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Определение методом дельфийского консенсуса списка оцениваемых с помощью опросников параметров при наблюдении пациентов с воспалительными заболеваниями кишечника

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АННОТАЦИЯ

Обоснование. Пациенты с воспалительными заболеваниями кишечника часто нуждаются в пожизненном наблюдении врача. Перспективным направлением таких услуг здравоохранения является телемедицинское наблюдение, часто основывающееся на оценке медицинским работником результатов удалённого анкетирования пациентов.

Цель. Используя дельфийский метод, определить список оцениваемых с помощью анкетирования параметров для последующего применения в наблюдении и лечении пациентов с воспалительными заболеваниями кишечника.

Материалы и методы. Экспертную группу участников исследования составили врачи-гастроэнтерологи с различным опытом работы. Для сбора информации была создана электронная форма опроса, при заполнении которой обязательно указывался стаж участника. Исследование состояло из трёх этапов. На первом этапе респонденты отвечали на открытый вопрос о том, какие параметры, оцениваемые с помощью опросников, необходимо мониторировать у пациентов с воспалительными заболеваниями кишечника. На втором этапе участники отвечали на тот же вопрос, выбирая пункты из предложенных, без ограничений по количеству. Третьим этапом исследования выполнен анализ полученных ответов. Первичной конечной точкой считалось достижение по каждому параметру консенсуса более чем 75% респондентов.

Результаты. В исследовании приняли участие 15 человек, из них 13,3% — мужчины. Из всех респондентов, 46% работают в амбулаторно-поликлинических организациях, 54% — в стационаре. Возрастной диапазон составил от 25 до 53 лет, при этом 53% участников имели стаж от 1 до 4 лет, 47% — от 17 до 29 лет. По результатам первого этапа ни один из параметров не достиг уровня согласия 75%. После второго этапа респонденты достигли согласия по 72% параметров. Связи между возрастом, полом, стажем респондентов, а также местом их работы и ответами как на первом, так и на втором этапах обнаружено не было.

Заключение. В итоговый список параметров, рекомендуемых для оценки во время лечения и наблюдения пациентов с ВЗК, вошли: боль в животе; частота дефекации и качество стула; наличие патологических примесей в кале; температура тела; боли в суставах/мышцах; качество сна; эмоциональное состояние: тревожность, настроение; трудоспособность для работающих/возможность посещать занятия для обучающихся; энергичность, количество сил; фиксированность на заболевании; общая оценка пациентом качества своей жизни; приверженность лечению.

Ключевые слова: дельфийский метод; качество жизни; оценка трудоспособности; приверженность к приёму лекарственных препаратов; воспалительные заболевания кишечника.

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Delphi method to determine a list of questionnaire-assessed parameters in the follow-up of patients with inflammatory bowel disease

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ABSTRACT

BACKGROUND: Patients with inflammatory bowel disease often require lifelong follow-up by a clinician. Telemedicine monitoring is a promising area of such healthcare services, often based on the evaluation of patients' remote questionnaire results by a medical practitioner.

AIM: To define, using the Delphi method, a list of questionnaire-assessed parameters for monitoring and treating patients with IBD.

MATERIALS AND METHODS: The study was conducted in three stages. An electronic survey form was created to collect information, ensuring that the respondent's experience was included when completing the survey. In the first stage, respondents answered an open-ended question about what parameters assessed by questionnaires should be monitored in patients with IBD. In the second stage, participants answered the same question but selected any number of items from a list. In the third stage, the responses were analyzed. The primary endpoint was a consensus on each parameter, defined as >75% respondent agreement.

RESULTS: The study had 15 participants, 13.3% of whom were male. Of all respondents, 46% worked in an outpatient setting, whereas 54% worked in an inpatient setting. Their ages ranged from 25 to 53 years, with 53% of the participants having 1–4 years of experience and 47% having 17–29 years of experience. None of the parameters reached a 75% agreement level based on the results of the first stage. In the second stage, respondents reached a consensus on 72% of the parameters. No relationship was found between respondents' age, sex, years of experience, or job settings and responses in the first and second stages.

CONCLUSIONS: The final list of parameters recommended for evaluation during the monitoring and treatment of patients with IBD included abdominal pain, frequency of defecation and stool quality, presence of pathological stool impurities, body temperature, joint/muscle pain, sleep quality, anxiety, depression, work capacity for employed/ability to attend lessons for students, energy and quantity of vigor, fixation on the disease, patients' general evaluation of their quality of life, and treatment adherence.

Keywords: Delphi method; quality of life; disability evaluation; medication adherence; inflammatory bowel diseases.

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在对炎症性肠病患者进行随访时采用德尔菲法确定一份通过问卷评估的参数清单

Yuliya F. Shumskaya[1], Dina A. Akhmedzyanova[1], Marina G. Mnatsakanyan[2], Ksenia Yu. Kolosova[2], Olga V. Tashchyan[2], Marta V. Yurazh [2], Roman V. Reshetnikov[1]

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简评

论证。炎症性肠病患者通常需要医生的终生随访。远程随访是提供此类医疗服务的一个很有前途的途径。远程随访通常基于医疗服务提供者对远程患者问卷调查结果的评估。

该研究的目的是采用德尔菲法，确定一份通过问卷评估的参数清单，以便日后应用于炎症性肠病患者的随访和治疗。

材料和方法。参与研究的专家组由具有不同工作经验的消化内科医生组成。我们制作了一份电子调查表来收集信息。在填写问卷时，必须注明参与者的工作年限。研究分为三个阶段。在第一阶段，受访者回答了一个开放式问题，即应该对炎症性肠病患者的哪些参数进行评估。在第二阶段，受访者回答了同样的问题。但在这一阶段，他们从建议的项目中选择项目，项目数量不限。研究的第三阶段是对回答进行分析。每个参数的主要终点是75%以上的受访者达成共识。

结果。15人参与了研究，其中13.3%为男性。在所有受访者中，46%在门诊机构工作，54%在医院工作。年龄范围为25岁至53岁之间。同时，53%的参与者拥有1至4年的工作经验，47%的参与者拥有17至29年的工作经验。在第一阶段结束时，没有一个参数达到75%的同意程度。第二阶段结束后，受访者对72%的参数达成了一致意见。在第一阶段和第二阶段，受访者的年龄、性别、工作年限和工作地点与答复之间都未发现相关性。

结论。炎症性肠病患者治疗和随访期间的最终评估参数清单包括：腹痛；排便次数和粪便质量；粪便中是否有病理性杂质；体温；关节/肌肉疼痛；睡眠质量；情绪状态：焦虑、情绪；工作的人的工作能力/学习的人的上课能力；精力、体力；对疾病的固执；患者对其生活质量的总体评价；坚持治疗的情况。

关键词：德尔菲法；生活质量；工作能力评估；坚持用药的情况；炎症性肠病。

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BACKGROUND

Inflammatory bowel diseases (IBDs), particularly ulcerative colitis and Crohn's disease, are major public health concerns because of their severity, comorbidities, and high treatment costs. IBDs frequently affect not only health but also quality of life, deteriorating patients' physical and mental well-being and limiting their social capabilities [1]. The incidence of IBD is steadily increasing both globally [2] and in Russia [3], with 55.4% of patients with ulcerative colitis and 48.5% of patients with Crohn's disease were 21 to 40 years old [4]. Because of the recurring nature of IBD, most patients require lifelong monitoring; however, no unified protocol has been established for the outpatient management of these patients during remission.

Telemedicine is a promising approach to the outpatient management of patients with IBD. Patients under remote follow-up have a significantly better quality of life and seek medical attention less frequently than patients receiving standard treatment [5]. However, with remote follow-up, the question of what must be assessed arises.

The assessment of critical laboratory parameters such as C-reactive protein and fecal calprotectin is undeniably important. However, in addition to IBD activity parameters, other factors are crucial for quality of life, such as psychological status, which are not assessed in routine practice.

Questionnaires are a convenient and relevant method for assessing a patient's condition. They provide the clinician with the necessary information, such as the clinical activity of IBD or compliance, without requiring high costs or time commitments. Most studies have assessed disease activity and associated quality of life; however, other studies have less frequently assessed the overall quality of life, depression severity, adherence to drug therapy, and patient satisfaction with medical care [5]. Moreover, few studies have assessed visceral sensitivity [6] and the effect of the disease on work productivity [7, 8] and sexual activity [9] in patients with IBD. In addition, researchers did not explain why they chose specific endpoints. As a result, the lack of consensus on the parameters assessed by questionnaires prevents their standardized use managing patients with IBD.

PURPOSE

This study aimed to use the Delphi method to assess the expert opinions of gastroenterologists to determine a list of questionnaire-assessed parameters in the follow-up of patients with IBD.

MATERIALS AND METHODS

Between May and June 2023, gastroenterologists treating IBD were invited to participate in a survey to achieve a consensus on the inclusion/exclusion of various parameters in patient assessment during treatment and follow-up. The Delphi method was used to obtain a collective opinion with reasonable level of validity and reliability and explore areas outside existing knowledge [10]. Before the study commenced, a literature review on the use of questionnaires in the assessment of patients with IBD was performed. Following the literature review, the areas assessed by Russian and foreign authors were determined (Table 1).

Participants were chosen at random by convenience sampling. No consensus on the sample size for studies using the Delphi method, guidelines, or a clear definition of a "small" or "large" sample was reached [11, 12]. In this study, the sample size was determined according to R.B. Akins et al., who demonstrated that the results of the Delphi method in a group of experts in the studied area are stable with 15 –23 participants [13].

The study included three stages. Information was collected using an electronic survey form using Yandex Forms.

Stage I

To participate in the survey, all participants had to specify their work experience as a gastroenterologist. In stage I, all participants answered the following open-ended questions:

"What aspects of life and health, in your opinion, should be assessed in a patient with inflammatory bowel disease, both during treatment of an attack and during follow-up in remission?"

Respondents could proceed to the next stage of the survey after filling out the answer field. Stage I answers were stratified into four:

- Clinical activity assessment
- Psychological status assessment
- Quality of life assessment
- Others

Stage II

In stage II, the participants had to select items from the list. The question was as follows:

"Select the items from the list below that you believe are crucial to assess in a patient with inflammatory bowel disease, both during treatment of an attack and during follow-up in remission."

The possible answers presented in Table 1 were derived from a literature review using PubMed. Original studies and systematic reviews that assessed the efficacy of treatment in patients with IBD were analyzed, and the endpoints of these studies were identified. No restrictions were set on the number of the selected items.

Upon completion of stage II, the survey participants were invited to optionally supplement their answers to stage I question (without showing respondents the text of their previous answers).

Stage III

In stage III, the responses were analyzed. The primary endpoint was the consensus on the inclusion of patient assessment parameters in the final list. The consensus on a

Table 1. Response options for multiple-choice questions in the second stage of the survey

Area	Proposed parameter
Clinical activity of the disease	Abdominal pain Defecation frequency and stool form Pathological admixtures in the feces Body temperature Joint/muscle pain
Psychological status	Emotional state: anxiety Emotional state: mood Sleep quality Body image perception (negative/positive)
Quality of life	Patient global assessment of quality of life Quality of communication Quality of sexual life Ability to work/study
Others	Anxious attitude toward the disease Visceral sensitivity Energy level Patient satisfaction with medical care

specific parameter was reached when >75% of respondents choose the parameter [14].

The software and language R 4.2.0 were used for data analysis. The Shapiro–Wilk test was employed to check the normality of the distribution. Variables with normal distribution are presented as mean ± standard deviation. Variables with non-normal distribution are presented as median and interquartile range. The correlation between variables was assessed by calculating Spearman's or Pearson's rank correlation coefficient, depending on the type of distribution.

After the study, the respondents were interviewed, using the following questions:

- Which was easier to answer: an open-ended question or a multiple-choice question?
- Why do you think some items did not receive enough votes? (This question included items that received <75% of the votes)

RESULTS

The study included 15 respondents, 13.3% of whom were men. The mean age of the participants was 36.6 ± 9.9 years, ranging from 25 to 53 years. Outpatient physicians accounted for 46% of all respondents, whereas hospital physicians accounted for 54%. None of the respondents withdrew from the study. The distribution of participants according to work experience is presented in Fig. 1.

According to the results of stage I, in which study participants must answer an open-ended question, no obvious overlaps were found in the answers because of the free format. After categorizing the answers, none of the categories attained the level of agreement (Fig. 2).

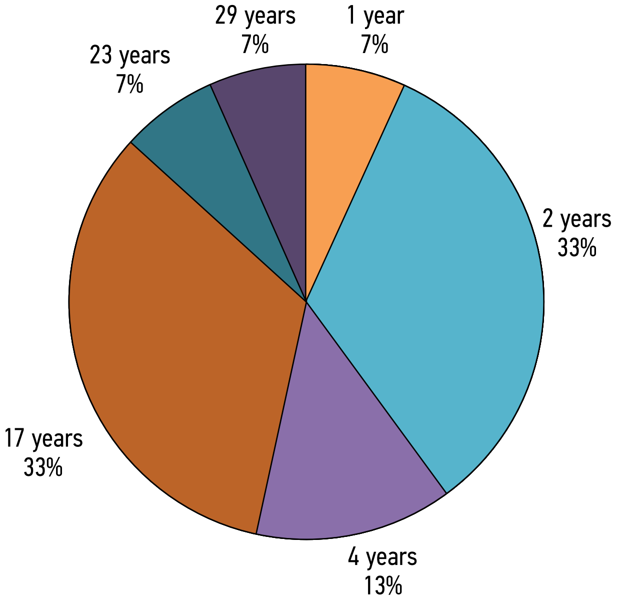

Fig. 1. Distribution of the study participants according to their work experience as gastroenterologists.

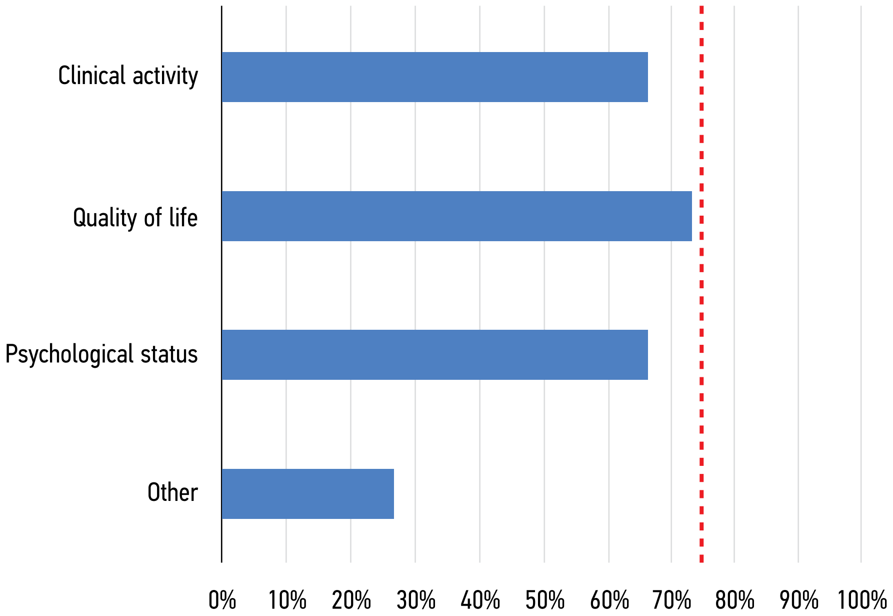

Fig. 2. Study results (first stage). The red dotted line indicates 75% of the respondents.

Based on the results of stage I, the "compliance" parameter was added to the possible answers in stage II (in addition to the items listed in Table 1). The results of stage II differed from those of stage I for each respondent: the number of questionnaire-assessed parameters (median number of parameters, 4 [3; 5.5] and 16 [13.5; 17] for stages I and II, respectively) increased.

In the correlation analysis, no link was found between the age, sex, work experience, and place of work (outpatient clinic/hospital) of respondents and their answers during stages I and II.

Participants were interviewed after receiving the results of stage II. Compared with answering a multiple-choice question, answering an open-ended question was more challenging for 100% of the respondents. In total, 27% of the participants responded when asked why some items did not receive enough votes. Each of them emphasized that the quality of sexual life and communication in patients with IBD is frequently influenced by factors other than the disease. According to the respondents, body image perception is unrelated to the disease and does not warrant assessment by a gastroenterologist. Respondents also did not believe that satisfaction with medical care was a parameter that clinicians should monitor in all patients with IBD. Regarding visceral sensitivity, respondents agreed on the importance of assessing this parameter in some patients whose symptoms cannot be explained solely by the clinical course of IBD and who may benefit from the addition of a functional component.

DISCUSSION

The study generated a final list of parameters recommended for assessment during the treatment and follow-up of patients with IBD, which included the following:

- Abdominal pain
- Defecation frequency and stool form
- Pathological admixtures in the feces
- Body temperature
- Joint/muscle pain
- Sleep quality
- Emotional state: anxiety
- Emotional state: mood
- Ability to work/study
- Energy level
- Anxious attitude toward the disease
- Patient global assessment of quality of life
- Compliance

This list was compiled after a two-stage survey of gastroenterologists. Two approaches were used to collect information in this study: an open-ended question and a multiple-choice question. In the first scenario, no consensus could be reached on any of the categories; however, in the second scenario, respondents agreed on 72% of the parameters. This could be due to the simplicity of stage II: during the interview, respondents stated that answering a multiple-choice question was easier and more convenient for them.

Furthermore, no correlation was found between the characteristics of the survey participants, such as sex, age, work experience, and place of work (outpatient clinic or hospital), and their answers during stages I and II.

Our findings support the use of the Delphi method, which offers equal opportunities to survey participants and allows for the concealment of expertise and skill level to prevent the authority pressure that is unavoidable in face-to-face discussions. In this study, clinicians with minimal experience had the same perceptions of follow-up strategies as their more experienced colleagues. There may be other scenarios

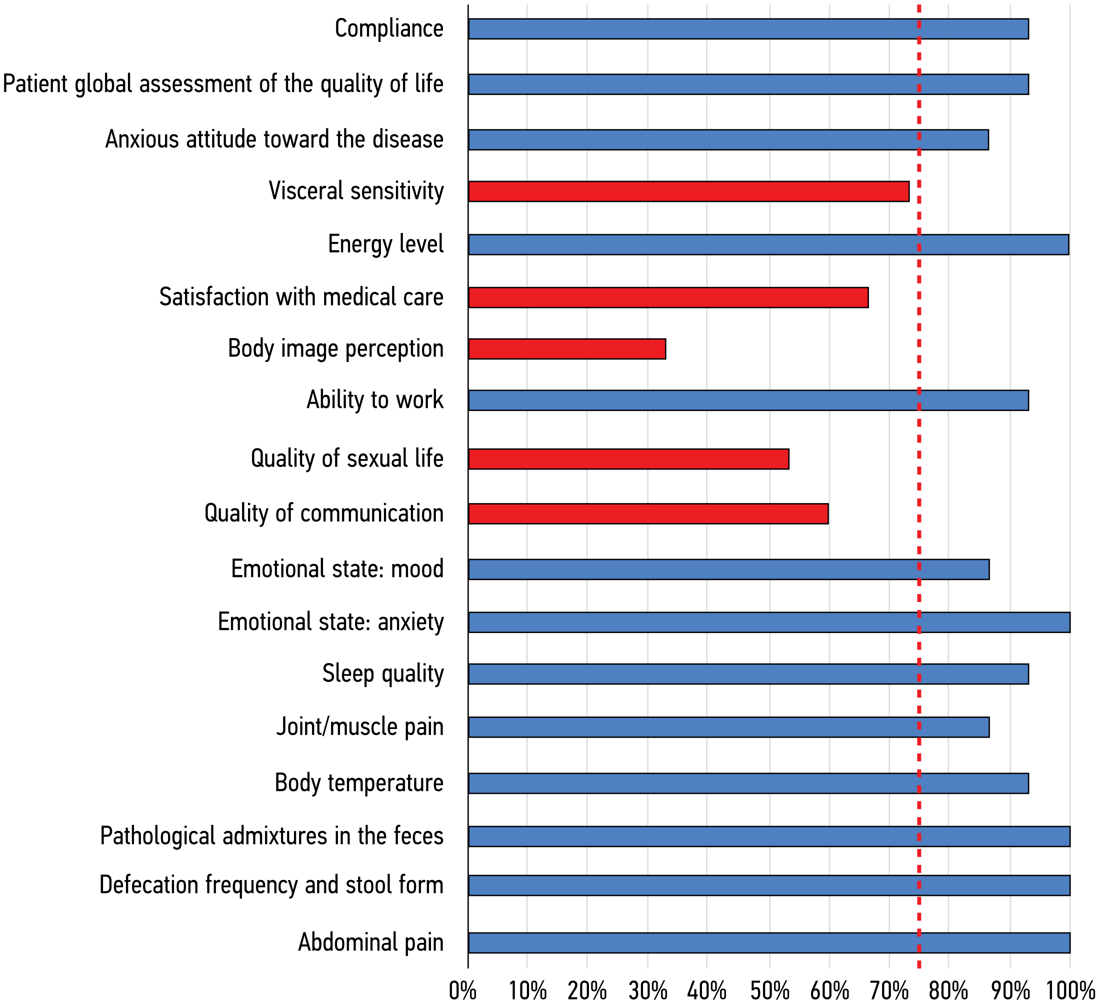

Fig. 3. Study results (second stage). The red columns indicate parameters that received <75% of the responses.

in which the consensus is not as strong; in such cases, a fresh look at the topic under discussion by young specialists may lead to a more objective decision.

According to foreign literature, health-related quality of life, disability/ability to work, and disease activity are the key questionnaire-assessed parameters in patients with IBD [15]. In this study, these areas were also included in the final list. The first five parameters selected by the participants (abdominal pain, defecation frequency and stool form, pathological admixtures in feces, body temperature, and joint/muscle pain) are related to assessing the clinical activity of IBD. The ability to work/study and patient global assessment of quality of life were also selected by >90% of the respondents.

Furthermore, the final list included parameters that assessed the emotional state, such as sleep quality, anxiety, and mood. Given the high incidence of anxiety and depression symptoms in patients with IBD [16], assessing these parameters will surely provide valuable information to researchers and clinicians.

Assessing energy levels in patients with IBD is also critical, given the subjective and complex nature of asthenic syndrome in these patients [17]. We believe that this parameter must be used by clinicians and researchers, depending on the clinical setting or study endpoints.

Compliance assessment in patients with IBD is also important, given the often lifelong drug therapy, including immunosuppressants. Because compliance is one of the treatment goals [18], its assessment is critical for clinicians and researchers.

In a systematic review, Pang et al. used disease-related quality of life, inflammation activity, and remission rate as primary endpoints. Secondary endpoints included overall quality of life, depression, compliance, and satisfaction with medical care [5]. However, the researchers did not explain why these specific parameters were selected as outcomes. Our study presents a consensus list of questionnaire-assessed parameters in the follow-up of patients with IBD.

Advantages and limitations

Clinicians from various backgrounds were invited to participate in the study, which has advantages and disadvantages. Analysis of a large proportion of young participants brings a fresh viewpoint; however, these participants have limited practical experience. Participation of both outpatient and inpatient care workers allows for a wider range of perspectives.

Further studies

A larger-scale survey with more gastroenterologists from various Russian regions appears to be a logical and necessary extension of this study. Professionals discussing scientific challenges together allow us to address current issues and propose new solutions [19]. Guidelines detailing a pool of questionnaires in areas determined by consensus will be developed as part of the practical implementation of the study findings.

ADDITIONAL INFORMATION

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Authors' contribution. All authors made a substantial contribution to the conception of the work, acquisition, analysis, interpretation of data for the work, drafting and revising the work, final approval of the version to be published and agree to be accountable for all aspects of the work. Yu.F. Shumskaya, D.A. Akhmedzynova, K.Yu. Kolosova, M.V. Yurazh — writing the original draft; Yu.F. Shumskaya, O.V. Tashchyan — data curation, investigation; M.G. Mnatsakanyan, R.V. Reshetnikov, Yu.F. Shumskaya — conceptualization, study design; Yu.F. Shumskaya, R.V. Reshetnikov — data curation.

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