Development and Validation of a Japanese-language Questionnaire to Screen for Tension-type Headaches and Migraines

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Abstract

Introduction

Tension-type headaches (TTH) and migraines are prevalent conditions. However, no reliable biological markers have been identified for screening. Validated screening tools are useful in clinical practice as they provide an objective and multifaceted understanding of the symptoms of headache patients. Therefore, there is a need to develop a screening tool in Japanese that can be used in clinical practice based on the criteria of the International Classification of Headache. The aim of this study is to develop a questionnaire for screening TTH and migraine. The procedure was performed with headache specialists and designed to better understand patients’ headache symptoms. Several items in the questionnaire were validated to ensure they adequately screened for these types of headaches.

Methods

The questionnaire included questions to confirm the presence or absence of chronic headache, other items to screen for migraine and TTH, and questions necessary for a deeper understanding of the patient’s symptoms, based on the third edition of the International Classification of Headache Disorders (ICHD-3) diagnostic criteria. The screening items were selected using Item Response Theory (IRT). Sensitivity and specificity were calculated for the final remaining items (migraine: 10 items, TTH: eight items).

Results

The study population comprised 69 patients (mean age ± standard deviation, 55.0 ± 18.7 years) aged 19-89 years who were visiting hospital specializing in headache. According to the neurologists’ diagnoses, twenty-two patients had migraine, 30 had TTH, and 17 had mixed migraine/TTH. The sensitivity and specificity, comparing the neurologists’ diagnosis to our screening questionnaire were as follows: migraine, 72.7% and 86.7%; TTH, 50.0% and 86.4%, respectively.

Conclusions

The screening tool developed in this study has sufficient validity except for TTH. The questionnaire developed in this study is a rapid and sensitive tool for diagnosing migraine in persons with headache symptoms, but the sensitivity for TTH was not high enough.

Categories: Psychiatry, Psychology
Keywords: screening, specificity, sensitivity, questionnaire, validity, migraine, tension-type headache

Introduction

Headache is the general term for pain that occurs in part or all of the head. Like fever and abdominal pain, headache is the name of a symptom, but chronic recurrent headache attacks are treated as headache disorders [1]. Primary headache is a condition in which the headache itself is the primary symptom. Migraine and tension-type headache (TTH) are the most common primary headaches.

Typical characteristics of migraine headaches are unilateral location, pulsating quality, moderate or severe intensity, aggravation by routine physical activity, and association with nausea and/or photophobia and phonophobia [1]. In Japan, a study found an annual migraine prevalence of 8.4% in a nationwide Japanese survey of subjects aged 15 years and older [2]. Another study in Oyama, Tottori Prefecture, which included residents aged 20 years and older, reported that 6.0% of residents had migraine [3]. Notably, migraine causes significant socioeconomic losses. The global prevalence of current migraine is estimated to be 10%, with a prevalence of 11% restricted to adults and a lifetime prevalence of 14% [4]. According to Pop et al.,
the cost associated with lost labor days due to migraine in the previous 4 weeks was estimated to be 5.565 US$, whereas loss of productivity was estimated to cost an additional 5.431 US$ [5].

Typical characteristics of TTH include bilateral pain of pressing or tightening quality and mild to moderate intensity (ICHD-3). Moreover, TTH has a higher prevalence than does migraine. In Japan, the annual prevalence of TTH was found to be 22.4% in a nationwide survey of residents 15 years of age and older [2]. A survey of residents aged 20 years and older in the town of Oyama, Tottori Prefecture, reported that 21.7% had TTH [3]. The global prevalence of current TTH was 38%, and when restricted to adults, it was 42% [4]. In contrast, the lifetime prevalence for TTH is estimated to be 46% [4].

Furthermore, like migraines, TTH cause significant socioeconomic losses. According to Pop et al., the cost of lost labor days due to TTH in the previous 4 weeks was estimated to be 1.523 US$, whereas loss of productivity cost another 2.795 US$ [5]. Therefore, there is a need for diagnostic tools to distinguish between migraine and TTH to prevent and correct the treatment of migraine and TTH. However, migraine and TTH present a challenge during screening because of the lack of biomarkers [6]. Thus, countries are developing such screening tools in their respective languages [7-21].

Validated screening tools are useful in clinical practice because they provide an objective and multifaceted understanding of the symptoms of headache patients. Therefore, there is a need to develop a screening tool in Japanese that can be used in clinical practice based on the criteria of the International Classification of Headache.

The aim of this study is to develop a questionnaire for screening TTH and migraine. The procedure was performed with headache specialists and designed to better understand patients’ headache symptoms.

The questionnaire was developed based on the International Classification of Headache Disorders (ICHD) [1], and its validity was assessed using screening items for each headache type.

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Materials And Methods

Questionnaire Structure

The questionnaire items were designed to facilitate the screening for migraine and TTH and to evaluate precisely the patient’s headache symptoms. First, two authors drafted the questionnaire based on the 3rd edition of the ICHD classification criteria (ICDH-3) [1]. Then, they added and modified questions with the help of three neurologists specialized in headaches, thereby deciding the final items (Figures 1, 2, and 3 in the Appendix). Although the questionnaire developed for this study was in Japanese, an English version is also provided in this paper (Figures 4, 5, and 6 in the Appendix).

The questionnaire comprises items to confirm the presence or absence of chronic headache (Q1, Q2, Q3, and Q4), others to screen for migraine and TTH (Q7, Q9, Q10ab, Q11abcd, Q12ab, Q13, and Q14), and questions for a deeper understanding of the patient’s symptoms (Q5ab, Q6, Q8abc, and Q12cd). Details on the questions are presented in the Appendix.

In total, 10 items were used to screen for migraine (Q7, Q9, Q10ab, Q11abcd, and Q12ab) and 11 for TTH (Q7, Q9, Q10ab, Q11abcd, Q12a, Q13, and Q14). These screening items were designed to meet the diagnostic criteria of the ICHD-3 based on the core symptoms of migraine and TTH, respectively.

Study subjects

The inclusion criteria were (1) age ≥18 years and (2) willingness to consent to participate in the study, (3) headache patients attending a hospital, and (4) patients with one of the following diagnoses: migraine, TTH, migraine/TTH. The exclusion criteria were (1) age <18 years, (2) reluctant to participate in the study.

Survey period and institution

The survey was conducted from March to June 2022 at the Department of Headache Neurology, Kotobukai Tominaga Hospital, Osaka, Japan.

Study flow

Patients with a diagnosis of migraine or TTH were given a written explanation and guide on filling out the questionnaire by three neurologists at the time of consultation. They asked patients whether they consented to survey participation. Patients who consented were asked to respond to the survey using their preferred
method: filling out the paper questionnaire or completing the online version via a QR code provided with the instructions.

Selection of screening items using IRT

The data were analyzed with JMP software program (JMP® Pro, Version 16.2.0; SAS Institute Inc., Cary, NC, USA). A two-parameter (2-PL) logistic Item Response Theory (IRT) model was developed to evaluate each screening item for its informativeness (discrimination).

Among the items required to screen for migraine and TTH (Q7, Q9, Q10ab, Q11abcd, Q13, and Q14), those with a calculated discrimination ≥1.35 (high or very high) were retained as screening (migraine: Q10ab and Q11abcd; TTH: Q10a, Q11abcd, and Q15) [22]. Other items (migraine: Q1 and Q2, Q13a; TTH: Q1 and Q5) were also retained as screening, being basic questions needed to check the diagnosis of primary headache, though they had low computational discrimination power. As a result, the final screening items were 10 for migraine and eight for TTH.

Calculation of sensitivity, specificity, and positive/negative predictive values

The sensitivity, specificity, and positive and negative predictive values were calculated for migraine, TTH. The 95% confidence intervals (CI) for each statistic were calculated using the Agresti-Coull method. The physician’s diagnosis (diagnosis previously issued to the patient) was used as the gold standard reference for calculating each statistic in comparison with the results of the screening questionnaire. Cohen’s kappa coefficients with 95% CIs were calculated to determine the agreement between the physician’s diagnosis and the questionnaire’s results. Statistical analyses were performed using EZR [23], a statistical software application that extends the capabilities of R and R Commander.

Approval of the Ethics Committee

This study was approved by the Ethics Committee on Research Involving Human Subjects of Waseda University in Japan (approval no., 2021-078) and the Ethics Committee of Kotobuki-kai Tominaga Hospital (approval no., 120116).

Results

A total of 79 patients completed the survey. Two patients were <18 years old, and two answered “no” to the question, “Have you ever had a headache?” Answering “no” to this question is a patient response error. Moreover, six patients provided incomplete answers. Therefore, 10 patients were excluded.

Finally, the responses of 69 patients (age, 19-89 years; mean age ± standard deviation, 55.0 ± 18.7 years), who were visiting Kotobuki Tominaga Hospital, were used in the statistical analysis. The demographic data of the surveyed population are shown in Table 1. According to the neurologists’ diagnoses, the headache types were migraine (n=22), TTH (n=30), and mixed migraine/TTH (n=17).

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>MIG</th>
<th>TTH</th>
<th>MIG + TTH</th>
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<tbody>
<tr>
<td>Age: Mean</td>
<td>55</td>
<td>42</td>
<td>67</td>
<td>51</td>
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<td>Range</td>
<td>19-89</td>
<td>19-75</td>
<td>23-89</td>
<td>27-72</td>
</tr>
<tr>
<td>Sex: Total</td>
<td>69</td>
<td>22</td>
<td>30</td>
<td>17</td>
</tr>
<tr>
<td>Male</td>
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<td>11</td>
<td>4</td>
</tr>
<tr>
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<td>51</td>
<td>21</td>
<td>18</td>
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<td>Other</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

TABLE 1: Demographic and clinical characteristics of the study population.

Abbreviations: MIG Migraine, TTH Tension-type headache

Sensitivity, specificity, and positive and negative predictive values

The sensitivity and specificity comparing the neurologists’ diagnosis to our screening questionnaire were as follows: for migraine, 72.7% and 86.7%, and for TTH, 50.0% and 86.4%. The kappa coefficients revealed moderate agreement in the case of migraine (κ = 0.60), whereas for TTH the agreement between the
physician’s diagnosis and the questionnaire’s results was low ($\kappa = 0.34$). Table 2 summarizes these results.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Sensitivity % (95%CI)</th>
<th>Specificity % (95%CI)</th>
<th>PPV % (95%CI)</th>
<th>NPV % (95%CI)</th>
<th>Kappa (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MIG</td>
<td>22</td>
<td>72.7 (51.6; 87.1)</td>
<td>86.7 (69.7; 95.3)</td>
<td>80.0 (57.8; 92.5)</td>
<td>81.3 (64.3; 91.5)</td>
<td>0.60 (0.38; 0.82)</td>
</tr>
<tr>
<td>TTH</td>
<td>30</td>
<td>50.0 (33.2; 66.9)</td>
<td>86.4 (65.8; 96.1)</td>
<td>83.3 (60.0; 95.0)</td>
<td>55.9 (39.4; 71.1)</td>
<td>0.34 (0.09; 0.59)</td>
</tr>
</tbody>
</table>

**TABLE 2: Sensitivity, specificity, and positive (PPV) and negative (NPV) predictive values for migraine, tension-type headache.**

Abbreviations: MIG Migraine, TTH Tension-type headache

**Discussion**

This study aimed to develop a headache-screening questionnaire to obtain a deeper understanding of a patient’s headache symptoms. Several items in the questionnaire were validated to ensure they adequately screened for TTH and migraine. The screening tool was valid, though only for migraine.

The specificity of the screening tool for migraine and TTH was reasonable. We developed screening items as rigorous diagnostic criteria based on discussions with neurologists specializing in headache and diagnostic classification. Many items in our screening tool were designed to exclude patients with even a single "no" response. These strict exclusion criteria may have increased the specificity of the screening items.

The sensitivity in screening TTH was low. Screening tools for TTH are less commonly reported than those for migraine. The characteristics of pain and associated symptoms were less likely to be captured than did those of migraine. Screening accuracy for TTH is expected to be more difficult than for migraine. In many previous studies, sensitivity for TTH was lower than for migraine [7,11,13-18]. Several previous studies [13,19,21] that reported high sensitivity in TTH screening focused on TTH subtypes and pain frequency. However, this study excluded some of the questions used to determine pain severity, such as pain intensity and frequency. This was due to the low discriminant value in the selection of items using IRT.

The agreement (kappa coefficient) between the neurologist’s headache diagnosis and questionnaire rating was lower than that in previous studies, except for migraine. The kappa coefficients reported in previous studies ranged from 0.42 to 0.82 for migraine and 0.39 to 1.00 for TTH [7,12,14-17,21]. In this study, to exclude secondary headaches that were not chronic, patients were first asked if they had experienced the same headache repeatedly and the number of times they had experienced that headache. If they answered "yes," the headache was classified as migraine or TTH. However, many subjects answered "no" and were not correctly identified. We speculate that this was due to patients struggling to determine whether their headaches were the same each time. Secondary headaches are headaches that are triggered by an illness or physical injury. Dangerous secondary headaches include, for example, headaches attributed to ischaemic stroke or attributed to non-traumatic intracranial hemorrhage [1].

The International Classification of Headache, 3rd edition states the following:

"In a number of other conditions that can induce both headache and stroke, such as dissections, cerebral venous thrombosis, giant cell arteritis and central nervous system angiitis, headache is often an initial warning symptom. It is therefore crucial to recognize the association of headache with these disorders in order to diagnose correctly the underlying vascular disease and start appropriate treatment as early as possible, thus preventing potentially devastating neurological consequences. A clue that points to an underlying vascular condition is the onset, usually sudden, of a new headache, so far unknown to the patient. Whenever this occurs, vascular conditions should urgently be looked for [1]."

Therefore, Screening for primary headaches requires, first and foremost, attention to the absence of this life-threatening secondary headache.
In this study, we tried to rule out the possibility of secondary headaches by simply asking the question, “Have you ever experienced headaches with similar symptoms over and over again?” No additional description of the pain characteristics of secondary headaches was provided. Patients were therefore unclear to what extent these headaches were considered the same headache, which likely created much misunderstanding and confusion.

The study had the following strengths. First, the questionnaire items for migraine and TTH were developed based on the ICHD-3 [1] diagnostic criteria. The ICHD-3 [1] criteria are standard and highly reliable criteria used worldwide. Second, the number of questions was relatively small; many were multiple-choice with “yes” or “no” responses. Questions with limited options are less burdensome for the subjects; thus, many symptomatic persons can answer the questions.

There are two limitations to this study. First, the questionnaire was not designed to classify the TTH subtypes. To classify subtypes, items corresponding to the diagnostic criteria would have to be included in our questionnaire. Second, the subjects in this study had already been diagnosed with headaches prior to participating in this study. Thus, it is likely that they have been educated about headache symptoms and diagnosis. This may have influenced their responses.

The tool developed in this study effectively determines determining the type of headache in patients diagnosed with migraine. However, it is not sufficient to rule out secondary headaches. This tool is expected to be used in clinical practice. For instance, it could be used as a diagnostic aid for physicians or as a tool for in-depth assessment of the course of a patient’s headache condition.

**Conclusions**

The screening tool developed in this study has sufficient validity except for TTH. The questionnaire developed in this study is a rapid and sensitive tool for determining migraine in persons with headache symptoms, but the sensitivity for TTH was not high enough.

** Appendices **

あなたの頭痛についての質問

この度は、調査へのご協力ありがとうございます。この質問紙は5分程度で終わります。

これからあなたの頭痛について質問をします。Q1 からの質問に順番に沿ってお答えください。

Q1. これまでに頭痛を経験したことがありますか？1つだけ〇をつけてください。
   （はい・いいえ）

Q2. これまでに同じような症状の頭痛を繰り返し何度も経験していますか？
   （2-4回・5-10回・10回以上）

Q3. これまで（生きてきた中で）、その頭痛を何回くらい経験していますか？
   （2-4回・5-10回・10回以上）

Q4. 一定以上の時間、頭痛が起こることが、直近1か月以上の期間ありますか？
   （はい・いいえ）

Q5. あなたの頭痛の持続時間について質問します。

   a. 腦病・治療などの対処をしなかった場合、1回の頭痛はどれくらい続きますか？最も
      当てはまる選択肢に〇をつけてください。

      | ☐ 30分未満 | ☐ 4時間以上〜1日以内 | ☐ 続きなく持続する |
      | ☐ 30分以上〜1時間未満 | ☐ 1日以上〜3日以内 |
      | ☐ 1時間以上〜4時間未満 | ☐ 3日以上〜7日以内 |
      | ☐ その他 ( ) |

   b. 腦病・治療などの対処をした場合、1回の頭痛はどれくらい続きますか？最も当ては
      まる選択肢に〇をつけてください。

      | ☐ 30分未満 | ☐ 4時間以上〜1日以内 | ☐ 続きなく持続する |
      | ☐ 30分以上〜1時間未満 | ☐ 1日以上〜3日以内 |
      | ☐ 1時間以上〜4時間未満 | ☐ 3日以上〜7日以内 |
      | ☐ その他 ( ) |

FIGURE 1: Figure 1: Headache Questionnaire in Japanese: page 1.
Q.6 ．頭痛はどれくらいの頻度で起こりますか？いずれか1つだけ〇をつけてください。

□ 1か月に1日未満
□ 1か月に15日未満
□ 1か月に15日以上
□ 数時間〜数日間、または週間ごとに

Q.7．痛みの強さは平均してどの程度ですか？いずれか1つに〇をつけてください。
（弱・中に中～中・中～弱・強）

Q.8．痛みの位置と強さについて質問します。
a．痛みの場所はどちら側ですか？いずれか1つにチェックをつけてください。

□いつも右側　□いつも片側だが左右どちら端によって違う
□いつも左側　□左右の時もあれば、片側の時もある　□いつも両側

b．aで「いつも片側が左右どちら端によって違う」か「両側の時もあれば、片側の時もある」と回答した方のみお答えください。①何時、②右側の時、③左側の時、④左右の時はそれぞれ何％ですか？
□①□②□③□④

e．痛みの強さの割合について聞きます。当てはまるもの1つに〇をつけてください。

□左右同じ□左＞右
□右＞左□左＞右のときと左＞右のときがある

Q.9．痛みの性質について当てはまるものに〇をつけてください（複数選択可）。
「その他」を選んだ場合には、（ ）内に具体的な内容をご記入ください。

□脈拍に合わせるような、ズキズキ、ズキズキという痛み
□ジョーカーっと絡め付けられるような、圧迫されるような重い痛み
□その他（ ）

Q.10．痛みの性質について質問します。以下の項目に「はい」または「いいえ」に〇をつけてください。

a．步行や、眼鏡の昇り降りのような日常的な動作によって痛みが悪化しますか？（はい・いいえ）

b. 頭痛が起きたときは、歩行や、樹木の昇り降りのような日常的な動作を続けますか？
( はい ・ いいえ )

Q11. 頭痛時の症状について、以下の a-d の項目にお答えください。
a. 吐き気（恶心）はありますか？（ はい ・ いいえ ）
b. 実際に吐くことはありますか？（ はい ・ いいえ ）
c. 光に敏感になって、光がまぶしく感じますか？（ はい ・ いいえ ）
d. 音に敏感になって、音がうるさく感じますか？（ はい ・ いいえ ）

Q12a. 頭痛のための薬を飲むことがありますか？（ ある ・ ない ）
Q12b. その薬はどれにあればなりませんか？
( 処方薬（トリプタムを含む） ・ 处方薬（抗痛薬のみ、トリプタムなし） ・ その他)
Q12c. 頭痛のために飲んでいる痛み止めの薬を、3ヶ月以上の間、定期的に飲んでいたことがありますか？
( はい ・ いいえ )
Q12d. その薬を飲む頻度はどれくらいですか？

| □月に15回以上 | □月に2〜4回 |
| □月に10〜14回 | □月に1回 |
| □月に5〜9回   | □月に1回以下 |

Q13. 頭痛が起きる直後に、下記に該当するような症状はありますか？
一過性視覚障害、感覚症状、言語症状、運動症状、制御症状、視覚症状
( あてはまる前見がある ・ あてはまる前見はない )

Q14. 頭痛が起こる直後の直前は、5分〜60分間度持続しますか？（ はい ・ いいえ ）

質問は以上となりますが、皆様の回答ありがとうございました。
Additional File 2: Headache Questionnaire in English.

Questions about your headache

Thank you for taking the time to complete this survey. This questionnaire will take about 5 minutes to complete.

We will now ask you some questions about your headaches. Please circle the answer that applies to you. Please answer the questions in the order that they appear, starting with Q1.

Q1. Have you ever experienced a headache? (Yes  No)
Q2. Have you ever experienced headaches with similar symptoms over and over again? (Yes  No)
Q3. How many times in your life have you experienced these headaches?
   (2-4 times  5-10 times  more than 10 times)
Q4. Have you had headaches over a certain amount of time in the last three months? (Yes  No)

Q5. Tell us about how long your headaches last.
   a. How long does one headache last if not treated with medication, therapy, or other measures? Please check the box that applies most to you.

   - [ ] Less than 30 minutes
   - [ ] Between 30 minutes and 1 hour
   - [ ] Between 1 and 4 hours
   - [ ] Between 4 hours and 1 day
   - [ ] More than 1 day

   b. If you take medication, have therapy, or use other measures to alleviate a headache, how long does each headache last? Please check the box that applies most to you.

   - [ ] Less than 30 minutes
   - [ ] Between 30 minutes and 1 hour
   - [ ] Between 1 and 4 hours
   - [ ] Between 4 hours and 1 day
   - [ ] More than 1 day

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**FIGURE 4: Headache Questionnaire in English: page 1.**
Q6. How often do you get headaches? Please check only one of the following.

- [ ] Less than one day per month
- [ ] Less than 15 days per month
- [ ] More than 15 days per month
- [ ] A few hours to a few days or incessantly

Q7. What is the average intensity of your pain? Please check only one of the following.
(Weak • Weak to medium • Medium • Medium to strong • Strong)

Q8. Questions about the location and intensity of the pain.
   a. On which side of your head is the pain located? Please check one of the following.

   - [ ] Always on the right side
   - [ ] Always on one side, but sometimes on the right and sometimes on the left
   - [ ] Always on the left side
   - [ ] Sometimes on both sides, sometimes on one side
   - [ ] Always on both

   b. If you checked "Always on one side, but sometimes on the right and sometimes on the left," or

   "Sometimes on both sides, sometimes on one side," in Q8a, please answer the following: When you have a
   headache, what percentage of the time is it (i) on both sides, (ii) on only the right side, and (iii) on only the
   left side?

   i)    ii)   iii)

   c. Please check one of the following regarding average pain intensity.

   - [ ] Slight for left and right sides
   - [ ] Left is worse than right side
   - [ ] Right is worse than left side
   - [ ] Sometimes right is worse and sometimes left is worse

Q9. Please check the appropriate box for the nature of your pain. If you choose "other," please provide specific
   details in parentheses.

   - [ ] Throbbing pain that feels like it is in time with my pulse
   - [ ] Heavy pain that feels as if it is squeezing
   - [ ] Other ( )
FIGURE 6: Headache Questionnaire in English: page 3.

Additional Information

Disclosures

Human subjects: Consent was obtained or waived by all participants in this study. Human Subjects of Waseda University in Japan, Kotobuki-kai Tominaga Hospital issued approval approval no., 2021-078(Waseda University), 120116(Kotobuki-kai Tominaga Hospital). Ethics approval and consent to participate This study was approved by the Ethics Committee on Research Involving Human Subjects of Waseda University in Japan (approval no. 2021-078) and the Ethics Committee of Kotobuki-kai Tominaga Hospital (approval no., 120116). All participants provided written informed consent. Animal subjects: All authors have confirmed that this study did not involve animal subjects or tissue. Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following: Payment/services info: All authors have declared that no financial support was received from any organization for the submitted work. Financial relationships: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. Other relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.
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