

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form ([see an example](#)) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

This paper was submitted to the JNNP but declined for publication following peer review. The authors addressed the reviewers' comments and submitted the revised paper to BMJ Open where it was re-reviewed and accepted.

ARTICLE DETAILS

TITLE (PROVISIONAL)	The Eye Response Test Alone Is Sufficient To Predict Stroke Outcome: Re-Introduction of Japan Coma Scale. A cohort study
AUTHORS	Shigematsu, Kazuo; Nakano, Hiromi; Watanabe, Yoshiyuki

VERSION 1 - REVIEW

REVIEWER	Batcho, Charles Université catholique de Louvain, Institute of Neuroscience
REVIEW RETURNED	18-Dec-2012

GENERAL COMMENTS	<p>General comment:</p> <p>The authors aimed to verify the predictability of the Japan Coma Scale, which is an attempt to make this scale attain international recognition. This study is interesting given the vital importance of accurate and prompt assessment of consciousness level during emergency care.</p> <p>Authors investigated relationships between the JCS score and activity of daily living or deaths within 30 days from stroke onset. Their investigation is based on a large population of stroke patients; and this could certainly be one of the strengths of this study. However, there are some points of discussion that authors may wish to consider.</p> <p>Points to consider :</p> <p>1- Authors did not investigate the predictability of the JCS in light of modern psychometric approach. Item Response Theory and some practical approaches such as Rasch model have been promoted to compensate the limitations of Classical Test Theory. And they are indeed widely used to investigate psychometric qualities of measurement tools, especially those designed to measure latent trait. Consciousness level is a latent trait and scales dedicated to its measurement should preferably undergo Rasch analysis to confirm or not their metric properties. I would like to invite authors to consider this approach in further investigations on the JCS. This would give more added-value to their findings.</p> <p>2- Otherwise, authors should consider more the literature and be critical about the existing coma scales, including the JCS, in their introduction and discussion. They should for example review existing scales and compare them to the JCS to give more reasons on why performing the present study. It looks like the result of their investigation is known prior to the analyses. For example at the end of the introduction section they write that the aim of the study is to show that the JCS predicts early outcome and to re-introduce this simple coma scale to the world.</p>
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	<p>3- Activity of daily living (ADL) constituted an important outcome in their investigation since this allowed to examine the predictability of the JCS. However, it is not clear how authors evaluated ADL. They described on page 6 a 5-categories likert-type scale to evaluate ADL. There was no reference to support the use of this “scale”. Moreover, there was no information about the validity of this “ADL scale”, neither about the consistency use of this 5-categories scale across different centers by different assessors. Unfortunately, as weak theory leads to weak conclusions, readers may have doubts about the real predictability of the JCS. I would advise authors to design a prospective study, selecting appropriate outcomes based on more powerful scales that measure activity or functional limitations to evaluate accurately the ADL level of patients before investigating the predictability of the JCS. There are a number of more powerful scales designed to measure activity or functional limitations in stroke that authors could use if validated in their stroke population (Batcho et al. Stroke, 2012 43:815-823; Duncan et al. Arch Phys Med Rehabil. 2003;84:950-963, etc...).</p> <p>4- On page 7, they indicated that they had sent out a questionnaire on what coma scale a selected sample of professionals (nurses and members of rescue squads) preferably used in practice. However, they did not explain how this matches the global aim of the study. What was the purpose of sending out this questionnaire? How were the 219 professionals selected?</p> <p>5- On page 11: Authors wrote that “the simplicity of the JCS provides consistency among raters”; however, they did not actually test that. How did they find out that “the four categories in the JCS are well defined” and that “they do not overlap...”?</p> <p>6- On page 12: there is large paragraph on the historical information on the JCS. This information does not seem to be put at the right place in the article. It would better having it (if necessary to have it!) in the introduction section rather than in the discussion section.</p> <p>7- Pages 13 and 14: Authors wrote that the simplicity of the JCS minimizes the possible variability of scores due to possible fluctuations of consciousness level in short period. But how is variability really minimized by JCS? This statement requires more explanations and evidence.</p> <p>8- The correlation between JCS scores and ADL level was moderate (0.6), and authors concluded that “the JCS is an excellent predictor of stroke outcome”. They should be more modest in the interpretation of their results.</p>
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- The manuscript received a second and third review at the JNNP but the reviewers did not give permission for their comments to be published.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Comments to the Author

Manuscript ID: jnnp-2012-304567

Title: A simple coma scale predicts stroke outcome. Re-introduction of Japan Coma Scale

General comment:

The authors aimed to verify the predictability of the Japan Coma Scale, which is an attempt to make this scale attain international recognition. This study is interesting given the vital importance of accurate and prompt assessment of consciousness level during emergency care.

Authors investigated relationships between the JCS score and activity of daily living or deaths within

30 days from stroke onset. Their investigation is based on a large population of stroke patients; and this could certainly be one of the strengths of this study. However, there are some points of discussion that authors may wish to consider.

Points to consider :

1- Authors did not investigate the predictability of the JCS in light of modern psychometric approach. Item Response Theory and some practical approaches such as Rasch model have been promoted to compensate the limitations of Classical Test Theory. And they are indeed widely used to investigate psychometric qualities of measurement tools, especially those designed to measure latent trait. Consciousness level is a latent trait and scales dedicated to its measurement should preferably undergo Rasch analysis to confirm or not their metric properties. I would like to invite authors to consider this approach in further investigations on the JCS. This would give more added-value to their findings.

Response:

We appreciate your advice. We would like to consider the approach you suggested in our further investigations on the JCS. The Kyoto Stroke Registry is progressing. We would like to keep improving it.

2- Otherwise, authors should consider more the literature and be critical about the existing coma scales, including the JCS, in their introduction and discussion. They should for example review existing scales and compare them to the JCS to give more reasons on why performing the present study. It looks like the result of their investigation is known prior to the analyses. For example at the end of the introduction section they write that the aim of the study is to show that the JCS predicts early outcome and to re-introduce this simple coma scale to the world.

Response:

You are right.

The predictability of the JCS is well known in Japan empirically. The JCS has been widely used in Japan. There is, however, little evidence published in international scientific journals to prove it. The main purpose of the study is to provide statistical analyses. Since we have a large stroke registry, we reviewed it to confirm the hypothesis that the JCS should predict outcome of stroke patients.

The definition of the JCS is so clear and simple. We believe readers will understand it easily. Each existing coma scale should have strengths and weaknesses. We don't have sufficient data to compare the JCS and others.

3- Activity of daily living (ADL) constituted an important outcome in their investigation since this allowed to examine the predictability of the JCS. However, it is not clear how authors evaluated ADL. They described on page 6 a 5-categories likert-type scale to evaluate ADL. There was no reference to support the use of this "scale". Moreover, there was no information about the validity of this "ADL scale", neither about the consistency use of this 5-categories scale across different centers by different assessors. Unfortunately, as weak theory leads to weak conclusions, readers may have doubts about the real predictability of the JCS. I would advise authors to design a prospective study, selecting appropriate outcomes based on more powerful scales that measure activity or functional limitations to evaluate accurately the ADL level of patients before investigating the predictability of the JCS. There are a number of more powerful scales designed to measure activity or functional limitations in stroke that authors could use if validated in their stroke population (Batcho et al. Stroke, 2012 43:815-823; Duncan et al. Arch Phys Med Rehabil. 2003;84:950-963, etc...).

Response:

You are right. There is no scientific paper on the scale published in English and there is no reference.

The ADL scale we used is most commonly used in Japan.

Social welfare and health care systems in Japan have used this scale commonly. The Kyoto Stroke Registry (KSR) has established since 1989 and has adopted the ADL scale since then. We believe that the scale should not have caused a major bias in this study.

4- On page 7, they indicated that they had sent out a questionnaire on what coma scale a selected sample of professionals (nurses and members of rescue squads) preferably used in practice. However, they did not explain how this matches the global aim of the study. What was the purpose of sending out this questionnaire? How were the 219 professionals selected?

Response:

The purpose of this was to provide quantitative data to show that the JCS is widely used in Japan, which is apparent for Japanese. The JCS is most widely used in Japan. It is the fact. However, there is no scientific literature which we can cite as a reference.

We omitted this section from the manuscript.

5- On page 11: Authors wrote that “the simplicity of the JCS provides consistency among raters”; however, they did not actually test that. How did they find out that “the four categories in the JCS are well defined” and that “they do not overlap...”?

Response:

You are right. Nobody tested that. We believe the simplicity of the JCS provides consistency. At emergency setting especially, the simplicity helps namely physicians, nurses, and emergency medical technicians. They use the JCS almost always.

6- On page 12: there is large paragraph on the historical information on the JCS. This information does not seem to be put at the right place in the article. It would better having it (if necessary to have it!) in the introduction section rather than in the discussion section.

Response:

We recognize your comment. However, we believe this information is important. We would like to leave the message as it is.

There is no study comparing the Glasgow Coma Scale (GCS) and the JCS. The GCS is a standard coma scale internationally. On the other hand, the JCS is a standard coma scale in Japan. They were published in the same year. However, the JCS was introduced only in Japanese. Although the JCS may not be known well outside of Japan, it is a practical coma scale and very useful. This study showed the predictability of the JCS.

7- Pages 13 and 14: Authors wrote that the simplicity of the JCS minimizes the possible variability of scores due to possible fluctuations of consciousness level in short period. But how is variability really minimized by JCS? This statement requires more explanations and evidence.

Response:

We don't have any written evidence which we can cite as a reference.

8- The correlation between JCS scores and ADL level was moderate (0.6), and authors concluded that "the JCS is an excellent predictor of stroke outcome". They should be more modest in the interpretation of their results.

Response:

We would like to be modest. We omitted "excellent".

VERSION 2 – REVIEW

REVIEWER	Charles Sèbiyo BATCHO Institute of Neuroscience, Faculty of Motricity Science Université catholique de Louvain, Belgium In relation to this manuscript I have no competing interests.
REVIEW RETURNED	12-Mar-2013

GENERAL COMMENTS	<p>General comment: The authors aimed to verify the predictability of the Japan Coma Scale, which is an attempt to make this scale attain international recognition. This study is interesting given the importance of accurate and prompt assessment of consciousness level during emergency care.</p> <p>Authors investigated relationships between the JCS score and activity of daily living or deaths within 30 days from stroke onset. Their investigation is based on a large population of stroke patients; and this could certainly be one of the strengths of this study. However, there are some points of discussion that authors may wish to consider.</p> <p>Points to consider :</p> <p>1- Authors should consider the literature and present in their introduction the pros and cons of coma scales, including GCS, JCS and other if they exist.</p> <p>2- The aim of the study is not consistently mentioned throughout the manuscript. In the abstract (page 2), they wrote "The aim of the study is to verify the predictability of the JCS, ...". In the article summary (page 4), they indicated that "the aim of the study is to confirm its predictability...". And in the introduction (page 6), it is indicated that "the aim of the study is to show that the JCS predicts early outcome...". I think Authors should use consistently the term that best describes the objective of their investigation between "verify", "confirm", and "show".</p> <p>3- Authors did not investigate the predictability of the JCS in light of modern psychometric approach. Consciousness level is a latent trait and scales dedicated to its measurement should preferably undergo Rasch analysis to confirm or not their metric properties. Applying Rasch analysis would give more added-value to this study since it would help authors to investigate some aspects of the measurement properties of the JCS such as the appropriateness of the response format through the examination of categories discrimination.</p>
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	<p>4- Activity of daily living (ADL) constituted an important outcome in their investigation since this allowed to examine the predictability of the JCS. They described on pages 7 and 8 a 5-categories likert-type scale to evaluate ADL. However, the validity of this “ADL scale” is not proved. Moreover, there is no information about how consistently different assessors from different centers used the 5-categories scale in this multicentric large study. This is a crucial point since there was no standardized description of the 5 ADL levels. This ADL scale was based on how each patient performed “usual activities”. Without standardization, “usual activities” may change from a patient to another one according to their lifestyle and environment. This means that a same score may represent different ADL levels for different patients. Authors should question the validity of their “ADL scale” and consider providing more evidence.</p> <p>5- There are some extrapolated statements in the discussion. For example:</p> <ul style="list-style-type: none"> ♣ On page 12: Authors stated that “it is much easier to grasp the outline of a patient condition with the JCS than any multi-axes scales”. But as I understand, they do not compare the predictability of JCS with any other coma scale. How do they justify this finding based only on the present analysis? ♣ On page 12: Authors wrote that “the simplicity of the JCS provides consistency among raters”; however, they did not actually test that. How did they find out that “the four categories in the JCS are well defined” and that “they do not overlap...”? ♣ Pages 14 and 15: Authors wrote that the simplicity of the JCS minimizes the possible variability of scores due to possible fluctuations of consciousness level in short period. But how is variability minimized by JCS? This statement requires more explanations and evidence. <p>6- On page 13: there is large paragraph on the historical information on the JCS. This information does not seem to be put at the right place in the article. This paragraph can be shortened and included in the introduction section as a background.</p>
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VERSION 2 – AUTHOR RESPONSE

Reviewer: Charles Sèbiyo BATCHO
 Institute of Neuroscience, Faculty of Motricity Science
 Université catholique de Louvain, Belgium

We are grateful to the reviewer for the critical comments and useful suggestions that have helped us to improve our paper. As indicated in the responses that follow, we have taken all these comments and suggestions into account in the revised version of our paper.

Comment

1- Authors should consider the literature and present in their introduction the pros and cons of coma

scales, including GCS, JCS and other if they exist.

Response

Thank you for your suggestion. As suggested, we added the sentences as follows:

Systems for describing patients with impaired consciousness were not consistent until 1974, when the GCS and the JCS were developed [1]. There was an abundance of alternative terms by which levels of coma or impaired consciousness were described and recorded [1]. Teasdale and Jennett described that some might have reservations about a system which seemed to undervalue the niceties of a full neurological examination. Just as the GCS, it is no part of the JCS to deny the value of a detailed appraisal of the patients as a whole, and of neurological function in particular [1].

Comment

2- The aim of the study is not consistently mentioned throughout the manuscript. In the abstract (page 2), they wrote "The aim of the study is to verify the predictability of the JCS, ...". In the article summary (page 4), they indicated that "the aim of the study is to confirm its predictability...". And in the introduction (page 6), it is indicated that "the aim of the study is to show that the JCS predicts early outcome...". I think Authors should use consistently the term that best describes the objective of their investigation between "verify", "confirm", and "show".

Response

Thank you for your suggestion. As suggested, we used the term "verify" consistently throughout the manuscript.

Comment

3- Authors did not investigate the predictability of the JCS in light of modern psychometric approach. Consciousness level is a latent trait and scales dedicated to its measurement should preferably undergo Rasch analysis to confirm or not their metric properties. Applying Rasch analysis would give more added-value to this study since it would help authors to investigate some aspects of the measurement properties of the JCS such as the appropriateness of the response format through the examination of categories discrimination.

Response

Thank you for your suggestion. As suggested, we added the sentences as follows:

We did not investigate the predictability of the JCS in light of modern psychometric approach in this study. Consciousness level is a latent trait and scales dedicated to its measurement should preferably undergo Rasch analysis to confirm or not their metric properties. Applying Rasch analysis would give more added-value to the study since it would help to investigate some aspects of the measurement properties of the JCS such as the appropriateness of the response format through the examination of categories discrimination.

Comment

4- Activity of daily living (ADL) constituted an important outcome in their investigation since this allowed to examine the predictability of the JCS. They described on pages 7 and 8 a 5-categories likert-type scale to evaluate ADL. However, the validity of this "ADL scale" is not proved. Moreover,

there is no information about how consistently different assessors from different centers used the 5-categories scale in this multicentric large study. This is a crucial point since there was no standardized description of the 5 ADL levels. This ADL scale was based on how each patient performed “usual activities”. Without standardization, “usual activities” may change from a patient to another one according to their lifestyle and environment. This means that a same score may represent different ADL levels for different patients. Authors should question the validity of their “ADL scale” and consider providing more evidence.

Response

Thank you for your suggestion. As suggested, we added the sentences as follows:

The validity of the ADL scale has not been proved yet. Moreover, there is no study about how consistently different assessors from different centers used the 5-categories scale yet. This ADL scale is based on how each patient performed “usual activities”, which may change from a patient to another according to their lifestyle and environment. However, the ADL Scale is widely used in Japan. It is also simple scale and may have a practical value. We would like to study the validity, consistency among assessors and the way to elaborate the ADL scale.

Comment

5- There are some extrapolated statements in the discussion. For example:

- ♣ On page 12: Authors stated that “it is much easier to grasp the outline of a patient condition with the JCS than any multi-axes scales”. But as I understand, they do not compare the predictability of JCS with any other coma scale. How do they justify this finding based only on the present analysis?
- ♣ On page 12: Authors wrote that “the simplicity of the JCS provides consistency among raters”; however, they did not actually test that. How did they find out that “the four categories in the JCS are well defined” and that “they do not overlap...”?
- ♣ Pages 14 and 15: Authors wrote that the simplicity of the JCS minimizes the possible variability of scores due to possible fluctuations of consciousness level in short period. But how is variability minimized by JCS? This statement requires more explanations and evidence.

Response

Thank you for your suggestion. As suggested, we rewrote the sentences as follows:

- ♣ On page 12: “it might be easier to grasp the outline of a patient condition with the JCS than any multi-axes scales”.
- ♣ On page 12: “the simplicity of the JCS might provide consistency among raters”
- ♣ Pages 14 and 15: the simplicity of the JCS might minimize the possible variability of scores due to possible fluctuations of consciousness level in short period.

Comment

On page 13: there is large paragraph on the historical information on the JCS. This information does not seem to be put at the right place in the article. This paragraph can be shortened and included in the introduction section as a background.

Response

Thank you for your suggestion. As suggested, we shortened the paragraph and put it in the introduction section as a background.

1. Teasdale G, Jennett B. Assessment of coma and impaired consciousness. A practical scale. *Lancet* 1974;2(7872):81-4