

Table 2. Univariate Ordinal Logistic Regression for Burnout

Predictors	Odds Ratio	95% CI	P Value
No. of hours slept/night	0.67	0.61–0.73	<0.0001
No. of hours worked/wk	1.02	1.02–1.03	<0.001
No. of day-offs/wk	0.62	0.54–0.70	<0.001
No. of nightshifts/mo	1.09	1.06–1.12	<0.001
No. of after-hours calls/wk	1.10	1.07–1.13	<0.001
Percentage of time spent in stroke care/10% of time	1.05	1.02–1.08	0.001
No. of t-PA cases/y	1.17	1.07–1.26	<0.001
No. of patients under care	1.11	1.06–1.17	<0.001
No. of years of experience	0.97	0.96–0.98	<0.001
Income (10 000 Yen) (1000 Euro)	1.00	1.00–1.00	<0.001
Extra calls/5 calls	1.60	1.40–1.83	<0.001
SF-36 MH Subscale	0.86	0.85–0.87	<0.001
Married, %	0.77	0.64–0.94	0.009
Children <23 y (%)	1.09	0.92–1.29	0.345
Divorced, %	1.20	0.68–2.13	0.529

Odds ratios were obtained from ordinal logistic regression analysis. 1 million Yen indicates 12 000 US\$; % time for spent stroke, % time for stroke care/10% incremental of time; experience year, experience years/10 incremental years (experience years were approximately proportional to age, and age was omitted for the adjustment); hours worked, hours worked/10 incremental hours; income, income/1 million Yen; number of extra calls, number of extra calls after hours/5 incremental calls/wk; number of holidays, number of holidays/wk; number of nightshifts, number of nightshifts/mo; number of patients, number of patients in charge/10 incremental patients; number of t-PA cases, number of t-PA cases/5 incremental cases/y; SF-36 MH score, Short Form 36 mental health subscale score; sleep time, sleep duration/d; and t-PA, tissue-type plasminogen activator.

physicians, 1525 (59.4%) were used at 578 teaching hospitals or CSC that were participating in a survey of CSC as part of the J-ASPECT study group. Because 3757 physicians were working at institutes participating in the J-ASPECT study in March 2011, the average response rate among active stroke care center physicians was estimated at 40.6%. Other relevant personal characteristics about the study sample are summarized in Table 1.

To investigate the possibility of selection bias, we checked the address of responders and nonresponders. The response rate was not statistically different in all 44 prefectures in this analysis ($P=0.683$). We also found no significant differences for age, sex, and specialty (neurologist versus neurosurgeon), burnout rate, workload per week, sleep duration per day, number of day-offs, and number of patients under care among early responders compared with late responders.

Review of the participants' MBI-GI scores indicates that 41.1% ($n=1055$) of the study sample was burned out and 21.8% ($n=560$) was severely burned out at the time of the survey (Figure 2A). Consideration of the MBI-GS scores of 2843 office workers and 751 civil servants indicates that the prevalence of burnout and severe burnout among stroke care physicians (41.1% and 21.8%, respectively) is significantly higher than that among civil servants (28.8%, $P<0.001$ and 17.8%, $P=0.0268$, respectively) and office workers (27.1%, $P<0.001$ and 12.2%, $P=0.004$, respectively).

Relationship Between Burnout and Workload, Sleep Duration, Work Experience, and Time Spent for Stroke Care and Other Significant Predictors

Analysis of the scores indicated that the number of hours worked per week and time spent in stroke care are positively associated with the severity of burnout (Figure 2B and 2C). In contrast, data analysis also indicates that sleep duration, years of experience, and SF-36 MH are inversely associated with burnout (Figure 2D–2F).

Thus, the study results indicate that a relatively greater workload per week, shorter sleep duration per night, less work experience, and low quality in mental health are all associated with increased prevalence of burnout and burnout severity.

To confirm this trend, we conducted univariate ordinal regression analysis (Table 2). The odds ratio (OR) for burnout was found to increase by $\approx 2\%$ per additional working hour by the every increase of hours worked (OR=1.02; 95% confidence interval [CI], 1.02–1.03; $P<0.001$). In contrast, burnout increased as the number of hours slept per night decreased (OR=0.67; 95% CI, 0.61–0.73; $P<0.001$). Likewise, the OR of burnout was found to be inversely associated with number of years of experience (OR=0.96; 95% CI, 0.96–0.98; $P<0.001$). The trend of increasing prevalence of burnout with an increasing proportion worked for stroke care is significant (OR=1.05; 95% CI, 1.02–1.08; $P=0.001$). Low SF-36 MH was also significantly associated with burnout (OR=0.86; 95% CI, 0.85–0.87; $P<0.001$).

Table 3 shows the predictors that remained in the final prediction model for burnout after performing forward selection. These predictors were number of hours worked per week, number of hours slept per night, number of day-offs per week, number of after-hours calls per week, number of years of experience, and number of patients under care and income (model 1). For neurosurgeons, the number of tissue-type plasminogen activator cases treated per year was also found to increase the risk of burnout by 17% (OR=1.17; 95% CI, 1.03–1.33; $P=0.018$; model 2). Including SF-36 MH gives a similar result (model 3). The factors associated with burnout are similar between all stroke providers and the subgroup of stroke providers that are neurosurgeons.

Neither combination of interaction terms among best predictor variables was significant. Predicted probabilities of burnout based on sleep duration, workload, and SF-36 MH adjusted for other significant predictors in multivariable ordinal logistic regression are shown in Figure 3.

Institutional Background, Quality of Care, and Burnout

The association of physicians working in teaching hospitals or CSC between the structure aspects of stroke care centers and burnout was investigated. After adjusting by age, working hours, and sleeping hours, those who were in the institutions for thrombolysis therapy certified by Japanese stroke society were slightly increased the risk of burnout. However, those who were in the institutes for hyperacute stroke care certified by government tended to be less burnout (Table 4). Number of beds, existence of stroke care unit, existence of 24-hour MRI/computed tomography, mean values of death rate within 24 hours, mean values of death rate within 30 days, and mean

Table 3. Best Predictors in Multivariable Ordinal Logistic Regression for Burnout

Predictors	Model 1			Model 2			Model 3		
	OR	P Value	95% CI	OR	P Value	95% CI	OR	P Value	95% CI
Hours slept/d	0.80	<0.001	0.73–0.89	0.84	0.019	0.72–0.97	0.84	0.002	0.75–0.94
Day-offs/wk	0.83	0.012	0.71–0.96	0.65	<0.001	0.52–0.82	Not selected
Hours worked/10 h	1.12	<0.001	1.05–1.18	1.17	<0.001	1.07–1.28	1.08	0.023	1.01–1.15
Experience years/10 y	0.90	0.051	0.81–1.00	0.96	0.021	0.93–0.99	Not selected
Income/1 million Yen	0.97	0.002	0.94–0.99	0.96	0.021	0.93–0.99	0.98	0.036	0.95–1.00
Patients in charge (n)	1.08	0.004	1.03–1.14	Not selected	1.08	0.013	1.02–1.15
Extra calls/5 calls	1.26	0.001	1.10–1.45	1.24	0.021	1.03–1.50	Not selected		
No. of operations	Not selected			0.90	0.011	0.83–0.98	Not selected		
No. of t-PA cases	Not selected			1.17	0.018	1.03–1.33	Not selected		
SF-36 MH Score	Not included			Not selected			0.86	<0.001	0.85–0.87

CI indicates confidence interval; OR, odds ratio; SF-36 MH score, Short Form 36 mental health subscale score; and t-PA, tissue-type plasminogen activator.

Model 1: Significant predictors in Table 2 were considered potential predictors. Forward selection with Akaike information criterion was conducted to select the best prediction model.

Model 2: Analyzed for neurosurgeon only (n=1673). Predictors specific for surgeons, number of operation, number of emergency operation, and number of operation for stroke were included.

Model 3: SF-36 MH score was included in model 1.

values of modified Rankin scale at 30 days were not associated with burnout. We also investigated the process measures, discharge with antithrombotic therapy, discharge with anticoagulation therapy for patients with atrial fibrillation, and discharge with thrombolytic therapy (tissue-type plasminogen activator) and antithrombotic therapy by the end of hospital day 2. They were not significantly associated with burnout.

Discussion

This nation-wide survey of Japanese physicians working in stroke care revealed that this population experiences burnout at a rate considerably higher than that of the general population of Japanese workers. We also demonstrated that longer working hours, short sleep duration, relatively little experience, and low mental quality of life are associated with physician burnout.

The primary hypothesis examined in this study is that the most important risk factor for burnout among physicians working in stroke care is heavy workload, more specifically working an excessive number of hours per week. Whereas the mean number of hours worked per week by the study sample was 66.3 hours, those by the general Japanese population was 45.8 hours in 2010.¹⁷ These findings accord with previous research for general population demonstrating that working an excessive number of hours is a risk factor for burnout¹ and fatigue.¹⁸ The study participants work considerably more hours per week, and they are at greater risk of burnout.

Although this association between high rates of burnout and long working hours accords with a study of US physicians² and US surgeons,^{2,3} neither of these studies investigated the factors quantitatively. Other previous studies focused on the

prevalence of burnout itself or the psychosocial background of the participants and did not discuss this point.^{19–21}

The results of the present study also may indicate that sleep duration is associated with burnout. One prospective study reported that insomnia increased emotional exhaustion 3-fold.²² In 1 prospective observational study, <6-hour sleep caused the risk of clinical burnout.²³ These support our finding, and less sleep is the potential risk factors for burnout. Among physicians, working long hours in addition to taking frequent after-hours calls may decrease sleep duration, cause sleep fragmentation, and increase the risk of burnout. Thus, sleep duration is another important and potential modifiable factor to consider in the prevention of burnout.

Furthermore, interventions aimed at reducing working hours and increasing sleep duration have been found to reduce the prevalence of burnout among physicians. Restriction of working hours in medical residency reduced the mean working hours of 7.5 hours and reduced burnout from 74% to 56%.²⁴ One intervention that limited the number of hours increases sleep duration and reduces medical errors by >50%.²⁵ All the findings may indicate that we should start the study whether the reduction of working hours and increase of sleep reduce the burnout among physicians in stroke care.

In addition, the burden of being responsible for emergency admission may have been associated with feelings of being overwhelmed,²⁶ and physicians working in emergency medicine have been found to experience the highest rate of burnout among all US physicians.² This is compatible with our study sample that tissue-type plasminogen activator cases, which are urgent, are associated with burnout for neurosurgeons. From the analysis of backgrounds of institutes, the

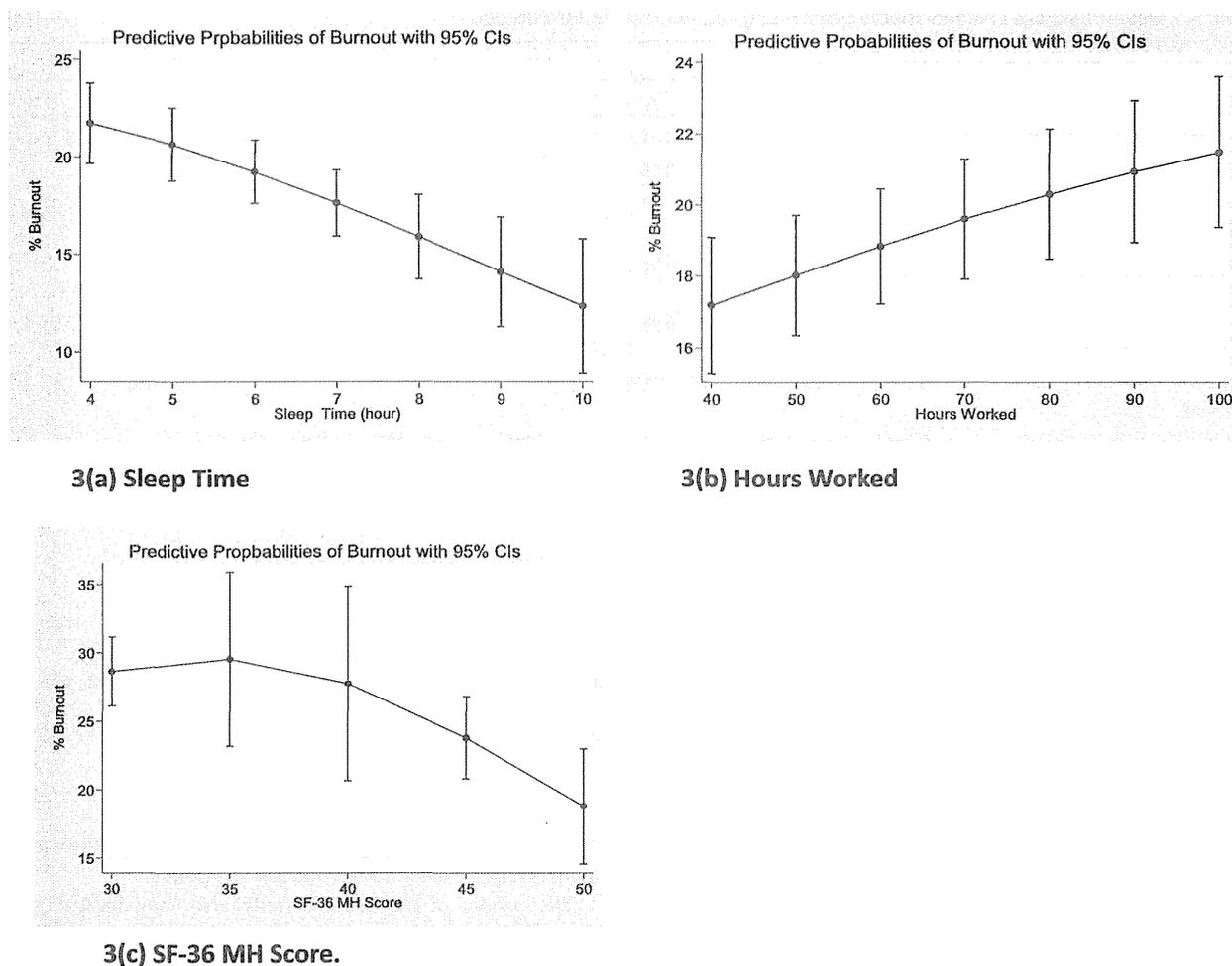


Figure 3. A–C, Relationship between prevalence of burnout and workload, sleep duration, and work experience predicted by multivariable ordinal logistic regression model. Marginal effect was estimated by margin command and plotted by marginsplot command by STATA software adjusted for the predictor in model 3 of Table 3. CI indicates confidence interval; and SF-36 MH score, Short Form 36 mental health subscale score.

officially credited institutes for thrombolysis therapy are associated with slightly increased the risk of burnout. But, simultaneously, the official credited centers for hyperacute stroke care centers that satisfied the criteria of CSC by Joint Commissions reduced the risk of stroke care $\approx 21\%$. This result might suggest that sufficient staffing can reduce burnout, even in intensive care situations.

This study had several strengths that contributed to the reliability and validity of the findings. First, it was the first large study to show an association between physician burnout and workload in Asian countries. Because the rate of burnout among the physicians in this study was found to be similar to that among physicians in western countries,^{2,3,27,28} burnout seems to be a common phenomenon among physicians in both the east and the west.

Second, this study examined a sufficiently large sample of physicians with a homogenous training and practice background and varying workloads. In contrast, most previous studies were conducted in a single center using a sample size insufficiently large to identify an association between burnout and workload,^{29,30} with even studies using a relatively large sample identifying no association.²⁷ However, these findings

may be attributed to the fact that all of the participants in these studies worked relatively long hours, preventing comparison of the effect of workload among them.

Third, to the best of our knowledge, this study is the first study that demonstrated the close association between burnout and low quality of life assessed by SF-36 MH. Klersy et al³¹ reported that lower physical score of SF-36 was associated with emotional exhaustion among Italian healthcare providers of dialysis but no association with SF-36 MH. The population

Table 4. Best Predictors in Multivariable Logistic Regression for Burnout From Institutional Backgrounds

Predictors	Odds Ratio	P Value	95% Confidence Interval
Hyperacute stroke care centers	0.79	0.089	0.61–1.04
Certified institutions for thrombolysis therapy	1.08	0.037	1.08–1.16
No. of experience years	0.73	<0.001	0.64–0.84
No. of hours slept/night	0.78	<0.001	0.68–0.88
No. of hours worked/wk	1.11	0.015	1.02–1.21

Forward selection with Akaike information criterion was conducted to select the best prediction model.

was considerably different from ours because the burnout rate of Italian health workers was not different from Italian citizens. Also, high burnout rate among Japanese physicians working in stroke care enabled us to reveal the association between burnout and low quality of life.

Finally, this study demonstrated that the risk of burnout is inversely associated with the number of years of experience as had several previous studies.^{2,3} This phenomenon is likely because of the fact that promotion to an administrative position after acquiring a certain number of years of experience leads to a decreased clinical workload. It may also reflect a selection bias in those who are more severely burned out quit practice earlier in their carrier. Recent studies suggest that burnout may influence quality of care and lead to early retirement.³²

In addition, we found some association between burnout and those who in the institutions credited for hyperacute stroke care by Japanese government, which satisfied the components of CSC by the Joint Commissions. This may suggest that the centralization of stroke care in CSC helps to reduce burnout among stroke care. However, the sample size is limited for 59.4% responders and further study is needed for this issues.

Despite these strengths, this study also faced several limitations. First, this study used a cross-sectional design and was thus unable to determine the existence of any direct causal relationships. For example, we demonstrated a cross-sectional association between SF-36 MH scores of the physicians and burnout. Our analysis showed that SF-36 MH is a significant explanatory variable in ordinal logistic regression. However, linear regression analysis showed that the existence of burnout is a significant predictor for low SF-36 MH after adjustment of age, hours slept, and hours worked (data not shown). Thus, we need a prospective cohort study to determine the causality between burnout and potential risk factors in this study. Second, the percentage of female physicians examined in this study was smaller than that of the general population of female physicians in Japan, which was 18.9% of all physicians in 2010.²² Therefore, the findings may not be generalizable to female physicians. Third, selection bias may have been a significant limitation because physicians who were burned out may have been more or less likely to complete the survey. We cannot comment on how it might influence the generalizability of these observations. We found no significant difference in backgrounds, burnout rate, and workload among early responders compared with late responders using the standard procedure for examining the existence of selection bias, as described by Shanafelt et al.² Direct comparison of responders and nonresponders could not be performed as the survey was anonymous.

In conclusion, the results of this study suggest that burnout is highly prevalent among Japanese physicians working in stroke care. The risk factors for burnout seem to be relatively fewer years of work experience, longer working hours per week, and shorter sleep duration per night. Additional prospective research is now needed to assist in the development of interventions to address this pressing problem.

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Disclosures

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare support from the Ministry of Health, Labor, and Welfare, Japan; no financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years; and no other relationships or activities that could seem to have influenced the submitted work.

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SUPPLEMENTAL MATERIAL

1. Do you have a part-time job besides a full-time job?

- No
- Yes

2. On average, how long do you work in a week?

(Check the appropriate box.)

- Less than 40 hours
- 40 to 49 hours
- 50 to 59 hours
- 60 to 69 hours
- 70 to 79 hours
- 80 to 100 hours
- More than 100 hours

3. How many times did you work night-duty last month?

Times of night duty _____ times per month

4. How many times were you called out at night? Please fill in the number of calls in each day of the last week.

Seven days ago	Six days ago	Five days ago	Four days ago	Three days ago	Two days ago	Yesterday

5. On average, how many holidays do you have in a week? Please check the most appropriate number.

- None
- One

- Two
- Three
- Four or more

6. On average, how many hours of sleep per day do you get at night during weekday? Please fill in the sleep hours and minutes. This time may be different from the time in which you are in bed.

_____ hours _____ minutes per day

7. On average, how many hours of sleep per day do you get at night during weekend? Please fill in the sleep hours and minutes. This time may be different from the time in which you are in bed.

_____ hours _____ minutes per day

8. On average, what percentage in a week do you spend as a non-medical care such as research or education? Please check the most appropriate box.

- None
- One to 10%
- 11 to 20%
- 21 to 30%
- 31 to 50%
- 51% or more

9. On average, what percentage in a week do you spend as a medical care for stroke patients? Please check the most appropriate box.

- None
- One to 24%
- 25 to 49%

- 50 to 74%
- 75 to 100%

10. On average, how many patients do you have in charge? Please check the most appropriate box

- None
- One to four patients
- Five to Nine patients
- 10 to 14 patients
- 15 to 19 patients
- 20 or more patients

11. For patients who occurred a stroke within three hours, how many did you treat as a t-PA last year? Please choose the most appropriate number.

- None
- One to four patients
- Five to Nine patients
- 10 to 14 patients
- 15 to 19 patients
- 20 or more patients

Please answer from number 12 to 14 only if you perform surgical treatments including intravascular interventions; otherwise, skip to question 15.

12. How many neurosurgical operations did you perform including intravascular interventions last year? Please choose the most appropriate number.

- None
- One to 39 patients
- 40 to 79 patients
- 80 to 99 patients
- 100 to 119 patients
- 120 or more patients

13. How many CDV operations did you perform including intravascular interventions last year? Please choose the most appropriate number.

- None
- One to 24 patients
- 25 to 49 patients
- 50 to 74 patients
- 75 to 99 patients
- 100 or more patients

14. How many emergency operations with CDV did you perform including intravascular interventions last year? Please choose the most appropriate number.

- None
- One to 24 patients
- 25 to 49 patients
- 50 to 74 patients
- 75 to 99 patients
- 100 or more patients

15. How many years are you in practice? Please choose the appropriate number

- Less than 10 years
- 10 to 19 years
- 20 to 29 patients
- 30 to 39 patients
- 40 or more years

16. What is your specialty? Please choose the appropriate box

- Neurosurgery
- Neurology
- Emergency medicine
- Rehabilitation

- Radiology

17. What are your Board Certifications? Please check all appropriate boxes.

- Japan Neurosurgical Society Certified Neurosurgeon
- Societas Neurologica Japonica certified Neurologists
- Japanese Associations for Acute Medicine certified Acute Care Physician
- Japan Stroke Society certified Stroke Physician
- Japanese Society for Neuroendvascular Therapy certified Physician

18. How much is your annual income? Please choose the appropriate number

- Less than 5,000,000 yen
- 5,000,000 to 9,990,000 yen
- 10,000,000 to 14,990,000 yen
- 15,000,000 to 19,990,000 yen
- 20,000,000 or more yen

19. What is your relationship status? Please choose the appropriate box

- Single
- Divorced
- Widowed or widower
- Married

20. If you choose “Married” in question 19, please answer the following question.

Does your spouse work outside of home?

- No
- Yes

If you choose “Yes” in question 20, please answer the following question.

21.What kind of professional field does your spouse work? Please check the box below.

- Medical doctor
- Other health care professionals
- Other

22.Do you have any children under 22 years old? Please check the box below.

- No
- Yes

Cross-Sectional Survey of Workload and Burnout Among Japanese Physicians Working in Stroke Care: The Nationwide Survey of Acute Stroke Care Capacity for Proper Designation of Comprehensive Stroke Center in Japan (J-ASPECT) Study
Kunihiro Nishimura, Fumiaki Nakamura, Misa Takegami, Schunichi Fukuhara, Jyoji Nakagawara, Kuniaki Ogasawara, Junichi Ono, Yoshiaki Shiokawa, Shigeru Miyachi, Izumi Nagata, Kazunori Toyoda, Shinya Matsuda, Hiroharu Kataoka, Yoshihiro Miyamoto, Kazuyo Kitaoka, Akiko Kada and Koji Iihara
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Consciousness Level and Off-Hour Admission Affect Discharge Outcome of Acute Stroke Patients: A J-ASPECT Study

Satoru Kamitani, MD; Kunihiro Nishimura, MD, PhD; Fumiaki Nakamura, MD, PhD; Akiko Kada, MPH; Jyoji Nakagawara, MD, PhD; Kazunori Toyoda, MD, PhD; Kuniaki Ogasawara, MD, PhD; Junichi Ono, MD, PhD; Yoshiaki Shiokawa, MD, PhD; Toru Aruga, MD, PhD; Shigeru Miyachi, MD, PhD; Izumi Nagata, MD, PhD; Shinya Matsuda, MD, PhD; Yoshihiro Miyamoto, MD, PhD; Michiaki Iwata, PhD; Akifumi Suzuki, MD, PhD; Koichi B. Ishikawa, PhD; Hiroharu Kataoka, MD, PhD; Kenichi Morita, MD, PhD; Yasuki Kobayashi, MD, PhD; Koji Iihara, MD, PhD

Background—Poor outcomes have been reported for stroke patients admitted outside of regular working hours. However, few studies have adjusted for case severity. In this nationwide assessment, we examined relationships between hospital admission time and disabilities at discharge while considering case severity.

Methods and Results—We analyzed 35 685 acute stroke patients admitted to 262 hospitals between April 2010 and May 2011 for ischemic stroke (IS), intracerebral hemorrhage (ICH), or subarachnoid hemorrhage (SAH). The proportion of disabilities/death at discharge as measured by the modified Rankin Scale (mRS) was quantified. We constructed 2 hierarchical logistic regression models to estimate the effect of admission time, one adjusted for age, sex, comorbidities, and number of beds; and the second adjusted for the effect of consciousness levels and the above variables at admission. The percentage of severe disabilities/death at discharge increased for patients admitted outside of regular hours (22.8%, 27.2%, and 28.2% for working-hour, off-hour, and nighttime; $P < 0.001$). These tendencies were significant in the bivariate and multivariable models without adjusting for consciousness level. However, the effects of off-hour or nighttime admissions were negated when adjusted for consciousness levels at admission (adjusted OR, 1.00 and 0.99; 95% CI, 1.00 to 1.13 and 0.89 to 1.10; $P = 0.067$ and 0.851 for off-hour and nighttime, respectively, versus working-hour). The same trend was observed when each stroke subtype was stratified.

Conclusions—The well-known off-hour effect might be attributed to the severely ill patient population. Thus, sustained stroke care that is sufficient to treat severely ill patients during off-hours is important. (*J Am Heart Assoc.* 2014;3:e001059 doi: 10.1161/JAHA.114.001059)

Key Words: hemorrhagic stroke • ischemic stroke • mortality • stroke • weekend effect

Stroke is a major cause of death in Japan, and residual disability after stroke is a heavy societal burden.¹ Death risk tendencies are high for patients hospitalized with serious medical conditions (including stroke) during off hours, especially on weekends.^{2–7} Reduced quality of care during off hours because of insufficient physician volume,

uneven staffing pattern for urgent procedures, and insufficient management of operative procedures, are among the possible reasons for this tendency.^{2,3,6–9} Acute stroke severity is an important prognostic factor,¹⁰ and stroke symptom severity is associated with healthcare-seeking behavior.^{11–13} However, only 5 previous studies have

From the Department of Public Health/Health Policy, Graduate School of Medicine, University of Tokyo, Bunkyo-ku, Tokyo (S.K., F.N., Y.K.); Departments of Preventive Medicine and Epidemiologic Informatics (K.N., Y.M.), Cerebrovascular Medicine and Neurology (K.T.), Intellectual Asset Management (M.I.), and Neurosurgery (H.K., K.M.), and Integrative Stroke Imaging Center (J.N.), National Cerebral and Cardiovascular Center, Suita, Japan; Clinical Research Center, Nagoya Medical Center, Nagoya, Japan (A.K.); Department of neurosurgery, Iwate Medical University, Morioka, Japan (K.O.); Chiba Cardiovascular Center, Chiba, Japan (J.O.); Department of Neurosurgery, Kyorin University, Mitaka, Japan (Y.S.); Showa University Hospital, Shinagawa-ku, Japan (T.A.); Department of Neurosurgery, Nagoya University, Nagoya, Japan (S. Miyachi); Department of Neurosurgery, Nagasaki University (I.N.); Department of Preventive Medicine and Community Health, School of Medicine, University of Occupational and Environmental Health, Kitakyushu, Japan (S. Matsuda); Research Institute for Brain and Blood Vessels, Akita, Japan (A.S.); Center for Cancer Control and Information Services, National Cancer Center, Chuo-ku, Japan (K.B.I.); Department of Neurosurgery, Graduate School of Medical Sciences, Kyushu University, Fukuoka, Japan (K.I.).

Correspondence to: Koji Iihara, MD, PhD, Department of Neurosurgery, Graduate School of Medical Sciences, Kyushu University, 3-1-1, Maidashi, Higashi-ku, Fukuoka, Japan, 812-8582. E-mail: kiihara@ns.med.kyushu-u.ac.jp

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adjusted for case severity, and these reports included relatively small numbers of hospitals (2 to 28).^{14–18} Furthermore, the results of these studies were inconsistent; 2 reported positive relationships between admission hours and outcomes^{14,15} and 3 reported negative relationships.^{16–18} We examined the relationship between admission time and disabilities/deaths at discharge by adjusting for case severity using data from a nationwide cohort of Japanese hospitals.

Materials and Methods

Database

This study included a nationwide retrospective cohort of stroke patients (J-ASPECT study).¹⁹ Among 749 certified training hospitals of the Japan Neurosurgical Society, the Societas Neurologica Japonica, and/or the Japan Stroke Society, 262 participated in this study. We collected Japanese Diagnosis Procedure Combination/Per Diem Payment System (DPC/PDPS) data, which list the lump-sum system of medical expenses evaluated based on diagnostic and procedural costs beginning in 2002.²⁰ Subject data were extracted from DPC/PDPS data at each hospital using specially developed computer software.

Inclusion and Exclusion Criteria

We included consecutive patients admitted to 262 hospitals between April 1, 2010 and May 31, 2011 for acute ischemic stroke (IS), non-traumatic intracerebral hemorrhage (ICH), or subarachnoid hemorrhage (SAH) according to the International Classification of Disease 10th revision (ICD-10 codes, I60.0 to I60.9, I61.0 to I61.9, I62.0, I62.1, I62.9, and I63.0 to I63.9). Because of major differences in their typical prognoses, we excluded patients with transient ischemic attack (TIA) (G45). We also excluded patients who experienced in-hospital stroke during treatment for other diseases.

Variables

The outcome measure was the proportion of severe disability/death (score 5 to 6 on the modified Rankin Scale [mRS]) at discharge.²¹ We classified admission into (1) working-hour (professed work hours [usually 8 h] in each hospital from Monday to Friday, except for national holidays), (2) off-hour (hours not included in working-hour or nighttime classifications), or (3) nighttime (22:00 to 6:00 on any day) by using calendar time and additional medical billings in case of admission outside of working hours (Figure 1). We could not count the total hours of each admission-hour category.

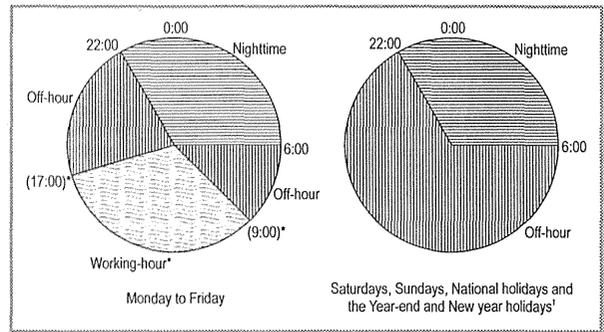


Figure 1. Classification of hospital admission time. *Working-hour was defined as working-hours professed by each hospital on consultation day (from Monday to Friday except for national holiday). †The YEAR-end and New Year holidays are from 29th December to 3rd January.

Proportions of total numbers of hours were hypothesized to be 22.2%, 44.5%, and 33.3% for working-hours, off-hours, and nighttime categories, respectively.

To account for the classical confounding factors for stroke and the capability of stroke care provided by hospitals, we adjusted for the following factors to estimate the effect of admission time: age (categorized as <35 years,

Table 1. Japan Coma Scale for Grading Impaired Consciousness*

Grade	Consciousness Level
1-digit code	The patient is awake without any stimuli, and is:
1	Almost fully conscious
2	Unable to recognize time, place, and person
3	Unable to recall name or date of birth
2-digit code	The patient can be aroused (then reverts to previous state after cessation of stimulation):
10	By easily by being spoken to (or is responsive with purposeful movements, phrases, or words) [†]
20	With a loud voice or shaking of shoulders (or is almost always responsive to very simple words like yes or no or to movements)
30	Only by repeated mechanical stimuli
3-digit code	The patient cannot be aroused with any forceful mechanical stimuli, and:
100	Responds with movements to avoid the stimulus
200	Responds with slight movements, including decerebrate and decorticate posture
300	Does not respond at all except for changes in respiratory rhythm

*"R" and "I" are added to the grade to indicate restlessness and incontinence of urine and feces, respectively; for example; 100-R and 30-RI.
[†]Criteria in parentheses are used in patients who cannot open their eyes for any reason.

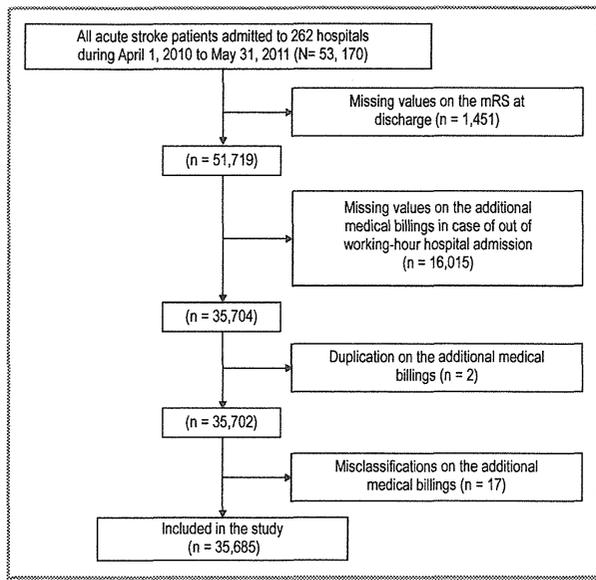


Figure 2. Flow chart for inclusion criteria.

every 5 years from 35 to 100 years, and ≥ 100 years), sex, comorbidities (hypertension, diabetes mellitus, and hyperlipidemia), and number of hospital beds (<100, 100 to 299, 300 to 499, and ≥ 500). Comorbidities were assessed from recorded disease name and prescription history in patient medical records.

To adjust effects of baseline consciousness level at admission, we used the Japan Coma Scale (JCS).^{22–25} The JCS – originally published in 1974 for the assessment of impaired consciousness of head trauma and stroke patients²² and published in the same year as the Glasgow Coma Scale²⁶ – remains one of the most popular scales used among health care professionals and personnel for emergency medical services in Japan.²⁵ Briefly, a normal level of consciousness is graded as 0. Other levels are graded with 1-, 2-, or 3-digit codes depending on status as shown in Table 1. We treated JCS as a categorical variable and classified patients as grade 0, 1 to 3, 10 to 30, or 100 to 300 for analysis. A 3-digit JCS score is roughly equivalent to a GCS score of ≤ 7 ($\leq E1V1M5$).

Table 2. Demographics and Clinical Characteristics of Patients Included and Excluded in the Analyses

	Total (n=53 170)		P Value
	Excluded Subjects	Included Subjects	
Number, %	n=17 485 (32.9)	n=35 685 (67.1)	
Male, %	58.1	53.8	<0.001
Age mean (SD)	74.0 (12.0)	71.7 (13.6)	<0.001
Stroke subtype, n (%)			
IS	68.1	58.2	<0.001
SAH	5.9	10.9	<0.001
ICH	26.2	31.1	<0.001
Comorbidity, %			
Hypertension	72.7	76.2	<0.001
Diabetes mellitus	28.9	24.3	<0.001
Hyperlipidemia	29.3	27.7	<0.001
Current/past smoking history (n=44 842) (%)	26.7	29.3	<0.001
Japan Coma Scale, %			
0	42.0	34.5	<0.001
1-digit code	34.8	37.2	
2-digit code	11.6	13.8	
3-digit code	11.6	14.6	
Emergency admission by ambulance (%)	51.4	64.5	<0.001
mRS at discharge (n=51 719) (%)			
mRS=6	11.4	12.2	0.014
mRS=5/6	24.1	25.4	0.001
mRS=4 to 6	41.3	44.0	<0.001

ICH indicates intracerebral hemorrhage; IS, ischemic stroke; mRS, modified Rankin Scale; SAH, subarachnoid hemorrhage.

Table 3. Patient Demographics and Clinical Characteristics by Inclusion in the Analyses for Each Stroke Subtype

	IS (n=32 671)			SAH (n=4934)			ICH (n=15 699)		
	Excluded	Included	<i>P</i> Value*	Excluded	Included	<i>P</i> Value*	Excluded	Included	<i>P</i> Value*
Number, %	11 913 (36.5)	20 758 (63.5)		1035 (21.0)	3899 (79.0)		4588 (29.2)	11 111 (70.8)	
Male, %	59.8	56.3	<0.001	29.1	32.9	0.019	60.4	56.3	<0.001
Age mean (SD)	75.1 (11.4)	74.1 (12.5)	<0.001	67.9 (14.1)	63.8 (14.8)	<0.001	72.5 (12.6)	70.0 (13.8)	<0.001
Comorbidity, %									
Hypertension	69.8	68.5	0.013	82.4	86.6	0.001	78.3	87.2	<0.001
Diabetes mellitus	31.3	27	<0.001	25.6	23.3	0.124	23.6	19.8	<0.001
Hyperlipidemia	34.2	33.9	0.511	26.5	29.2	0.086	17.2	15.7	0.015
Current/past smoking history (n=44 842) (%)	27.6	30.1	<0.001	22.5	28.2	0.001	25.1	28.2	<0.001
Japan Coma Scale, %									
0	48.8	44.4	<0.001	23.4	20.1	<0.001	28.6	20.8	<0.001
1-digit code	35.7	39.2		19.3	23.5		36.2	38.5	
2-digit code	9.9	10.7		14.7	18		15.2	18.1	
3-digit code	5.7	5.7		42.6	38.5		20	22.7	
Emergency admission by ambulance (%)	46.3	57	<0.001	73.8	78.6	0.001	59.7	73.5	<0.001
mRS at discharge (n=51 719) (%)									
mRS=6	7.8	7.2	0.099	29.1	26.8	0.165	17	16.3	0.284
mRS=5/6	19.1	19.5	0.413	46.4	37.8	<0.001	32.1	32.3	0.812
mRS=4 to 6	36.4	37.5	0.061	56.8	47.8	<0.001	50.8	55	<0.001

ICH indicates intracerebral hemorrhage; IS, ischemic stroke; mRS, modified Rankin Scale; SAH, subarachnoid hemorrhage.

*Off-hour and nighttime were compared with working-hours.

Statistical Analysis

We performed descriptive analyses for demographic and clinical characteristics for each group using the working-hour group as the control. Chi-square tests and *t* tests were used to compare categorical and continuous variables, respectively. For outcome analysis, we first compared crude outcome proportions among admission times in the total population, and then analyzed for each stroke subtype (IS, ICH, and SAH). For multivariable analysis, we used unique hospital ID in random-intercept hierarchical regression models to assess the relationships between hospital admission times and outcomes, while adjusting for patient characteristics and the hospitals at which patients received stroke care. This modeling adjusts for hospital-level cluster effects on outcome, which arise from various factors such as geographical location and ageing of the local population. We constructed 2 models to assess the impact of case severity. Model 1 included age, sex, hypertension, diabetes mellitus, hyperlipidemia, and number of beds. Baseline consciousness level was included in model 2 in addition to the variables in model 1. Moreover, to examine whether outcomes were

consistent across admission times for patients with the same level of consciousness at admission, we performed subgroup analysis by JCS. To test the sex-specific differences, we performed sex-stratified analysis after the main analysis. Furthermore, to test whether results differ when age is treated as a continuous variable, we performed additional analyses. For sensitivity analyses, we substituted outcomes to death (mRS=6) (sensitivity analysis 1) and moderately severe disability to death (mRS=4 to 6) (sensitivity analysis 2). To confirm the robustness of our results, we also estimated the off-hours effects at admission using the modified Rankin Scale. Unlike JCS, mRS uses 5 categories to assess severity. All statistical analyses were performed using STATA version 12 (StataCorp LP). All tests were 2-tailed, and $P<0.025$ was considered statistically significant in consideration of multiple comparisons.

Ethical Approval

The Institutional Review Board of the National Cerebral and Cardiovascular Center and the University of Tokyo approved this research.

Table 4. Patient Demographic and Clinical Characteristics by Admission Time

	Total (n=35 685)				
	Working-Hour	Off-Hour	P Value*	Nighttime	P Value*
Number, %	15 084 (42.3)	16 908 (47.4)		3693 (10.4)	
Male, %	54.7	52.8	0.001	54.6	0.957
Age mean (SD)	72.4 (13.3)	71.8 (13.5)	<0.001	68.3 (14.3)	<0.001
Comorbidity, %					
Hypertension	74.8	77.2	<0.001	77.8	<0.001
Diabetes mellitus	24.9	23.8	0.015	24.2	0.329
Hyperlipidemia	29.5	26.5	<0.001	26.1	<0.001
Current/past smoking history (n=30 179) (%)	30	28.3	0.001	31.3	0.191
Japan Coma Scale, %					
0	38.4	32.1	<0.001	29.2	<0.001
1-digit code	37.7	37.6		33.9	
2-digit code	12.4	14.6		15.7	
3-digit code	11.6	15.8		21.3	
Emergency admission by ambulance (%)	54.2	69.9	<0.001	81.4	<0.001

*Off-hour and nighttime were compared with working-hours.

Results

Demographic and Clinical Characteristics

Out of 53 170 patients, we analyzed 35 685 patients. The inclusion criteria are shown in Figure 2. Demographics and clinical characteristics of excluded and included subjects for each stroke subtype are shown in Tables 2 and 3. IS, SAH, and ICH patients accounted for 58.2% (n=20 758), 10.9% (n=3899), and 31.1% (n=11 111), respectively. Overall, 42.3% (n=15 084), 47.4% (n=16 908), and 10.4% (n=3693) of patients were admitted during working hours, off hours, and nighttime, respectively. Patient demographics and clinical characteristics categorized according to admission time are shown in Table 4. Patients admitted during off hours and nighttime had lower baseline consciousness levels, and the percentage of these patients transferred to hospitals by ambulance was higher than that of patients admitted by ambulance during working hours. Patient demographics and clinical characteristics for each stroke subtype are shown in Table 5. The trends for age, baseline consciousness levels, and ambulance use by admission time were the same for each stroke subtype as observed for the total population.

Table 6 shows differences in primary outcomes among the 3 admission times for each stroke subtype. In the total population, increasing proportions of severe disability/death (mRS=5 to 6) at discharge were observed (22.8%, 27.2% and 28.2% for working-hour, off-hour, and nighttime, respectively). This remained the case when results were stratified by stroke subtype, although nighttime IS and off-hour and nighttime

SAH patients did not have statistically significant higher disabilities/death at discharge compared with patients admitted during working hours.

Figure 3 shows adjusted odds ratios (ORs) and 95% confidence intervals (CIs) for severe disability/death at discharge depending on stroke subtype and admission time. In model 1, which was adjusted for age, sex, comorbidities, and number of beds, off-hour and nighttime admitted patients had higher risks of severe disability/death than working-hour admitted patients irrespective of stroke subtype (adjusted OR, 1.23; 95% CI, 1.17 to 1.30 for off-hour and adjusted OR, 1.45; 95% CI, 1.33 to 1.58 for nighttime). When we further adjusted for consciousness level at admission (model 2), the effects of admission time were no longer significant (adjusted OR, 1.06; 95% CI, 1.00 to 1.13; $P=0.067$ for off-hour and adjusted OR, 0.99; 95% CI, 0.89 to 1.10; $P=0.851$ for nighttime compared with working-hour). The same trends were observed when we stratified by stroke subtype: off-hour and nighttime admission times were associated with significantly higher risks of severe disability/death at discharge in each stroke subtype except for off-hour SAH (adjusted OR, 1.12; 95% CI, 0.95 to 1.32, $P=0.168$) in model 1, and these effects were no longer significant in model 2 (Figure 3). Table 7 shows the effects of consciousness level at admission using Model 2.

In the subgroup analysis by using JCS at admission, proportions of severe disabilities/death were larger during off hours/nighttime than during working hours among IS and ICH patients with a JCS of 0. Proportions of primary outcome were larger during working hours than off hours/nighttime among

Table 5. Patient Demographic and Clinical Characteristics by Admission Time for Each Stroke Subtype

Stroke Subtype	IS (n=20 758)					SAH (n=3899)					ICH (n=11 111)				
	W	O	P Value*	N	P Value*	W	O	P Value*	N	P Value*	W	O	P Value*	N	P Value*
Number, %	9275 (44.7)	9630 (46.4)		1853 (8.9)		1407 (36.1)	1886 (48.4)		606 (15.5)		4436 (39.9)	5434 (48.9)		1241 (11.2)	
Male, %	56.7	55.2	0.047	60.7	<0.001	33.6	31.9	0.289	34.5	0.705	57.3	55.8	0.134	44.7	0.208
Age mean (SD)	74.2 (12.4)	74.5 (12.5)	0.046	71.4 (13.0)	<0.001	64.0 (14.6)	64.6 (14.7)	0.219	61.2 (15.3)	<0.001	71.3 (13.7)	69.6 (13.6)	<0.001	67.2 (14.3)	<0.001
Comorbidity, %															
Hypertension	68.5	68.6	0.930	67.6	0.411	88.2	86.2	0.085	84.2	0.013	83.5	89.6	<0.001	90.1	<0.001
Diabetes mellitus	28.0	26.1	0.003	26.2	0.111	24.1	23.3	0.610	21.5	0.198	18.9	19.8	0.215	22.6	0.004
Hyperlipidemia	35.9	32.3	<0.001	32.0	0.002	28.8	29.6	0.594	28.7	0.974	16.3	15.1	0.107	15.9	0.734
Smoking history (n=30 179) (%)	30.9	28.8	0.002	33.1	0.092	28.7	27.7	0.550	28.9	0.943	28.5	27.7	0.388	29.6	0.492
JCS, %															
0	47.3	42.1	<0.001	42.2	<0.001	24.5	17.9	<0.001	16.5	<0.001	24.1	19.2	<0.001	16.0	<0.001
1-digit code	38.2	40.2		38.5		24.5	22.9		23.4		40.6	38.2		32.1	
2-digit code	9.6	11.5		11.7		17.8	18.0		18.2		16.4	18.9		20.4	
3-digit code	4.8	6.3		7.7		33.3	41.3		41.9		19.0	23.8		31.5	
Ambulance admission (%)	46.9	62.8	<0.001	77.1	<0.001	72.2	80.9	<0.001	86.6	<0.001	63.9	78.7	<0.001	85.4	<0.001

ICH indicates intracerebral hemorrhage; IS, ischemic stroke; JCS, Japan Coma Scale; SAH, subarachnoid hemorrhage.

*Off-hour (O) and Nighttime (N) were separately compared with Working-hour (W).

Table 6. Crude Primary Outcome Comparisons Between Each Admission Time by Stroke Subtype

Stroke Subtype	Admission Time	N	Severe Disability/Death at Discharge, n (%)	Crude OR (95% CI)	P Value
Total population	Working-hour	15 084	3434 (22.8)	—	
	Off-hour	16 908	4597 (27.2)	1.24 (1.18 to 1.31)	<0.001
	Nighttime	3693	1042 (28.2)	1.30 (1.19 to 1.41)	<0.001
IS	Working-hour	9275	1659 (17.9)	—	—
	Off-hour	9630	2039 (21.2)	1.21 (1.13 to 1.31)	<0.001
	Nighttime	1853	355 (19.2)	1.06 (0.93 to 1.21)	0.361
SAH	Working-hour	1407	499 (35.5)	—	—
	Off-hour	1886	733 (38.9)	1.14 (0.99 to 1.32)	0.077
	Nighttime	606	240 (39.6)	1.18 (0.97 to 1.44)	0.105
ICH	Working-hour	4436	1293 (29.2)	—	—
	Off-hour	5434	1842 (33.9)	1.24 (1.13 to 1.35)	<0.001
	Nighttime	1241	449 (36.2)	1.38 (1.20 to 1.58)	<0.001

ICH indicates intracerebral hemorrhage; IS, ischemic stroke; SAH, subarachnoid hemorrhage.

IS and ICH patients who had a 3-digit JCS score (Table 8). Table 9 shows the results of subgroup analysis adjusted for age, sex, comorbidities, and number of hospital beds. Effects of nighttime admission were significantly higher (adjusted OR, 1.59; 95% CI, 1.11 to 2.29; IS and adjusted OR, 2.87; 95% CI, 1.66 to 4.98; for ICH) in patients with a JCS score of 0 and

significantly lower (adjusted OR, 0.50; 95% CI, 0.31 to 0.81; for IS and adjusted OR, 0.67; 95% CI, 0.49 to 0.90; for ICH) in patients with a 3-digit JCS score. Furthermore, no sex-based differences were present in these trends. Results obtained with age as a continuous variable were comparable with those obtained when it was treated as a categorical variable.

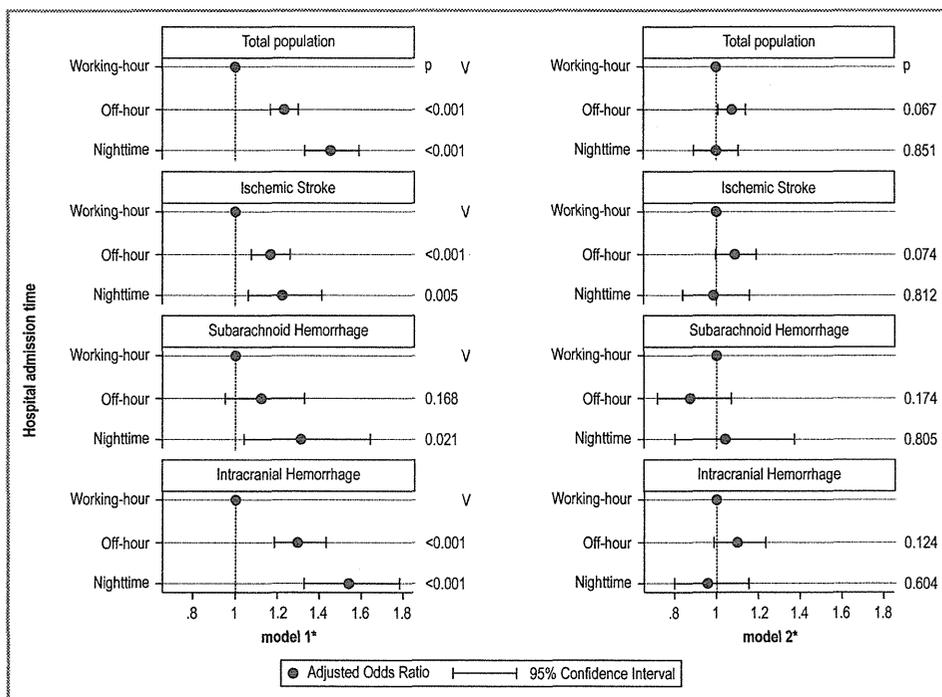


Figure 3. Effects of admission time on primary outcomes (modified Rankin Scale [mRS]=5 to 6) among acute stroke patients with 2 different models. *Model 1 adjusted for age, sex, hypertension, diabetes mellitus, hyperlipidemia, and number of beds. Model 2 further adjusted for Japan Coma Scale.