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Re-introduction of the Japan Coma Scale

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2013-002736
Article Type:	Research
Date Submitted by the Author:	16-Feb-2013
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Primary Subject Heading:	Emergency medicine
Secondary Subject Heading:	Epidemiology, Neurology
Keywords:	Stroke < NEUROLOGY, Neurology < INTERNAL MEDICINE, Stroke medicine < INTERNAL MEDICINE

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Short title: The Japan Coma Scale predicts stroke outcome

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Key Words: scales; coma; consciousness; stroke

Contributorship: All authors contributed equally in the data collection and analysis. KS wrote the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest: None
Funding: None

Abstract

Objective

Prompt assessment of consciousness level is vitally important during the emergency care of stroke patients. Requirements for a better scale include simplicity, reliability, applicability and predictability for outcome. The Japan Coma Scale (JCS) is a one-axis coma scale published in 1974 with outstanding simplicity. The hypothesis is that the JCS is sufficient to predict the stroke outcome. The aim of the study is to verify the predictability of the JCS, which should help the JCS attain international recognition.

Methods

We investigated the relationship between consciousness level based on the JCS at the stroke onset and activities of daily living (ADL) at 30 days or deaths within 30 days in a large population-based stroke registry. We calculated Spearman's correlation coefficients for the correlation between the JCS and ADL scale, generated estimated survival curves by the Kaplan-Meier method and finally compared hazard ratios for

death within 30 days after onset, comparing patients with different conscious levels based on the JCS.

Results

A total of 13,788 (97.2%) patients were graded based on the JCS. The JCS correlated to ADL scores with a Spearman's correlation coefficient of 0.61. Hazard ratios for death within 30 days were 1 (reference), 5.55, 9.54 and 35.21 in those scored as JCS0, JCS1, JCS2 and JCS3, respectively.

Conclusions

Using a single test of eye response, the JCS has outstanding merits as a coma scale: i.e. simplicity and applicability. The present study adds predictability for the early outcome in stroke patients. The JCS is valuable especially at an emergency setting when a prompt assessment of consciousness level is needed.

Article summary

Article focus

The Japan Coma Scale (JCS) is a one-axis coma scale published in 1974. It is so simple and easy to use that it has been established as a standard coma scale in Japan. Nevertheless, it has little recognition internationally. The aim of the study is to confirm its predictability in stroke patients. We hope the JCS will contribute to the medical profession and especially to the emergency medical-care.

Key messages

Using a single test of eye response, the JCS has outstanding merits as a coma scale: i.e. simplicity and applicability. The present study adds predictability for the early outcome in stroke patients. The JCS is valuable especially at an emergency setting when a prompt assessment of consciousness level is needed.

Strengths and limitations of this study

Strengths: the study is based on a large stroke registry and the JCS has been used widely in Japan.

Limitations: there are few studies on the JCS and on the ADL scale in scientific international journals yet.

Introduction

Prompt assessment of consciousness levels is vitally important during the emergency care of stroke patients. There is no current perfect coma scale, and requirements for a better scale include:

1) Simplicity: ease of assessment, ease of recording, ease of sharing with medical and co-medical staff.
2) Reliability: consistency among assessors.
3) Applicability: for any patient in any setting.
4) Predictability for the outcome.

The Japan Coma Scale (JCS) has become widely used in Japan since it was first published in 1974[1-3] . An outstanding feature of the JSC is its simplicity, which has prompted both pre-hospital personnel and in-hospital staff to use the scale. The JCS enables prompt communication among emergency service staff and hospital staff and among nurses and physicians. However, the JSC's predictability of the outcome has not been clarified to date. The lack of evidence of its predictability may have prevented the JCS from attaining international recognition.

Our hypothesis is that consciousness levels categorized by the JCS should correlate with the severity of stroke and therefore should predict outcome of stroke. If the predictability of the JCS is demonstrated, it should be re-appraised as a prompt coma scale. Although we have the Glasgow Coma Scale (GCS), which was also published in 1974 [4 5], it would be more pragmatic to have a simpler coma scale especially in an emergency. The major difference between the GCS and the JCS is that the former is a three-axis scale whereas the latter is a one-axis scale.

The aim of the study is to show that the JSC predicts early outcome, including the level of activity of daily life (ADL) and the hazard ratios for death, and, subsequently, to re-introduce this simple coma scale to the world.

Materials and Methods

We studied the relationship between the outcome at 30 days after stroke and the consciousness levels based on the JCS at the onset of neurological impairment. We analyzed all new stroke patients identified from January 1999 to December 2009 inclusive in the entire Kyoto prefecture and registered in the Kyoto Stroke Registry (KSR) [6]. Detailed information on the KSR has been described previously (Shigematsu

et al. BMJ Open, in press). The diagnosis of stroke was confirmed by local neurologists and/or neurosurgeons according to the WHO definition [7]. We categorized the patients into cerebral infarction (CI), cerebral hemorrhage (CH), subarachnoid hemorrhage (SAH) and others, based on the neurological findings, laboratory data, and findings of CT, MRI and angiography.

We used the following definitions.

1) Consciousness levels based on the JCS encompassed four levels:

   1 JCS 0 (alert)

   2 JCS 1 (not fully alert but awake without any stimuli)

   3 JCS 2 (arousable with stimulation)

   4 JSC 3 (unarousable)

2) ADL scale at 30 days after stroke onset included five levels:

   1 ADL1 (No symptoms or no significant disability. Able to carry out all usual activities without help. Able to walk without a mobility aide)

   2 ADL2 (mildly disabled, or utilization of mobility aide. Unable to carry out all usual activities without help. Unable to walk without mobility aide.)

   3 ADL3 (moderately disabled, or wheelchair-bound condition. Unable to walk

without assistance.)

4 ADL4 (severely disabled, or bed-bound condition. Unable to use wheel chairs without help.)

5 ADL5 (Dead)

Ethics Statement

This research was performed in accordance with the ethical principles for medical research involving human subjects outlined in the Declaration of Helsinki. This research was approved by the Board of Directors, the Kyoto Medical Association, the Department of Health and Welfare, Kyoto Prefecture and Ethics Committee of the National Hospital Organization, Minami Kyoto Hospital. Since all identifying personal information was stripped from the secondary files before analysis, the boards waived the requirement for written informed consent from the patients involved.

Statistical Analyses

The frequencies of characteristics among the four conscious levels were determined and evaluated for univariate associations by Chi-square analysis. Numerical data such as age and blood pressure were compared with Student-t test. Spearman's rank correlation

coefficients were used to identify the correlation between the JCS and ADL scale. We used the Kaplan-Meier method for curves of estimated survival, a log-rank test for comparisons of estimated survival among the JCS categories, and Cox proportional hazards regression for hazard ratios for death. Adjustments for age, sex, systolic and diastolic blood pressures, histories of hypertension, arrhythmia and diabetes mellitus, stroke type and paresis were also utilized. Analyses were performed using SPSS ver.19. All reported p values are 2-sided.

Results

The characteristics of patients are summarized in Table 1. Data on age, and sex were complete in all patients in the study cohort. The other characteristics had missing data in a few patients. The numbers of patients examined are shown in the tables.

We evaluated the consciousness levels of 13,406 patients out of 13,788 (97.2%), based on the JCS. JCS data were mission for 382 patients (2.8%). Among the 13,406 patients, the number and percentage per group were as follows: JCS0 (7,676 [55.7%]), JCS1 (2,619 [9.0%]), JCS2 (1,602 [11.6%]) and JCS3 (1,509 [10.9%]), respectively. We evaluated the ADL scale in 12,601 (91.4%) patients at 30 days after the onset of

neurological impairment. We obtained data on both the JCS and the ADL scale in 12,277 (89.0%) of the stroke patients (Table 2).

The Spearman's correlation coefficient was 0.608 for the correlation between the JCS and ADL scale ($p<0.001$). Kaplan-Meier Survival curves of patients in each JCS category are presented (Figure 1). A log-rank test proved the differences were significant ($p<0.001$). For Kaplan-Meier Survival curves in each JCS category in each stroke subtype, see supplementary figures (Figure 1A, 1B and 1C).

Hazard ratios for death, comparing JCS categories and their 95% confidential intervals, are summarized in Table 3.

Discussion

The JCS principally focuses on eye responses. Being a single test, the JCS has outstanding merits as a coma scale: i.e. simplicity and applicability, which should minimize interpreter errors. Simplicity is very important in communication among physicians, nurses and paramedics, especially in emergency settings. The present study adds to its virtues the predictability for early outcome in stroke patients.

In summary, the advantages of the JCS include four points:

1) Predictability for stroke outcome.

This study showed the predictability of the JCS for the stroke outcome.

The JSC correlated with ADL scale. Hazard ratios for death were significantly different among JCS categories: 1.00 (as reference), 5.55, 9.54 and 34.21 in JCS0, 1, 2 and 3, respectively. It is noteworthy that a simple one-axis test alone predicts early mortality with such clear differences. The JCS could be useful especially at an emergency setting when more detailed evaluation of a patient condition is difficult to obtain and prompt communications among doctors and co-medicals are needed. The JCS provides minimum but critical/essential information.

2) Simplicity.

The JCS is a 4-points scale (from 0 to 3) and comprises only one test: eye responses. The Glasgow coma scale (GCS), for example, is a 13-points scale (from 3 to 15) and comprises three tests: eye, verbal and motor responses. The JCS is similar to the eye response test in the GCS but even simpler than the GCS (i.e. both E2 and E3 belong in JCS2). Being a uni-coordinate axis scale is very important for simplicity. Although summing up scores in a multi-coordinate axes scale may not be difficult, the scores in different axes may have different values and therefore the interpretation of a total score can be difficult. Hypothetically, both E3V2M1 and E2V3M1 in the GCS, for example,

give the same total score of 6. A same total score in a multi-coordinate axes scale could reflect different underlying conditions and might be difficult to interpret. The description within the JCS is also simple (e.g. JCS, JCS0, JCS1, JCS2 and JCS3), which makes communication among staff easy, prompt and less misleading. It is much easier to grasp the outline of a patient condition with the JCS than with any multi-axes scales.

3) Reliability.

The simplicity of the JCS provides consistency among raters.

The four categories in the JCS are well defined. They do not overlap and they encompass all consciousness levels.

4) Applicability.

The JCS focuses on eye response, which broadens its applicability both for raters and for patients. Raters need only check eye responses in terms of three clearly differentiated categories: open, open only after stimuli and closed. No special knowledge, such as is needed to assess the decerebrate or decorticate response, is necessary. The JCS is applicable to almost all patients, including patients with aphasia, paresis and even in intubated patients, where it might be difficult to apply the GCS, because that has verbal and motor responses tests. In this population-based study, the JCS was applied to 13,406 out of 13,788 stroke patients (97.2%).

Historical information on the JCS

Ohta et al. launched a national survey on craniotomy for ruptured cerebral aneurysms, and described the JCS to define the consciousness level to be included in the survey, at the first meeting of the Society on Surgery for Cerebral Stroke, which was held at Miyagi, Japan (Sakunami Kanko Hotel) on May 13-14, 1972 [8]. At that meeting, he also organized a team to evaluate the scale, because there was no standardized coma scale established in those days. The JCS was based on his study on factors affecting the prognosis of ruptured aneurysm patients after surgical interventions [9]. The JCS was called the 3 group 3 grade method at first and then the "3-3-9 method"[1 10], since the detailed version of the scale composed of four categories: alert, 1-digit code, 2-digit code and 3-digit code, with each digit code having three subcategories (1, 2 and 3 in the 1-digit code, 10, 20 and 30 in the 2-digit code, and 100, 200 and 300 in the 3-digit code) [1]. It had 10 grades in total: alert plus 9 (3 by 3) grades. This version of the JCS included a motor response test in the 3-digit code patients and three special conditions: restlessness, incontinence and apathy. The first full paper was accepted on 30 November 1973 and published in 1974[1]. In this study, we applied the simple JCS without

subcategories, which is commonly used in Japan.

Limitations & Responses

1) Simplicity means lack of detail. The JCS does not evaluate verbal or motor responses, which are tested in the GCS. The total score in the GCS ranges from 3 to15 and the GCS can theoretically describe 120 (4 by 5 by 6) different conditions. The more tests a scale includes, the more details a scale can evaluate[11 12].

Response:

As far as the hazard ratios for early death and ADL scores, the JCS is sufficient as a predictor. A single-dimensional test is the best if the purpose of the test is fulfilled. If needed, we can describe a patient's condition in a detailed way: such as decerebrate posture and decorticate posture. In the JCS, three capital letters, R, I and A, are provided to describe restlessness, incontinence and apathy, respectively.

2) Consciousness levels may fluctuate even in a short period and scores may therefore be different from time to time.

Response:

This difficulty is common to every coma scale, and the simplicity of the JCS minimizes it. A multi-dimensional scale might cause more difficulty with evaluation .

3) Predictability of the outcome has inherent limitations [13]. The outcomes and therefore the hazard ratios for death depend not only on the baseline severity but also on the treatment and patient conditions, including complications. This study did not include the treatments which must affect outcomes.

Response:

For precise evaluation of a relationship between two factors, it should be important to adjust for all the other factors. Treatments, for example, often vary from a case to case. Adjustments for them are virtually impossible in a population based study. Major treatments for stroke, such as tPA therapy or surgical interventions, however, should not have caused a major bias in this study, because the differences in hazard ratios among the consciousness levels based on the JCS remain significant after adjustment for stroke subtypes, i.e. CI, CH and SAH. The JCS also predicted the outcomes in each three subtype of stroke by uni-variable analyses. A tPA therapy is not applied for hemorrhagic stroke and surgical interventions are rarely applied for ischemic stroke (In this study cohort, 374 (4.2%) out of 8896 CI patients had

surgical treatment).

There are two types of complications: ones that patients had before stroke onset and ones that they got after the onset. Although the former comprises numerous diseases, risk factors such as hypertension, arrhythmia and diabetes mellitus might be important. The difference in hazard ratios remained significant after adjustment for these three. The latter may include urinary tract infections, decubitus ulcers and pneumonia. They, however, occur as results of stroke, namely after the consciousness level estimation based on the JCS. Although they could be related to the initial severity of the stroke, data on this type of complications were not available in this study.

Conclusions

The Japan Coma Scale is a good predictor of stroke outcome. Its two outstanding advantages, simplicity and predictability, should make the JCS re-appreciated internationally as a standard coma scale.

Acknowledgments

We acknowledge the contribution of participating institutions and their staffs who provided data in the development of the Kyoto Stroke Registry. We thank Dr Tomio Ohta for the information on the establishment of the JCS.

Funding

None

Contributorship

All authors contributed equally in the data collection and analysis. KS wrote the manuscript. All authors read and approved the final manuscript.

Data Sharing

Annual reports of the Kyoto Stroke Registry are available at the Kyoto Medical Association.

Competing Interests

None

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Legends

Figure 1. Kaplan-Meier Survival curves for patients in each JCS category

Table 1 The characteristics of patients in the study cohort

Characteristic
1) Age
2) Sex (%of female, (n=female /male))
3) Subtype (CI/CH/SAH, % (n))
4) Systolic blood pressure
5) Diastolic blood pressure
6) Paresis (%, (n=with/without))
7) Hypertension history (%, (n= with/without))
8) Arrhythmia history (%, (n= with/without))
9) Diabetes mellitus history (%, (n= with/without))

Table 1 Continued

	JCS0 (n=7676)	JCS1 (n=2619)	JCS2 (n=1602)	JCS3 (n=1509)
1)	69.7±12.3*[123]	73.4±12.3*[3]	73.6±14.2*[3]	72.3±14.0
2)	39.8 (3056/4620)*[123]	47.7 (1249/1370)*[23]	56.9 (911/691)*[3]	54.7 (826/683)
3)	78.9/15.7/5.4 (6048/1201/415) *[123]	57.7/35.2/7.1 (1508/921/185) *[23]	48.5/39.0/12.5 (774/622/200)*[3]	28.0/47.7/24.3 (421/716/365)
4)	159.3±28.2*[123]	162.7±31.7*[3]	163.6±33.3*[3]	167.4±42.1
5)	87.0±17.1*[123]	88.0±19.0*[3]	88.6±20.6	89.8±24.4
6)	67.0 (5085/2501)*[123]	78.2 (2014/561)*[23]	83.1 (1278/260)*[3]	89.2 (1060/128)
7)	64.5 (4724/2605)*[123]	61.0 (1476/942)*[23]	59.8 (857/576)*[3]	59.3 (755/518)
8)	14.5 (1058/6233)*[123]	23.3 (569/1870)*[23]	28.2 (412/1047)*[3]	20.1 (254/1010)
9)	23.6 (1734/5629)*[123]	18.3 (449/2006)*[23]	15.1 (220/1237)	16.4 (209/1067)

*[1]: significant difference between JCS0 and JCS1

*[2]: significant difference between JCS1 and JCS2

*[3]: significant difference between JCS2 and JCS3

Data on some characteristics were missing in a few patients.

Table 2 Numbers of patients categorized by JCS and by ADL scale.

	Japan Coma Scale				Total
	JCS0	JCS1	JCS 2	JCS 3	
ADL1	4621	608	199	65	5493
ADL2	1908	816	365	104	3193
ADL3	417	442	287	111	1257
ADL4	146	276	325	296	1043
ADL5	102	201	227	761	1291
Total	7194	2343	1403	1337	12277

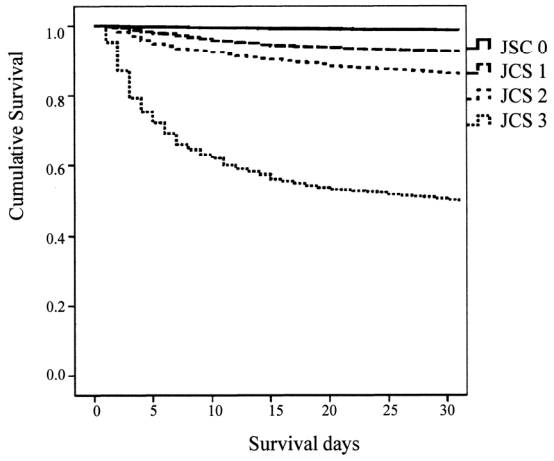
We obtained data on both the JCS and the ADL scale in 12,277 (89.0%) of the stroke patients.

Table 3 Hazard ratios for death, comparing JCS categories

	Hazard Ratio	95% Confidence Interval		p
		Lower	Upper	
JCS 0	Reference			
JSC 1	5.55	4.19	7.37	<0.001
JCS 2	9.54	7.16	12.71	<0.001
JSC 3	34.21	26.10	44.83	<0.001

Adjusted for age, sex, systolic and diastolic blood pressures, history (hypertension, arrhythmia and diabetes mellitus), stroke type and paresis

Figure 1



Kaplan-Meier Survival curves for patients in each JCS category
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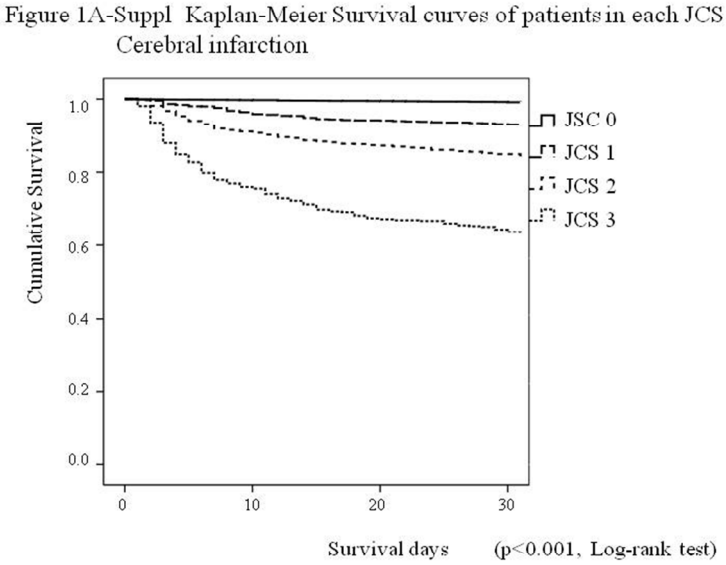
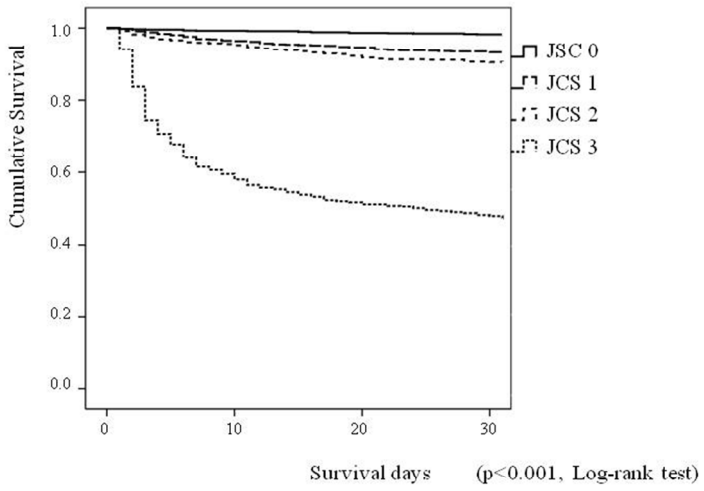


Kaplan-Meier Survival curves of patients in each JCS category
Cerebral infarction

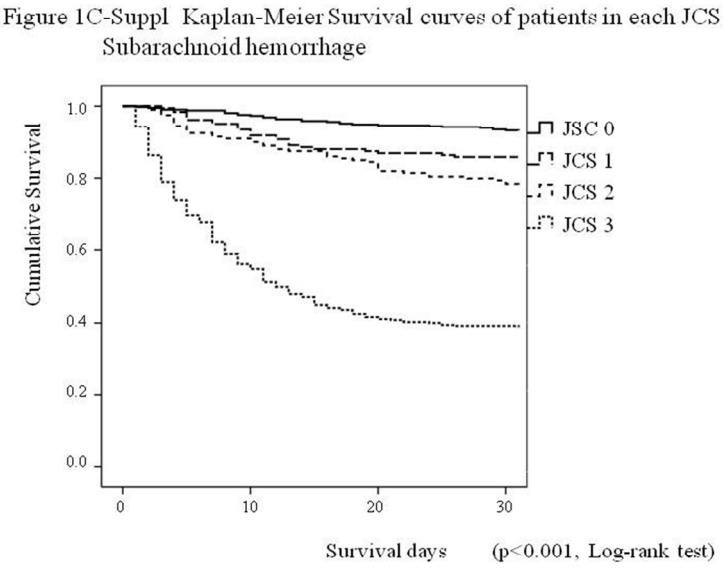
254x190mm (96 x 96 DPI)

Figure 1B-Suppl Kaplan-Meier Survival curves of patients in each JCS category
Cerebral hemorrhage



Kaplan-Meier Survival curves of patients in each JCS category
Cerebral hemorrhage

254x190mm (96 x 96 DPI)



Kaplan-Meier Survival curves of patients in each JCS category
Subarachnoid hemorrhage

254x190mm (96 x 96 DPI)

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Key Words: scales; coma; consciousness; stroke

~~Contributors~~Contributorship: All authors contributed equally ~~to this study~~in the data collection and analysis. KS wrote the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest: None
Funding: None
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Abstract

Objective

Prompt assessment of consciousness level is vitally important during the emergency care of stroke patients. Requirements for a better scale include simplicity, reliability, applicability and predictability for outcome. The Japan Coma Scale (JCS) is a one-axis coma scale published in 1974 with outstanding simplicity. The hypothesis is that the JCS is sufficient to predict the stroke outcome. The aim of the study is to verify the predictability of the JCS, which should help the JCS attain international recognition.

Methods

We investigated the relationship between consciousness level based on the JCS at the stroke onset and activities of daily living (ADL) at 30 days or deaths within 30 days in a large population-based stroke registry. We calculated Spearman's correlation coefficients for the correlation between the JCS and ADL scale, generated estimated survival curves by the Kaplan-Meier method and finally compared hazard ratios for

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death within 30 days after onset, comparing patients with different conscious levels based on the JCS.

Results

A total of 13,788 (97.2%) patients were graded based on the JCS. The JCS correlated to ADL scores with a Spearman's correlation coefficient of 0.61. Hazard ratios for death within 30 days were 1 (reference), 5.~~6~~55, 9.~~5~~54 and 35.~~2~~21 in those scored as JCS0, JCS1, JCS2 and JCS3, respectively.~~–~~

Conclusions

Using a single test of eye response, the JCS has outstanding merits as a coma scale: i.e. simplicity and applicability. The present study adds predictability for the early outcome in stroke patients. The JCS is valuable especially at an emergency setting when a prompt assessment of consciousness level is needed.

Article summary

Article focus

The Japan Coma Scale (JCS) is a one-axis coma scale published in 1974. It is so simple and easy to use that it has been established as a standard coma scale in Japan. Nevertheless, it has little recognition internationally. The aim of the study is to confirm its predictability in stroke patients. We hope the JCS will contribute to the medical profession and especially to the emergency medical-care.

Key messages

Using a single test of eye response, the JCS has outstanding merits as a coma scale: i.e. simplicity and applicability. The present study adds predictability for the early outcome in stroke patients. The JCS is valuable especially at an emergency setting when a prompt assessment of consciousness level is needed.

Strengths and limitations of this study

Strengths: the study is based on a large stroke registry and the JCS has been used widely in Japan.

Limitations: there are few studies on the JCS and on the ADL scale in scientific international journals yet.

Introduction

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Prompt assessment of consciousness levels is vitally important during the emergency care of stroke patients. There is no current perfect coma scale, and requirements for a better scale include:

1) Simplicity: ease of assessment, ease of recording, ease of sharing with medical and co-medical staff.
2) Reliability: consistency among assessors.
3) Applicability: for any patient in any setting.
4) Predictability for the outcome.

The Japan Coma Scale (JCS) has become widely used in Japan since it was first published in 1974[1-3] . An outstanding feature of the JSC is its simplicity, which has prompted both pre-hospital personnel and in-hospital staff to use the scale. The JCS enables prompt communication among emergency service staff and hospital staff and among nurses and physicians. However, the JSC's predictability of the outcome has not been clarified to date. The lack of evidence of its predictability may have prevented the JCS from attaining international recognition.

Our hypothesis is that consciousness levels categorized by the JCS should correlate with the severity of stroke and therefore should predict outcome of stroke. If the predictability of the JCS is demonstrated, it should be re-appraised as a prompt coma scale. Although we have the Glasgow Coma Scale (GCS), which was also published in 1974 [4 5], it would be more pragmatic to have a simpler coma scale especially in an emergency. The major difference between the GCS and the JCS is that the former is a three-axis scale whereas the latter is a one-axis scale.

The aim of the study is to show that the JSC predicts early outcome, including the level of activity of daily life (ADL) and the hazard ratios for death, and, subsequently, to re-introduce this simple coma scale to the world.

Materials and Methods

We studied the relationship between the outcome at 30 days after stroke and the consciousness levels based on the JCS at the onset of neurological impairment. We analyzed all new stroke patients identified from January 1999 to December 2009 inclusive in the entire Kyoto prefecture and registered in the Kyoto Stroke Registry (KSR) [6]. Detailed information on the KSR has been described previously (Shigematsu

et al. BMJ Open, in press). The diagnosis of stroke was confirmed by local neurologists and/or neurosurgeons according to the WHO definition [7]. We categorized the patients into cerebral infarction (CI), cerebral hemorrhage (CH), subarachnoid hemorrhage (SAH) and others, based on the neurological findings, laboratory data, and findings of CT, MRI and angiography.

We used the following definitions ~~for the purpose of this study~~.

1) Consciousness levels based on the JCS encompassed four levels:

   1 JCS 0 (alert)

   2 JCS 1 (not fully alert but awake without any stimuli)

   3 JCS 2 (arousable with stimulation)

   4 JSC 3 (unarousable)

2) ADL scale at 30 days after stroke onset included five levels:

   1 ADL1 (No symptoms or no significant disability. Able to carry out all usual activities without help. Able to walk without a mobility aide)

   2 ADL2 (mildly disabled, or utilization of mobility aide. Unable to carry out all usual activities without help. Unable to walk without mobility aide.)

   3 ADL3 (moderately disabled, or wheelchair-bound condition. Unable to walk

without assistance.)

4 ADL4 (severely disabled, or bed-bound condition. Unable to use wheel chairs without help.)

5 ADL5 (Dead)

~~We sent out a questionnaire on what coma scale they preferably used in practice to 219 local nurses and members of rescue squads.~~

Ethics Statement

This research was performed in accordance with the ethical principles for medical research involving human subjects outlined in the Declaration of Helsinki. This research was approved by the Board of Directors, the Kyoto Medical Association, the Department of Health and Welfare, Kyoto Prefecture and Ethics Committee of the National Hospital Organization, Minami Kyoto Hospital. Since all identifying personal information was stripped from the secondary files before analysis, the boards waived the requirement for written informed consent from the patients involved.

Statistical Analyses

The frequencies of characteristics among the four conscious levels were determined and

evaluated for univariate associations by Chi-square analysis. Numerical data such as age and blood pressure were compared with Student-t ~~tests~~test. Spearman's rank correlation coefficients were used to identify the correlation between the JCS and ADL scale. We used the Kaplan-Meier method for curves of estimated survival, a log-rank test for comparisons of estimated survival among the JCS categories, and ~~the~~ Cox proportional hazards regression for hazard ratios for death. Adjustments for age, sex, systolic and diastolic blood pressures, histories of hypertension, arrhythmia and diabetes mellitus, stroke type and paresis were also utilized. Analyses were performed using SPSS ver.19. All reported p values are 2-sided.

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Results

The characteristics of patients are summarized in Table 1. Data on age, and sex were complete in all patients in the study cohort. The other characteristics had missing data in a few patients. The numbers of patients examined are shown in the tables.

We evaluated the consciousness levels of 13,406 patients out of 13,788 (97.2%), based on the JCS. JCS data were mission for 382 patients (2.8%). Among the 13,406 patients, the number and percentage per group were as follows: JCS0 (~~7676~~7,676 [55.7%]), JCS1

(~~2619~~2,619 [9.0%]), JCS2 (~~1602~~1,602 [11.6%]) and JCS3 (~~1509~~1,509 [10.9%]), respectively. We evaluated the ADL scale in 12,601 (91.4%) patients at 30 days after the onset of neurological impairment. We obtained data on both the JCS and the ADL scale in 12,277 (89.0%) of the stroke patients (Table 2).

The Spearman's correlation coefficient was 0.608 for the correlation between the JCS and ADL scale ($p<0.001$). Kaplan-Meier Survival curves of patients in each JCS category are presented (Figure 1). A log-rank test proved the differences were significant ($p<0.001$). For Kaplan-Meier Survival curves in each JCS category in each stroke subtype, see supplementary figures (Figure 1A, 1B and 1C).

Hazard ratios for death, comparing JCS categories and their 95% confidential intervals, are summarized in Table 3.

~~As for the questionnaire on coma scales, 204 out of 219 (93.1%) nurses and members of rescue squads answered that they mainly used the JCS.~~

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Discussion

The JCS principally focuses on eye responses. Being a single test, the JCS has outstanding merits as a coma scale: i.e. simplicity and applicability, which should

minimize interpreter errors. Simplicity is very important in communication among physicians, nurses and paramedics, especially in emergency settings. The present study adds to its virtues the predictability for early outcome in stroke patients.

In summary, the advantages of the JCS include four points:

1) Predictability for stroke outcome.

This study showed the predictability of the JCS for the stroke outcome.

~~The JSC correlated with ADL scale and hazard ratios for death in stroke patients. The likelihood of the differences in hazard ratios occurring by chance is estimated to be 6.32×10^{-171} (after adjustment for age, gender, blood pressure, histories of hypertension, arrhythmia and diabetes, stroke type and paresis).~~The JSC correlated with ADL scale. Hazard ratios for death were significantly different among JCS categories: 1.00 (as reference), 5.55, 9.54 and 34.21 in JCS0, 1, 2 and 3, respectively. It is noteworthy that a simple one-axis test alone predicts early mortality with such clear differences. The JCS could be useful especially at an emergency setting when more detailed evaluation of a patient condition is difficult to obtain and prompt communications among doctors and co-medicals are needed. The JCS provides minimum but critical/essential information.

2) Simplicity.

The JCS is a 4-points scale (from 0 to 3) and comprises only one test: eye responses.

The Glasgow coma scale (GCS), for example, is a 13-points scale (from 3 to 15) and comprises three tests: eye, verbal and motor responses. The JCS is similar to the eye response test in the GCS but even simpler than the GCS (i.e. both E2 and E3 belong in JCS2). Being a uni-coordinate axis scale is very important for simplicity. Although summing up scores in a multi-coordinate axes scale may not be difficult, the scores in different axes may have different values and therefore the interpretation of a total score can be difficult. Hypothetically, both E3V2M1 and E2V3M1 in the GCS, for example, give the same total score of 6. A same total score in a multi-coordinate axes scale could reflect different underlying conditions and might be difficult to interpret. The description within the JCS is also simple (e.g. JCS, JCS0, JCS1, JCS2 and JCS3), which makes communication among staff easy, prompt and less misleading. It is much easier to grasp the outline of a patient condition with the JCS than with any multi-axes scales.

3) Reliability.

The simplicity of the JCS provides consistency among raters.

The four categories in the JCS are well defined. They do not overlap and they encompass all consciousness levels.

4) Applicability.

The JCS focuses on eye response, which broadens its applicability both for raters and

for patients. Raters need only check eye responses in terms of three clearly differentiated categories: open, open only after stimuli and closed. No special knowledge, such as is needed to assess the decerebrate or decorticate response, is necessary. The JCS is applicable to almost all patients, including patients with aphasia, paresis and even in intubated patients, where it might be difficult to apply the GCS, because that has verbal and motor responses tests. In this population-based study, the JCS was applied to 13,406 out of 13,788 stroke patients (97.2%).

Historical information on the JCS

Ohta et al. launched a national survey on craniotomy for ruptured cerebral aneurysms, and described the JCS to define the consciousness level to be included in the survey, at the first meeting of the Society on Surgery for Cerebral Stroke, which was held at Miyagi, Japan (Sakunami Kanko Hotel) on May 13-14, 1972 [8]. At that meeting, he also organized a team to evaluate the scale, because there was no standardized coma scale established in those days. The JCS was based on his study on factors affecting the prognosis of ruptured aneurysm patients after surgical interventions [9]. The JCS was called the 3 group 3 grade method at first and then the "3-3-9 method"[1 10], since the

detailed version of the scale composed of four categories: alert, 1-digit code, 2-digit code and 3-digit code, with each digit code having three subcategories (1, 2 and 3 in the 1-digit code, 10, 20 and 30 in the 2-digit code, and 100, 200 and 300 in the 3-digit code) [1]. It had 10 grades in total: alert plus 9 (3 by 3) grades. This version of the JCS included a motor response test in the 3-digit code patients and three special conditions: restlessness, incontinence and apathy. The first full paper was accepted on 30 November 1973 and published in 1974[1]. In this study, we applied the simple JCS without subcategories, which is commonly used in Japan.

Limitations & Responses

1) Simplicity means lack of detail. The JCS does not evaluate verbal or motor responses, which are tested in the GCS. The total score in the GCS ranges from 3 to15 and the GCS can theoretically describe 120 (4 by 5 by 6) different conditions. The more tests a scale includes, the more details a scale can evaluate[11 12].

Response:

As far as the hazard ratios for early death and ADL scores, the JCS is sufficient as a predictor. A single-dimensional test is the best if the purpose of the test is fulfilled. If

needed, we can describe a patient's condition in a detailed way: such as decerebrate posture and decorticate posture. In the JCS, three capital letters, R, I and A, are provided to describe restlessness, incontinence and apathy, respectively.

2) Consciousness levels may fluctuate even in a short period and scores may therefore be different from time to time.

Response:

This difficulty is common to every coma scale, and the simplicity of the JCS minimizes it. A multi-dimensional scale might cause more difficulty with evaluation .

3) Predictability of the outcome has inherent limitations [13]. The outcomes and therefore the hazard ratios for death depend not only on the baseline severity but also on the treatment and patient conditions, including complications. This study did not include the treatments which must affect outcomes.

Response:

For precise evaluation of a relationship between two factors, it should be important to adjust for all the other factors. Treatments, for example, often vary from a case to case. Adjustments for them are virtually impossible in a population based study.

Major treatments for stroke, such as tPA therapy or surgical interventions, however, should not have caused a major bias in this study, because the differences in hazard ratios among the consciousness levels based on the JCS remain significant after adjustment for stroke subtypes, i.e. CI, CH and SAH. The JCS also predicted the outcomes in each three subtype of stroke by uni-variable analyses. A tPA therapy is not applied for hemorrhagic stroke and surgical interventions are rarely applied for ischemic stroke (In this study cohort, 374 (4.2%) out of 8896 CI patients had surgical treatment).

There are two types of complications: ones that patients had before stroke onset and ones that they got after the onset. Although the former comprises numerous diseases, risk factors such as hypertension, arrhythmia and diabetes mellitus might be important. The difference in hazard ratios remained significant after adjustment for these three. The latter may include urinary tract infections, decubitus ulcers and pneumonia. They, however, occur as results of stroke, namely after the consciousness level estimation based on the JCS. Although they could be related to the initial severity of the stroke, data on this type of complications were not available in this study.

Conclusions

The Japan Coma Scale is ~~an excellent~~a good predictor of stroke outcome. Its two outstanding advantages, simplicity and predictability, should make the JCS re-appreciated internationally as a standard coma scale.

Acknowledgments

We acknowledge the contribution of participating institutions and their staffs who provided data in the development of the Kyoto Stroke Registry. We thank Dr Tomio Ohta for the information on the establishment of the JCS.

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Legends

Figure 1. Kaplan-Meier Survival curves for patients in each JCS category

Table 1 The characteristics of patients in the study cohort

Characteristic	~~Overall (n=13788)~~
1) Age	~~71.3±12.9~~
2) Sex (%of female, (n=female /male))	~~45.2 (6233/7555)~~
3) Subtype (CI/CH/SAH, % (n))	~~65.4/25.7/8.7 (9011/3549/1197/31)~~
4) Systolic blood pressure	~~161±31.5~~
5) Diastolic blood pressure	~~87.6±18.9~~
6) Paresis (%, (n=with/without))	~~73.2 (9437/3450)~~
7) Hypertension history (%, (n= with/without))	~~62.6 (8005/4780)~~
8) Arrhythmia history (%, (n= with/without))	~~18.5 (2357/10415)~~
9) Diabetes mellitus history (%, (n= with/without))	~~20.9 (2689/10198)~~

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Table 1 Continued

	JCS0 (n=7676)	JCS1 (n=2619)	JCS2 (n=1602)	JCS3 (n=1509)
1)	69.7±12.3*[123]	73.4±12.3*[3]	73.6±14.2*[3]	72.3±14.0
2)	39.8 (3056/4620)*[123]	47.7 (1249/1370)*[23]	56.9 (911/691)*[3]	54.7 (826/683)
3)	78.9/15.7/5.4 (6048/1201/415) *[123]	57.7/35.2/7.1 (1508/921/185) *[23]	48.5/39.0/12.5 (774/622/200)*[3]	28.0/47.7/24.3 (421/716/365)
4)	159.3±28.2*[123]	162.7±31.7*[3]	163.6±33.3*[3]	167.4±42.1
5)	87.0±17.1*[123]	88.0±19.0*[3]	88.6±20.6	89.8±24.4
6)	67.0 (5085/2501)*[123]	78.2 (2014/561)*[23]	83.1 (1278/260)*[3]	89.2 (1060/128)
7)	64.5 (4724/2605)*[123]	61.0 (1476/942)*[23]	59.8 (857/576)*[3]	59.3 (755/518)
8)	14.5 (1058/6233)*[123]	23.3 (569/1870)*[23]	28.2 (412/1047)*[3]	20.1 (254/1010)
9)	23.6 (1734/5629)*[123]	18.3 (449/2006)*[23]	15.1 (220/1237)	16.4 (209/1067)

*[1]: significant difference between JCS0 and JCS1

*[2]: significant difference between JCS1 and JCS2

*[3]: significant difference between JCS2 and JCS3

Data on some characteristics were missing in a few patients.

Table 2 Numbers of patients categorized by JCS and by ADL scale.

	Japan Coma Scale				Total
	JCS0	JCS1	JCS 2	JCS 3	
ADL1	4621	608	199	65	5493
ADL2	1908	816	365	104	3193
ADL3	417	442	287	111	1257
ADL4	146	276	325	296	1043
ADL5	102	201	227	761	1291
Total	7194	2343	1403	1337	12277

We obtained data on both the JCS and the ADL scale in 12,277 (89.0%) of the stroke patients.

Table 3 Hazard ratios for death, comparing JCS categories

	Hazard Ratio	95% Confidence Interval		p
		Lower	Upper	
JCS 0	Reference			~~<0.001*~~
JSC 1	5.55	4.19	7.37	<0.001
JCS 2	9.54	7.16	12.71	<0.001
JSC 3	34.21	26.10	44.83	<0.001

Adjusted for age, sex, systolic and diastolic blood pressures, ~~histories~~history (hypertension, arrhythmia and diabetes mellitus), stroke type and paresis

~~* Statistical significance of consciousness levels as a whole ($p=6.32\times10^{-171}$)~~

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-4
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5, 6
Objectives	3	State specific objectives, including any prespecified hypotheses	5, 6
Methods			
Study design	4	Present key elements of study design early in the paper	6-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-8
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	6-8
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*6-8*
Bias	9	Describe any efforts to address potential sources of bias	6-8
Study size	10	Explain how the study size was arrived at	6-8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7, 8
		(*b*) Describe any methods used to examine subgroups and interactions	7, 8
		(*c*) Explain how missing data were addressed	9
		(*d*) If applicable, explain how loss to follow-up was addressed	
		(*e*) Describe any sensitivity analyses	7, 8
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9, 10
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9, 10 Table 1-3
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	9, 10 Table 1-3
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9, 10 Table 1-3
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9, 10 Table 1-3
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-14
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-16
Generalisability	21	Discuss the generalisability (external validity) of the study results	14-16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

The Eye Response Test Alone Is Sufficient To Predict Stroke Outcome: Re-Introduction of Japan Coma Scale. A cohort study

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2013-002736.R1
Article Type:	Research
Date Submitted by the Author:	19-Mar-2013
Complete List of Authors:	Shigematsu, Kazuo; National Hospital Organization, Minami Kyoto Hospital, Neurology Nakano, Hiromi; Kyoto Kidugawa Hospital, Neurosurgery Watanabe, Yoshiyuki; Kyoto Prefectural University of Medicine, Graduate School of Medical Science, Epidemiology for Community Health and Medicine
Primary Subject Heading:	Emergency medicine
Secondary Subject Heading:	Neurology, Epidemiology, Emergency medicine, Intensive care
Keywords:	Stroke < NEUROLOGY, Neurology < INTERNAL MEDICINE, Stroke medicine < INTERNAL MEDICINE

The Eye Response Test Alone Is Sufficient To Predict Stroke Outcome: Re-Introduction of Japan Coma Scale. A cohort study

Short title: The Japan Coma Scale predicts stroke outcome

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Key Words: scales; coma; consciousness; stroke

Contributorship: All authors contributed equally in the data collection and analysis. KS wrote the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest: None
Funding: None

Abstract

Objective

Prompt assessment of consciousness level is vitally important during the emergency care of stroke patients. Requirements for a better scale include simplicity, reliability, applicability and predictability for outcome. The Japan Coma Scale (JCS) is a one-axis coma scale published in 1974 with outstanding simplicity. The hypothesis is that the JCS is sufficient to predict the stroke outcome. The aim of the study is to verify the predictability of the JCS, which should help the JCS attain international recognition.

Methods

We investigated the relationship between consciousness level based on the JCS at the stroke onset and activities of daily living (ADL) at 30 days or deaths within 30 days in a large population-based stroke registry. We calculated Spearman's correlation coefficients for the correlation between the JCS and ADL scale, generated estimated survival curves by the Kaplan-Meier method and finally compared hazard ratios for

death within 30 days after onset, comparing patients with different conscious levels based on the JCS.

Results

A total of 13,788 (97.2%) patients were graded based on the JCS. The JCS correlated to ADL scores with a Spearman's correlation coefficient of 0.61. Hazard ratios for death within 30 days were 1 (reference), 5.55, 9.54 and 35.21 in those scored as JCS0, JCS1, JCS2 and JCS3, respectively.

Conclusions

Using a single test of eye response, the JCS has outstanding merits as a coma scale: i.e. simplicity and applicability. The present study adds predictability for the early outcome in stroke patients. The JCS is valuable especially at an emergency setting when a prompt assessment of consciousness level is needed.

Article summary

Article focus

The Japan Coma Scale (JCS) is a one-axis coma scale published in 1974. It is so simple and easy to use that it has been established as a standard coma scale in Japan. Nevertheless, it has little recognition internationally. The aim of the study is to varify its predictability in stroke patients. We hope the JCS will contribute to the medical profession and especially to the emergency medical-care.

Key messages

Using a single test of eye response, the JCS has outstanding merits as a coma scale: i.e. simplicity and applicability. The present study adds predictability for the early outcome in stroke patients. The JCS is valuable especially at an emergency setting when a prompt assessment of consciousness level is needed.

Strengths and limitations of this study

Strengths: the study is based on a large stroke registry and the JCS has been used widely in Japan.

Limitations: there are few studies on the JCS and on the activity daily life (ADL) scale in scientific international journals yet.

Introduction

Prompt assessment of consciousness levels is vitally important during the emergency care of stroke patients. There is no current perfect coma scale, and requirements for a better scale include:

1) Simplicity: ease of assessment, ease of recording, ease of sharing with medical and co-medical staff.
2) Reliability: consistency among assessors.
3) Applicability: for any patient in any setting.
4) Predictability for the outcome.

The Japan Coma Scale (JCS) has become widely used in Japan since it was first published in 1974[1-3] . Ohta et al. launched a national survey on craniotomy for ruptured cerebral aneurysms, and described the JCS to define the consciousness level to be included in the survey, at the first meeting of the Society on Surgery for Cerebral Stroke, which was held at Miyagi, Japan (Sakunami Kanko Hotel) on May 13-14, 1972 [4]. At that meeting, he also organized a team to evaluate the scale, because there was no standardized coma scale established in those days. The JCS was based on his study on factors affecting the prognosis of ruptured aneurysm patients after surgical interventions

[5]. The JCS was called the 3 group 3 grade method at first and then the "3-3-9 method"[1 6], since the detailed version of the scale composed of four categories: alert, 1-digit code, 2-digit code and 3-digit code, with each digit code having three subcategories (1, 2 and 3 in the 1-digit code, 10, 20 and 30 in the 2-digit code, and 100, 200 and 300 in the 3-digit code) [1]. It had 10 grades in total: alert plus 9 (3 by 3) grades. This version of the JCS included a motor response test in the 3-digit code patients and three special conditions: restlessness, incontinence and apathy. The first full paper was accepted on 30 November 1973[1].

In this study, we applied the simple JCS without subcategories, which is commonly used in Japan.

An outstanding feature of the JSC is its simplicity, which has prompted both pre-hospital personnel and in-hospital staff to use the scale. The JCS enables prompt communication among emergency service staff and hospital staff and among nurses and physicians. However, the JSC's predictability of the outcome has not been clarified to date. The lack of evidence of its predictability may have prevented the JCS from attaining international recognition.

Our hypothesis is that consciousness levels categorized by the JCS should

correlate with the severity of stroke and therefore should predict outcome of stroke. If the predictability of the JCS is demonstrated, it should be re-appraised as a prompt coma scale. Although we have the Glasgow Coma Scale (GCS), which was also published in 1974 [7 8], it would be more pragmatic to have a simpler coma scale especially in an emergency. The major difference between the GCS and the JCS is that the former is a three-axis scale whereas the latter is a one-axis scale.

The aim of the study is to verify that the JSC predicts early outcome, including the level of activity of daily life (ADL) and the hazard ratios for death, and, subsequently, to re-introduce this simple coma scale to the world.

Materials and Methods

We studied the relationship between the outcome at 30 days after stroke and the consciousness levels based on the JCS at the onset of neurological impairment. We analyzed all new stroke patients identified from January 1999 to December 2009 inclusive in the entire Kyoto prefecture and registered in the Kyoto Stroke Registry (KSR)[9]. Detailed information on the KSR has been described previously [10]. The diagnosis of stroke was confirmed by local neurologists and/or neurosurgeons according

to the WHO definition [11]. We categorized the patients into cerebral infarction (CI), cerebral hemorrhage (CH), subarachnoid hemorrhage (SAH) and others, based on the neurological findings, laboratory data, and findings of CT, MRI and angiography.

We used the following definitions.

1) Consciousness levels based on the JCS encompassed four levels:

    1 JCS 0 (alert)

    2 JCS 1 (not fully alert but awake without any stimuli)

    3 JCS 2 (arousable with stimulation)

    4 JSC 3 (unarousable)

2) The ADL scale at 30 days after stroke onset included five levels:

    1 ADL1 (No symptoms or no significant disability. Able to carry out all usual activities without help. Able to walk without a mobility aide)

    2 ADL2 (mildly disabled, or utilization of mobility aide. Unable to carry out all usual activities without help. Unable to walk without mobility aide.)

    3 ADL3 (moderately disabled, or wheelchair-bound condition. Unable to walk without assistance.)

    4 ADL4 (severely disabled, or bed-bound condition. Unable to use wheel chairs

without help.)

5 ADL5 (Dead)

Ethics Statement

This research was performed in accordance with the ethical principles for medical research involving human subjects outlined in the Declaration of Helsinki. This research was approved by the Board of Directors, the Kyoto Medical Association, the Department of Health and Welfare, Kyoto Prefecture and Ethics Committee of the National Hospital Organization, Minami Kyoto Hospital. Since all identifying personal information was stripped from the secondary files before analysis, the boards waived the requirement for written informed consent from the patients involved.

Statistical Analyses

The frequencies of characteristics among the four conscious levels were determined and evaluated for univariate associations by Chi-square analysis. Numerical data such as age and blood pressure were compared with Student-t test. Spearman's rank correlation coefficients were used to identify the correlation between the JCS and the ADL scale. We used the Kaplan-Meier method for curves of estimated survival, a log-rank test for

comparisons of estimated survival among the JCS categories, and Cox proportional hazards regression for hazard ratios for death. Adjustments for age, sex, systolic and diastolic blood pressures, histories of hypertension, arrhythmia and diabetes mellitus, stroke type and paresis were also utilized. Analyses were performed using SPSS ver.19. All reported p values are 2-sided.

Results

The characteristics of patients are summarized in Table 1. Data on age, and sex were complete in all patients in the study cohort. The other characteristics had missing data in a few patients. The numbers of patients examined are shown in the tables.

We evaluated the consciousness levels of 13,406 patients out of 13,788 (97.2%), based on the JCS. JCS data were missing for 382 patients (2.8%). Among the 13,406 patients, the number and percentage per group were as follows: JCS0 (7,676 [55.7%]), JCS1 (2,619 [9.0%]), JCS2 (1,602 [11.6%]) and JCS3 (1,509 [10.9%]), respectively. We evaluated the ADL scale in 12,601 (91.4%) patients at 30 days after the onset of neurological impairment. We obtained data on both the JCS and the ADL scale in 12,277 (89.0%) of the stroke patients (Table 2).

The Spearman's correlation coefficient was 0.608 for the correlation between the JCS and the ADL scale ($p<0.001$). Kaplan-Meier Survival curves of patients in each JCS category are presented (Figure 1). A log-rank test proved the differences were significant ($p<0.001$). For Kaplan-Meier Survival curves in each JCS category in each stroke subtype, see supplementary figures (Figure 1A, 1B and 1C).

Hazard ratios for death, comparing JCS categories and their 95% confidential intervals, are summarized in Table 3.

Discussion

Systems for describing patients with impaired consciousness were not consistent until 1974, when the GCS and the JCS were developed[7]. There was an abundance of alternative terms by which levels of coma or impaired consciousness were described and recorded [7]. 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 [7].

The JCS principally focuses on eye responses. Being a single test, the JCS has outstanding merits as a coma scale: i.e. simplicity and applicability, which should

minimize interpreter errors. Simplicity is very important in communication among physicians, nurses and paramedics, especially in emergency settings. The present study adds to its virtues the predictability for early outcome in stroke patients.

In summary, the advantages of the JCS include four points:

1) Predictability for stroke outcome.

This study showed the predictability of the JCS for the stroke outcome.

The JSC correlated with the ADL scale. Hazard ratios for death were significantly different among JCS categories: 1.00 (as reference), 5.55, 9.54 and 34.21 in JCS0, 1, 2 and 3, respectively. It is noteworthy that a simple one-axis test alone predicts early mortality with such clear differences. The JCS could be useful especially at an emergency setting when more detailed evaluation of a patient condition is difficult to obtain and prompt communications among doctors and co-medicals are needed. The JCS provides minimum but critical/essential information.

2) Simplicity.

The JCS is a 4-points scale (from 0 to 3) and comprises only one test: eye responses. The Glasgow Coma Scale (GCS), for example, is a 13-points scale (from 3 to 15) and comprises three tests: eye, verbal and motor responses. The JCS is similar to the eye response test in the GCS but even simpler than the GCS (i.e. both E2 and E3 belong in

JCS2). Being a uni-coordinate axis scale is very important for simplicity. Although summing up scores in a multi-coordinate axes scale may not be difficult, the scores in different axes may have different values and therefore the interpretation of a total score can be difficult. Hypothetically, both E3V2M1 and E2V3M1 in the GCS, for example, give the same total score of 6. A same total score in a multi-coordinate axes scale could reflect different underlying conditions and might be difficult to interpret. The description within the JCS is also simple (e.g. JCS0, JCS1, JCS2 and JCS3), which makes communication among staff easy, prompt and less misleading. It might be easier to grasp the outline of a patient condition with the JCS than with any multi-axes scales.

3) Reliability.

The simplicity of the JCS might provide consistency among raters.

The four categories in the JCS are well defined. They do not overlap and they encompass all consciousness levels.

4) Applicability.

The JCS focuses on eye response, which broadens its applicability both for raters and for patients. Raters need only check eye responses in terms of three clearly differentiated categories: open, open only after stimuli and closed. No special knowledge, such as is needed to assess the decerebrate or decorticate response, is

necessary. The JCS is applicable to almost all patients, including patients with aphasia, paresis and even in intubated patients, where it might be difficult to apply the GCS, because that has verbal and motor responses tests. In this population-based study, the JCS was applied to 13,406 out of 13,788 stroke patients (97.2%).

There are some limitations.

First, simplicity means lack of detail. The JCS does not evaluate verbal or motor responses, which are tested in the GCS. The total score in the GCS ranges from 3 to15 and the GCS can theoretically describe 120 (4 by 5 by 6) different conditions. The more tests a scale includes, the more details a scale can evaluate[12 13].

As far as the hazard ratios for early death and the ADL scores, however, the JCS is sufficient as a predictor. A single-dimensional test is the best if the purpose of the test is fulfilled. If needed, we can describe a patient's condition in a detailed way: such as decerebrate posture and decorticate posture. In the JCS, three capital letters, R, I and A, are provided to describe restlessness, incontinence and apathy, respectively.

Second, consciousness levels may fluctuate even in a short period and scores may therefore be different from time to time. This difficulty is common to every coma scale, and the simplicity of the JCS might minimize it. A multi-dimensional scale might cause

more difficulty with evaluation.

Third, predictability of the outcome has inherent limitations[14]. The outcomes and therefore the hazard ratios for death depend not only on the baseline severity but also on the treatment and patient conditions, including complications. This study did not include the treatments which must affect outcomes. For precise evaluation of a relationship between two factors, it should be important to adjust for all the other factors. Treatments, for example, often vary from a case to case. Adjustments for them are virtually impossible in a population based study. Major treatments for stroke, such as tPA therapy or surgical interventions, however, should not have caused a major bias in this study, because the differences in hazard ratios among the consciousness levels based on the JCS remain significant after adjustment for stroke subtypes, i.e. CI, CH and SAH. The JCS also predicted the outcomes in each three subtype of stroke by uni-variable analyses. A tPA therapy is not applied for hemorrhagic stroke and surgical interventions are rarely applied for ischemic stroke (In this study cohort, 374 (4.2%) out of 8896 CI patients had surgical treatment).

There are two types of complications: ones that patients had before stroke onset and ones that they got after the onset. Although the former comprises numerous diseases, risk factors such as hypertension, arrhythmia and diabetes mellitus might be important.

The difference in hazard ratios remained significant after adjustment for these three. The latter may include urinary tract infections, decubitus ulcers and pneumonia. They, however, occur as results of stroke, namely after the consciousness level estimation based on the JCS. Although they could be related to the initial severity of the stroke, data on this type of complications were not available in this study.

Last, 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[15 16 17] 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. 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.

Conclusions

The JCS is a good predictor of stroke outcome. Its two outstanding advantages, simplicity and predictability, should make the JCS re-appreciated internationally as a standard coma scale.

Acknowledgments

We acknowledge the contribution of participating institutions and their staffs who provided data in the development of the Kyoto Stroke Registry. We thank Dr Tomio Ohta for the information on the establishment of the JCS. We are grateful to many colleagues for their assistance in this study; particularly Dr Osamu Simamura, Dr Tatsuyuki Sekimoto, Dr Kouichiro Shimizu, Dr Akihiko Nishizawa, Dr Atsushi Okumura, Dr. Masahiro Makino and Dr Kazuhiko Bando.

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Legends

Figure 1. Kaplan-Meier Survival curves for patients in each JCS category

Table 1 The characteristics of patients in the study cohort

Characteristic
1) Age
2) Sex (%of female, (n=female /male))
3) Subtype (CI/CH/SAH, % (n))
4) Systolic blood pressure
5) Diastolic blood pressure
6) Paresis (%, (n=with/without))
7) Hypertension history (%, (n= with/without))
8) Arrhythmia history (%, (n= with/without))
9) Diabetes mellitus history (%, (n= with/without))

Table 1 Continued

	JCS0 (n=7676)	JCS1 (n=2619)	JCS2 (n=1602)	JCS3 (n=1509)
1)	69.7±12.3*[123]	73.4±12.3*[3]	73.6±14.2*[3]	72.3±14.0
2)	39.8 (3056/4620)*[123]	47.7 (1249/1370)*[23]	56.9 (911/691)*[3]	54.7 (826/683)
3)	78.9/15.7/5.4 (6048/1201/415) *[123]	57.7/35.2/7.1 (1508/921/185) *[23]	48.5/39.0/12.5 (774/622/200)*[3]	28.0/47.7/24.3 (421/716/365)
4)	159.3±28.2*[123]	162.7±31.7*[3]	163.6±33.3*[3]	167.4±42.1
5)	87.0±17.1*[123]	88.0±19.0*[3]	88.6±20.6	89.8±24.4
6)	67.0 (5085/2501)*[123]	78.2 (2014/561)*[23]	83.1 (1278/260)*[3]	89.2 (1060/128)
7)	64.5 (4724/2605)*[123]	61.0 (1476/942)*[23]	59.8 (857/576)*[3]	59.3 (755/518)
8)	14.5 (1058/6233)*[123]	23.3 (569/1870)*[23]	28.2 (412/1047)*[3]	20.1 (254/1010)
9)	23.6 (1734/5629)*[123]	18.3 (449/2006)*[23]	15.1 (220/1237)	16.4 (209/1067)

*[1]: significant difference between JCS0 and JCS1

*[2]: significant difference between JCS1 and JCS2

*[3]: significant difference between JCS2 and JCS3

Data on some characteristics were missing in a few patients.

Table 2 Numbers of patients categorized by JCS and by ADL scale.

	Japan Coma Scale				Total
	JCS0	JCS1	JCS 2	JCS 3	
ADL1	4621	608	199	65	5493
ADL2	1908	816	365	104	3193
ADL3	417	442	287	111	1257
ADL4	146	276	325	296	1043
ADL5	102	201	227	761	1291
Total	7194	2343	1403	1337	12277

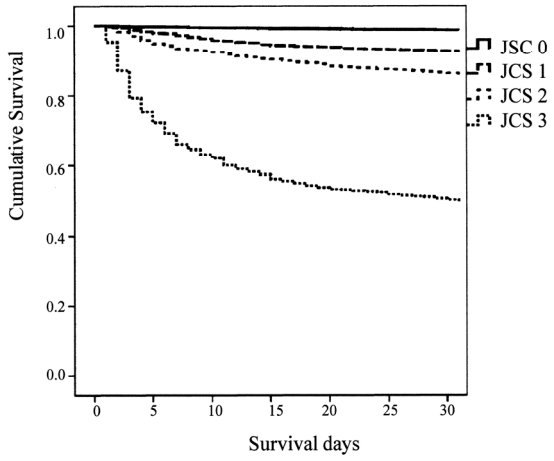
We obtained data on both the JCS and the ADL scale in 12,277 (89.0%) of the stroke patients.

Table 3 Hazard ratios for death, comparing JCS categories

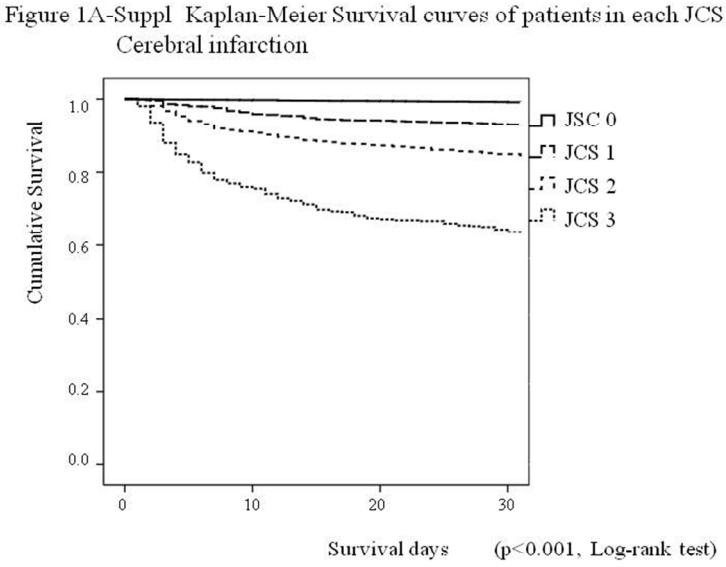
	Hazard Ratio	95% Confidence Interval		p
		Lower	Upper	
JCS 0	Reference			
JSC 1	5.55	4.19	7.37	<0.001
JCS 2	9.54	7.16	12.71	<0.001
JSC 3	34.21	26.10	44.83	<0.001

Adjusted for age, sex, systolic and diastolic blood pressures, history (hypertension, arrhythmia and diabetes mellitus), stroke type and paresis

Figure 1



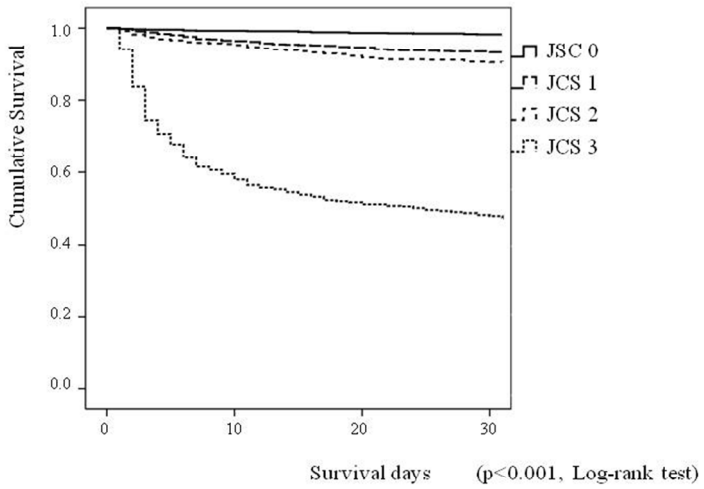
Kaplan-Meier Survival curves for patients in each JCS category
215x156mm (300 x 300 DPI)



Kaplan-Meier Survival curves of patients in each JCS category
Cerebral infarction

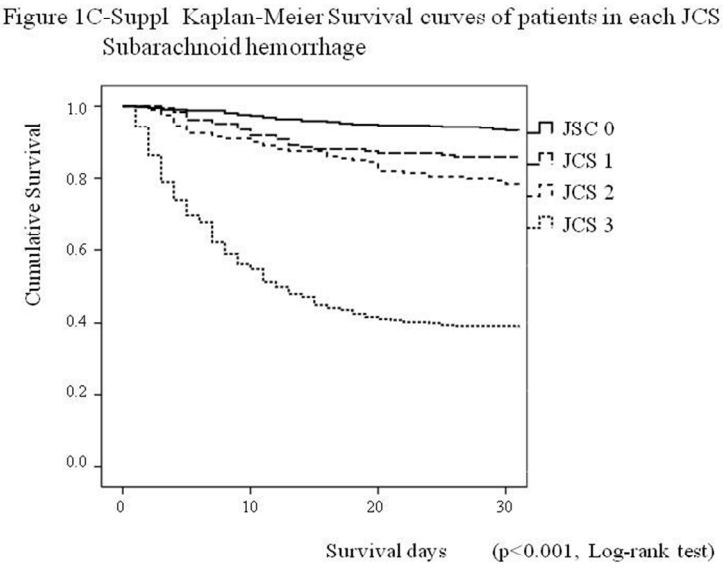
254x190mm (96 x 96 DPI)

Figure 1B-Suppl Kaplan-Meier Survival curves of patients in each JCS category
Cerebral hemorrhage



Kaplan-Meier Survival curves of patients in each JCS category
Cerebral hemorrhage

254x190mm (96 x 96 DPI)



Kaplan-Meier Survival curves of patients in each JCS category
Subarachnoid hemorrhage

254x190mm (96 x 96 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-4
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5, 6
Objectives	3	State specific objectives, including any prespecified hypotheses	5, 6
Methods			
Study design	4	Present key elements of study design early in the paper	6-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-8
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	6-8
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*6-8*
Bias	9	Describe any efforts to address potential sources of bias	6-8
Study size	10	Explain how the study size was arrived at	6-8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7, 8
		(*b*) Describe any methods used to examine subgroups and interactions	7, 8
		(*c*) Explain how missing data were addressed	9
		(*d*) If applicable, explain how loss to follow-up was addressed	
		(*e*) Describe any sensitivity analyses	7, 8
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9, 10
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9, 10 Table 1-3
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	9, 10 Table 1-3
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9, 10 Table 1-3
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9, 10 Table 1-3
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-14
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-16
Generalisability	21	Discuss the generalisability (external validity) of the study results	14-16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

~~A simple coma scale predicts stroke outcome~~

The Eye Response Test Alone Is Sufficient To Predict Stroke Outcome: Re-~~introduction~~Introduction of ~~the~~ Japan Coma Scale. A cohort study

Short title: The Japan Coma Scale predicts stroke outcome

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Key Words: scales; coma; consciousness; stroke

Contributorship: All authors contributed equally in the data collection and analysis. KS wrote the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest: None

Funding: None

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Abstract

Objective

Prompt assessment of consciousness level is vitally important during the emergency care of stroke patients. Requirements for a better scale include simplicity, reliability, applicability and predictability for outcome. The Japan Coma Scale (JCS) is a one-axis coma scale published in 1974 with outstanding simplicity. The hypothesis is that the JCS is sufficient to predict the stroke outcome. The aim of the study is to verify the predictability of the JCS, which should help the JCS attain international recognition.

Methods

We investigated the relationship between consciousness level based on the JCS at the stroke onset and activities of daily living (ADL) at 30 days or deaths within 30 days in a large population-based stroke registry. We calculated Spearman's correlation coefficients for the correlation between the JCS and ADL scale, generated estimated survival curves by the Kaplan-Meier method and finally compared hazard ratios for

death within 30 days after onset, comparing patients with different conscious levels based on the JCS.

Results

A total of 13,788 (97.2%) patients were graded based on the JCS. The JCS correlated to ADL scores with a Spearman's correlation coefficient of 0.61. Hazard ratios for death within 30 days were 1 (reference), 5.55, 9.54 and 35.21 in those scored as JCS0, JCS1, JCS2 and JCS3, respectively.

Conclusions

Using a single test of eye response, the JCS has outstanding merits as a coma scale: i.e. simplicity and applicability. The present study adds predictability for the early outcome in stroke patients. The JCS is valuable especially at an emergency setting when a prompt assessment of consciousness level is needed.

Article summary

Article focus

The Japan Coma Scale (JCS) is a one-axis coma scale published in 1974. It is so simple and easy to use that it has been established as a standard coma scale in Japan. Nevertheless, it has little recognition internationally. The aim of the study is to ~~confirm~~varify its predictability in stroke patients. We hope the JCS will contribute to the medical profession and especially to the emergency medical-care.

Key messages

Using a single test of eye response, the JCS has outstanding merits as a coma scale: i.e. simplicity and applicability. The present study adds predictability for the early outcome in stroke patients. The JCS is valuable especially at an emergency setting when a prompt assessment of consciousness level is needed.

Strengths and limitations of this study

Strengths: the study is based on a large stroke registry and the JCS has been used widely in Japan.

Limitations: there are few studies on the JCS and on the activity daily life (ADL) scale in scientific international journals yet.

Introduction

Prompt assessment of consciousness levels is vitally important during the emergency care of stroke patients. There is no current perfect coma scale, and requirements for a better scale include:

1) Simplicity: ease of assessment, ease of recording, ease of sharing with medical and co-medical staff.
2) Reliability: consistency among assessors.
3) Applicability: for any patient in any setting.
4) Predictability for the outcome.

The Japan Coma Scale (JCS) has become widely used in Japan since it was first published in 1974[1-3]. Ohta et al. launched a national survey on craniotomy for ruptured cerebral aneurysms, and described the JCS to define the consciousness level to be included in the survey, at the first meeting of the Society on Surgery for Cerebral Stroke, which was held at Miyagi, Japan (Sakunami Kanko Hotel) on May 13-14, 1972 [4]. At that meeting, he also organized a team to evaluate the scale, because there was no standardized coma scale established in those days. The JCS was based on his study on factors affecting the prognosis of ruptured aneurysm patients after surgical interventions

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[5]. The JCS was called the 3 group 3 grade method at first and then the "3-3-9 method"[16], since the detailed version of the scale composed of four categories: alert, 1-digit code, 2-digit code and 3-digit code, with each digit code having three subcategories (1, 2 and 3 in the 1-digit code, 10, 20 and 30 in the 2-digit code, and 100, 200 and 300 in the 3-digit code) [1]. It had 10 grades in total: alert plus 9 (3 by 3) grades. This version of the JCS included a motor response test in the 3-digit code patients and three special conditions: restlessness, incontinence and apathy. The first full paper was accepted on 30 November 1973[1].

In this study, we applied the simple JCS without subcategories, which is commonly used in Japan.

An outstanding feature of the JSC is its simplicity, which has prompted both pre-hospital personnel and in-hospital staff to use the scale. The JCS enables prompt communication among emergency service staff and hospital staff and among nurses and physicians. However, the JSC's predictability of the outcome has not been clarified to date. The lack of evidence of its predictability may have prevented the JCS from attaining international recognition.

Our hypothesis is that consciousness levels categorized by the JCS should

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correlate with the severity of stroke and therefore should predict outcome of stroke. If the predictability of the JCS is demonstrated, it should be re-appraised as a prompt coma scale. Although we have the Glasgow Coma Scale (GCS), which was also published in 1974 [47 58], it would be more pragmatic to have a simpler coma scale especially in an emergency. The major difference between the GCS and the JCS is that the former is a three-axis scale whereas the latter is a one-axis scale.

The aim of the study is to ~~show~~verify that the JSC predicts early outcome, including the level of activity of daily life (ADL) and the hazard ratios for death, and, subsequently, to re-introduce this simple coma scale to the world.

Materials and Methods

We studied the relationship between the outcome at 30 days after stroke and the consciousness levels based on the JCS at the onset of neurological impairment. We analyzed all new stroke patients identified from January 1999 to December 2009 inclusive in the entire Kyoto prefecture and registered in the Kyoto Stroke Registry (KSR~~))~~[69]. ~~Detailed information on the KSR has been described previously (Shigematsu et al. BMJ Open, in press).~~ Detailed information on the KSR has been

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described previously [10]. The diagnosis of stroke was confirmed by local neurologists and/or neurosurgeons according to the WHO definition [7,11]. We categorized the patients into cerebral infarction (CI), cerebral hemorrhage (CH), subarachnoid hemorrhage (SAH) and others, based on the neurological findings, laboratory data, and findings of CT, MRI and angiography.

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We used the following definitions.

1) Consciousness levels based on the JCS encompassed four levels:

   1 JCS 0 (alert)

   2 JCS 1 (not fully alert but awake without any stimuli)

   3 JCS 2 (arousable with stimulation)

   4 JSC 3 (unarousable)

2) The ADL scale at 30 days after stroke onset included five levels:

   1 ADL1 (No symptoms or no significant disability. Able to carry out all usual activities without help. Able to walk without a mobility aide)

   2 ADL2 (mildly disabled, or utilization of mobility aide. Unable to carry out all usual activities without help. Unable to walk without mobility aide.)

   3 ADL3 (moderately disabled, or wheelchair-bound condition. Unable to walk

without assistance.)

4 ADL4 (severely disabled, or bed-bound condition. Unable to use wheel chairs without help.)

5 ADL5 (Dead)

Ethics Statement

This research was performed in accordance with the ethical principles for medical research involving human subjects outlined in the Declaration of Helsinki. This research was approved by the Board of Directors, the Kyoto Medical Association, the Department of Health and Welfare, Kyoto Prefecture and Ethics Committee of the National Hospital Organization, Minami Kyoto Hospital. Since all identifying personal information was stripped from the secondary files before analysis, the boards waived the requirement for written informed consent from the patients involved.

Statistical Analyses

The frequencies of characteristics among the four conscious levels were determined and evaluated for univariate associations by Chi-square analysis. Numerical data such as age and blood pressure were compared with Student-t test. Spearman's rank correlation

coefficients were used to identify the correlation between the JCS and the ADL scale. We used the Kaplan-Meier method for curves of estimated survival, a log-rank test for comparisons of estimated survival among the JCS categories, and Cox proportional hazards regression for hazard ratios for death. Adjustments for age, sex, systolic and diastolic blood pressures, histories of hypertension, arrhythmia and diabetes mellitus, stroke type and paresis were also utilized. Analyses were performed using SPSS ver.19. All reported p values are 2-sided.

Results

The characteristics of patients are summarized in Table 1. Data on age, and sex were complete in all patients in the study cohort. The other characteristics had missing data in a few patients. The numbers of patients examined are shown in the tables.

We evaluated the consciousness levels of 13,406 patients out of 13,788 (97.2%), based on the JCS. JCS data were ~~mission~~missing for 382 patients (2.8%). Among the 13,406 patients, the number and percentage per group were as follows: JCS0 (7,676 [55.7%]), JCS1 (2,619 [9.0%]), JCS2 (1,602 [11.6%]) and JCS3 (1,509 [10.9%]), respectively. We evaluated the ADL scale in 12,601 (91.4%) patients at 30 days after the onset of

neurological impairment. We obtained data on both the JCS and the ADL scale in 12,277 (89.0%) of the stroke patients (Table 2).

The Spearman's correlation coefficient was 0.608 for the correlation between the JCS and the ADL scale ($p<0.001$). Kaplan-Meier Survival curves of patients in each JCS category are presented (Figure 1). A log-rank test proved the differences were significant ($p<0.001$). For Kaplan-Meier Survival curves in each JCS category in each stroke subtype, see supplementary figures (Figure 1A, 1B and 1C).

Hazard ratios for death, comparing JCS categories and their 95% confidential intervals, are summarized in Table 3.

Discussion

Systems for describing patients with impaired consciousness were not consistent until 1974, when the GCS and the JCS were developed[7]. There was an abundance of alternative terms by which levels of coma or impaired consciousness were described and recorded [7]. 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 [7].

The JCS principally focuses on eye responses. Being a single test, the JCS has outstanding merits as a coma scale: i.e. simplicity and applicability, which should minimize interpreter errors. Simplicity is very important in communication among physicians, nurses and paramedics, especially in emergency settings. The present study adds to its virtues the predictability for early outcome in stroke patients.

In summary, the advantages of the JCS include four points:

1) Predictability for stroke outcome.

This study showed the predictability of the JCS for the stroke outcome.

The JSC correlated with the ADL scale. Hazard ratios for death were significantly different among JCS categories: 1.00 (as reference), 5.55, 9.54 and 34.21 in JCS0, 1, 2 and 3, respectively. It is noteworthy that a simple one-axis test alone predicts early mortality with such clear differences. The JCS could be useful especially at an emergency setting when more detailed evaluation of a patient condition is difficult to obtain and prompt communications among doctors and co-medicals are needed. The JCS provides minimum but critical/essential information.

2) Simplicity.

The JCS is a 4-points scale (from 0 to 3) and comprises only one test: eye responses.

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The Glasgow ~~coma scale~~Coma Scale (GCS), for example, is a 13-points scale (from 3 to 15) and comprises three tests: eye, verbal and motor responses. The JCS is similar to the eye response test in the GCS but even simpler than the GCS (i.e. both E2 and E3 belong in JCS2). Being a uni-coordinate axis scale is very important for simplicity. Although summing up scores in a multi-coordinate axes scale may not be difficult, the scores in different axes may have different values and therefore the interpretation of a total score can be difficult. Hypothetically, both E3V2M1 and E2V3M1 in the GCS, for example, give the same total score of 6. A same total score in a multi-coordinate axes scale could reflect different underlying conditions and might be difficult to interpret.

The description within the JCS is also simple (e.g. ~~JCS,~~ JCS0, JCS1, JCS2 and JCS3), which makes communication among staff easy, prompt and less misleading. It ~~is much~~might be easier to grasp the outline of a patient condition with the JCS than with any multi-axes scales.

3) Reliability.

The simplicity of the JCS ~~provides~~might provide consistency among raters.

The four categories in the JCS are well defined. They do not overlap and they encompass all consciousness levels.

4) Applicability.

The JCS focuses on eye response, which broadens its applicability both for raters and for patients. Raters need only check eye responses in terms of three clearly differentiated categories: open, open only after stimuli and closed. No special knowledge, such as is needed to assess the decerebrate or decorticate response, is necessary. The JCS is applicable to almost all patients, including patients with aphasia, paresis and even in intubated patients, where it might be difficult to apply the GCS, because that has verbal and motor responses tests. In this population-based study, the JCS was applied to 13,406 out of 13,788 stroke patients (97.2%).

Historical information on the JCS

Ohta et al. launched a national survey on craniotomy for ruptured cerebral aneurysms, and described the JCS to define the consciousness level to be included in the survey, at the first meeting of the Society on Surgery for Cerebral Stroke, which was held at Miyagi, Japan (Sakunami Kanko Hotel) on May 13–14, 1972 [8]. At that meeting, he also organized a team to evaluate the scale, because there was no standardized coma scale established in those days. The JCS was based on his study on factors affecting the prognosis of ruptured aneurysm patients after surgical interventions [9]. The JCS was

~~called the 3-group 3-grade method at first and then the "3-3-9 method"[1 10], since the detailed version of the scale composed of four categories: alert, 1-digit code, 2-digit code and 3-digit code, with each digit code having three subcategories (1, 2 and 3 in the 1-digit code, 10, 20 and 30 in the 2-digit code, and 100, 200 and 300 in the 3-digit code)[‡]. It had 10 grades in total: alert plus 9 (3 by 3) grades. This version of the JCS included a motor response test in the 3-digit code patients and three special conditions: restlessness, incontinence and apathy. The first full paper was accepted on 30 November 1973 and published in 1974~~There are some limitations.

First, simplicity[‡]~~. In this study, we applied the simple JCS without subcategories, which is commonly used in Japan.~~

~~Limitations & Responses~~

~~1)~~ ~~Simplicity~~ means lack of detail. The JCS does not evaluate verbal or motor responses, which are tested in the GCS. The total score in the GCS ranges from 3 to15 and the GCS can theoretically describe 120 (4 by 5 by 6) different conditions. The more tests a scale includes, the more details a scale can evaluate[~~11 12~~12 13].

~~Response:~~

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As far as the hazard ratios for early death and the ADL scores, however, the JCS is sufficient as a predictor. A single-dimensional test is the best if the purpose of the test is fulfilled. If needed, we can describe a patient's condition in a detailed way: such as decerebrate posture and decorticate posture. In the JCS, three capital letters, R, I and A, are provided to describe restlessness, incontinence and apathy, respectively.

2) ~~Consciousness~~Second, consciousness levels may fluctuate even in a short period and scores may therefore be different from time to time. This difficulty is common to every coma scale, and the simplicity of the JCS might minimize it. A multi-dimensional scale might cause more difficulty with evaluation.

~~***Response:***~~

~~This difficulty is common to every coma scale, and the simplicity of the JCS minimizes it. A multi-dimensional scale might cause more difficulty with evaluation~~

~~3) Predictability~~Third, predictability of the outcome has inherent limitations~~[13]~~[14]. The outcomes and therefore the hazard ratios for death depend not only on the baseline severity but also on the treatment and patient conditions, including complications. This study did not include the treatments which must affect outcomes.

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For precise evaluation of a relationship between two factors, it should be important to adjust for all the other factors. Treatments, for example, often vary from a case to case. Adjustments for them are virtually impossible in a population based study. Major treatments for stroke, such as tPA therapy or surgical interventions, however, should not have caused a major bias in this study, because the differences in hazard ratios among the consciousness levels based on the JCS remain significant after adjustment for stroke subtypes, i.e. CI, CH and SAH. The JCS also predicted the outcomes in each three subtype of stroke by uni-variable analyses. A tPA therapy is not applied for hemorrhagic stroke and surgical interventions are rarely applied for ischemic stroke (In this study cohort, 374 (4.2%) out of 8896 CI patients had surgical treatment).

There are two types of complications: ones that patients had before stroke onset and ones that they got after the onset. Although the former comprises numerous diseases, risk factors such as hypertension, arrhythmia and diabetes mellitus might be important. The difference in hazard ratios remained significant after adjustment for these three. The latter may include urinary tract infections, decubitus ulcers and pneumonia. They, however, occur as results of stroke, namely after the consciousness level estimation based on the JCS. Although they could be related to the initial severity of the stroke,

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data on this type of complications were not available in this study.

Last, 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[15 16 17] 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. 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.

Conclusions

The ~~Japan Coma Scale~~JCS is a good predictor of stroke outcome. Its two

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outstanding advantages, simplicity and predictability, should make the JCS re-appreciated internationally as a standard coma scale.

Acknowledgments

We acknowledge the contribution of participating institutions and their staffs who provided data in the development of the Kyoto Stroke Registry. We thank Dr Tomio Ohta for the information on the establishment of the JCS. We are grateful to many colleagues for their assistance in this study; particularly Dr Osamu Simamura, Dr Tatsuyuki Sekimoto, Dr Kouichiro Shimizu, Dr Akihiko Nishizawa, Dr Atsushi Okumura, Dr. Masahiro Makino and Dr Kazuhiko Bando.

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Legends

Figure 1. Kaplan-Meier Survival curves for patients in each JCS category

Table 1 The characteristics of patients in the study cohort

Characteristic
1) Age
2) Sex (%of female, (n=female /male))
3) Subtype (CI/CH/SAH, % (n))
4) Systolic blood pressure
5) Diastolic blood pressure
6) Paresis (%, (n=with/without))
7) Hypertension history (%, (n= with/without))
8) Arrhythmia history (%, (n= with/without))
9) Diabetes mellitus history (%, (n= with/without))

Table 1 Continued

	JCS0 (n=7676)	JCS1 (n=2619)	JCS2 (n=1602)	JCS3 (n=1509)
1)	69.7±12.3*[123]	73.4±12.3*[3]	73.6±14.2*[3]	72.3±14.0
2)	39.8 (3056/4620)*[123]	47.7 (1249/1370)*[23]	56.9 (911/691)*[3]	54.7 (826/683)
3)	78.9/15.7/5.4 (6048/1201/415) *[123]	57.7/35.2/7.1 (1508/921/185) *[23]	48.5/39.0/12.5 (774/622/200)*[3]	28.0/47.7/24.3 (421/716/365)
4)	159.3±28.2*[123]	162.7±31.7*[3]	163.6±33.3*[3]	167.4±42.1
5)	87.0±17.1*[123]	88.0±19.0*[3]	88.6±20.6	89.8±24.4
6)	67.0 (5085/2501)*[123]	78.2 (2014/561)*[23]	83.1 (1278/260)*[3]	89.2 (1060/128)
7)	64.5 (4724/2605)*[123]	61.0 (1476/942)*[23]	59.8 (857/576)*[3]	59.3 (755/518)
8)	14.5 (1058/6233)*[123]	23.3 (569/1870)*[23]	28.2 (412/1047)*[3]	20.1 (254/1010)
9)	23.6 (1734/5629)*[123]	18.3 (449/2006)*[23]	15.1 (220/1237)	16.4 (209/1067)

*[1]: significant difference between JCS0 and JCS1

*[2]: significant difference between JCS1 and JCS2

*[3]: significant difference between JCS2 and JCS3

Data on some characteristics were missing in a few patients.

Table 2 Numbers of patients categorized by JCS and by ADL scale.

	Japan Coma Scale				Total
	JCS0	JCS1	JCS 2	JCS 3	
ADL1	4621	608	199	65	5493
ADL2	1908	816	365	104	3193
ADL3	417	442	287	111	1257
ADL4	146	276	325	296	1043
ADL5	102	201	227	761	1291
Total	7194	2343	1403	1337	12277

We obtained data on both the JCS and the ADL scale in 12,277 (89.0%) of the stroke patients.

Table 3 Hazard ratios for death, comparing JCS categories

	Hazard Ratio	95% Confidence Interval		p
		Lower	Upper	
JCS 0	Reference			
JSC 1	5.55	4.19	7.37	<0.001
JCS 2	9.54	7.16	12.71	<0.001
JSC 3	34.21	26.10	44.83	<0.001

Adjusted for age, sex, systolic and diastolic blood pressures, history (hypertension, arrhythmia and diabetes mellitus), stroke type and paresis