it in my room as well as I can in my kitchen”), mode of administration (eg “What I like are the little pencils”), treatment impact (eg “I’m full of energy again”), and overall satisfaction (eg “I’m happy with it”). The different treatment attributes were all expressed in terms of experience, and compared with previous expectations to form a satisfaction evaluation. The detailed concepts corresponding to these groups of concepts were further discussed with the clinical advisory board: 5 global concepts and 41 corresponding detailed concepts were selected and agreed on for measurement using the future questionnaire. General concepts covered efficacy, side-effects, convenience and constraints (including the previous “mode of administration” general concept), overall impact, and satisfaction.

**Development of the pilot version of the questionnaire**

**Item generation**

Item generation resulted in the first test version of the questionnaire containing 57 items in French organized into 5 dimensions: efficacy (16 items), side-effects (7 items), convenience and constraints (13 items), overall impact (8 items), and satisfaction (13 items). Answer choices were 4- and 5-point Likert-like scales. For questions on symptoms (6 items), each item was divided into 2 questions: the first one assesses whether the symptom was present in the past using a dichotomous answer choice; in the case of a positive answer, the second one assesses how the medication has been effective on the symptom using a Likert-like scale.

**Comprehension tests**

Each age group and level of education were represented among the 12 patients who participated in the comprehension
tests (Table 1). During the first set of comprehension tests, the 7 patients found the questionnaire easy to understand, easy to answer, and well formatted. Based on patients’ suggestions, 4 questions corresponding to 4 new detailed concepts were added (intensity of attacks, speed of efficacy on attacks, work organization, and organization with children) and 1 was removed (side-effects) due to grouping of 2 questions; 13 items were slightly reformulated to improve patients’ understanding; and a few modifications were made on format and structure of the questionnaire to provide the second test version containing 60 items organized into the same sections as the first test version. Based on the second set of 5 patients’ suggestions, 2 questions corresponding to 2 new detailed concepts were added (efficacy of relief from attacks, reassuring mode of administration), and minor modifications similar to those made on the first test version were made on the second test version to provide the pilot version of the questionnaire.

Pilot version

Finally, the pilot version of the questionnaire contained 62 items organized into the same 5 dimensions as the test versions: efficacy (19 items), side-effects (6 items), convenience and constraints (16 items), overall impact (8 items), and satisfaction (12 items). The questionnaire ends with an open-ended question on patients’ expectations of a potential future treatment. The detailed item content of the pilot questionnaire is presented in Table 2. Among the 62 items, 45 are defined as “factual” questions (eg, “With my current treatment, my disease is stabilized”), and the 17 remaining are defined as “evaluation” questions (eg, “Today, are you satisfied with the efficacy of your treatment?”). These “evaluation” questions are related to comparison with expectations, acceptability, and overall satisfaction. The questionnaire is to be filled out by the patients at study visits; time for completion should be about 10 to 15 minutes.

As the questionnaire is intended to measure patients’ satisfaction with treatments in CD, the questionnaire was called SPACE© questionnaire (Satisfaction of PAtients with Crohn’s disease). The pilot version of SPACE© is currently being validated.

Discussion

In the past 5 years, anti-TNFα has become a cornerstone in the management of CD refractory to conventional treatment algorithms.30 Randomized controlled trials have shown their efficacy for active CD;3,4 several studies demonstrated that

<table>
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<th>Table 2</th>
<th>Pilot questionnaire version item content (concepts and detailed concepts measured by dimension)a</th>
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<tr>
<td>Dimensions (no. items)</td>
<td>Item content</td>
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<tr>
<td>Efficacy (19 items)</td>
<td>Psychological well-being</td>
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<td>Physical well-being</td>
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<td>Speed of improvement</td>
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<td>Overall well-being (2 items)</td>
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<td></td>
<td>Crohn’s attacks (4 items: frequency, intensity, efficacy, speed of efficacy)</td>
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<td>Diarrhea</td>
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<td>Abdominal pain</td>
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<td>Incontrollable need to defecate</td>
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<td>Comparison to expectations</td>
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<td>Comparison to expectations</td>
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<td>Acceptability</td>
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<tr>
<td>Convenience and constraints (16 items)</td>
<td>Mode of administration (7 items): type, practical, constraining, unpleasant, reassuring, worrisome, easy</td>
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<td></td>
<td>Organization constraints (7 items): travel, medical appointments, time, costs, conservation, work, children</td>
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<td>Comparison to expectations</td>
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<td>Acceptability</td>
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<td>Overall impact (8 items)</td>
<td>Impact on mood</td>
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<td>Impact on energy</td>
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<td>Impact on physical status</td>
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<td>Impact on professional life</td>
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<td>Impact on family life</td>
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<td>Impact on social life</td>
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<td>Overall impact on life</td>
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<td>Efficacy on Crohn’s attacks</td>
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<td>Overall evaluation</td>
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<td>Expectations toward new treatment</td>
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Notes: *Item content presented in this table was translated into English, but did not follow a linguistic validation process at this stage.*
HRQL of patients with CD treated with anti-TNFα was improved.2,8,17 Nevertheless, the burden of these treatments’ administration should be considered when choosing among different anti-TNFα medications. Perception of the different constraints of administration and other attributes of treatment (efficacy, side-effects) can widely differ among patients; these differences in patients’ perceptions can be captured through the assessment of patient satisfaction with medication.

Research has widely focused on the pathophysiology and management of the disease. Some studies assessed patients’ perceptions on benefits and risks of anti-TNF treatments;31,32 but to our knowledge, satisfaction with treatment has been poorly reported in the literature.10 The SPACE© questionnaire is thus the first tool to assess patient satisfaction with anti-TNFα treatment in CD. Even though focused on anti-TNFα treatment, the profile of patients who have been involved in the design of the questionnaire should allow its wider use to a population of patients treated with alternative Crohn’s disease treatment that are the corticosteroids. One of the challenges when developing a questionnaire is to specifically address its defined topic and purpose. That is the reason why interviews were carried out using specific interview guides; this provided a framework to obtain feedback of their experience and perception of their treatment. Prior to item generation, a selection process involving both clinical and patient-reported outcomes experts was applied to select appropriate concepts and detailed concepts relevant to the purpose of the study. During patient interview analysis, concepts and detailed concepts were extracted if they corresponded to the central concept of satisfaction as such; if they corresponded to one of the determinants of satisfaction, ie, experience, either or not compared with previous expectations; or if they corresponded to the result of the satisfaction process, ie, acceptability or intentions of behavior. This ensured that the concepts to be measured in the questionnaire corresponded to one of the elements belonging to satisfaction models.31,19,21 Moreover, as all these concepts have been discussed by domain with the clinical advisory board before detailed concept selection, it is expected that there is no bias in the selection of concepts to be measured. Through its 62 items, the developed questionnaire assesses patients’ satisfaction with concepts that are important for treatment evaluation. Moreover, the questionnaire is composed of both “factual” and “evaluation” questions, with “factual questions” expected to favor reliable and valuable answers to the evaluation questions. A short form of the questionnaire including only evaluating questions could be envisaged for future use.

Another challenge in the development of questionnaires is to ensure the reproducibility of the work. The SPACE© questionnaire was developed following a well-established qualitative methodology involving predefined objectives and hypothesis on satisfaction with anti-TNFα treatment in CD, which should ensure the reproducibility of the results.21,24 The first set of 3 patient interviews confirmed the applicability of the thematic approach; moreover, the involvement of the clinical advisory board at each milestone of questionnaire development (patient inclusion criteria, choice of concepts to be measured, and validation of modifications) ascertained the clinical relevance and the consolidation of the results.

To ensure item appropriateness, specific attention was paid to ensure that patients included in the questionnaire development corresponded to those patients targeted for future use of the questionnaire, ie, patients with CD treated either with anti-TNFα or corticosteroids. Two comprehension tests were thus realized with patients treated with corticosteroids. The usefulness of qualitative research has already been recognized in the field of inflammatory bowel diseases.13 Following this rigorous methodology while developing the SPACE© questionnaire allows patient perspective to be adequately captured.

One limitation that should be noted at this stage is the absence of a formal saturation process.33 However, it was noted when analyzing the second set of patient interviews that the analysis of the last 2 interviews did not reveal any additional concepts related to satisfaction with treatment compared to the content of the first 11 interviews. Moreover, interviews of 3 experienced nurses and 3 gastroenterologists in a preliminary phase supported the identified concepts and did not show any additional concepts compared with those of the exploratory patient interviews (data not shown). In addition to the participation of the clinical advisory board in the choice of concepts to be measured, this guaranteed the comprehensiveness of the conceptual content of the SPACE© questionnaire, both from the patient and clinical perspective. Finally, the comprehension tests carried out with patients confirmed the relevance of the questionnaire content in the context of CD treated with anti-TNFα or corticosteroids; they also improved overall comprehension of the questionnaire and guaranteed acceptability thanks to the iterative process used. One could also argue the French nature of the study as another limitation of the questionnaire as other cultures might not consider the same attributes to define their satisfaction with anti-TNFα treatments. In case the questionnaire is to be used in non-French studies, it will need to be validated in this country.
Other questionnaires evaluating satisfaction with treatments are used in the field of CD. Among these, TSQ-C is a disease-specific questionnaire evaluating patients’ satisfaction with pharmacological treatment in CD. However, this questionnaire aims at evaluating satisfaction of patients with mild to moderate CD, thus considering treatments that differ from anti-TNFα prescribed in more severe CD. It also measures concepts different from satisfaction with medication itself (e.g., satisfaction with their relationships with their physician or preference between different treatments). Moreover, the TSQ-C was developed from a gastroesophageal reflux disease-specific questionnaire by item reduction, without involving patients in its qualitative development process.

TSQM and SATMED-Q are 2 other satisfaction questionnaires used to assess patient satisfaction with treatment in various areas, including CD. The TSQM was designed to measure patients’ satisfaction with different types of medication and with different types of patient populations, whereas the SATMED-Q was developed to be used in chronic patients undergoing pharmacological treatment for any disease. The first questionnaire assesses effectiveness, side-effects, convenience, and overall satisfaction with treatment, and the second assesses the same domains with additional questions on the effect on daily activities, and patient satisfaction with medical care. However, both these satisfaction questionnaires are a generic measure of patient satisfaction and do not specifically assess patient satisfaction with anti-TNFα in severe CD, as does the SPACE© questionnaire.

Numerous studies have shown the relationship between patients’ satisfaction and treatment compliance, or at least intentions to or persistence in taking medications. It can thus be expected that satisfaction with medication is related to patient adherence to prescription regimens. As the adverse decisional consequences of low treatment satisfaction on medication compliance is of particular concern to caregivers treating patients with chronic conditions, measuring patient satisfaction with medication is of particular interest in severe CD to assess treatment benefits, or to understand the needs and expectations of patients.

The SPACE© questionnaire has been translated into French for Canada, English for Canada, Greek, and Portuguese following a backward and forward standard linguistic validation process. This will facilitate its use in international studies. The SPACE© questionnaire is currently being validated in a multicenter, longitudinal, noninterventional observational study in patients with severe CD treated with anti-TNFα, which will allow it to be further refined (item reduction) and its psychometric properties (validity, reproducibility, reliability) to be documented. The instrument will be then fully available for use in future clinical research studies or epidemiological studies to compare satisfaction with different anti-TNFα treatments in CD, or to observe the evolution of satisfaction with medication when patients switch from corticosteroids to anti-TNFα.

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