



**A simple coma scale predicts stroke outcome
Re-introduction of the Japan Coma Scale**

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2013-002736
Article Type:	Research
Date Submitted by the Author:	16-Feb-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 Sekimoto, Tatsuyuki; Kyoto Prefectural Yosanoumi Hospital, Neurosurgery Shimizu, Kouichiro; Kyoto Fushimi Shimizu Hospital, Neurology Nishizawa, Akihiko; The Nishizawa Clinic, Internal Medicine Okumura, Atsushi; Jujyo Rehabilitation Hospital, Neurosurgery Makino, Masahiro; Kyoto Prefectural University of Medicine, Neurology; Bando, Kazuhiko; The Bando Clinic, Internal Medicine
Primary Subject Heading:	Emergency medicine
Secondary Subject Heading:	Epidemiology, Neurology
Keywords:	Stroke < NEUROLOGY, Neurology < INTERNAL MEDICINE, Stroke medicine < INTERNAL MEDICINE

SCHOLARONE™
Manuscripts

1
2
3
4
5 **A simple coma scale predicts stroke outcome**
6 **Re-introduction of Japan Coma Scale**
7

8
9
10 **Short title: The Japan Coma Scale predicts stroke outcome**
11

12 Kazuo Shigematsu¹, Hiromi Nakano², Yoshiyuki Watanabe³, Tatsuyuki Sekimoto⁴,
13 Kouichiro Shimizu⁵, Akihiko Nishizawa⁶, Atsushi Okumura⁷, Masahiro Makino⁸,
14 Kazuhiko Bando⁹
15
16

17
18 ¹Department of Neurology, National Hospital Organization, Minami Kyoto Hospital,
19 Kyoto, Japan
20

21 ²Department of Neurosurgery, Kyoto Kidugawa Hospital, Kyoto, Japan
22

23 ³Department of Epidemiology for Community Health and Medicine, Kyoto Prefectural
24 University of Medicine, Graduate School of Medical Science, Kyoto, Japan
25

26 ⁴Department of Neurosurgery, Kyoto Prefectural Yosanoumi Hospital, Kyoto, Japan
27

28 ⁵Department of Neurosurgery, Kyoto Fushimi Shimizu Hospital, Kyoto, Japan
29

30 ⁶Department of Internal Medicine, The Nishizawa Clinic, Kyoto, Japan
31

32 ⁷Department of Neurosurgery, Jujyo Rehabilitation Hospital, Kyoto, Japan
33

34 ⁸Department of Neurology, Japanese Red Cross Kyoto Daini Hospital, Kyoto, Japan
35

36 ⁹Department of Internal Medicine, The Bando Clinic, Kyoto, Japan
37

38 Correspondence to Kazuo Shigematsu
39

40 Department of Neurology, the National Hospital Organization, Minami Kyoto Hospital
41

42 11 Nakaashihara, Jyo, Kyoto, Japan, 610-0113
43

44 Phone 81-774-52-0065, Fax 81-75-821-9610, E-mail: neuron@k07.gmail.com]
45

46 **Key Words:** scales; coma; consciousness; stroke
47

48 Contributorship: All authors contributed equally in the data collection and analysis. KS
49 wrote the manuscript. All authors read and approved the final manuscript.
50

51 Conflicts of Interest: None
52

53 Funding: None
54
55
56
57
58
59
60

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

1
2
3
4
5
6 death within 30 days after onset, comparing patients with different conscious levels
7
8
9 based on the JCS.

10 11 12 13 14 **Results**

15
16
17
18
19
20 A total of 13,788 (97.2%) patients were graded based on the JCS. The JCS correlated to
21
22
23 ADL scores with a Spearman's correlation coefficient of 0.61. Hazard ratios for death
24
25
26 within 30 days were 1 (reference), 5.55, 9.54 and 35.21 in those scored as JCS0, JCS1,
27
28
29 JCS2 and JCS3, respectively.
30
31
32
33
34

35 **Conclusions**

36
37
38
39
40 Using a single test of eye response, the JCS has outstanding merits as a coma scale: i.e.
41
42
43 simplicity and applicability. The present study adds predictability for the early outcome
44
45
46 in stroke patients. The JCS is valuable especially at an emergency setting when a
47
48
49 prompt assessment of consciousness level is needed.
50
51
52
53
54
55
56
57
58
59
60

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 1974¹⁻³. An outstanding feature of the JCS 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 JCS'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.

1
2
3
4
5
6 Our hypothesis is that consciousness levels categorized by the JCS should correlate with
7
8
9 the severity of stroke and therefore should predict outcome of stroke. If the
10
11
12 predictability of the JCS is demonstrated, it should be re-appraised as a prompt coma
13
14
15 scale. Although we have the Glasgow Coma Scale (GCS), which was also published in
16
17
18 1974^{4,5}, it would be more pragmatic to have a simpler coma scale especially in an
19
20
21 emergency. The major difference between the GCS and the JCS is that the former is a
22
23
24 three-axis scale whereas the latter is a one-axis scale.

25
26 The aim of the study is to show that the JSC predicts early outcome, including the level
27
28
29 of activity of daily life (ADL) and the hazard ratios for death, and, subsequently, to
30
31
32 re-introduce this simple coma scale to the world.
33
34
35
36
37

38 **Materials and Methods**

39
40
41
42
43
44 We studied the relationship between the outcome at 30 days after stroke and the
45
46
47 consciousness levels based on the JCS at the onset of neurological impairment. We
48
49
50 analyzed all new stroke patients identified from January 1999 to December 2009
51
52
53 inclusive in the entire Kyoto prefecture and registered in the Kyoto Stroke Registry
54
55
56 (KSR)⁶. Detailed information on the KSR has been described previously (Shigematsu
57
58
59
60

1
2
3
4
5
6 et al. BMJ Open, in press). The diagnosis of stroke was confirmed by local neurologists
7
8
9 and/or neurosurgeons according to the WHO definition ⁷. We categorized the patients
10
11 into cerebral infarction (CI), cerebral hemorrhage (CH), subarachnoid hemorrhage
12
13 (SAH) and others, based on the neurological findings, laboratory data, and findings of
14
15 CT, MRI and angiography.
16
17
18
19

20
21
22
23 We used the following definitions.
24

25
26 1) Consciousness levels based on the JCS encompassed four levels:
27

- 28
29 1 JCS 0 (alert)
- 30
31 2 JCS 1 (not fully alert but awake without any stimuli)
- 32
33 3 JCS 2 (arousable with stimulation)
- 34
35 4 JCS 3 (unarousable)

36
37
38
39
40 2) ADL scale at 30 days after stroke onset included five levels:
41

- 42
43 1 ADL1 (No symptoms or no significant disability. Able to carry out all usual
44
45 activities without help. Able to walk without a mobility aide)
- 46
47 2 ADL2 (mildly disabled, or utilization of mobility aide. Unable to carry out all
48
49 usual activities without help. Unable to walk without mobility aide.)
- 50
51 3 ADL3 (moderately disabled, or wheelchair-bound condition. Unable to walk
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6 without assistance.)
7

8
9 4 ADL4 (severely disabled, or bed-bound condition. Unable to use wheel chairs
10
11 without help.)
12

13
14 5 ADL5 (Dead)
15
16
17
18
19

20 21 ***Ethics Statement*** 22

23
24
25
26 This research was performed in accordance with the ethical principles for medical
27
28 research involving human subjects outlined in the Declaration of Helsinki. This research
29
30 was approved by the Board of Directors, the Kyoto Medical Association, the
31
32 Department of Health and Welfare, Kyoto Prefecture and Ethics Committee of the
33
34 National Hospital Organization, Minami Kyoto Hospital. Since all identifying personal
35
36 information was stripped from the secondary files before analysis, the boards waived
37
38 the requirement for written informed consent from the patients involved.
39
40
41
42
43
44
45
46

47 ***Statistical Analyses*** 48

49
50 The frequencies of characteristics among the four conscious levels were determined and
51
52 evaluated for univariate associations by Chi-square analysis. Numerical data such as age
53
54 and blood pressure were compared with Student-t test. Spearman's rank correlation
55
56
57
58
59
60

1
2
3
4
5
6 coefficients were used to identify the correlation between the JCS and ADL scale. We
7
8
9 used the Kaplan-Meier method for curves of estimated survival, a log-rank test for
10
11
12 comparisons of estimated survival among the JCS categories, and Cox proportional
13
14
15 hazards regression for hazard ratios for death. Adjustments for age, sex, systolic and
16
17
18 diastolic blood pressures, histories of hypertension, arrhythmia and diabetes mellitus,
19
20
21 stroke type and paresis were also utilized. Analyses were performed using SPSS ver.19.
22
23
24 All reported p values are 2-sided.
25
26
27
28

29 **Results**

30
31
32
33
34
35 The characteristics of patients are summarized in Table 1. Data on age, and sex were
36
37
38 complete in all patients in the study cohort. The other characteristics had missing data in
39
40
41 a few patients. The numbers of patients examined are shown in the tables.
42

43
44 We evaluated the consciousness levels of 13,406 patients out of 13,788 (97.2%), based
45
46
47 on the JCS. JCS data were missing for 382 patients (2.8%). Among the 13,406 patients,
48
49
50 the number and percentage per group were as follows: JCS0 (7,676 [55.7%]), JCS1
51
52 (2,619 [9.0%]), JCS2 (1,602 [11.6%]) and JCS3 (1,509 [10.9%]), respectively. We
53
54
55 evaluated the ADL scale in 12,601 (91.4%) patients at 30 days after the onset of
56
57
58
59
60

1
2
3
4
5
6 neurological impairment. We obtained data on both the JCS and the ADL scale in
7
8
9 12,277 (89.0%) of the stroke patients (Table 2).

10
11 The Spearman's correlation coefficient was 0.608 for the correlation between the JCS
12
13 and ADL scale ($p < 0.001$). Kaplan-Meier Survival curves of patients in each JCS
14
15 category are presented (Figure 1). A log-rank test proved the differences were
16
17 significant ($p < 0.001$). For Kaplan-Meier Survival curves in each JCS category in each
18
19 stroke subtype, see supplementary figures (Figure 1A, 1B and 1C).

20
21 Hazard ratios for death, comparing JCS categories and their 95% confidential intervals,
22
23 are summarized in Table 3.
24
25

26 27 28 29 30 31 32 33 34 35 **Discussion**

36
37
38
39
40 The JCS principally focuses on eye responses. Being a single test, the JCS has
41
42 outstanding merits as a coma scale: i.e. simplicity and applicability, which should
43
44 minimize interpreter errors. Simplicity is very important in communication among
45
46 physicians, nurses and paramedics, especially in emergency settings. The present study
47
48 adds to its virtues the predictability for early outcome in stroke patients.
49
50

51
52
53
54
55 In summary, the advantages of the JCS include four points:
56
57
58
59
60

1
2
3
4
5
6 1) Predictability for stroke outcome.
7

8
9 This study showed the predictability of the JCS for the stroke outcome.

10
11 The JCS correlated with ADL scale. Hazard ratios for death were significantly different
12 among JCS categories: 1.00 (as reference), 5.55, 9.54 and 34.21 in JCS0, 1, 2 and 3,
13
14 respectively. It is noteworthy that a simple one-axis test alone predicts early mortality
15
16 with such clear differences. The JCS could be useful especially at an emergency setting
17
18 when more detailed evaluation of a patient condition is difficult to obtain and prompt
19
20 communications among doctors and co-medicals are needed. The JCS provides
21
22 minimum but critical/essential information.
23
24
25
26
27
28
29
30

31
32 2) Simplicity.
33

34
35 The JCS is a 4-points scale (from 0 to 3) and comprises only one test: eye responses.
36
37 The Glasgow coma scale (GCS), for example, is a 13-points scale (from 3 to 15) and
38
39 comprises three tests: eye, verbal and motor responses. The JCS is similar to the eye
40
41 response test in the GCS but even simpler than the GCS (i.e. both E2 and E3 belong in
42
43 JCS2). Being a uni-coordinate axis scale is very important for simplicity. Although
44
45 summing up scores in a multi-coordinate axes scale may not be difficult, the scores in
46
47 different axes may have different values and therefore the interpretation of a total score
48
49 can be difficult. Hypothetically, both E3V2M1 and E2V3M1 in the GCS, for example,
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6 give the same total score of 6. A same total score in a multi-coordinate axes scale could
7
8
9 reflect different underlying conditions and might be difficult to interpret. The
10
11 description within the JCS is also simple (e.g. JCS, JCS0, JCS1, JCS2 and JCS3), which
12
13 makes communication among staff easy, prompt and less misleading. It is much easier
14
15 to grasp the outline of a patient condition with the JCS than with any multi-axes scales.
16
17
18
19

20 3) Reliability.

21
22 The simplicity of the JCS provides consistency among raters.

23
24 The four categories in the JCS are well defined. They do not overlap and they
25
26 encompass all consciousness levels.
27
28
29
30

31 4) Applicability.

32
33 The JCS focuses on eye response, which broadens its applicability both for raters and
34
35 for patients. Raters need only check eye responses in terms of three clearly
36
37 differentiated categories: open, open only after stimuli and closed. No special
38
39 knowledge, such as is needed to assess the decerebrate or decorticate response, is
40
41 necessary. The JCS is applicable to almost all patients, including patients with aphasia,
42
43 paresis and even in intubated patients, where it might be difficult to apply the GCS,
44
45 because that has verbal and motor responses tests. In this population-based study, the
46
47 JCS was applied to 13,406 out of 13,788 stroke patients (97.2%).
48
49
50
51
52
53
54
55
56
57
58
59
60

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, 1972⁸. 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 interventions⁹. The JCS was called the 3 group 3 grade method at first and then the “3-3-9 method”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 1974¹. In this study, we applied the simple JCS without

1
2
3
4
5
6 subcategories, which is commonly used in Japan.
7
8
9

10
11
12 ***Limitations & Responses***
13

- 14
15
16
17
18 1) Simplicity means lack of detail. The JCS does not evaluate verbal or motor
19
20 responses, which are tested in the GCS. The total score in the GCS ranges from 3
21
22 to 15 and the GCS can theoretically describe 120 (4 by 5 by 6) different conditions.
23
24
25 The more tests a scale includes, the more details a scale can evaluate^{11 12}.
26
27
28

29 ***Response:***
30

31
32 As far as the hazard ratios for early death and ADL scores, the JCS is sufficient as a
33
34 predictor. A single-dimensional test is the best if the purpose of the test is fulfilled. If
35
36 needed, we can describe a patient's condition in a detailed way: such as decerebrate
37
38 posture and decorticate posture. In the JCS, three capital letters, R, I and A, are
39
40 provided to describe restlessness, incontinence and apathy, respectively.
41
42
43
44
45
46
47
48

- 49
50 2) Consciousness levels may fluctuate even in a short period and scores may therefore
51
52 be different from time to time.
53
54

55 ***Response:***
56
57
58
59
60

1
2
3
4
5
6 This difficulty is common to every coma scale, and the simplicity of the JCS
7
8
9 minimizes it. A multi-dimensional scale might cause more difficulty with evaluation
10
11
12 .

- 13
14
15 3) Predictability of the outcome has inherent limitations¹³. The outcomes and therefore
16
17 the hazard ratios for death depend not only on the baseline severity but also on the
18
19 treatment and patient conditions, including complications. This study did not
20
21 include the treatments which must affect outcomes.
22
23
24

25
26 **Response:**
27

28
29 For precise evaluation of a relationship between two factors, it should be important
30
31 to adjust for all the other factors. Treatments, for example, often vary from a case to
32
33 case. Adjustments for them are virtually impossible in a population based study.
34
35 Major treatments for stroke, such as tPA therapy or surgical interventions, however,
36
37 should not have caused a major bias in this study, because the differences in hazard
38
39 ratios among the consciousness levels based on the JCS remain significant after
40
41 adjustment for stroke subtypes, i.e. CI, CH and SAH. The JCS also predicted the
42
43 outcomes in each three subtype of stroke by uni-variable analyses. A tPA therapy is
44
45 not applied for hemorrhagic stroke and surgical interventions are rarely applied for
46
47 ischemic stroke (In this study cohort, 374 (4.2%) out of 8896 CI patients had
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6 surgical treatment).

7
8
9 There are two types of complications: ones that patients had before stroke onset and
10
11 ones that they got after the onset. Although the former comprises numerous diseases,
12
13 risk factors such as hypertension, arrhythmia and diabetes mellitus might be
14
15 important. The difference in hazard ratios remained significant after adjustment for
16
17 these three. The latter may include urinary tract infections, decubitus ulcers and
18
19 pneumonia. They, however, occur as results of stroke, namely after the
20
21 consciousness level estimation based on the JCS. Although they could be related to
22
23 the initial severity of the stroke, data on this type of complications were not
24
25 available in this study.
26
27
28
29
30
31
32
33
34
35
36
37

38 **Conclusions**

39
40
41
42
43 The Japan Coma Scale is a good predictor of stroke outcome. Its two outstanding
44
45 advantages, simplicity and predictability, should make the JCS re-appreciated
46
47 internationally as a standard coma scale.
48
49
50
51
52
53
54
55
56
57
58
59
60

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

References

1. Ohta T, Waga S, Handa W, Saito I, Takeuchi K. [New grading of level of disordered consciousness (author's transl)]. *No shinkei geka. Neurological surgery* 1974;2(9):623-7.
2. Ohta T, Kikuchi H, Hashi K, Kudo Y. Nizofenone administration in the acute stage following subarachnoid hemorrhage. Results of a multi-center controlled double-blind clinical study. *Journal of neurosurgery* 1986;64(3):420-6.
3. Shigemori M, Abe T, Aruga T, Ogawa T, Okudera H, Ono J, et al. Guidelines for the Management of Severe Head Injury, 2nd edition guidelines from the Guidelines Committee on the Management of Severe Head Injury, the Japan Society of Neurotraumatology. *Neurologia medico-chirurgica* 2012;52(1):1-30.
4. Teasdale G, Jennett B. Assessment of coma and impaired consciousness. A practical scale. *Lancet* 1974;2(7872):81-4.
5. Weir CJ, Bradford AP, Lees KR. The prognostic value of the components of the Glasgow Coma Scale following acute stroke. *QJM : monthly journal of the Association of Physicians* 2003;96(1):67-74.
6. Shigematsu K, Shimamura O, Nakano H, Watanabe Y, Sekimoto T, Shimizu K, et al. Vomiting should be a prompt predictor of stroke outcome. *Emergency medicine journal : EMJ* 2012.
7. Hatano S. Experience from a multicentre stroke register: a preliminary report. *Bulletin of the World Health Organization* 1976;54(5):541-53.
8. Ohta T SN. The research on prognosis prediction of surgical interventions for ruptured cerebral aneurysm - production of ABC index- the first report: the shortcomings of the conventional classification system of severity and determination of predicting factors of surgical prognosis. *The First Meeting of Society on Surgery for Cerebral Stroke (In Japanese)* 1972:1-20.
9. Ohta T WS, Saito I, Masugi N, Suzuki J, Takaku A. The survey on therapeutic strategy of cerebral aneurysm and prognosis after surgical interventions. *The Second Meeting of Society on Surgery for Cerebral Stroke (In Japanese)* 1973;2:55-75.
10. Ohta T WS, Handa H, Saito I, Takeuchi K, Masugi N, Suzuki J, Takaku A. The new grading system for disturbed consciousness and its numerical expression; the 3-3-9 degrees method. *The Third Meeting of Society on Surgery for Cerebral Stroke (In Japanese)* 1974;3:61-68.

11. Lingsma HF, Roozenbeek B, Steyerberg EW, Murray GD, Maas AI. Early prognosis in traumatic brain injury: from prophecies to predictions. *Lancet neurology* 2010;9(5):543-54.
12. Wijdicks EF, Rabinstein AA, Bamlet WR, Mandrekar JN. FOUR score and Glasgow Coma Scale in predicting outcome of comatose patients: a pooled analysis. *Neurology* 2011;77(1):84-5.
13. Chandra RV, Law CP, Yan B, Dowling RJ, Mitchell PJ. Glasgow coma scale does not predict outcome post-intra-arterial treatment for basilar artery thrombosis. *AJNR. American journal of neuroradiology* 2011;32(3):576-80.

1
2
3
4
5
6 **Legends**
7

8 **Figure 1. Kaplan-Meier Survival curves for patients in each JCS category**
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

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

1
2
3
4
5
6 *²: significant difference between JCS1 and JCS2
7

8
9 *³: significant difference between JCS2 and JCS3
10

11 Data on some characteristics were missing in a few patients.
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

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.

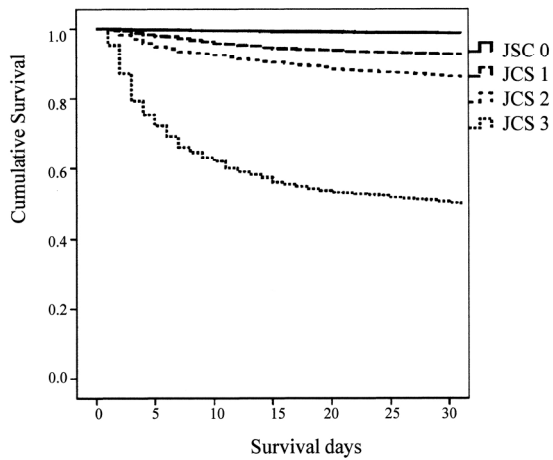
Table 3 Hazard ratios for death, comparing JCS categories

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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Figure 1

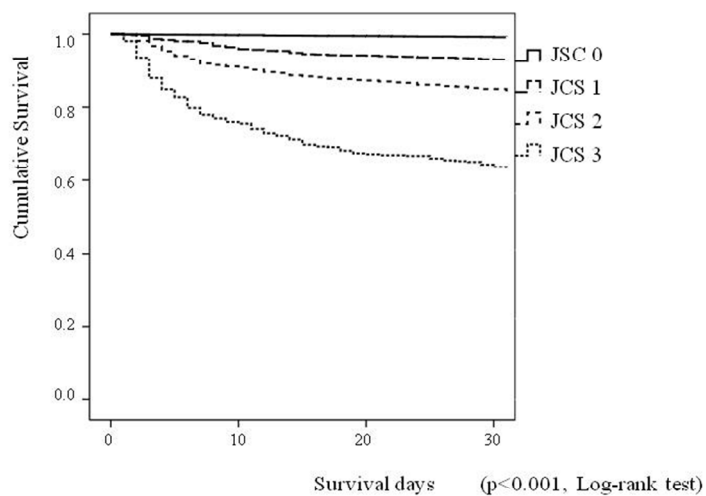


Kaplan-Meier Survival curves for patients in each JCS category
215x156mm (300 x 300 DPI)

view only

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Figure 1A-Suppl Kaplan-Meier Survival curves of patients in each JCS category
Cerebral infarction

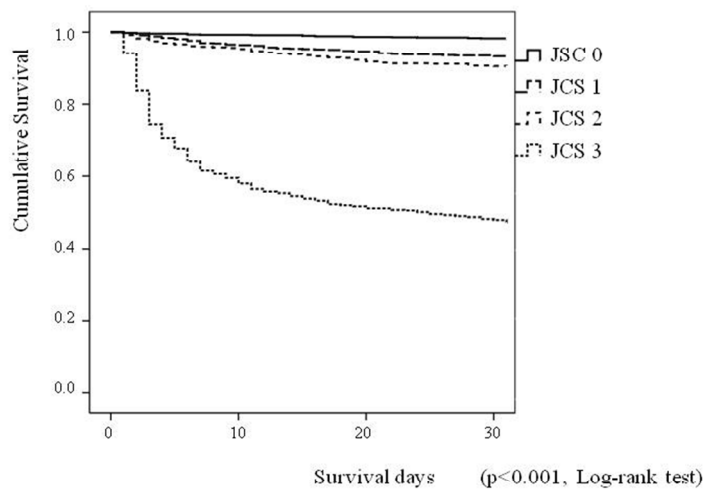


Kaplan-Meier Survival curves of patients in each JCS category
Cerebral infarction

254x190mm (96 x 96 DPI)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

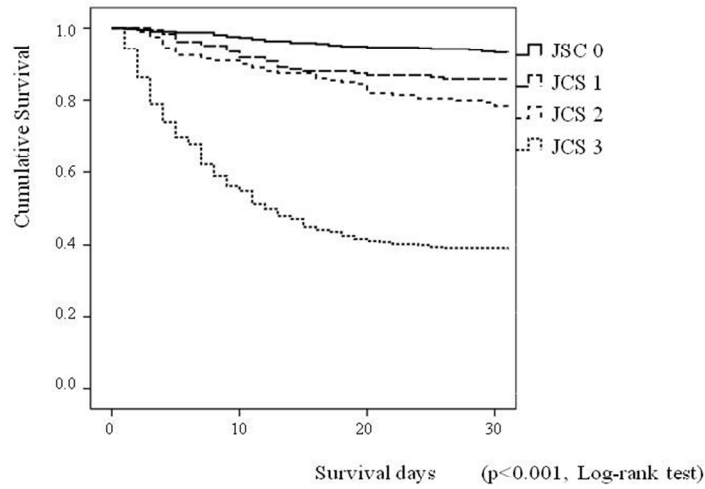


Kaplan-Meier Survival curves of patients in each JCS category
Cerebral hemorrhage

254x190mm (96 x 96 DPI)

Peer Review Only

Figure 1C-Suppl Kaplan-Meier Survival curves of patients in each JCS category Subarachnoid hemorrhage



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

254x190mm (96 x 96 DPI)

Peer Review Only

1
2
3
4
5
6
7
8 **A simple coma scale predicts stroke outcome**

9 **Re-introduction of Japan Coma Scale**

10
11
12 **Short title: The Japan Coma Scale predicts stroke outcome**

13
14
15 Kazuo Shigematsu¹, Hiromi Nakano², Yoshiyuki Watanabe³, Tatsuyuki Sekimoto⁴,
16 Kouichiro Shimizu⁵, Akihiko Nishizawa⁶, Atsushi Okumura⁷, Masahiro Makino⁸,
17 Kazuhiko Bando⁹, ~~Yasushi Kitagawa¹⁰~~

18
19
20 ¹Department of Neurology, National Hospital Organization, Minami Kyoto Hospital,
21 Kyoto, Japan

22 ²Department of Neurosurgery, Kyoto Kidugawa Hospital, Kyoto, Japan

23 ³Department of Epidemiology for Community Health and Medicine, Kyoto Prefectural
24 University of Medicine, Graduate School of Medical Science, Kyoto, Japan

25 ⁴Department of Neurosurgery, Kyoto Prefectural Yosanoumi Hospital, Kyoto, Japan

26 ⁵Department of Neurosurgery, Kyoto Fushimi Shimizu Hospital, Kyoto, Japan

27 ⁶Department of Internal Medicine, The Nishizawa Clinic, Kyoto, Japan

28 ⁷Department of Neurosurgery, Jujyo Rehabilitation Hospital, Kyoto, Japan

29 ⁸Department of Neurology, Japanese Red Cross Kyoto Daini Hospital, Kyoto, Japan

30 ⁹Department of Internal Medicine, The Bando Clinic, Kyoto, Japan

31 ~~¹⁰Department of Internal Medicine, The Kitagawa Clinic, Kyoto, Japan~~

32
33
34
35
36 Correspondence to Kazuo Shigematsu

37 Department of Neurology, the National Hospital Organization, Minami Kyoto Hospital

38 11 Nakaashihara, Joyo, Kyoto, Japan, 610-0113

39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
Phone 81-774-52-0065, Fax 81-75-821-9610, E-mail: neuron@k07.gmail.com]

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

~~Word Count: 2454~~

Formatted: Left, Don't adjust space between Latin and Asian text, Don't adjust space between Asian text and numbers

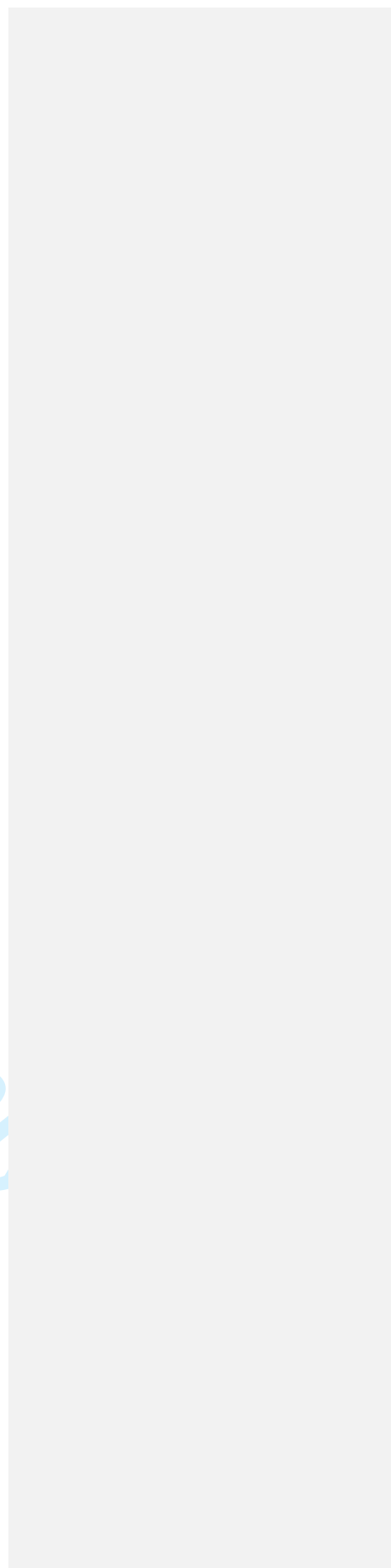
Formatted: Font: Times New Roman, 12 pt, Font color: Custom Color(RGB(34,34,34)), Pattern: Clear (White)

Formatted: Font: Times New Roman, 12 pt, Bold, Italic

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

|

For peer review only



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

Formatted: Font color: Auto

Formatted: Font color: Text 1

1
2
3
4
5
6
7
8
9 death within 30 days after onset, comparing patients with different conscious levels
10
11 based on the JCS.
12
13

14 15 16 17 **Results**

18
19
20
21 A total of 13,788 (97.2%) patients were graded based on the JCS. The JCS correlated to
22
23 ADL scores with a Spearman's correlation coefficient of 0.61. Hazard ratios for death
24
25 within 30 days were 1 (reference), 5.655, 9.554 and 35.221 in those scored as JCS0,
26
27 JCS1, JCS2 and JCS3, respectively.–
28
29
30
31
32
33

34 35 **Conclusions**

36
37
38
39 Using a single test of eye response, the JCS has outstanding merits as a coma scale: i.e.
40
41 simplicity and applicability. The present study adds predictability for the early outcome
42
43 in stroke patients. The JCS is valuable especially at an emergency setting when a
44
45 prompt assessment of consciousness level is needed.
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9 **Article summary**

10
11 **Article focus**

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

17
18
19
20
21
22
23
24
25
26
27 **Key messages**

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

32
33
34
35
36
37
38
39 **Strengths and limitations of this study**

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

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

Introduction

Formatted: Font: Not Bold

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 1974¹⁻³. An outstanding feature of the JCS 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 JCS'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.

1
2
3
4
5
6
7
8
9 Our hypothesis is that consciousness levels categorized by the JCS should correlate with
10
11 the severity of stroke and therefore should predict outcome of stroke. If the
12
13 predictability of the JCS is demonstrated, it should be re-appraised as a prompt coma
14
15 scale. Although we have the Glasgow Coma Scale (GCS), which was also published in
16
17 1974⁴⁵, it would be more pragmatic to have a simpler coma scale especially in an
18
19 emergency. The major difference between the GCS and the JCS is that the former is a
20
21 three-axis scale whereas the latter is a one-axis scale.
22
23

24
25
26 The aim of the study is to show that the JCS predicts early outcome, including the level
27
28 of activity of daily life (ADL) and the hazard ratios for death, and, subsequently, to
29
30 re-introduce this simple coma scale to the world.
31
32
33
34
35
36

37 **Materials and Methods**

38
39
40
41

42 We studied the relationship between the outcome at 30 days after stroke and the
43
44 consciousness levels based on the JCS at the onset of neurological impairment. We
45
46 analyzed all new stroke patients identified from January 1999 to December 2009
47
48

49 inclusive in the entire Kyoto prefecture and registered in the Kyoto Stroke Registry.

50
51
52 (KSR)⁶. Detailed information on the KSR has been described previously (Shigematsu
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9 [et al. BMJ Open, in press](#)). The diagnosis of stroke was confirmed by local neurologists
10 and/or neurosurgeons according to the WHO definition ⁷. We categorized the patients
11 into cerebral infarction (CI), cerebral hemorrhage (CH), subarachnoid hemorrhage
12 (SAH) and others, based on the neurological findings, laboratory data, and findings of
13 CT, MRI and angiography. ~~—~~

14
15
16
17
18
19
20
21
22
23
24 We used the following definitions ~~for the purpose of this study~~.

25
26
27 1) Consciousness levels based on the JCS encompassed four levels:

- 28 1 JCS 0 (alert)
- 29 2 JCS 1 (not fully alert but awake without any stimuli)
- 30 3 JCS 2 (arousable with stimulation)
- 31 4 JCS 3 (unarousable)

32
33
34
35
36
37
38
39 2) ADL scale at 30 days after stroke onset included five levels:

- 40 1 ADL1 (No symptoms or no significant disability. Able to carry out all usual
41 activities without help. Able to walk without a mobility aide)
- 42 2 ADL2 (mildly disabled, or utilization of mobility aide. Unable to carry out all
43 usual activities without help. Unable to walk without mobility aide.)
- 44 3 ADL3 (moderately disabled, or wheelchair-bound condition. Unable to walk
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9 without assistance.)

10
11 4 ADL4 (severely disabled, or bed-bound condition. Unable to use wheel chairs

12
13 without help.)

14
15
16 5 ADL5 (Dead)

17
18
19 ~~We sent out a questionnaire on what coma scale they preferably used in practice to 219-~~
20
21 ~~local nurses and members of rescue squads.~~
22
23

24
25
26
27
28 ***Ethics Statement***

29
30
31 This research was performed in accordance with the ethical principles for medical
32
33 research involving human subjects outlined in the Declaration of Helsinki. This research
34
35 was approved by the Board of Directors, the Kyoto Medical Association, the
36
37 Department of Health and Welfare, Kyoto Prefecture and Ethics Committee of the
38
39 National Hospital Organization, Minami Kyoto Hospital. Since all identifying personal
40
41 information was stripped from the secondary files before analysis, the boards waived
42
43 the requirement for written informed consent from the patients involved.
44
45
46
47
48

49
50 ***Statistical Analyses***

51
52 The frequencies of characteristics among the four conscious levels were determined and
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9 evaluated for univariate associations by Chi-square analysis. Numerical data such as age
10
11 and blood pressure were compared with Student-t ~~teststest~~. Spearman's rank correlation
12
13 coefficients were used to identify the correlation between the JCS and ADL scale. We
14
15 used the Kaplan-Meier method for curves of estimated survival, a log-rank test for
16
17 comparisons of estimated survival among the JCS categories, and ~~the~~ Cox proportional
18
19 hazards regression for hazard ratios for death. Adjustments for age, sex, systolic and
20
21 diastolic blood pressures, histories of hypertension, arrhythmia and diabetes mellitus,
22
23 stroke type and paresis were also utilized. Analyses were performed using SPSS ver.19.
24
25
26
27
28
29 All reported p values are 2-sided.
30
31
32
33

34 Results

35
36
37
38
39 The characteristics of patients are summarized in Table 1. Data on age, and sex were
40
41 complete in all patients in the study cohort. The other characteristics had missing data in
42
43 a few patients. The numbers of patients examined are shown in the tables.
44
45

46
47 We evaluated the consciousness levels of 13,406 patients out of 13,788 (97.2%), based
48
49 on the JCS. JCS data were missing for 382 patients (2.8%). Among the 13,406 patients,
50
51 the number and percentage per group were as follows: JCS0 (~~76767~~,676 [55.7%]), JCS1
52
53
54
55
56
57
58
59
60

Formatted: Font color: Auto

1
2
3
4
5
6
7
8
9 | (~~26192.619~~ [9.0%]), JCS2 (~~16021.602~~ [11.6%]) and JCS3 (~~15091.509~~ [10.9%]),
10
11 | respectively. We evaluated the ADL scale in 12,601 (91.4%) patients at 30 days after the
12
13 | onset of neurological impairment. We obtained data on both the JCS and the ADL scale
14
15 | in 12,277 (89.0%) of the stroke patients (Table 2).
16
17 |

18
19 | The Spearman's correlation coefficient was 0.608 for the correlation between the JCS
20
21 | and ADL scale ($p < 0.001$). Kaplan-Meier Survival curves of patients in each JCS
22
23 | category are presented (Figure 1). A log-rank test proved the differences were
24
25 | significant ($p < 0.001$). For Kaplan-Meier Survival curves in each JCS category in each
26
27 | stroke subtype, see supplementary figures (Figure 1A, 1B and 1C).
28
29 |

30
31 | Hazard ratios for death, comparing JCS categories and their 95% confidential intervals,
32
33 | are summarized in Table 3.
34
35 |

36
37 | ~~As for the questionnaire on coma scales, 204 out of 219 (93.1%) nurses and members of~~
38
39 | ~~rescue squads answered that they mainly used the JCS.~~
40
41 |

42 43 44 | **Discussion**

45
46
47
48
49 | The JCS principally focuses on eye responses. Being a single test, the JCS has
50
51 | outstanding merits as a coma scale: i.e. simplicity and applicability, which should
52
53 |

Formatted: Font color: Auto

1
2
3
4
5
6
7
8
9 minimize interpreter errors. Simplicity is very important in communication among
10
11 physicians, nurses and paramedics, especially in emergency settings. The present study
12
13 adds to its virtues the predictability for early outcome in stroke patients.
14
15

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

17
18
19 1) Predictability for stroke outcome.

20
21 This study showed the predictability of the JCS for the stroke outcome.

22
23
24 ~~The JCS correlated with ADL scale and hazard ratios for death in stroke patients. The~~
25
26 ~~likelihood of the differences in hazard ratios occurring by chance is estimated to be~~
27
28 ~~6.32×10^{-171} (after adjustment for age, gender, blood pressure, histories of hypertension,~~
29
30 ~~arrhythmia and diabetes, stroke type and paresis). The JCS correlated with ADL scale.~~
31
32 Hazard ratios for death were significantly different among JCS categories: 1.00 (as
33
34 reference), 5.55, 9.54 and 34.21 in JCS0, 1, 2 and 3, respectively. It is noteworthy that a
35
36 simple one-axis test alone predicts early mortality with such clear differences. The JCS
37
38 could be useful especially at an emergency setting when more detailed evaluation of a
39
40 patient condition is difficult to obtain and prompt communications among doctors and
41
42 co-medicals are needed. The JCS provides minimum but critical/essential information.
43
44
45
46
47
48

49
50 2) Simplicity.

51
52 The JCS is a 4-points scale (from 0 to 3) and comprises only one test: eye responses.
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9 The Glasgow coma scale (GCS), for example, is a 13-points scale (from 3 to 15) and
10
11 comprises three tests: eye, verbal and motor responses. The JCS is similar to the eye
12
13 response test in the GCS but even simpler than the GCS (i.e. both E2 and E3 belong in
14
15 JCS2). Being a uni-coordinate axis scale is very important for simplicity. Although
16
17 summing up scores in a multi-coordinate axes scale may not be difficult, the scores in
18
19 different axes may have different values and therefore the interpretation of a total score
20
21 can be difficult. Hypothetically, both E3V2M1 and E2V3M1 in the GCS, for example,
22
23 give the same total score of 6. A same total score in a multi-coordinate axes scale could
24
25 reflect different underlying conditions and might be difficult to interpret. The
26
27 description within the JCS is also simple (e.g. JCS, JCS0, JCS1, JCS2 and JCS3), which
28
29 makes communication among staff easy, prompt and less misleading. It is much easier
30
31 to grasp the outline of a patient condition with the JCS than with any multi-axes scales.
32
33
34
35
36
37
38
39

40 3) Reliability.

41
42 The simplicity of the JCS provides consistency among raters.

43
44 The four categories in the JCS are well defined. They do not overlap and they
45
46 encompass all consciousness levels.
47
48

49 4) Applicability.

50
51 The JCS focuses on eye response, which broadens its applicability both for raters and
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9 for patients. Raters need only check eye responses in terms of three clearly
10
11 differentiated categories: open, open only after stimuli and closed. No special
12
13 knowledge, such as is needed to assess the decerebrate or decorticate response, is
14
15 necessary. The JCS is applicable to almost all patients, including patients with aphasia,
16
17 paresis and even in intubated patients, where it might be difficult to apply the GCS,
18
19 because that has verbal and motor responses tests. In this population-based study, the
20
21 JCS was applied to 13,406 out of 13,788 stroke patients (97.2%).
22
23
24
25
26
27
28

29 *Historical information on the JCS*

30
31
32
33

34 Ohta et al. launched a national survey on craniotomy for ruptured cerebral aneurysms,
35
36 and described the JCS to define the consciousness level to be included in the survey, at
37
38 the first meeting of the Society on Surgery for Cerebral Stroke, which was held at
39
40 Miyagi, Japan (Sakunami Kanko Hotel) on May 13-14, 1972⁸. At that meeting, he also
41
42 organized a team to evaluate the scale, because there was no standardized coma scale
43
44 established in those days. The JCS was based on his study on factors affecting the
45
46 prognosis of ruptured aneurysm patients after surgical interventions⁹. The JCS was
47
48 called the 3 group 3 grade method at first and then the “3-3-9 method”¹⁰, since the
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9 detailed version of the scale composed of four categories: alert, 1-digit code, 2-digit
10 code and 3-digit code, with each digit code having three subcategories (1, 2 and 3 in the
11 1-digit code, 10, 20 and 30 in the 2-digit code, and 100, 200 and 300 in the 3-digit code)
12
13
14
15
16
17 ¹. It had 10 grades in total: alert plus 9 (3 by 3) grades. This version of the JCS included
18 a motor response test in the 3-digit code patients and three special conditions:
19
20
21 restlessness, incontinence and apathy. The first full paper was accepted on 30 November
22
23
24 1973 and published in 1974¹. In this study, we applied the simple JCS without
25
26
27 subcategories, which is commonly used in Japan.
28
29
30
31

32 *Limitations & Responses*

- 33
34
35
36
37 1) Simplicity means lack of detail. The JCS does not evaluate verbal or motor
38 responses, which are tested in the GCS. The total score in the GCS ranges from 3
39
40 to 15 and the GCS can theoretically describe 120 (4 by 5 by 6) different conditions.
41
42
43
44 The more tests a scale includes, the more details a scale can evaluate^{11 12}.
45
46

47 *Response:*

48
49
50 As far as the hazard ratios for early death and ADL scores, the JCS is sufficient as a
51
52 predictor. A single-dimensional test is the best if the purpose of the test is fulfilled. If
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9 needed, we can describe a patient's condition in a detailed way: such as decerebrate
10 posture and decorticate posture. In the JCS, three capital letters, R, I and A, are
11 provided to describe restlessness, incontinence and apathy, respectively.
12
13
14
15
16
17
18

- 19 2) Consciousness levels may fluctuate even in a short period and scores may therefore
20 be different from time to time.
21
22

23
24 **Response:**

25
26 This difficulty is common to every coma scale, and the simplicity of the JCS
27 minimizes it. A multi-dimensional scale might cause more difficulty with evaluation
28
29
30
31
32
33

- 34 3) Predictability of the outcome has inherent limitations¹³. The outcomes and therefore
35 the hazard ratios for death depend not only on the baseline severity but also on the
36 treatment and patient conditions, including complications. This study did not
37 include the treatments which must affect outcomes.
38
39
40
41
42
43
44

45 **Response:**

46
47 For precise evaluation of a relationship between two factors, it should be important
48 to adjust for all the other factors. Treatments, for example, often vary from a case to
49 case. Adjustments for them are virtually impossible in a population based study.
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9 Major treatments for stroke, such as tPA therapy or surgical interventions, however,
10
11 should not have caused a major bias in this study, because the differences in hazard
12
13 ratios among the consciousness levels based on the JCS remain significant after
14
15 adjustment for stroke subtypes, i.e. CI, CH and SAH. The JCS also predicted the
16
17 outcomes in each three subtype of stroke by uni-variable analyses. A tPA therapy is
18
19 not applied for hemorrhagic stroke and surgical interventions are rarely applied for
20
21 ischemic stroke (In this study cohort, 374 (4.2%) out of 8896 CI patients had
22
23 surgical treatment).
24
25
26
27
28

29 There are two types of complications: ones that patients had before stroke onset and
30
31 ones that they got after the onset. Although the former comprises numerous diseases,
32
33 risk factors such as hypertension, arrhythmia and diabetes mellitus might be
34
35 important. The difference in hazard ratios remained significant after adjustment for
36
37 these three. The latter may include urinary tract infections, decubitus ulcers and
38
39 pneumonia. They, however, occur as results of stroke, namely after the
40
41 consciousness level estimation based on the JCS. Although they could be related to
42
43 the initial severity of the stroke, data on this type of complications were not
44
45 available in this study.
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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.

Formatted: Font: Not Bold, Not Italic

References

1. Ohta T, Waga S, Handa W, Saito I, Takeuchi K. [New grading of level of disordered consciousness (author's transl)]. *No shinkei geka. Neurological surgery* 1974;2(9):623-7.
2. Ohta T, Kikuchi H, Hashi K, Kudo Y. Nizofenone administration in the acute stage following subarachnoid hemorrhage. Results of a multi-center controlled double-blind clinical study. *Journal of neurosurgery* 1986;64(3):420-6.
3. Shigemori M, Abe T, Aruga T, Ogawa T, Okudera H, Ono J, et al. Guidelines for the Management of Severe Head Injury, 2nd edition guidelines from the Guidelines Committee on the Management of Severe Head Injury, the Japan Society of Neurotraumatology. *Neurologia medico-chirurgica* 2012;52(1):1-30.
4. Teasdale G, Jennett B. Assessment of coma and impaired consciousness. A practical scale. *Lancet* 1974;2(7872):81-4.
5. Weir CJ, Bradford AP, Lees KR. The prognostic value of the components of the Glasgow Coma Scale following acute stroke. *QJM : monthly journal of the Association of Physicians* 2003;96(1):67-74.
6. Shigematsu K, Shimamura O, Nakano H, Watanabe Y, Sekimoto T, Shimizu K, et al. Vomiting should be a prompt predictor of stroke outcome. *Emergency medicine journal : EMJ* 2012.
7. Hatano S. Experience from a multicentre stroke register: a preliminary report. *Bulletin of the World Health Organization* 1976;54(5):541-53.
8. Ohta T SN. The research on prognosis prediction of surgical interventions for ruptured cerebral aneurysm - production of ABC index- the first report: the shortcomings of the conventional classification system of severity and determination of predicting factors of surgical prognosis. *The First Meeting of Society on Surgery for Cerebral Stroke (In Japanese)* 1972:1-20.
9. Ohta T WS, Saito I, Masugi N, Suzuki J, Takaku A. The survey on therapeutic strategy of cerebral aneurysm and prognosis after surgical interventions. *The Second Meeting of Society on Surgery for Cerebral Stroke (In Japanese)* 1973;2:55-75.
10. Ohta T WS, Handa H, Saito I, Takeuchi K, Masugi N, Suzuki J, Takaku A. The new grading system for disturbed consciousness and its numerical expression; the 3-3-9 degrees method. *The Third Meeting of Society on Surgery for Cerebral Stroke (In Japanese)* 1974;3:61-68.

11. Lingsma HF, Roozenbeek B, Steyerberg EW, Murray GD, Maas AI. Early prognosis in traumatic brain injury: from prophecies to predictions. *Lancet neurology* 2010;9(5):543-54.
12. Wijdicks EF, Rabinstein AA, Bamlet WR, Mandrekar JN. FOUR score and Glasgow Coma Scale in predicting outcome of comatose patients: a pooled analysis. *Neurology* 2011;77(1):84-5.
13. Chandra RV, Law CP, Yan B, Dowling RJ, Mitchell PJ. Glasgow coma scale does not predict outcome post-intra-arterial treatment for basilar artery thrombosis. *AJNR. American journal of neuroradiology* 2011;32(3):576-80.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Legends

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

For peer review only

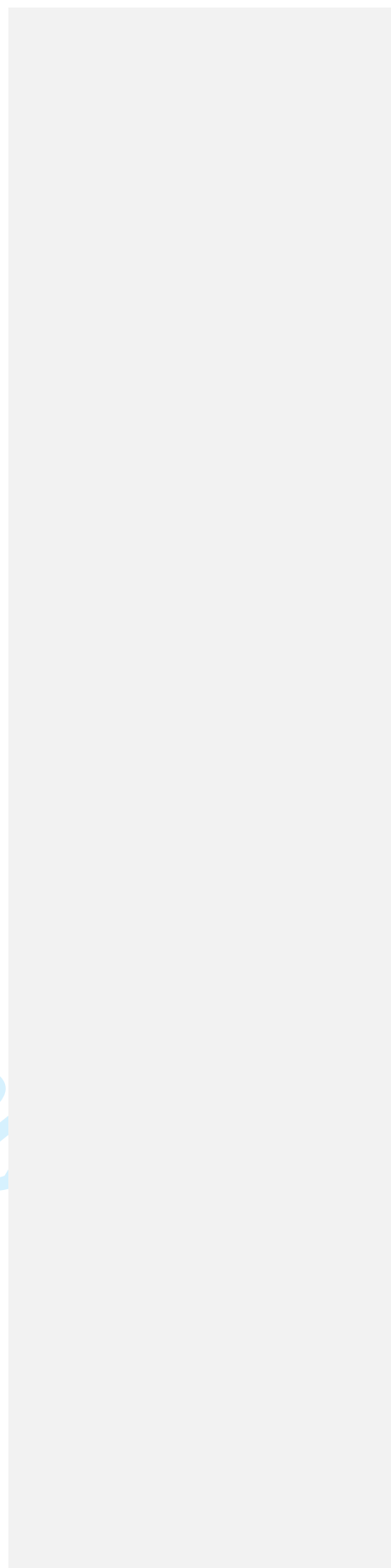


Table 1 The characteristics of patients in the study cohort

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)

Formatted Table

Deleted Cells

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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

*²: significant difference between JCS1 and JCS2

*³: significant difference between JCS2 and JCS3

Data on some characteristics were missing in a few patients.

For peer review only

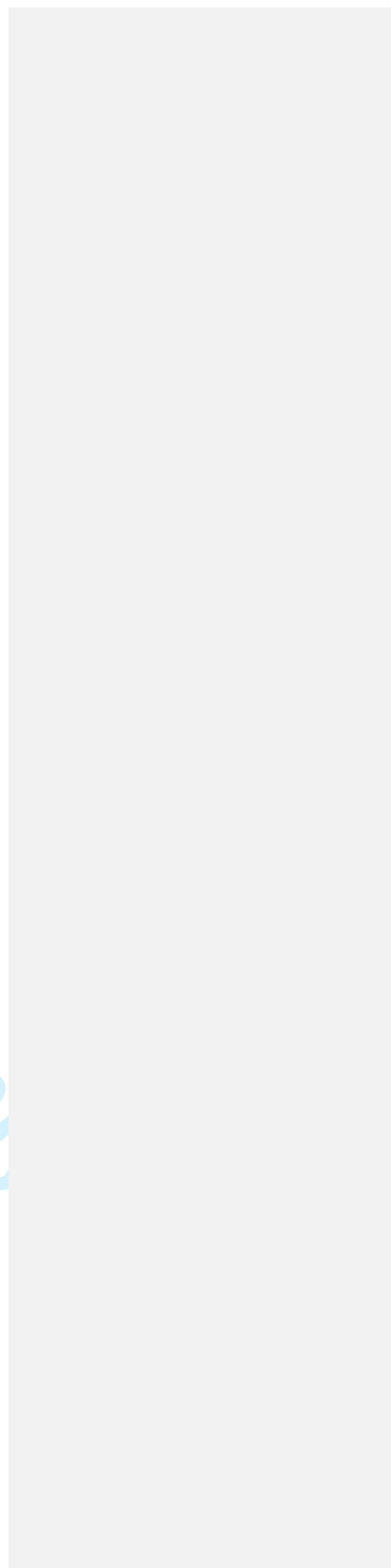


Table 2 Numbers of patients categorized by JCS and by ADL scale.

	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*
JCS 1	5.55	4.19	7.37	<0.001
JCS 2	9.54	7.16	12.71	<0.001
JCS 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 ($p=6.32 \times 10^{-171}$)

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 (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	9, 10
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	9, 10 Table 1-3
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 (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	9, 10 Table 1-3
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:	<i>BMJ Open</i>
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

SCHOLARONE™
Manuscripts

1
2
3
4
5 **The Eye Response Test Alone Is Sufficient To Predict Stroke Outcome:**
6 **Re-Introduction of Japan Coma Scale. A cohort study**
7
8
9

10
11 **Short title: The Japan Coma Scale predicts stroke outcome**
12

13
14 Kazuo Shigematsu¹, Hiromi Nakano², Yoshiyuki Watanabe³,

15 ¹Department of Neurology, National Hospital Organization, Minami Kyoto Hospital,
16 Kyoto, Japan

17 ²Department of Neurosurgery, Kyoto Kidugawa Hospital, Kyoto, Japan

18 ³Department of Epidemiology for Community Health and Medicine, Kyoto Prefectural
19 University of Medicine, Graduate School of Medical Science, Kyoto, Japan
20
21
22
23

24
25
26 Correspondence to Kazuo Shigematsu

27 Department of Neurology, the National Hospital Organization, Minami Kyoto Hospital

28 11 Nakaashihara, Joyo, Kyoto, Japan, 610-0113

29 Phone 81-774-52-0065, Fax 81-75-821-9610, E-mail: neuron@k07.gmail.com]
30
31
32

33 **Key Words:** scales; coma; consciousness; stroke
34
35

36 Contributorship: All authors contributed equally in the data collection and analysis. KS
37 wrote the manuscript. All authors read and approved the final manuscript.
38
39

40 Conflicts of Interest: None

41 Funding: None
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3
4
5
6 death within 30 days after onset, comparing patients with different conscious levels
7
8
9 based on the JCS.

10 11 12 13 14 15 **Results**

16
17
18
19
20 A total of 13,788 (97.2%) patients were graded based on the JCS. The JCS correlated to
21
22
23 ADL scores with a Spearman's correlation coefficient of 0.61. Hazard ratios for death
24
25
26 within 30 days were 1 (reference), 5.55, 9.54 and 35.21 in those scored as JCS0, JCS1,
27
28
29 JCS2 and JCS3, respectively.
30
31
32
33
34

35 **Conclusions**

36
37
38
39
40 Using a single test of eye response, the JCS has outstanding merits as a coma scale: i.e.
41
42
43 simplicity and applicability. The present study adds predictability for the early outcome
44
45
46 in stroke patients. The JCS is valuable especially at an emergency setting when a
47
48
49 prompt assessment of consciousness level is needed.
50
51
52
53
54
55
56
57
58
59
60

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 1974¹⁻³. 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, 1972⁴. 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

1
2
3
4
5
6⁵. The JCS was called the 3 group 3 grade method at first and then the “3-3-9 method”^{1 6},
7
8
9 since the detailed version of the scale composed of four categories: alert, 1-digit code,
10
11 2-digit code and 3-digit code, with each digit code having three subcategories (1, 2 and
12
13 3 in the 1-digit code, 10, 20 and 30 in the 2-digit code, and 100, 200 and 300 in the
14
15 3-digit code)¹. It had 10 grades in total: alert plus 9 (3 by 3) grades. This version of the
16
17 JCS included a motor response test in the 3-digit code patients and three special
18
19 conditions: restlessness, incontinence and apathy. The first full paper was accepted on
20
21 30 November 1973¹.
22
23
24
25
26
27
28

29 In this study, we applied the simple JCS without subcategories, which is
30
31 commonly used in Japan.
32
33

34
35 An outstanding feature of the JSC is its simplicity, which has prompted both
36
37 pre-hospital personnel and in-hospital staff to use the scale. The JCS enables prompt
38
39 communication among emergency service staff and hospital staff and among nurses and
40
41 physicians. However, the JSC’s predictability of the outcome has not been clarified to
42
43 date. The lack of evidence of its predictability may have prevented the JCS from
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
attaining international recognition.

Our hypothesis is that consciousness levels categorized by the JCS should

1
2
3
4
5
6 correlate with the severity of stroke and therefore should predict outcome of stroke. If
7
8
9 the predictability of the JCS is demonstrated, it should be re-appraised as a prompt
10
11 coma scale. Although we have the Glasgow Coma Scale (GCS), which was also
12
13 published in 1974^{7,8}, it would be more pragmatic to have a simpler coma scale
14
15 especially in an emergency. The major difference between the GCS and the JCS is that
16
17
18 the former is a three-axis scale whereas the latter is a one-axis scale.
19
20
21

22
23 The aim of the study is to verify that the JCS predicts early outcome, including the level
24
25 of activity of daily life (ADL) and the hazard ratios for death, and, subsequently, to
26
27 re-introduce this simple coma scale to the world.
28
29
30
31
32
33
34

35 **Materials and Methods**

36
37
38
39
40

41 We studied the relationship between the outcome at 30 days after stroke and the
42
43 consciousness levels based on the JCS at the onset of neurological impairment. We
44
45 analyzed all new stroke patients identified from January 1999 to December 2009
46
47 inclusive in the entire Kyoto prefecture and registered in the Kyoto Stroke Registry
48
49 (KSR)⁹. Detailed information on the KSR has been described previously¹⁰. The
50
51 diagnosis of stroke was confirmed by local neurologists and/or neurosurgeons according
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6 to the WHO definition ¹¹. We categorized the patients into cerebral infarction (CI),
7
8
9 cerebral hemorrhage (CH), subarachnoid hemorrhage (SAH) and others, based on the
10
11 neurological findings, laboratory data, and findings of CT, MRI and angiography.
12
13

14
15
16
17
18 We used the following definitions.
19

20
21 1) Consciousness levels based on the JCS encompassed four levels:
22

- 23
24 1 JCS 0 (alert)
25
26 2 JCS 1 (not fully alert but awake without any stimuli)
27
28 3 JCS 2 (arousable with stimulation)
29
30 4 JCS 3 (unarousable)
31
32
33

34
35 2) The ADL scale at 30 days after stroke onset included five levels:
36

- 37
38 1 ADL1 (No symptoms or no significant disability. Able to carry out all usual
39
40 activities without help. Able to walk without a mobility aide)
41
42
43 2 ADL2 (mildly disabled, or utilization of mobility aide. Unable to carry out all
44
45 usual activities without help. Unable to walk without mobility aide.)
46
47
48 3 ADL3 (moderately disabled, or wheelchair-bound condition. Unable to walk
49
50 without assistance.)
51
52
53
54
55 4 ADL4 (severely disabled, or bed-bound condition. Unable to use wheel chairs
56
57
58
59
60

1
2
3
4
5
6 without help.)
7
8

9 5 ADL5 (Dead)
10
11
12
13

14 15 16 *Ethics Statement* 17

18
19
20 This research was performed in accordance with the ethical principles for medical
21
22 research involving human subjects outlined in the Declaration of Helsinki. This research
23
24 was approved by the Board of Directors, the Kyoto Medical Association, the
25
26 Department of Health and Welfare, Kyoto Prefecture and Ethics Committee of the
27
28 National Hospital Organization, Minami Kyoto Hospital. Since all identifying personal
29
30 information was stripped from the secondary files before analysis, the boards waived
31
32 the requirement for written informed consent from the patients involved.
33
34
35
36
37
38
39

40 41 42 *Statistical Analyses* 43

44 The frequencies of characteristics among the four conscious levels were determined and
45
46 evaluated for univariate associations by Chi-square analysis. Numerical data such as age
47
48 and blood pressure were compared with Student-t test. Spearman's rank correlation
49
50 coefficients were used to identify the correlation between the JCS and the ADL scale.
51
52
53 We used the Kaplan-Meier method for curves of estimated survival, a log-rank test for
54
55
56
57
58
59
60

1
2
3
4
5
6 comparisons of estimated survival among the JCS categories, and Cox proportional
7
8 hazards regression for hazard ratios for death. Adjustments for age, sex, systolic and
9
10 diastolic blood pressures, histories of hypertension, arrhythmia and diabetes mellitus,
11
12 stroke type and paresis were also utilized. Analyses were performed using SPSS ver.19.
13
14
15
16
17
18 All reported p values are 2-sided.
19
20
21
22

23 **Results**

24
25
26
27
28
29 The characteristics of patients are summarized in Table 1. Data on age, and sex were
30
31 complete in all patients in the study cohort. The other characteristics had missing data in
32
33 a few patients. The numbers of patients examined are shown in the tables.
34
35
36

37
38 We evaluated the consciousness levels of 13,406 patients out of 13,788 (97.2%), based
39
40 on the JCS. JCS data were missing for 382 patients (2.8%). Among the 13,406 patients,
41
42 the number and percentage per group were as follows: JCS0 (7,676 [55.7%]), JCS1
43
44 (2,619 [9.0%]), JCS2 (1,602 [11.6%]) and JCS3 (1,509 [10.9%]), respectively. We
45
46
47
48 evaluated the ADL scale in 12,601 (91.4%) patients at 30 days after the onset of
49
50 neurological impairment. We obtained data on both the JCS and the ADL scale in
51
52
53
54
55
56
57
58
59
60
12,277 (89.0%) of the stroke patients (Table 2).

1
2
3
4
5
6 The Spearman's correlation coefficient was 0.608 for the correlation between the JCS
7
8
9 and the ADL scale ($p < 0.001$). Kaplan-Meier Survival curves of patients in each JCS
10
11
12 category are presented (Figure 1). A log-rank test proved the differences were
13
14
15 significant ($p < 0.001$). For Kaplan-Meier Survival curves in each JCS category in each
16
17
18 stroke subtype, see supplementary figures (Figure 1A, 1B and 1C).
19
20
21 Hazard ratios for death, comparing JCS categories and their 95% confidential intervals,
22
23
24 are summarized in Table 3.
25
26
27
28

29 Discussion

30
31
32 Systems for describing patients with impaired consciousness were not
33
34
35 consistent until 1974, when the GCS and the JCS were developed⁷. There was an
36
37
38 abundance of alternative terms by which levels of coma or impaired consciousness were
39
40
41 described and recorded⁷. Teasdale and Jennett described that some might have
42
43
44 reservations about a system which seemed to undervalue the niceties of a full
45
46
47 neurological examination. Just as the GCS, it is no part of the JCS to deny the value of a
48
49
50 detailed appraisal of the patients as a whole, and of neurological function in particular⁷.
51

52
53 The JCS principally focuses on eye responses. Being a single test, the JCS has
54
55
56 outstanding merits as a coma scale: i.e. simplicity and applicability, which should
57
58
59
60

1
2
3
4
5
6 minimize interpreter errors. Simplicity is very important in communication among
7
8
9 physicians, nurses and paramedics, especially in emergency settings. The present study
10
11
12 adds to its virtues the predictability for early outcome in stroke patients.
13

14
15 In summary, the advantages of the JCS include four points:
16

17
18 1) Predictability for stroke outcome.
19

20
21 This study showed the predictability of the JCS for the stroke outcome.
22

23
24 The JCS correlated with the ADL scale. Hazard ratios for death were significantly
25
26 different among JCS categories: 1.00 (as reference), 5.55, 9.54 and 34.21 in JCS0, 1, 2
27
28 and 3, respectively. It is noteworthy that a simple one-axis test alone predicts early
29
30 mortality with such clear differences. The JCS could be useful especially at an
31
32 emergency setting when more detailed evaluation of a patient condition is difficult to
33
34 obtain and prompt communications among doctors and co-medicals are needed. The
35
36 JCS provides minimum but critical/essential information.
37
38
39
40
41
42

43
44 2) Simplicity.
45

46
47 The JCS is a 4-points scale (from 0 to 3) and comprises only one test: eye responses.
48

49
50 The Glasgow Coma Scale (GCS), for example, is a 13-points scale (from 3 to 15) and
51
52 comprises three tests: eye, verbal and motor responses. The JCS is similar to the eye
53
54 response test in the GCS but even simpler than the GCS (i.e. both E2 and E3 belong in
55
56
57
58
59
60

1
2
3
4
5
6 JCS2). Being a uni-coordinate axis scale is very important for simplicity. Although
7
8
9 summing up scores in a multi-coordinate axes scale may not be difficult, the scores in
10
11 different axes may have different values and therefore the interpretation of a total score
12
13 can be difficult. Hypothetically, both E3V2M1 and E2V3M1 in the GCS, for example,
14
15 give the same total score of 6. A same total score in a multi-coordinate axes scale could
16
17 reflect different underlying conditions and might be difficult to interpret. The
18
19 description within the JCS is also simple (e.g. JCS0, JCS1, JCS2 and JCS3), which
20
21 makes communication among staff easy, prompt and less misleading. It might be easier
22
23 to grasp the outline of a patient condition with the JCS than with any multi-axes scales.
24
25
26
27
28
29
30
31

32 3) Reliability.

33
34
35 The simplicity of the JCS might provide consistency among raters.

36
37
38 The four categories in the JCS are well defined. They do not overlap and they
39
40 encompass all consciousness levels.
41
42

43 4) Applicability.

44
45
46 The JCS focuses on eye response, which broadens its applicability both for raters and
47
48 for patients. Raters need only check eye responses in terms of three clearly
49
50 differentiated categories: open, open only after stimuli and closed. No special
51
52 knowledge, such as is needed to assess the decerebrate or decorticate response, is
53
54
55
56
57
58
59
60

1
2
3
4
5
6 necessary. The JCS is applicable to almost all patients, including patients with aphasia,
7
8
9 paresis and even in intubated patients, where it might be difficult to apply the GCS,
10
11
12 because that has verbal and motor responses tests. In this population-based study, the
13
14
15 JCS was applied to 13,406 out of 13,788 stroke patients (97.2%).
16
17
18
19

20
21 There are some limitations.

22
23 First, simplicity means lack of detail. The JCS does not evaluate verbal or
24
25
26 motor responses, which are tested in the GCS. The total score in the GCS ranges from 3
27
28
29 to 15 and the GCS can theoretically describe 120 (4 by 5 by 6) different conditions. The
30
31
32 more tests a scale includes, the more details a scale can evaluate^{12 13}.
33
34

35
36 As far as the hazard ratios for early death and the ADL scores, however, the JCS is
37
38
39 sufficient as a predictor. A single-dimensional test is the best if the purpose of the test is
40
41
42 fulfilled. If needed, we can describe a patient's condition in a detailed way: such as
43
44
45 decerebrate posture and decorticate posture. In the JCS, three capital letters, R, I and A,
46
47
48 are provided to describe restlessness, incontinence and apathy, respectively.

49
50 Second, consciousness levels may fluctuate even in a short period and scores may
51
52
53 therefore be different from time to time. This difficulty is common to every coma scale,
54
55
56 and the simplicity of the JCS might minimize it. A multi-dimensional scale might cause
57
58
59
60

1
2
3
4
5
6 more difficulty with evaluation.
7

8
9 Third, predictability of the outcome has inherent limitations¹⁴. The outcomes and
10
11 therefore the hazard ratios for death depend not only on the baseline severity but also on
12
13 the treatment and patient conditions, including complications. This study did not include
14
15 the treatments which must affect outcomes. For precise evaluation of a relationship
16
17 between two factors, it should be important to adjust for all the other factors. Treatments,
18
19 for example, often vary from a case to case. Adjustments for them are virtually
20
21 impossible in a population based study. Major treatments for stroke, such as tPA therapy
22
23 or surgical interventions, however, should not have caused a major bias in this study,
24
25 because the differences in hazard ratios among the consciousness levels based on the
26
27 JCS remain significant after adjustment for stroke subtypes, i.e. CI, CH and SAH. The
28
29 JCS also predicted the outcomes in each three subtype of stroke by uni-variable
30
31 analyses. A tPA therapy is not applied for hemorrhagic stroke and surgical interventions
32
33 are rarely applied for ischemic stroke (In this study cohort, 374 (4.2%) out of 8896 CI
34
35 patients had surgical treatment).
36
37
38
39
40
41
42
43
44
45
46
47
48

49 There are two types of complications: ones that patients had before stroke onset and
50
51 ones that they got after the onset. Although the former comprises numerous diseases,
52
53 risk factors such as hypertension, arrhythmia and diabetes mellitus might be important.
54
55
56
57
58
59
60

1
2
3
4
5
6 The difference in hazard ratios remained significant after adjustment for these three. The
7
8
9 latter may include urinary tract infections, decubitus ulcers and pneumonia. They,
10
11
12 however, occur as results of stroke, namely after the consciousness level estimation
13
14 based on the JCS. Although they could be related to the initial severity of the stroke,
15
16
17 data on this type of complications were not available in this study.
18
19

20
21 Last, we did not investigate the predictability of the JCS in light of modern
22
23 psychometric approach in this study. Consciousness level is a latent trait and scales
24
25 dedicated to its measurement should preferably undergo Rasch analysis to confirm or
26
27 not their metric properties. Applying Rasch analysis^{15 16 17} would give more added-value
28
29
30 to the study since it would help to investigate some aspects of the measurement
31
32
33 properties of the JCS such as the appropriateness of the response format through the
34
35 examination of categories discrimination. The validity of the ADL scale has not been
36
37
38 proved yet. Moreover, there is no study about how consistently different assessors from
39
40
41 different centers used the 5-categories scale yet. This ADL scale is based on how each
42
43
44 patient performed “usual activities”, which may change from a patient to another
45
46
47 according to their lifestyle and environment. However, the ADL Scale is widely used in
48
49
50 Japan. It is also simple scale and may have a practical value. We would like to study the
51
52
53 validity, consistency among assessors and the way to elaborate the ADL scale.
54
55
56
57
58
59
60

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.

References

1. Ohta T, Waga S, Handa W, et al. [New grading of level of disordered consciousness (author's transl)]. *No shinkei geka. Neurological surgery* 1974;2(9):623-7.
2. Ohta T, Kikuchi H, Hashi K, et al. Nizofenone administration in the acute stage following subarachnoid hemorrhage. Results of a multi-center controlled double-blind clinical study. *Journal of neurosurgery* 1986;64(3):420-6.
3. Shigemori M, Abe T, Aruga T, et al. Guidelines for the Management of Severe Head Injury, 2nd edition guidelines from the Guidelines Committee on the Management of Severe Head Injury, the Japan Society of Neurotraumatology. *Neurologia medico-chirurgica* 2012;52(1):1-30.
4. Ohta T SN. The research on prognosis prediction of surgical interventions for ruptured cerebral aneurysm - production of ABC index- the first report: the shortcomings of the conventional classification system of severity and determination of predicting factors of surgical prognosis. *The First Meeting of Society on Surgery for Cerebral Stroke (In Japanese)* 1972:1-20.
5. Ohta T WS, Saito I, Masugi N, et al. The survey on therapeutic strategy of cerebral aneurysm and prognosis after surgical interventions. *The Second Meeting of Society on Surgery for Cerebral Stroke (In Japanese)* 1973;2:55-75.
6. Ohta T WS, Handa H, Saito I, et al. The new grading system for disturbed consciousness and its numerical expression; the 3-3-9 degrees method. *The Third Meeting of Society on Surgery for Cerebral Stroke (In Japanese)* 1974;3:61-68.
7. Teasdale G, Jennett B. Assessment of coma and impaired consciousness. A practical scale. *Lancet* 1974;2(7872):81-4.
8. Weir CJ, Bradford AP, Lees KR. The prognostic value of the components of the Glasgow Coma Scale following acute stroke. *QJM : monthly journal of the Association of Physicians* 2003;96(1):67-74.
9. Shigematsu K, Shimamura O, Nakano H, et al. Vomiting should be a prompt predictor of stroke outcome. *Emergency medicine journal : EMJ* 10.1136/emmermed-2012-201586 (in press).
10. Shigematsu K, Nakano H, Watanabe Y, et al. Characteristics, risk factors and mortality of stroke patients in Kyoto, Japan. *BMJ open* 2013;3(3).
11. Hatano S. Experience from a multicentre stroke register: a preliminary report. *Bulletin of the World Health Organization* 1976;54(5):541-53.

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
12. Lingsma HF, Roozenbeek B, Steyerberg EW, et al. Early prognosis in traumatic brain injury: from prophecies to predictions. *Lancet neurology* 2010;9(5):543-54.
 13. Wijdicks EF, Rabinstein AA, Bamlet WR, et al. FOUR score and Glasgow Coma Scale in predicting outcome of comatose patients: a pooled analysis. *Neurology* 2011;77(1):84-5.
 14. Chandra RV, Law CP, Yan B, et al. Glasgow coma scale does not predict outcome post-intra-arterial treatment for basilar artery thrombosis. *AJNR. American journal of neuroradiology* 2011;32(3):576-80.
 15. Aggestrup LM, Hestbech MS, Siersma V, et al. Psychosocial consequences of allocation to lung cancer screening: a randomised controlled trial. *BMJ open* 2012;2(2):e000663.
 16. Arnould C, Vandervelde L, Batcho CS, et al. Can manual ability be measured with a generic ABILHAND scale? A cross-sectional study conducted on six diagnostic groups. *BMJ open* 2012;2(6).
 17. Friberg P, Hagquist C, Osika W. Self-perceived psychosomatic health in Swedish children, adolescents and young adults: an internet-based survey over time. *BMJ open* 2012;2(4).

1
2
3
4
5
6 **Legends**
7

8 **Figure 1. Kaplan-Meier Survival curves for patients in each JCS category**
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

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

1
2
3
4
5
6 *²: significant difference between JCS1 and JCS2
7

8
9 *³: significant difference between JCS2 and JCS3
10

11 Data on some characteristics were missing in a few patients.
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

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.

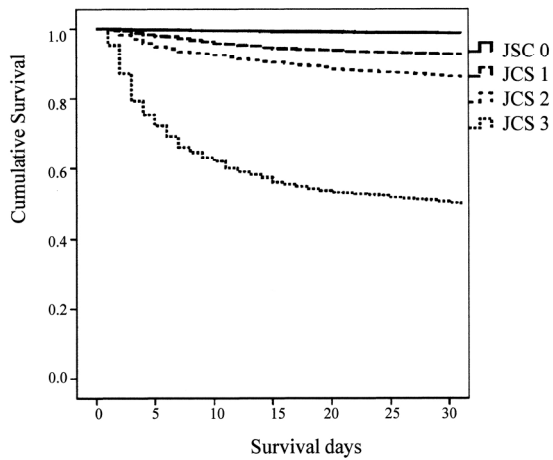
Table 3 Hazard ratios for death, comparing JCS categories

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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Figure 1

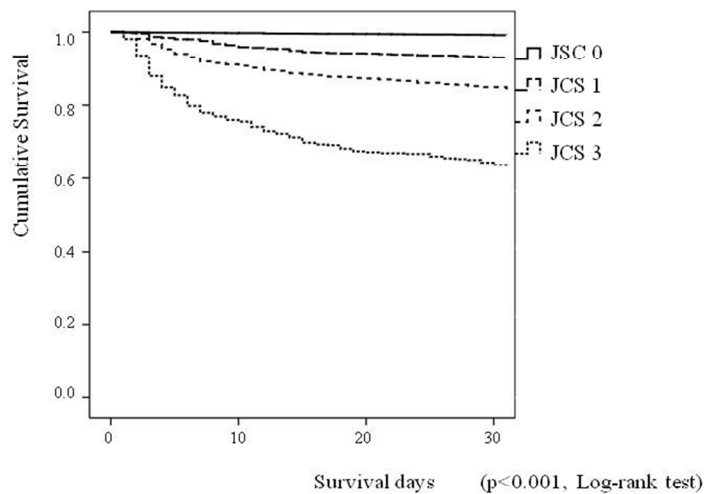


Kaplan-Meier Survival curves for patients in each JCS category
215x156mm (300 x 300 DPI)

view only

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Figure 1A-Suppl Kaplan-Meier Survival curves of patients in each JCS category
Cerebral infarction

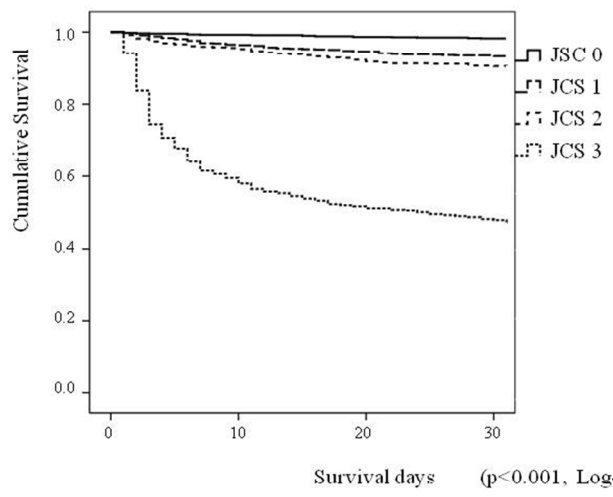


Kaplan-Meier Survival curves of patients in each JCS category
Cerebral infarction

254x190mm (96 x 96 DPI)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

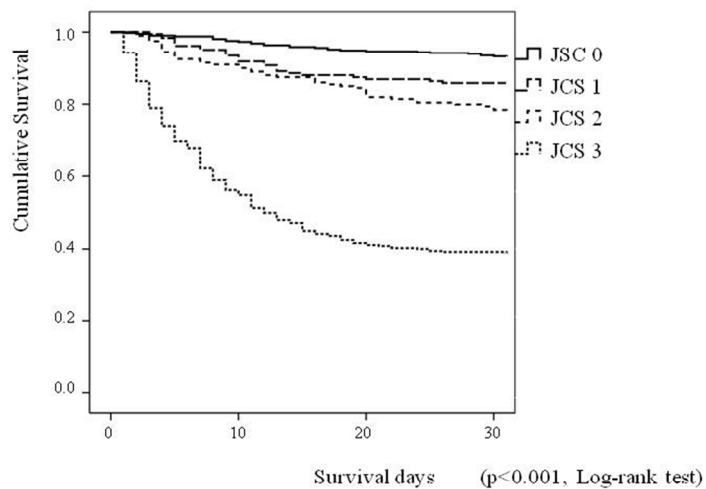


Kaplan-Meier Survival curves of patients in each JCS category
Cerebral hemorrhage

254x190mm (96 x 96 DPI)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Figure 1C-Suppl Kaplan-Meier Survival curves of patients in each JCS category Subarachnoid hemorrhage



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 (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	9, 10
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	9, 10 Table 1-3
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 (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	9, 10 Table 1-3
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-introductionIntroduction of the Japan Coma Scale. A cohort study~~

Formatted

Formatted

Formatted

Formatted

Short title: The Japan Coma Scale predicts stroke outcome

Kazuo Shigematsu¹, Hiromi Nakano², Yoshiyuki Watanabe³, ~~Tatsuyuki Sekimoto⁴,
Kouichiro Shimizu⁵, Akihiko Nishizawa⁶, Atsushi Okumura⁷, Masahiro Makino⁸,
Kazuhiko Bando⁹~~

Formatted: Superscript

¹Department of Neurology, National Hospital Organization, Minami Kyoto Hospital, Kyoto, Japan

²Department of Neurosurgery, Kyoto Kidugawa Hospital, Kyoto, Japan

³Department of Epidemiology for Community Health and Medicine, Kyoto Prefectural University of Medicine, Graduate School of Medical Science, Kyoto, Japan

~~⁴Department of Neurosurgery, Kyoto Prefectural Yosanoumi Hospital, Kyoto, Japan~~

~~⁵Department of Neurosurgery, Kyoto Fushimi Shimizu Hospital, Kyoto, Japan~~

~~⁶Department of Internal Medicine, The Nishizawa Clinic, Kyoto, Japan~~

~~⁷Department of Neurosurgery, Jujyo Rehabilitation Hospital, Kyoto, Japan~~

~~⁸Department of Neurology, Japanese Red Cross Kyoto Daini Hospital, Kyoto, Japan~~

~~⁹Department of Internal Medicine, The Bando Clinic, Kyoto, Japan~~

Formatted: Superscript

Correspondence to Kazuo Shigematsu

Department of Neurology, the National Hospital Organization, Minami Kyoto Hospital

11 Nakaashihara, Jogyo, Kyoto, Japan, 610-0113

Phone 81-774-52-0065, Fax 81-75-821-9610, E-mail: neuron@k07.gmail.com]

Key Words: scales; coma; consciousness; stroke

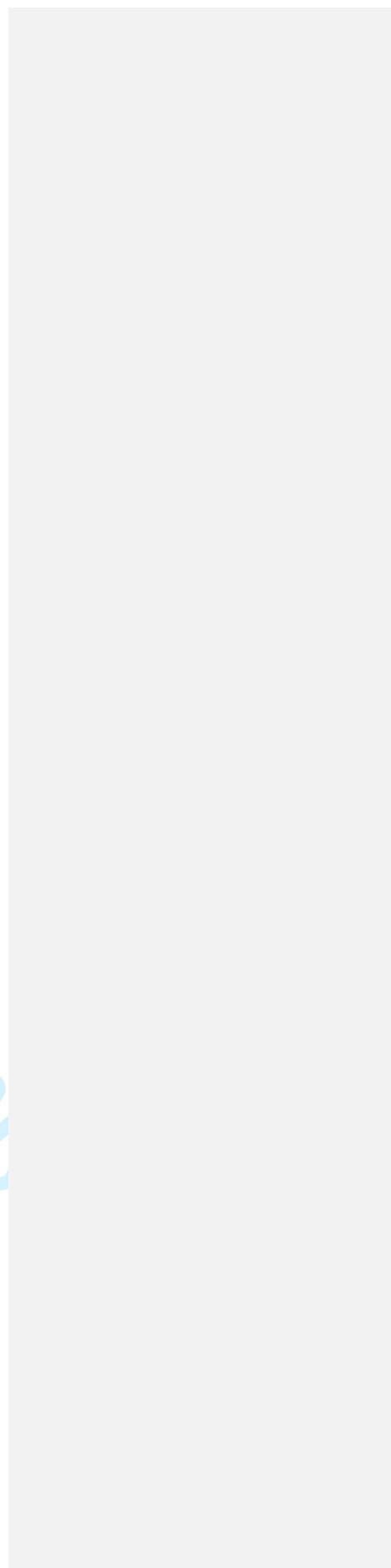
Contributorship: All authors contributed equally in the data collection and analysis. KS wrote the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest: None

Funding: None

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only



1
2
3
4
5
6
7
8
9 **Abstract**

10
11
12
13
14 **Objective**

15
16
17
18
19 Prompt assessment of consciousness level is vitally important during the emergency
20
21 care of stroke patients. Requirements for a better scale include simplicity, reliability,
22
23 applicability and predictability for outcome. The Japan Coma Scale (JCS) is a one-axis
24
25 coma scale published in 1974 with outstanding simplicity. The hypothesis is that the
26
27 JCS is sufficient to predict the stroke outcome. The aim of the study is to verify the
28
29 predictability of the JCS, which should help the JCS attain international recognition.
30
31
32
33
34
35
36

37 **Methods**

38
39
40
41
42 We investigated the relationship between consciousness level based on the JCS at the
43
44 stroke onset and activities of daily living (ADL) at 30 days or deaths within 30 days in a
45
46 large population-based stroke registry. We calculated Spearman's correlation
47
48 coefficients for the correlation between the JCS and ADL scale, generated estimated
49
50 survival curves by the Kaplan-Meier method and finally compared hazard ratios for
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9 death within 30 days after onset, comparing patients with different conscious levels
10
11 based on the JCS.
12
13

14 15 16 **Results** 17

18
19
20
21 A total of 13,788 (97.2%) patients were graded based on the JCS. The JCS correlated to
22
23 ADL scores with a Spearman's correlation coefficient of 0.61. Hazard ratios for death
24
25 within 30 days were 1 (reference), 5.55, 9.54 and 35.21 in those scored as JCS0, JCS1,
26
27 JCS2 and JCS3, respectively.
28
29
30
31
32
33

34 35 **Conclusions** 36

37
38
39 Using a single test of eye response, the JCS has outstanding merits as a coma scale: i.e.
40
41 simplicity and applicability. The present study adds predictability for the early outcome
42
43 in stroke patients. The JCS is valuable especially at an emergency setting when a
44
45 prompt assessment of consciousness level is needed.
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9 **Article summary**

10
11 *Article focus*

12
13
14 The Japan Coma Scale (JCS) is a one-axis coma scale published in 1974. It is so simple
15
16 and easy to use that it has been established as a standard coma scale in Japan.

17
18
19 Nevertheless, it has little recognition internationally. The aim of the study is to

20
21 ~~confirm~~verify its predictability in stroke patients. We hope the JCS will contribute to
22
23
24 the medical profession and especially to the emergency medical-care.

25
26
27 *Key messages*

28
29 Using a single test of eye response, the JCS has outstanding merits as a coma scale: i.e.
30
31 simplicity and applicability. The present study adds predictability for the early outcome
32
33 in stroke patients. The JCS is valuable especially at an emergency setting when a
34
35 prompt assessment of consciousness level is needed.
36
37
38

39
40 *Strengths and limitations of this study*

41
42 Strengths: the study is based on a large stroke registry and the JCS has been used widely
43
44 in Japan.

45
46
47 Limitations: there are few studies on the JCS and on the activity daily life (ADL) scale
48
49
50 in scientific international journals yet.
51
52
53
54
55
56
57
58
59
60

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 1974¹⁻³. [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, 1972⁴. 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](#)

Formatted: Indent: First line: 0.32"

1
2
3
4
5
6
7
8
9 ⁵. The JCS was called the 3 group 3 grade method at first and then the “3-3-9 method”^{1 6}
10 since the detailed version of the scale composed of four categories: alert, 1-digit code,
11 2-digit code and 3-digit code, with each digit code having three subcategories (1, 2 and
12 3 in the 1-digit code, 10, 20 and 30 in the 2-digit code, and 100, 200 and 300 in the
13 3-digit code) ¹. It had 10 grades in total: alert plus 9 (3 by 3) grades. This version of the
14 JCS included a motor response test in the 3-digit code patients and three special
15 conditions: restlessness, incontinence and apathy. The first full paper was accepted on
16 30 November 1973¹.

17
18
19
20
21
22 In this study, we applied the simple JCS without subcategories, which is
23 commonly used in Japan.

24
25
26
27
28
29
30
31
32
33
34
35 An outstanding feature of the JCS is its simplicity, which has prompted both
36 pre-hospital personnel and in-hospital staff to use the scale. The JCS enables prompt
37 communication among emergency service staff and hospital staff and among nurses and
38 physicians. However, the JCS’s predictability of the outcome has not been clarified to
39 date. The lack of evidence of its predictability may have prevented the JCS from
40 attaining international recognition.

41
42
43
44
45
46
47
48
49
50
51
52 Our hypothesis is that consciousness levels categorized by the JCS should

Formatted: Indent: First line: 0.58"

Formatted: Indent: First line: 0.58"

1
2
3
4
5
6
7
8
9 correlate with the severity of stroke and therefore should predict outcome of stroke. If

10 the predictability of the JCS is demonstrated, it should be re-appraised as a prompt

11
12
13 coma scale. Although we have the Glasgow Coma Scale (GCS), which was also

14
15 published in 1974^{47,58}, it would be more pragmatic to have a simpler coma scale

16
17
18 especially in an emergency. The major difference between the GCS and the JCS is that

19
20
21 the former is a three-axis scale whereas the latter is a one-axis scale.

22
23
24 The aim of the study is to ~~show~~verify that the JCS predicts early outcome, including the

25
26
27 level of activity of daily life (ADL) and the hazard ratios for death, and, subsequently, to

28
29
30 re-introduce this simple coma scale to the world.

31 32 33 34 **Materials and Methods**

35
36
37
38
39 We studied the relationship between the outcome at 30 days after stroke and the

40
41
42 consciousness levels based on the JCS at the onset of neurological impairment. We

43
44
45 analyzed all new stroke patients identified from January 1999 to December 2009

46
47
48 inclusive in the entire Kyoto prefecture and registered in the Kyoto Stroke Registry

49
50 ~~(KSR)⁶⁹. Detailed information on the KSR has been described previously~~

51
52 ~~(Shigematsu et al. BMJ Open, in press). Detailed information on the KSR has been~~

Field Code Changed

Field Code Changed

Formatted: Indent: First line: 0.58"

Field Code Changed

Field Code Changed

1
2
3
4
5
6
7
8
9 described previously¹⁰. The diagnosis of stroke was confirmed by local neurologists
10
11 and/or neurosurgeons according to the WHO definition⁷¹¹. We categorized the patients
12
13 into cerebral infarction (CI), cerebral hemorrhage (CH), subarachnoid hemorrhage
14
15 (SAH) and others, based on the neurological findings, laboratory data, and findings of
16
17 CT, MRI and angiography.
18
19
20
21
22
23

24 We used the following definitions.

25
26
27 1) Consciousness levels based on the JCS encompassed four levels:

- 28 1 JCS 0 (alert)
- 29 2 JCS 1 (not fully alert but awake without any stimuli)
- 30 3 JCS 2 (arousable with stimulation)
- 31 4 JSC 3 (unarousable)

32
33
34
35
36
37
38
39 2) The ADL scale at 30 days after stroke onset included five levels:

- 40 1 ADL1 (No symptoms or no significant disability. Able to carry out all usual
41 activities without help. Able to walk without a mobility aide)
- 42 2 ADL2 (mildly disabled, or utilization of mobility aide. Unable to carry out all
43 usual activities without help. Unable to walk without mobility aide.)
- 44 3 ADL3 (moderately disabled, or wheelchair-bound condition. Unable to walk
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Field Code Changed

Field Code Changed

1
2
3
4
5
6
7
8
9 without assistance.)

10
11 4 ADL4 (severely disabled, or bed-bound condition. Unable to use wheel chairs

12
13 without help.)

14
15
16
17 5 ADL5 (Dead)

18
19
20
21
22
23 ***Ethics Statement***

24
25
26 This research was performed in accordance with the ethical principles for medical
27
28 research involving human subjects outlined in the Declaration of Helsinki. This research
29
30 was approved by the Board of Directors, the Kyoto Medical Association, the
31
32 Department of Health and Welfare, Kyoto Prefecture and Ethics Committee of the
33
34 National Hospital Organization, Minami Kyoto Hospital. Since all identifying personal
35
36 information was stripped from the secondary files before analysis, the boards waived
37
38 the requirement for written informed consent from the patients involved.
39
40
41
42
43
44

45
46 ***Statistical Analyses***

47
48 The frequencies of characteristics among the four conscious levels were determined and
49
50 evaluated for univariate associations by Chi-square analysis. Numerical data such as age
51
52 and blood pressure were compared with Student-t test. Spearman's rank correlation
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9 coefficients were used to identify the correlation between the JCS and the ADL scale.

10
11 We used the Kaplan-Meier method for curves of estimated survival, a log-rank test for
12
13 comparisons of estimated survival among the JCS categories, and Cox proportional
14
15 hazards regression for hazard ratios for death. Adjustments for age, sex, systolic and
16
17 diastolic blood pressures, histories of hypertension, arrhythmia and diabetes mellitus,
18
19 stroke type and paresis were also utilized. Analyses were performed using SPSS ver.19.
20
21
22
23

24 All reported p values are 2-sided.
25
26
27

28 29 **Results**

30
31
32
33
34 The characteristics of patients are summarized in Table 1. Data on age, and sex were
35
36 complete in all patients in the study cohort. The other characteristics had missing data in
37
38 a few patients. The numbers of patients examined are shown in the tables.
39
40
41

42 We evaluated the consciousness levels of 13,406 patients out of 13,788 (97.2%), based
43
44 on the JCS. JCS data were missionmissing for 382 patients (2.8%). Among the 13,406
45
46 patients, the number and percentage per group were as follows: JCS0 (7,676 [55.7%]),
47
48 JCS1 (2,619 [9.0%]), JCS2 (1,602 [11.6%]) and JCS3 (1,509 [10.9%]), respectively. We
49
50 evaluated the ADL scale in 12,601 (91.4%) patients at 30 days after the onset of
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9 neurological impairment. We obtained data on both the JCS and the ADL scale in
10
11 12,277 (89.0%) of the stroke patients (Table 2).

12
13
14 The Spearman's correlation coefficient was 0.608 for the correlation between the JCS
15
16 and the ADL scale ($p < 0.001$). Kaplan-Meier Survival curves of patients in each JCS
17
18 category are presented (Figure 1). A log-rank test proved the differences were
19
20 significant ($p < 0.001$). For Kaplan-Meier Survival curves in each JCS category in each
21
22 stroke subtype, see supplementary figures (Figure 1A, 1B and 1C).

23
24
25 Hazard ratios for death, comparing JCS categories and their 95% confidential intervals,
26
27 are summarized in Table 3.
28
29
30
31
32
33

34 Discussion

35
36
37
38
39 Systems for describing patients with impaired consciousness were not
40
41 consistent until 1974, when the GCS and the JCS were developed⁷. There was an
42
43 abundance of alternative terms by which levels of coma or impaired consciousness were
44
45 described and recorded⁷. Teasdale and Jennett described that some might have
46
47 reservations about a system which seemed to undervalue the niceties of a full
48
49 neurological examination. Just as the GCS, it is no part of the JCS to deny the value of a
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9 detailed appraisal of the patients as a whole, and of neurological function in particular⁷.

10
11 The JCS principally focuses on eye responses. Being a single test, the JCS has
12
13
14 outstanding merits as a coma scale: i.e. simplicity and applicability, which should
15
16 minimize interpreter errors. Simplicity is very important in communication among
17
18 physicians, nurses and paramedics, especially in emergency settings. The present study
19
20 adds to its virtues the predictability for early outcome in stroke patients.
21
22

23
24 In summary, the advantages of the JCS include four points:

25
26 1) Predictability for stroke outcome.

27
28 This study showed the predictability of the JCS for the stroke outcome.

29
30 The JCS correlated with the ADL scale. Hazard ratios for death were significantly
31
32 different among JCS categories: 1.00 (as reference), 5.55, 9.54 and 34.21 in JCS0, 1, 2
33
34 and 3, respectively. It is noteworthy that a simple one-axis test alone predicts early
35
36 mortality with such clear differences. The JCS could be useful especially at an
37
38 emergency setting when more detailed evaluation of a patient condition is difficult to
39
40 obtain and prompt communications among doctors and co-medicals are needed. The
41
42 JCS provides minimum but critical/essential information.
43
44
45
46
47
48

49
50 2) Simplicity.

51
52 The JCS is a 4-points scale (from 0 to 3) and comprises only one test: eye responses.
53
54
55
56
57
58
59
60

Formatted: Indent: First line: 0.58"

1
2
3
4
5
6
7
8
9 The Glasgow ~~coma scale~~ Coma Scale (GCS), for example, is a 13-points scale (from 3
10 to 15) and comprises three tests: eye, verbal and motor responses. The JCS is similar to
11 the eye response test in the GCS but even simpler than the GCS (i.e. both E2 and E3
12 belong in JCS2). Being a uni-coordinate axis scale is very important for simplicity.
13

14 Although summing up scores in a multi-coordinate axes scale may not be difficult, the
15 scores in different axes may have different values and therefore the interpretation of a
16 total score can be difficult. Hypothetically, both E3V2M1 and E2V3M1 in the GCS, for
17 example, give the same total score of 6. A same total score in a multi-coordinate axes
18 scale could reflect different underlying conditions and might be difficult to interpret.
19

20 The description within the JCS is also simple (e.g. ~~JCS~~, JCS0, JCS1, JCS2 and JCS3),
21 which makes communication among staff easy, prompt and less misleading. It ~~is~~
22 ~~much~~ might be easier to grasp the outline of a patient condition with the JCS than with
23 any multi-axes scales.
24

25 3) Reliability.

26 The simplicity of the JCS ~~provides~~ might provide consistency among raters.
27

28 The four categories in the JCS are well defined. They do not overlap and they
29 encompass all consciousness levels.
30

31 4) Applicability.

32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9 The JCS focuses on eye response, which broadens its applicability both for raters and
10
11 for patients. Raters need only check eye responses in terms of three clearly
12
13 differentiated categories: open, open only after stimuli and closed. No special
14
15 knowledge, such as is needed to assess the decerebrate or decorticate response, is
16
17 necessary. The JCS is applicable to almost all patients, including patients with aphasia,
18
19 paresis and even in intubated patients, where it might be difficult to apply the GCS,
20
21 because that has verbal and motor responses tests. In this population-based study, the
22
23 JCS was applied to 13,406 out of 13,788 stroke patients (97.2%).
24
25
26
27
28
29
30
31

Historical information on the JCS

32
33
34
35
36
37 ~~Ohta et al. launched a national survey on craniotomy for ruptured cerebral aneurysms,~~
38
39 ~~and described the JCS to define the consciousness level to be included in the survey, at~~
40
41 ~~the first meeting of the Society on Surgery for Cerebral Stroke, which was held at~~
42
43 ~~Miyagi, Japan (Sakunami Kanko Hotel) on May 13-14, 1972⁸. At that meeting, he also~~
44
45 ~~organized a team to evaluate the scale, because there was no standardized coma scale~~
46
47 ~~established in those days. The JCS was based on his study on factors affecting the~~
48
49 ~~prognosis of ruptured aneurysm patients after surgical interventions⁹. The JCS was~~
50
51
52
53
54
55
56
57
58
59
60

called the 3 group 3 grade method at first and then the “3-3-9 method”^{11,10}, 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

†) **-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 to 15 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^{11,12,13}.

Response:-

Formatted: Indent: First line: 0.58"

Formatted: Indent: First line: 0.58", No bullets or numbering

1
2
3
4
5
6
7
8
9 As far as the hazard ratios for early death and the ADL scores, however, the JCS is
10 sufficient as a predictor. A single-dimensional test is the best if the purpose of the test is
11 fulfilled. If needed, we can describe a patient's condition in a detailed way: such as
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

decrebrate posture and decorticate posture. In the JCS, three capital letters, R, I and A,
are provided to describe restlessness, incontinence and apathy, respectively. —

Formatted: Indent: Left: 0"

—
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.

Formatted: Indent: First line: 0.25", No bullets or numbering

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

Field Code Changed

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,

Formatted: Indent: Left: 0", First line: 0.25"

1
2
3
4
5
6
7
8
9 data on this type of complications were not available in this study.

10
11 Last, we did not investigate the predictability of the JCS in light of modern
12 psychometric approach in this study. Consciousness level is a latent trait and scales
13 dedicated to its measurement should preferably undergo Rasch analysis to confirm or
14 not their metric properties. Applying Rasch analysis^{15 16 17} would give more added-value
15 to the study since it would help to investigate some aspects of the measurement
16 properties of the JCS such as the appropriateness of the response format through the
17 examination of categories discrimination. The validity of the ADL scale has not been
18 proved yet. Moreover, there is no study about how consistently different assessors from
19 different centers used the 5-categories scale yet. This ADL scale is based on how each
20 patient performed “usual activities”, which may change from a patient to another
21 according to their lifestyle and environment. However, the ADL Scale is widely used in
22 Japan. It is also simple scale and may have a practical value. We would like to study the
23 validity, consistency among assessors and the way to elaborate the ADL scale.
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44

45 46 47 **Conclusions**

48
49
50
51
52 The ~~Japan Coma Scale~~JCS is a good predictor of stroke outcome. Its two
53
54
55
56
57
58
59
60

Formatted: Indent: First line: 0.58"

1
2
3
4
5
6
7
8
9 outstanding advantages, simplicity and predictability, should make the JCS
10
11 re-appreciated internationally as a standard coma scale.
12
13

14 Acknowledgments

15
16
17
18 We acknowledge the contribution of participating institutions and their staffs
19 who provided data in the development of the Kyoto Stroke Registry. We thank Dr
20 Tomio Ohta for the information on the establishment of the JCS. We are grateful to
21 many colleagues for their assistance in this study; particularly Dr Osamu Simamura, Dr
22 Tatsuyuki Sekimoto, Dr Kouichiro Shimizu, Dr Akihiko Nishizawa, Dr Atsushi
23 Okumura, Dr Masahiro Makino and Dr Kazuhiko Bando.
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Formatted: Justified, Indent: First line: 0.58", Line spacing: single, Adjust space between Latin and Asian text, Adjust space between Asian text and numbers

Formatted: Font: Century, 10.5 pt

References

1. Ohta T, Waga S, Handa W, Saito I, Takeuchi K. [New grading of level of disordered consciousness (author's transl)]. *No shinkei geka. Neurological surgery* 1974;2(9):623-7.
2. Ohta T, Kikuchi H, Hashi K, Kudo Y. Nizofenone administration in the acute stage following subarachnoid hemorrhage. Results of a multi-center controlled double-blind clinical study. *Journal of neurosurgery* 1986;64(3):420-6.
3. Shigemori M, Abe T, Aruga T, Ogawa T, Okudera H, Ono J, et al. Guidelines for the Management of Severe Head Injury, 2nd edition guidelines from the Guidelines Committee on the Management of Severe Head Injury, the Japan Society of Neurotraumatology. *Neurologia medico-chirurgica* 2012;52(1):1-30.
4. ~~Teasdale G, Jennett B. Assessment of coma and impaired consciousness. A practical scale. *Lancet* 1974;2(7872):81-4.~~
5. ~~Weir CJ, Bradford AP, Lees KR. The prognostic value of the components of the Glasgow Coma Scale following acute stroke. *QJM: monthly journal of the Association of Physicians* 2003;96(1):67-74.~~
6. ~~Shigematsu K, Shimamura O, Nakano H, Watanabe Y, Sekimoto T, Shimizu K, et al. Vomiting should be a prompt predictor of stroke outcome. *Emergency medicine journal: EMJ* 2012.~~
7. ~~Hatano S. Experience from a multicentre stroke register: a preliminary report. *Bulletin of the World Health Organization* 1976;54(5):541-53.~~
8. Ohta T SN. The research on prognosis prediction of surgical interventions for ruptured cerebral aneurysm - production of ABC index- the first report: the shortcomings of the conventional classification system of severity and determination of predicting factors of surgical prognosis. *The First Meeting of Society on Surgery for Cerebral Stroke (In Japanese)* 1972:1-20.
95. Ohta T WS, Saito I, Masugi N, Suzuki J, Takaku A. The survey on therapeutic strategy of cerebral aneurysm and prognosis after surgical interventions. *The Second Meeting of Society on Surgery for Cerebral Stroke (In Japanese)* 1973;2:55-75.
106. Ohta T WS, Handa H, Saito I, Takeuchi K, Masugi N, Suzuki J, Takaku A. The new grading system for disturbed consciousness and its numerical expression; the 3-3-9 degrees method. *The Third Meeting of Society on Surgery for Cerebral Stroke (In Japanese)* 1974;3:61-68.

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
- ~~4~~7. Teasdale G, Jennett B. Assessment of coma and impaired consciousness. A practical scale. *Lancet* 1974;2(7872):81-4.
8. Weir CJ, Bradford AP, Lees KR. The prognostic value of the components of the Glasgow Coma Scale following acute stroke. *QJM : monthly journal of the Association of Physicians* 2003;96(1):67-74.
9. Shigematsu K, Shimamura O, Nakano H, Watanabe Y, Sekimoto T, Shimizu K, et al. Vomiting should be a prompt predictor of stroke outcome. *Emergency medicine journal : EMJ* 10.1136/emmermed-2012-201586 (in press).
10. Shigematsu K, Nakano H, Watanabe Y, Sekimoto T, Shimizu K, Nishizawa A, et al. Characteristics, risk factors and mortality of stroke patients in Kyoto, Japan. *BMJ open* 2013;3(3).
11. Hatano S. Experience from a multicentre stroke register: a preliminary report. *Bulletin of the World Health Organization* 1976;54(5):541-53.
12. Lingsma HF, Roozenbeek B, Steyerberg EW, Murray GD, Maas AI. Early prognosis in traumatic brain injury: from prophecies to predictions. *Lancet neurology* 2010;9(5):543-54.
- ~~4~~13. Wijdicks EF, Rabinstein AA, Bamlet WR, Mandrekar JN. FOUR score and Glasgow Coma Scale in predicting outcome of comatose patients: a pooled analysis. *Neurology* 2011;77(1):84-5.
- ~~4~~14. Chandra RV, Law CP, Yan B, Dowling RJ, Mitchell PJ. Glasgow coma scale does not predict outcome post-intra-arterial treatment for basilar artery thrombosis. *AJNR. American journal of neuroradiology* 2011;32(3):576-80.
15. Aggestrup LM, Hestbech MS, Siersma V, Pedersen JH, Brodersen J. Psychosocial consequences of allocation to lung cancer screening: a randomised controlled trial. *BMJ open* 2012;2(2):e000663.
16. Arnould C, Vandervelde L, Batcho CS, Penta M, Thonnard JL. Can manual ability be measured with a generic ABILHAND scale? A cross-sectional study conducted on six diagnostic groups. *BMJ open* 2012;2(6).
17. Friberg P, Hagquist C, Osika W. Self-perceived psychosomatic health in Swedish children, adolescents and young adults: an internet-based survey over time. *BMJ open* 2012;2(4).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Legends

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

For peer review only

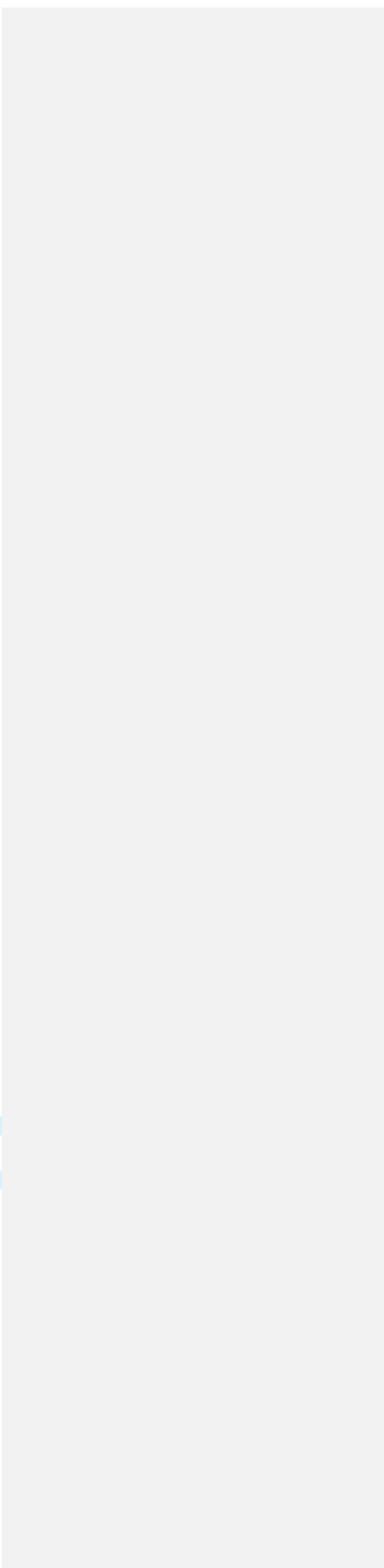


Table 1 The characteristics of patients in the study cohort

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	47.7	56.9	54.7 (826/683)
3)	(3056/4620)* ¹²³	(1249/1370)* ²³	(911/691)* ³	
	78.9/15.7/5.4	57.7/35.2/7.1	48.5/39.0/12.5	28.0/47.7/24.3
	(6048/1201/415)	(1508/921/185)	(774/622/200)* ³	(421/716/365)
	* ¹²³	* ²³		
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	78.2	83.1	89.2
	(5085/2501)* ¹²³	(2014/561)* ²³	(1278/260)* ³	(1060/128)
7)	64.5	61.0	59.8	59.3 (755/518)
	(4724/2605)* ¹²³	(1476/942)* ²³	(857/576)* ³	
8)	14.5	23.3	28.2	20.1
	(1058/6233)* ¹²³	(569/1870)* ²³	(412/1047)* ³	(254/1010)
9)	23.6	18.3	15.1 (220/1237)	16.4
	(1734/5629)* ¹²³	(449/2006)* ²³		(209/1067)

*¹: significant difference between JCS0 and JCS1

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

*²: significant difference between JCS1 and JCS2

*³: significant difference between JCS2 and JCS3

Data on some characteristics were missing in a few patients.

For peer review only

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			
JCS 1	5.55	4.19	7.37	<0.001
JCS 2	9.54	7.16	12.71	<0.001
JCS 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