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特許権等知的財産権の取得及び申請状況

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発明の名称: 体腔用医療機器及びその製造方法.

出願日: 2008.2.1

出願人: 岐阜大学、(株) カネカ

出願番号: 特願 2008-556206 号 特許権

農田 一則

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13. 厚生労働科学研究費補助金の各研究推進事業に推薦する予定の研究者

年	度	外国人研究者招へい事業	外国への日本人研究者派遣事業	若手研究者育成活用事業 (リサーチ・レジデント)
平成25年	年度	0 名	0 名	0 名
平成26年	年度	0 名	0 名	0 名
平成27年	年度	0 名	0 名	0 名

平成25-27年度厚生労働科学研究費補助金事業

脳卒中急性期医療の地域格差の 可視化と縮小に関する研究 (J-ASPECT Study)

研究代表者

九州大学大学院 医学研究院 脳神経外科 飯原弘二

背景と目的

- ・ 脳卒中の救急医療の整備は喫緊の課題であ
- 緊急性の高い脳卒中治療については、医療 機関の集約化、広域化と連携強化は避けて 通れない。
- 全国的な俯瞰した視点で、地域の脳卒中の 救急医療の実態を調査し、脳卒中センターの 適正な配備を策定することが必要である。

脳卒中救急疫学の確立を目指して (J-ASPECT Study)

1. 包括的脳卒中センターの要件 (本邦での実態調査)



- 2. 脳卒中診療医の燃え尽き症候群、立ち去り型退職の実態調査
- 3. DPC情報を活用した大規模包括的脳卒中データベースの構築
- 4. GIS情報と医療機関情報(DPC)との連結



平成22-24年度 厚生労働科学研究費 (主任研究者 飯原弘二) 「包括的脳卒中センターの整備に向けた脳卒中の救急医療に関する研究」

包括的脳卒中センターの要件

(Comprehensive Stroke Center, Albers et al. Stroke 2005)

- Primary Stroke Centerの要件 (t-PA静注療法)
- 脳卒中内科医、脳血管外科医などの専門家
- 高度な Neuroimaging,、神経放射線科医
- 脳血管外科治療、急性期脳血管再開通療法
 - 年間SAH治療 (クリッピング)> 20 (10)
 - AVMなど高度な外科治療
- インフラ(集中治療室)、レジストリー
- リハビリテーション、ストロークナース

脳卒中診療施設調查 (平成23年2月)

- 目的: 脳卒中センターの機能 と 脳卒中治療件数
 対象: 日本脳神経外科学会、神経学会、日本脳卒中学会研修教育施設 1369施設
- 調查項目:
- 一次脳卒中センター (t-PA 静注療法の適正使用)の要件
 - t-PA protocolの整備 etc
- 包括的脳卒中センターの要件(25項目)
 - 人的資源 (7): 専門医 (脳外科 神経内科 血管内治療 救急) etc 診断機器 (6): CT MRI-DWI 血管撮影 etc 常時施行可能

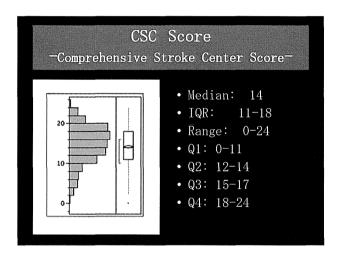
 - 専門的治療(5): 脳動脈瘤治療 脳内血腫除去 再開通療法 etc
 - インフラ (5): SCU ICU 手術・血管内治療 常時施行可能教育 (2): 院内外多職種、地域住民 対象

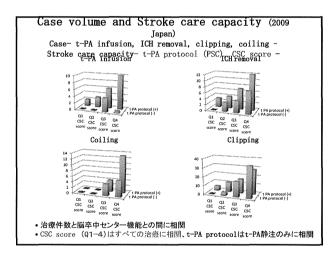
施設調査協力施設 (749施設、回答率 54%)

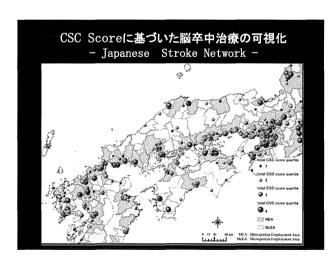
Variables	Category	n	%
No. of Beds	<50	20	2.7
	50-99	30	4
	100-299	232	31
	300-499	260	34.7
	≥500	207	27.6
Annual stroke	5500	201	27.0
volume*	<50	51	7.2
	50-99	78	11
	100-199	199	28
	200-299	155	21.8
	≧300	228	32.1
Academic hospita	ı	90	12
DPC hospital		553	73.8
Geographical			
locations	MEA-central	381	50.9
	MEA-outlying	239	31.9
	McEA-central	90	12
	McEA-outlying	12	1.6
	Unclassified	27	3.6
PSC component	t-PA protocol	637	85
	t-PA physician*	688	92
	NIHSS*	529	70.7
	Acute stroke team*	198	26.5
	Direct phone with EMS*	435	58.5

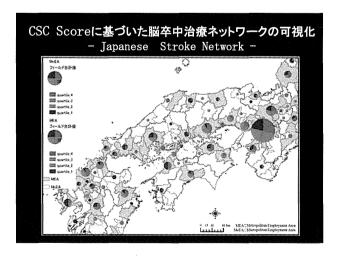
	センター の 推奨要件 人的要因、診断機器		区(1)
Components	ltems	n	%
	Board-certified neurologist	358	47.8
	Board-certified neurosurgeon	694	92.7
	Endovascular physicians	272	36.3
Personnel	Critical care medicine	162	21.6
	Physical medicine and rehabilitation	113	15.1
	Rehabilitation therapy	742	99.1
	Stroke rehabilitation nurses*	102	13.8
	CT*	742	99.2
	MRI with diffusion	647	86.4
Diagnostic (24/7)	Digital cerebral angiography*	602	80.8
	CTA*	627	84
	Carotid duplex U/S*	257	34.5
	TCD*	121	16.2

	介入治療、インフラ、教	育研究	
Components	Items	n	%
	CEA*	603	80.6
	Clipping of intracranial ancurysm	685	91.5
Surgical	Hematoma removal/draining	689	92
	Coiling of intracranial anenrysm	360	48,1
	IA reperfusion therapy	498	66.5
	Stroke unit*	132	17,6
	ICU	445	59.4
Infrastructure	Operating room staffed 24/7*	451	60.4
	Interventional services coverage 24/7	279	37.3
	Stroke registry*	235	31.7
P.4	Community education*	369	49.4
Education	Professional education*	436	58.6





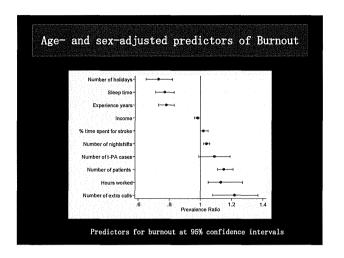


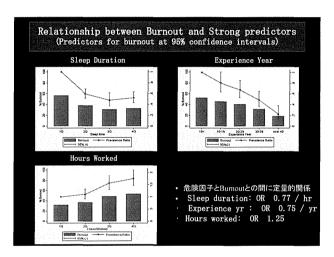


脳卒中診療医の勤務状況と疲労度調査 (平成23年5月)

- 目的:脳卒中治療に携わる医師のQuality of Life (QOL)、 燃え尽き症候群の頻度を測定
- 対象:日本脳神経外科学会専門医、日本神経学会専門医 10,741名 (震災の影響を考慮し、東北3県を除く全国調査)
- 方法:アンケート調査により、脳卒中治療に携わる医師の QOL、燃え尽き症候群の頻度を測定
- 疲弊度の測定
 - 燃え尽き症候群: 日本版 MBI-GS を使用
 - OOL測定: SF-8(SF-36の短縮版)+ MHI-5
- 背景因子

労働時間、睡眠時間、施設要因など合わせて評価





脳卒中患者の退院調査 ーDPC, 電子レセプト情報の活用− (平成23年、24年) 目的:脳卒中治療の大規模データベースの作成と、ベンチ マーキングの可能性 対象: 日本脳神経外科学会、日本神経学会教育訓練施設の中で、脳卒中診療施設調査に参加した 749病院 方法:前年度に治療した脳卒中症例を、ICD 10 codeで抽

- 臨床指標の測定
 - アウトカム指標 (入院死亡率)、プロセス指標 など
- 診療施設調査データ (CSC Score)とアウトカムと関係
- 背景因子

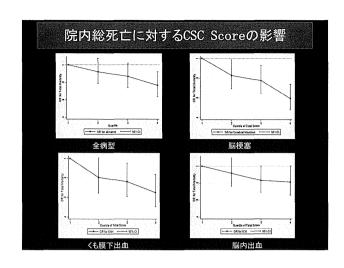
出

- 年齢、性、重症度、病院など合わせて評価
- Hierarchical regression analysis

Demographics ((脳卒中緊急入院 256病院 53,170例)				
	Total	Ischemic stroke	Intracerebral hemorrhage	Subarachnoic hemorrhage	
	(n=53,170)	(n=32.671)	(n=15,699)	(n=4,934)	
Male, n (%)	29,353 (55.2)	18,816 (57.6)	9,030 (57.5)	1,584 (32.1)	
Age, yr mean ± SD	72.5 ± 13.1	74.4 ± 12.2	70.7 ± 13.5	64.7 ± 14.8	
Hypertension, n (%)	39,918 (75.1)	22,531 (69.0)	13,281 (84.6)	4.229 (85.7)	
Diabetes Mellitus, n (%)	13,725 (25.8)	9,318 (28.5)	3,278 (20.9)	1,174 (23.8)	
Hyperlipidemia, n (%)	15,015 (28.2)	11,104 (34.0)	2,529 (16.1)	1,412 (28.6)	
Smoking (n=4,4842)	12,761 (24.0)	8,188 (25.1)	3,540 (22.5)	1,074 (21.8)	
Japan Coma Scale					
0, n (%)	19,635 (36.9)	15,027 (46.0)	3,620 (23.1)	1,024 (20.8)	
I-digit code, n (%)	19,371 (36.4)	12,375 (37.9)	5,934 (37.8)	1,117 (22.6)	
2-digit code, n (%)	6,937 (13.0)	3,396 (10.4)	2,705 (17.2)	852 (17.3)	
3-digit code, n (%)	7,227 (13.6)	1,873 (5.7)	3,440 (21.9)	1,941 (39.3)	
Emergency admission by ambulance, n (%)	31,995 (60.2)	17,336 (53.1)	10,909 (69.5)	3,830 (77.6)	

	Total	Ischemic stroke	Intracerebral hemorrhage	Subarachnoid hemorrhage
	(n=53,170)	(n=32,671)	(n=15,699)	(n=4,934)
Hospital characteristics (CSC scores)				
Total score (25 items)		16.4 ± 3.7	16.6 ± 3.4	16.8 ± 3.2
Personnel with expertise (7 items)		3.7 ± 1.2	3.7 ± 1.2	3.8 ± 1.2
Diagnostic techniques (6 items)		4.4 ± 1.1	4.5 ± 1.0	4.5 ± 1.0
Surgical/interventional Tx (5 items)		4.4 ± 1.1	4.4 ± 1.0	4.5 ± 0.9
Infrastructure (5 items)		2.6 ± 1.1	2.6 ± 1.1	2.7 ± 1.1
Education/research (2 items)		1.4 ± 0.8	1.4 ± 0.8	1.4 ± 0.8

CSC Score の院内死亡への影響 (脳梗塞 緊急入院 32,671例)							
Cerebral Infarction (adjusted by age, gender, and JCS)							
Factor	β	SE	OR	95%CI	P value		
Male	0.2	0.05	1.23	1.12 – 1.35	<0.001		
Age	0.34	0.02	1,4	1.34 - 1.47	<0.001		
CSC total score	-0.03	0.01	0.97	0.96 - 0.99	0.001		
JCS							
normal			1				
one-digit code	0.88	0.07	2.4	2,11 - 2,74	<0.001		
two-digit code	2.01	0.07	7.40	6.47 - 8.60	<0.001		
three-digit code	3.07	0.07	21.62	18.68 - 25.02	<0.001		



J-ACCESS Study 一GIS**の活用**ー (平成23年、24年) 目的:脳卒中治療の大規模データベースを活用し、施設の 脳卒中診療能力と、実効医療圏のサイズがアウトカムに与 える影響を検証 • 対象: - 退院調査に参加した施設の脳卒中症例

- 患者自宅と病院の郵便番号から、GISを用いて運転時間を計算 運転時間の中央値で、実効医療圏を分類 CSC Scoreの中央値で、施設の脳卒中診療能力を分類

- ・アウトカム
 - 入院死亡率
- 背景因子 年齢、性、重症度、病院など合わせて評価
 - Hierarchical regression analysis

実効医物質	寮圏 (Catchmo	ent Area)
全体	脳梗塞	非外傷性脳内出血
全病院の中央値 =19.3分	搬送時間の中央値を	《も膜下出血

脳梗塞	OR	95%C1	P value	脳内出血	OR	95%CI	P valu
Sex	1, 20	1.07-1.34	0.001	Sex	1. 73	1, 52-1, 96	0.001
Age	1. 34	1.27-1.42	<0.001	Age	1, 34	1.28-1.41	<0.001
CSC score	0.97	0, 95-0, 99	-70, 001	CSC score	0, 96	0, 93-0, 98	10, 001
範囲大小	1, 16	1,00-1,35	0,044	範囲大小	1.16	0.98-1.37	0.088
JCS4分類	2. 56	2. 43-2. 71	<0.001	JCS4分類	6. 33	5. 80-6. 91	<0.001
類		L	L	病床数大小	1. 10	1.00-1.22	0.042
	脳卒	中入院死亡率	3	〈も膜下出血	OR	95%CI	P value
				l con	1 46	1 10-1 70	0.001

1. 46 1. 19-1. 79 0. 001 1. 37 1. 29-1. 46 <0. 001 Age 0.91 0.91-0.97 10,001 範囲大小 1.05 0.84-1.32 0.645 JCS4分類 5.09 4.36-5.81

* <u>脳梗塞では、Catchment Areaが大きいほど、死亡率が高い</u>

平成24年度 J-ASPECT Study 退院患者調査 臨床指標速報值

2013年1月29日

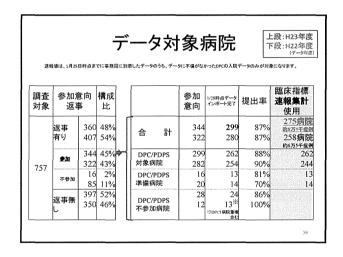
上段:H23年度 下段:H22年度 (データ共享) データ対象病院 連報値は、1月25日時点までに審務局に到着したデータのうち、データに不備がなかったDPCの入院データのみが対象になります。 臨床指標 参加意向 構成 調査 参加 1/28時点データ インポート完了 提出率 速報集計 象饺 HŁ. 意向 使用 275病院 275病院 258病院 360 48% 返事 299 344 合 計 407 54% 322 280 87% 約6万5千症例 262 344 45% 88% 参加 322 43% 16 2% 85 11% 対象病院 282 254 90% 244 757 16 85 397 DPC 16 81% 準備病院 20 70% 14 28 DPC調査 仮事無 350 46% 100% 不参加病院 25

平成24年度 J-ASPECT Study 退院患者調査 臨床指標速報値

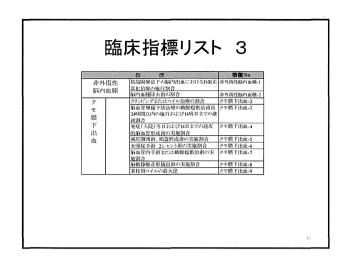
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対象データ データ DPC 入院 外来 提出類型 調査 EFファイル 全月 対象 DPC調査データ 全月 病院 2 3 EFファイル 全月 DPC調査データ 全月 準備 病院 (Dファイル除く) 4 非参加 電子レセプト 病院 データ 全月 平成23年4月~平成24年3月分

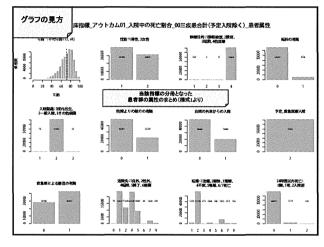


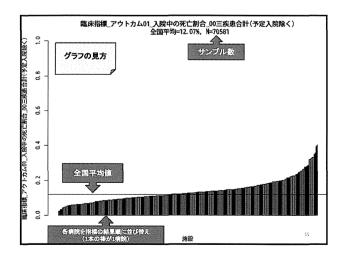


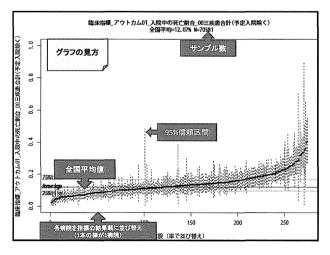


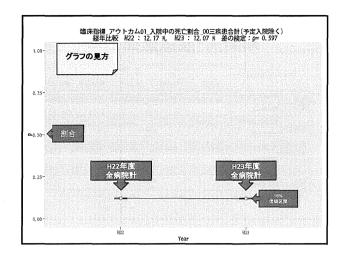


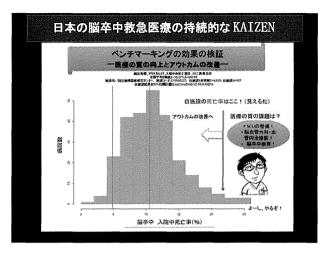


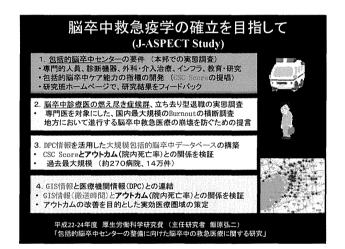


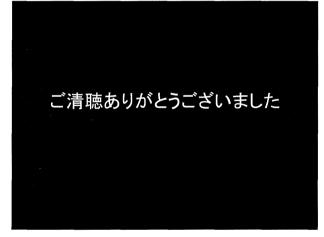












Cross-Sectional Survey of Workload and Burnout among Japanese Physicians Working

in Stroke Care:

The J-ASPECT Study

J-ASPECT Study Group

Short title: Nishimura, J-ASPECT Study

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Journal Subject Code: [8] Epidemiology

Abstract

Background: Burnout is common among physicians and affects the quality of care. We aimed to determine the prevalence of burnout among Japanese physicians working in stroke care and evaluate personal and professional characteristics associated with burnout.

Methods and Results: A cross-sectional design was used to develop and distribute a survey to 11,211 physicians. Physician burnout was assessed using the Maslach Burnout Inventory General Survey. The predictors of burnout and the relationships among them were identified by multivariate logistic regression analysis. A total of 2,724 (25.3%) physicians returned the surveys. After excluding those who were not working in stroke care or did not complete the survey appropriately, 2,564 surveys were analysed. Analysis of the participants' scores revealed that 41.1% were burned out. Multivariate analysis indicated that number of hours worked per week and after-hours calls per week are positively associated with burnout. Hours slept per night, day offs per week, years of experience as well as income are inversely associated with burnout.

Conclusion: The primary risk factors for burnout are heavy workload, short sleep duration, and relatively little experience. Prospective research is required to confirm these findings and develop programs for preventing burnout.

Key words: burnout, J-ASPECT study, Maslach Burnout Inventory, neurosurgery, stroke, tissue plasminogen activator

Introduction

Burnout is a syndrome characterized by emotional exhaustion and depersonalization leading to decreased effectiveness at work.¹ In a recent large survey of U.S. physicians, approximately 40% of neurosurgeons were found to have experienced symptoms of burnout.² Another U.S. study found that approximately 40% of surgeons were burned out,³ conditions that are both associated with medical errors.^{4, 5} However, limited research has been conducted into the relationship between specific demographic and practice characteristics and burnout among physicians working in stroke care, and no survey research has been conducted among Japanese physicians. Such lack of research is troubling, as stroke is the fourth-leading cause of death in Japan, as well as a leading cause of long-term disability.⁶

The objective of this study was to determine the prevalence of burnout among Japanese neurosurgeons and neurologists working in stroke care and evaluate the personal and professional characteristics associated with burnout among this physician population.

Methods

Study design

In March 2011, a cross-sectional survey was sent to 11,211 physicians, among whom were all board-certified members of the Japanese Neurosurgical Society and the Societas Neurologica Japonica working throughout Japan. The survey was developed by J-ASPECT researchers, based on the previous studies on physician burnout^{3, 7, 8}. We sent the survey to a

total of 10,791 physicians via postal mail; however, we could not mail the questionnaire to 420 physicians in the 3 Tohoku prefectures that were affected by Great Tohoku Earthquake. The cover letter accompanying the survey informed the physicians that only physicians who are currently working for stroke care are eligible for the survey, that their participation was voluntary, and that their responses would remain anonymous. They were requested to return the completed survey within 8 weeks. The survey contained items that collected data regarding relevant demographic variables and variables related to practice patterns. (Appendix Survey foam) This study was approved by the Institutional Review Board of the National Cerebral and Cardiovascular Center, Japan.

Measurement of burnout, depression, and quality of life

Burnout among physicians was measured using the Japanese version of the Maslach Burnout Inventory-General Survey (MBI-GS), a validated version of the Maslach Burnout Inventory (MBI), which is currently considered the gold standard for measuring burnout. ⁹⁻¹¹ This 16-item questionnaire contains 3 subscales that evaluate what are considered the 3 major domains of burnout: exhaustion, cynicism (depersonalization), and professional efficacy. Based on the results of previous studies using the MBI-GS, which reported that a high score on the emotional exhaustion and/or depersonalization subscale is an indication of physician burnout, ^{2, 11-13} and the findings from a survey of Japanese population, ¹⁴ an

exhaustion score greater than 4.0 and/or a cynicism (depersonalization) score greater than 2.6 were selected as primary criteria for burnout. The criteria for severe burnout status were an exhaustion score greater than 4.0 and either a cynicism score greater than 2.6 or a professional efficacy score lower than 4.17. The use of at least one additional criterion for severe burnout (i.e. the use of 'exhaustion+1' criteria) was adopted because exhibiting at least one other symptom of burnout besides exhaustion has been reported to be a more appropriate and reliable indicator of severe burnout among the general population ¹⁵ compared to the approaches used in former studies of physician burnout.

For comparison of the study population with the general population of Japanese workers, the MBI-GS scores of the participants were compared with the MBI-GS scores of 2,843 Japanese office workers and 751 civil servants that one of our investigators had previously published.¹⁴

Statistical analysis

Standard descriptive summary statistics were used to determine whether the participants had not been burned out, had been burned out, or had been severely burned out at the time of the survey. Continuous variables were analysed using the t-test for independent and paired samples or the Mann-Whitney U test for independent samples and Wilcoxon's rank test for paired samples. The Wilcoxon type test for trend was used to identify any trends in the data ¹⁶.

Multivariate logistic regression was used to identify demographic and professional

characteristics associated with burnout. Forward selection using the Akaike information criterion (AIC) was used to select the best predictors. Observations from the missing data in the survey questionnaire were not incorporated in this study. The interaction (effect modification) between predictors was determined by evaluating whether the interaction terms were significant. All statistical analyses were conducted using SAS version 9.3 (SAS Institute Inc., Cary, NC, USA) and STATA 11 (STATA Corp., College Station, TX, USA) software, all tests were 2-sided, and all values that had a p-value less than 0.05 were considered significant.

Results

Burnout among Japanese physicians working in stroke care

Figure 1 shows the process used to select the study participants. Of a total of 11,211 board-certified neurosurgeons and neurologists practicing in any prefecture excluding the three prefectures affected by the Tohoku earthquake (n = 469), 2,724 (25.3%) returned the survey. Among these, 2,635 (97.0%) completed the questionnaire appropriately for analysis of their responses. After excluding 71 (2.7%) physicians who reported that they were not working actively in the field of stroke care, a total of 2,564 physicians remained for analysis. At the time that they completed this survey, the study population had been in practice for a mean of 21.7 years, worked a mean of 66.3 hours per week, were on duty a mean of 2.91

nights per month, and received a mean of 2.00 after-hours calls per week. Among these 2,564 physicians 1,525 (59.4%) were employed at 578 teaching hospitals or comprehensive stroke centers (CSC) that were participating in a survey of CSC as part of the J-ASPECT study group. As 3,757 physicians were working at institutes participating in the J-ASPECT study in March 2011, the average response rate among active stroke-care centre physicians was estimated at 40.6%. Other relevant personal characteristics regarding the study population are summarized in Table 1.

To investigate the possibility of selection bias, we checked the address of responders and non-responders. The response rate was not statistically different in all 44 prefectures in this analysis (P=0.683). We also found no statistically significant differences for age, sex, and specialty (neurologist vs neurosurgeon) among early responders compared with late responders.

Review of the participants' MBI-GI scores indicates that 41.1% (N = 1,055) of the study population was burned out and 21.8% (N = 560) was severely burned out at the time of the survey (Figure 2). Consideration of the scores of the study population as representative of the population of Japanese physicians working in stroke care and comparison of their scores with the MBI-GS scores of 2,843 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