

Adaptation of the O'Leary-Sant and the PUF, for the diagnosis of interstitial cystitis for the Brazilian culture*

ADAPTAÇÃO À CULTURA BRASILEIRA DOS QUESTIONÁRIOS THE O'LEARY-SANT E PUF, USADOS PARA CISTITE INTERSTICIAL

ADAPTACIÓN A LA CULTURA BRASILEÑA DE LOS CUESTIONARIOS THE O'LEARY-SANT Y PUF, USADOS PARA CISTITIS INTERSTICIAL

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ABSTRACT

The aim of this study was to translate and adapt the instruments known as The O'Leary-Sant and PUF to the Brazilian culture used in the diagnosis of interstitial cystitis. We followed the methodological steps recommended by the international literature for cultural adaptation. The steps of translation, synthesis of translations and back translation were performed satisfactorily and evaluation the versions of the synthesis by the panel of experts has resulted in some changes, ensuring the equivalence between the original and translated versions. The PUF was pretested among 40 subjects and The O'Leary-Sant in a sample of 50 individuals due to the need for adjustments due to the low education population. The translation and adaptation process was successful and the instruments, after some modifications, proved easy to understand and complete quickly. However, this is a study prior to the validation process and will be promoting the use of the instrument in new research to assess its measurement properties.

DESCRIPTORS

Interstitial cystitis
Diagnosis
Questionnaires
Cross-cultural comparison

RESUMO

O objetivo deste estudo foi traduzir e adaptar à cultura brasileira os instrumentos The O'Leary-Sant e PUF, utilizados no diagnóstico de cistite intersticial. Foram realizadas as etapas metodológicas recomendadas pela literatura internacional para a adaptação cultural. As etapas de tradução, síntese das traduções e retrotradução foram realizadas satisfatoriamente, e a avaliação das versões sintéticas pelo comitê de especialistas resultou em algumas alterações, assegurando as equivalências entre as versões originais e traduzidas. O PUF foi pré-testado entre 40 sujeitos e The O'Leary-Sant em uma amostra de 50 indivíduos, devido à necessidade de ajustes em decorrência da baixa escolaridade da população. O processo de tradução e adaptação foi realizado com sucesso e os instrumentos, após as modificações, demonstraram ser de fácil compreensão e rápido preenchimento. Entretanto, este é um estudo que antecede o processo de validação e será premente o emprego do instrumento em novas pesquisas para que sejam avaliadas suas propriedades psicométricas.

DESCRITORES

Cistite intersticial
Diagnóstico
Questionários
Comparação transcultural

RESUMEN

Se objetivó traducir y adaptar a la cultura brasileña los instrumentos The O'Leary-Sant y PUF, utilizados para diagnosticar cistitis intersticial. Fueron efectuadas las etapas metodológicas recomendadas por la literatura internacional para adaptación cultural. Las etapas de traducción, síntesis de traducciones y retrotraducción se realizaron satisfactoriamente, la evaluación de las versiones sintetizadas por parte del comité de especialistas derivó en algunas alteraciones, asegurando las equivalencias entre versiones originales y traducidas. El PUF fue pre-testeado con 40 sujetos y The O'Leary-Sant en muestra de 50 individuos, por la necesidad de ajustes derivados de la baja escolarización de la población. El proceso de traducción y adaptación se efectuó con suceso y los instrumentos luego de las modificaciones demostraron ser de sencilla comprensión y rápido completado. Sin embargo, este estudio es previo al proceso de validación, será imprescindible el uso del instrumento en nuevas investigaciones para evaluar sus propiedades psicométricas.

DESCRIPTORES

Cistitis intersticial
Diagnóstico
Cuestionarios
Comparación transcultural

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INTRODUCTION

Interstitial cystitis, also called painful bladder syndrome, is a chronic inflammatory disorder that affects the urinary bladder and is characterized by pain in the bladder region⁽¹⁻³⁾. Its etiology remains unknown.

In 2005, the International Continence Society (ICS) defined interstitial cystitis as a disease of unknown cause that includes suprapubic pain near the bladder accompanied by other symptoms, such as increased urination frequency during the day (>8x) and overnight (>1x), with glomerulations upon cystoscopy and Hunner lesions or histopathological features (mononuclear cell inflammation including mast cell infiltration) in the absence of infection or other diseases⁽⁴⁾.

The symptoms that characterize the disease are pelvic pain, urgency, urinary frequency and nocturia⁽¹⁻⁶⁾. It is very difficult to diagnose interstitial cystitis; therefore, its prevalence is not precisely known. It affects approximately ten individuals in every hundred thousand people, with an eight to one ratio of men to women⁽¹⁻²⁾.

Some researchers identify the disease with questionnaires that address urinary symptoms; emotional, physical and sexual history; menstrual cycles; and quality of life, which can produce an accurate diagnosis of the disease⁽⁵⁻⁹⁾.

These questionnaires are considered an important diagnostic tool. Because there is no questionnaire available for use in our language, the purpose of this study was to translate the Interstitial Cystitis Symptoms Index and Problem Index (The O'Leary-Sant) and the Pelvic Pain and Urgency/Frequency (PUF) Patient Symptoms Scale and adapt these tools for Brazilian culture.

METHOD

The methodological process of cultural adaptation aims to produce an instrument that is consistent with the original instrument but appropriate for the culture of the country where it will be applied⁽¹⁰⁾.

This study followed the guidelines developed by the American Academy of Orthopedic Surgeons, which aimed to standardize the process of culturally adapting instruments for measuring health-related issues using theoretical findings and a systematic review of published studies about this methodology. The following steps are included in this process: translating the original instrument, synthesizing the translations, back translating the instrument into the original language, submitting the translations to a panel of experts and pretesting⁽¹⁰⁾. All of these steps are essential in the process of translation and cultural adaptation⁽¹⁰⁻¹¹⁾.

Ethical Aspects

Before conducting the study, the original instrument authors were contacted, and formal authorization to perform the translation and cultural adaptation of the instruments was obtained. All ethical principles for human research were followed, and the study was approved by the Research Ethics Committee of the Faculty of Medical Sciences, State University of Campinas (Unicamp), under protocol no. 545/2010. All participants read and signed the Free and Informed Consent Form.

Instruments

To assess the profile of the study sample, we collected socio-demographic information, such as age, income (amounts in reais), occupation, education level (from no schooling to postgraduate education), and the results of previous tests performed to determine the diagnosis of interstitial cystitis (cystoscopy, urodynamics, laboratory tests, biopsies and a potassium sensitivity test). A specific instrument was developed for the data collection.

Some researchers identify the disease with questionnaires that address urinary symptoms; emotional, physical and sexual history; menstrual cycles; and quality of life, which can produce an accurate diagnosis of the disease.

The Interstitial Cystitis Symptom Index and Problem Index (The O'Leary-Sant) aims to evaluate the treatment of patients with interstitial cystitis. It consists of two indices (symptoms and problems), each containing four questions. The score of each index is calculated by summing the points for each item. The score can range from zero to 20 on the first index and zero and 16 on the second index. For both indices, a score greater than six indicates a diagnosis of interstitial cystitis.

The index that evaluates the symptoms of interstitial cystitis investigates aspects of urinary urgency and frequency, nocturia and pelvic pain in the month before the evaluation. The index that evaluates the problem of interstitial cystitis evaluates whether the aspects mentioned above were problems during the past month.

The Pelvic Pain and Urgency/Frequency (PUF) Patient Symptoms Scale is also used to diagnose interstitial cystitis. It consists of eight items covering aspects of urinary pain, urgency, frequency and symptoms associated with sexual intercourse.

The items measure the symptoms of interstitial cystitis and associated discomfort, including questions related to urinary frequency, nocturia, pain during the sexual intercourse and pain associated with the bladder or pelvis. These items ask whether these symptoms negatively affect the patient's life. The score ranges from zero to 35, and scores greater than five indicate a diagnosis of interstitial cystitis.

Phases of cultural adaptation

Initial translation

In the first phase, two initial translations (T1 and T2) of The O'Leary-Sant and the PUF were produced independently by two translators, both Brazilians who were fluent in English with experience living in an English-speaking country.

The first translators of The O'Leary-Sant and the PUF instruments were a urogynecologist and a urologist, respectively, who were knowledgeable about the topic; the second translator of both instruments had no knowledge about the topic. The translators were made aware of the fundamental objectives of the instrument and of the methodological process so that they could produce a translation that met the particular needs of the instrument from the clinical perspective as well as from the perspective of the studied subject.

Summary of translations

At the end of the first phase, the authors of this study independently analyzed T1 and T2, compared them to the original document and began the reconciliation process for obtaining a single version (T1,2).

Producing the T1,2 required a thorough analysis of the discrepancies between T1 and T2. The suggested modifications were made after consensus was achieved by the authors.

Translation of the instrument back into the original language

This stage, also known as back translation, involved two translators who were born and educated in the country that speaks the original language of the instruments. Both of these translators were familiar with the Brazilian language and culture.

The translators, who had no knowledge of the original instrument, received a synthesized version (T1,2) and were asked to translate the instrument from Portuguese to English, creating two versions (RT1 and RT2).

This process was intended to check the validity of the translated version in the target language and to identify discrepancies in meaning and content between the original and translated instruments.

Panel of experts

Both instruments were reviewed by an expert panel consisting of a urologist, a methodologist, a linguist, a patient with a clinical diagnosis of interstitial cystitis and the researchers.

The committee members received the final versions of the questionnaires and instructions for evaluation. At this stage, the committee members focused on the appropriateness, clarity and equivalence (semantic and idiomatic, cultural and conceptual) of the vocabulary and expressions.

Semantic equivalence refers to the meaning of words, and idiomatic equivalence corresponds to the use of idiomatic expressions and colloquialisms in each language. Cultural equivalence must be analyzed and considered if there are terms, expressions and everyday situations that are different between the cultures of the countries, and conceptual equivalence refers to the relationship between the item and the concept it is intended to measure(12).

Two reviews were conducted: the first measured the agreement among the judges who conducted their evaluations independently, and the second was conducted after the consensus meeting. A level of 80% agreement was considered an adequate concordance index.

Once completed, the draft versions of The O'Leary-Sant and the PUF were pretested.

Pretest

The pretest is the final stage of the adaptation process. The new versions of The O'Leary-Sant and the PUF were applied to a sample of subjects who had symptoms suggestive of interstitial cystitis (urinary urgency and frequency, nocturia, dysuria and chronic pelvic pain). Because the prevalence of the disease is low, it was difficult to test the questionnaire solely on patients who had been diagnosed with interstitial cystitis.

The participants were informed about the purpose of the questionnaire and the stage of the research, and it was emphasized that the participants should express their opinions about their understanding of each item on the questionnaire.

RESULTS

The translation, synthesis and back translation steps were completed successfully. Experts previously produced individual considerations for each item in both instruments, and the concordance rate was calculated based on their answers. With regard to the experts' answers, the semantic, idiomatic, cultural and conceptual equivalences for the title and all of the items, including the symptoms and problems on The O'Leary-Sant, did not exceed 80%. As for the instruments' adequacy and clarity, only question number 3 on the symptom index reached a concordance level greater than 80%. On the PUF, only issues 1 and 5 achieved levels of equivalence and clarity greater than 80%. During the consensus meeting in which were sought consensus, items that should be modified were identified and new wording was proposed for these items. The rate of final concordance among the experts was 100%.

During the consensus meeting, which lasted approximately 3 hours and 30 minutes, it was unanimously decided to change seven of the 15 items we evaluated, including the title, the statement of completion and the question and answer choices on The O'Leary-Sant ques-

tionnaire. On the PUF, it was necessary to change six of the 14 items we evaluated, including the title and the question and answer choices.

After making the changes proposed by the panel of experts, the new versions of The O'Leary-Sant and the PUF were ready for pretesting.

The two questionnaires are both self-administered, and thus, the researchers found that all of the items needed to be changed to make the instruments more understandable to the audience and to obtain cultural equivalence.

Because of the doubts generated about the subjects' understanding of the issues, it was necessary to conduct the pretest of the first instrument with three different groups of subjects (a total of 50 individuals) and the second instrument with two groups (40 participants). Both instruments changed in response to the questions or suggestions that emerged from the respondents.

Thirty subjects, 29 women and one man with suggestive symptoms of interstitial cystitis, participated in the first pretest group. Their ages ranged from 23 to 83 years, with an average age of 53.2 years (SD = 13.5 years), and their educational level ranged from no schooling to completion of higher education, with a high proportion of individuals having completed primary education (66.6%). The average income was R\$ 842.20 (SD = R\$ 401.90), and the value of the minimum wage at the time was R\$ 545.00.

After they completed the questionnaires, the subjects were asked about the clarity of the items. They reported their doubts about the vocabulary used and suggested the use of other expressions that would facilitate their understanding of the issues. Thus, the subsequent versions of the instruments were more consistent, clear and appropriate.

More than 60% of interviewees had doubts about the expression *with little or no notice* in question 1 on the index of symptoms and question 2 on the problem index of The O'Leary-Sant. The same subjects had doubts about the expression *awake for 1 day (24 hours)* and the expression *sexually active* on the PUF.

These doubts were discussed with members of the expert panel via e-mail, and each member sent new suggestions for each question to the researchers. Next, the

authors met and discussed the best suggestions from the committee members and the subjects who participated in the pretest. The questions were changed, and the new version of the instrument was administered to a second group of ten women with symptoms suggestive of interstitial cystitis. Their ages ranged from 30 to 78 years, with an average age of 57.9 years (SD = 13.9 years old), and their educational level ranged from no schooling to the completion of higher education, with a high proportion of individuals having completed primary education (80%). The average income was R\$ 733.00 (SD = R\$ 377.54). The second pretest was completed satisfactorily; the PUF instrument was understood by 100% of the subjects.

Even after the new changes, 60% of the subjects still had doubts about question 1 of the symptom index of The O'Leary-Sant. Consequently, the issue was reviewed again by the members of the panel of experts to produce a third modification to this question. The modified instrument was tested again with a third group of ten women with symptoms suggestive of interstitial cystitis. Their ages ranged from 29 to 79 years, with a mean age of 49.7 years (SD = 15.7 years old), and their educational level ranged from no schooling to the completion of higher education, with a high proportion of individuals having completed primary education (60%). The average income was R\$ 1,474.00 (SD = R\$ 982.30).

After the final pretest of The O'Leary-Sant, 100% of the respondents understood all of the issues, completing the last step in the process of cultural adaptation (i.e., the pretest of the questionnaire).

The average time required to complete the questionnaires was 20 to 30 minutes for all of the groups.

The final versions (Charts 1 and 2) were delivered to a translator who was born and educated in the country where the original versions of the instruments were developed (the United States) but who had lived in Brazil for over 30 years to perform the translation back into English. The purpose of this additional translation was to certify that the items that were translated into Brazilian Portuguese and did not lose their meaning when they were translated from the original language (English) because the questionnaires are used to diagnose interstitial cystitis. These versions were sent to the authors of the original versions so that they could assess them. The authors of both The O'Leary-Sant and the PUF approved the final translations.

Table 1 - Brazilian version of The Interstitial Cystitis Symptom Index and Problem Index approved by the panel of experts and the final version after the pretest - Campinas, 2012

	Brazilian version approved by experts	Brazilian final version after the last pretest
Title	Symptom index and problem index of interstitial cystitis	Symptom index and problem index of interstitial cystitis
Instruction for filling out	Name: ____ Date: ____ Please circle the response that best describes how you feel about each question.	Name: ____ Date: ____ Please circle the response that best describes how you feel about each question.
Q1. Index of symptoms	During the last month, how often have you felt a strong desire (need) to urinate suddenly (with little or no warning)? 0. Never 1. Seldom 2. Less than half the time 3. Almost half the time 4. More than half the time 5. Almost always	During the last month, how often have you felt a very strong desire to urinate suddenly? 0_ Never 1_ Seldom 2_ Less than half the time 3_ Almost half the time 4_ More than half the time 5_ Almost always
Q2. Index of symptoms	During the past month, have you had to urinate less than two hours after urinating last time? 0. None 1. Seldom 2. Less than half of the times 3. Almost half of the times 4. More than half of the times 5. Almost always	During the past month, have you had to urinate less than two hours after urinating last time? 0_ None 1_ Seldom 2_ Less than half of the times 3_ Almost half of the times 4_ More than half of the times 5_ Almost always
Q3. Index of symptoms	During the last month, how many times did you get up during the night to urinate? 0. None 1. Once 2. Twice 3. Three 4. Four times 5. Five or more times	During the last month, how many times did you get up each night to urinate? 0_ None 1_ Once 2_ Twice 3_ Three 4_ Four times 5_ Five or more times
Q4. Index of symptoms	During the last month, did you feel pain or burning in the bladder? 0. No 1. Seldom 2. Almost half of the times 3. More than half of the times 4. Almost always	During the last month, did you feel pain or burning in the bladder? 0_ No 1_ Seldom 2_ Almost half of the times 3_ More than half of the times 4_ Almost always
Q1. Index of problems	During the last month, how big of a problem has it been for you to urinate many times during the day? 0. No problem 1. Very little problem 2. Small problem 3. Medium problem 4. Big problem	During the last month, how big of a problem was it for you to urinate many times during the day? 0_ No problem 1_ Very little problem 2_ Small problem 3_ Medium problem 4_ Big problem
Q2. Index of problems	During the last month, how big of a problem has it been for you to get up during the night to urinate? 0. No problem 1. Very little problem 2. Small problem 3. Medium problem 4. Big problem	During the last month, how big of a problem was it for you to get up during the night to urinate? 0_ No problem 1_ Very little problem 2_ Small problem 3_ Medium problem 4_ Big problem
Q3. Index of problems	During the last month, how much has the (need) to urinate with little warning been a problem for you? 0. No problem 1. Very little problem 2. Small problem 3. Medium problem 4. Big problem	During the last month, how big of a problem was it for you to have the strong urge to urinate suddenly? 0_ No problem 1_ Very little problem 2_ Small problem 3_ Medium problem 4_ Big problem
Q4. Index of problems	During the last month, how much has burning, pain, discomfort or pressure in the bladder been a problem for you? 0. No problem 1. Very little problem 2. Small problem 3. East problem 4. Big problem	During the last month, how much of a problem was burning, pain, discomfort or pressure in the bladder for you? 0_ No problem 1_ Very little problem 2_ Small problem 3_ East problem 4_ Big problem

Table 2 - Brazilian version of the Pelvic Pain and Urgency/Frequency (PUF) Patient Symptom Scale approved by the committee of experts and the final version after the pretest - Campinas, 2012

	Brazilian version approved by experts	Brazilian final version after the last pretest
Title	Assessment scale of patient symptoms of pelvic pain, urgency / frequency (PUF)	Assessment scale of patient symptoms of pelvic pain, urgency / frequency (PUF)
Q1	How often do you go to the bathroom when you are awake for 1 day (24 hours)? 0. 3-6 times 1. 7-10 times 2. 11-14 times 3. 15-19 times 4. More than 20 times	How often do you go to the bathroom from the time you wake up until the time you go to sleep? 0. 3-6 times 1. 7-10 times 2. 11-14 times 3. 15-19 times 4. More than 20 times
Q2 a	How often do you go to the bathroom during the night after you fell asleep? 0. 0 time 1. 1 time 2. 2 times 3. 3 times 4. More than four times	How often do you go to the bathroom during the night after you fell asleep? 0. 0 time 1. 1 time 2. 2 times 3. 3 times 4. More than four times
Q2 b	If you wake up during the night to go to the bathroom, how much does this bother you? 0. Nothing 1. Little 2. Average 3. Very	If you wake up during the night to go to the bathroom, how much does this bother you? 0. Nothing 1. Little 2. Average 3. Very
Q3	Currently, do you have SEXUAL RELATIONSHIPS? YES _____ NO _____	Currently, do you have SEXUAL RELATIONSHIPS? YES _____ NO _____
Q4 a	IF YOU ARE SEXUALLY ACTIVE, do you have or have you had pain or the strong urge to urinate during sexual relations? 0. Never 1. Sometimes 2. Often 3. Always	During sexual relations, do you have or have you had pain or the strong urge to urinate? 0. Never 1. Sometimes 2. Often 3. Always
Q4 b	Have you ever avoided having intercourse because of pain or the strong urge to urinate? 0. Never 1. Sometimes 2. Often 3. Always	Have you ever avoided having intercourse because of pain or the strong urge to urinate? 0. Never 1. Sometimes 2. Often 3. Always
Q5	Do you feel pain in the bladder or pelvic area (vagina, lower abdomen, urethra, perineum, testicles, penis or scrotum)? 0. Never 1. Sometimes 2. Often 3. Always	Do you feel pain in the bladder or pelvic area (vagina, lower abdomen, urethra, perineum, testicles, penis or scrotum)? 0. Never 1. Sometimes 2. Often 3. Always
Q6	Do you still have the urge to urinate soon after going to the bathroom? 0. Never 1. Sometimes 2. Often 3. Always	Do you still have the urge to urinate soon after going to the bathroom? 0. Never 1. Sometimes 2. Often 3. Always
Q7 a	If you have pain in the bladder or pelvic area, it usually is: 0. Weak 1. Average 2. Strong	If you have pain in the bladder or pelvic area, it usually is: 0. Weak 1. Average 2. Strong
Q7 b	When does pain in the bladder or pelvic region bother you? 0. Never 1. Sometimes 2. Often 3. Always	When does pain in the bladder or pelvic region bother you? 0. Never 1. Sometimes 2. Often 3. Always
Q8 a	If you have the strong urge to urinate, it usually is: 0. Weak 1. Average 2. Strong	If you have the strong urge to urinate suddenly, it usually is: 0. Weak 1. Average 2. Strong
Q8 b	When does the strong urge to urinate bother you? 0. Never 1. Sometimes 2. Often 3. Always	Has a strong urge to urinate suddenly bothered you? 0. Never 1. Sometimes 2. Often 3. Always

DISCUSSION

Because English is spoken relatively frequently in Brazil, the steps used to obtain the final version of the questionnaires were completed without many difficulties. It was easy to obtain high-quality translations because all of the translators involved in the process of translation and cultural adaptation had experience conducting research and thus understood that accuracy would result in a high-quality version. In addition, the questionnaires are relatively simple, with few items.

Interdisciplinary qualitative evaluations are extremely valuable in the cultural adaptation of instruments(10). The meeting of the panel of experts, though long, allowed the final understanding of the instrument. The connection that came from professionals in the areas of health and language was enriched and facilitated by the presence of the representative of the target population, women with interstitial cystitis. The integrant expressed important opinions, which was considered by the others, because it is the opinion of the primordial part of the study, the research subject.

Contact with another language means, invariably, results in cross-cultural comparisons. Thus, certain items were modified before pretesting the instruments with Brazilian patients because of the need to obtain cultural equivalence between the original questionnaires in English and the final versions in Portuguese.

Based on the consensus of the experts, the titles of both instruments were translated into Portuguese to facilitate the subjects' understanding, and it was suggested that the title should remain in English only in the title of the dissertation and in published articles to facilitate searches in databases.

The partnership between the researchers and the members of the expert panel, along with the suggestions of the subjects who participated in the pretest, was essential for producing Brazilian versions with vocabulary that is appropriate for the educational level of the Brazilian population. Because urinary symptoms are very common in this population, the instruments should be appropriate for subjects with any level of schooling.

As stated previously, the majority of the subjects had a low level of education, which may have limited their understanding of the instruments. This characteristic has been defined by some authors as limiting(13), especially in regard to questionnaires designed to be answered by the subject of the research. Some subjects had moderate or high levels of education but were unable to respond unassisted for various reasons. They claimed, for example, to have forgotten their glasses at home or that they had some type of visual impairment. Therefore, although the original instruments were self-reported, it was not always possible for the Brazilian version to be completed in this manner.

Because they are simple instruments(5-6) it is believed that they can be used routinely in clinical practice by various health professionals in a variety of practice scenarios. Thus, this instrument supports a multidisciplinary approach for diagnosing interstitial cystitis, a disease that causes significant physical and psychological morbidity in both men and women ^(1-2,4,6-7).

CONCLUSION

The adaptation of The Interstitial Cystitis Symptom Index and Problem Index and the Pelvic Pain and Urgency/Frequency (PUF) Patient Symptom Scale for Brazilian culture was performed successfully. Carefully defined methodology was used to obtain Portuguese versions that are faithful to the originals in English.

Applying both instruments to more than one group of individuals during the pretest was crucial for obtaining Brazilian versions that are easily understandable and widely applicable. Confusion and doubt that arise as a result of poor education or cultural differences in the target population will require attention if the instrument is used in other cultural contexts.

This is a study that predates the validation process, and these results are important in terms of the use of the questionnaire produced in new studies so the properties of its psychometric measures can be properly evaluated.

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