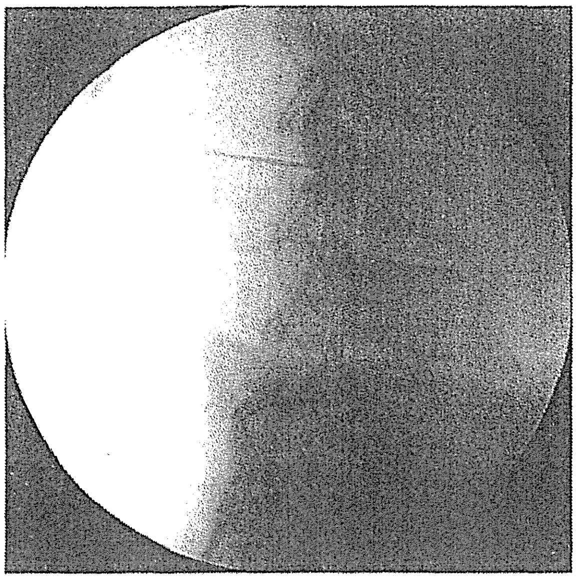

図 2　術中透視画像：L2/3 レベル

位腰椎レベル，あるいは上位と下位腰椎レベルの 2ヵ所に自家血を注入している．頸椎レベルからの髄液漏出も疑う場合は前述の体位をとり，頸胸椎移行部にも穿刺注入をする(図 1)．

穿刺針は腰椎レベルへは 17 G 硬膜外針(TUOHY 針)を用い，頸椎レベルへは 18 G 硬膜外針を用いている．局所麻酔をした後，透視下に正中法を用いて硬膜外穿刺を行う．硬膜外腔の確認は生理食塩水を用いた抵抗消失法で行った後，造影剤を用いて透視下でも確認している(図 2)．

腰椎 L3 レベル以下でのブラッドパッチの場合は，plica mediana dorsalis の存在により注入血液が片側のみに偏ってしまうことがあるので注意が必要である．透視で確認しながら注入し，片側のみに注入されている場合は穿刺し直して対側へも注入するようにしている．

硬膜外穿刺と同時進行で助手に採血をしてもらう．自家血注入量は男性の場合 30〜40 m*l*，女性の場合は 20〜30 m*l* 程度を目安にしている．血液量の 1 割程度造影剤を混ぜて注入することで，どのあたりまで注入した血液が及んだか，硬膜を介して脊髄腔の圧迫はどの程度あるかを透視にて確認することができる．注入血にはヘパリン等は使用しないため凝固しやすく，採取後直ちに注入する必要がある．注入中は患者に頻回に声を掛け，意識状態，注入時痛，下肢への放散痛などを確認しながら施行する．ゆっくりと注入して乱暴な投与は行わない．患者が痛みを強く訴えた場合は無理せずその時点で終了としている．複数ヵ所で髄液漏出を認めた場合は穿刺位置を変えて再度施行する．

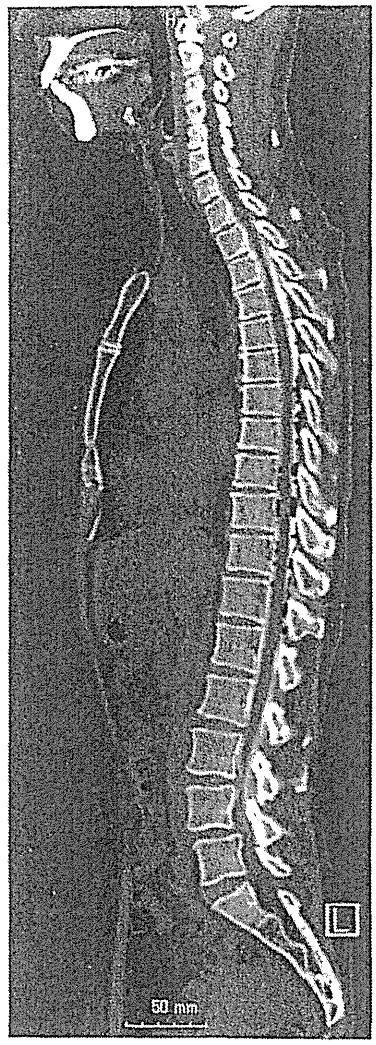

図 3　Th12/L1 レベルより自家血注入直後の CT
注入血液が硬膜外腔に広く分布

ブラッドパッチ終了後はストレッチャーを使用して腹臥位のまま帰室し，少なくとも 15 分間は腹臥位を保ってもらっている．これにより神経根部へ注入した血液が行き渡ることを期待している(図 3)．その後も 1 時間はベッド上臥床とし，それを過ぎてからもしばらくは可能な限り安静を指示している．

発熱などの感染徴候に注意し必要に応じて抗生剤を投与するが，基本的には術後は補液のみで経過観察し，術後 2〜3 日で退院となる．退院後，暫くは自宅にて安静を心掛けてもらい，様子を見ながら徐々に日常生活に戻ってもらうよう指導している．

施術後 1〜2ヵ月間を空けてから症状の改善度を確認し，2 回目のブラッドパッチ療法を施術するか検討する．当院では施術 1〜2 回毎に髄液漏出所見の再評価をするように

している．

ブラッドパッチの終了点について

われわれはブラッドパッチの終了点を，① 症状の軽快，② 症状が残存する場合は再検査をして髄液漏出所見が止まったことを確認すること，のいずれかをもって終了としている．ブラッドパッチ1回あるいは2回の施術で約80%の症例に髄液漏出所見の陰性化を確認しており，少ない施術回数でも髄液漏出所見の軽快が期待できる．

ブラッドパッチの合併症について

頻度の多い症状としては腰背部痛や腰部重圧感である．必要に応じて鎮痛剤，硬膜外ブロックを併用して対応するが，多くは一過性である．椎間板ヘルニア合併症例等の場合は圧迫により神経根症状等が強くなることがあるので術前のMRI評価が必要である．

急激な頭蓋内圧亢進により頭痛，嘔吐が生じることがある．この場合は座位をとると症状が緩和される．グリセロールのような脳圧降下剤を用いることもある．頭蓋内圧が安定してくれば症状は改善してゆく．

注入部の感染に対しては抗生剤を使用する．前述の通り，当院では予防的な抗生剤投与はしていないが，硬膜外膿瘍等に至った症例は経験していない．

硬膜が薄い場合や癒着により硬膜外腔が狭くなっている場合に硬膜穿刺になることがある．そのまま誤注入するとくも膜下出血になる可能性があるが，造影剤を用いて針先が硬膜外腔にあることを注意して確認すれば避けられる合併症である．

注入血液量が多いと圧迫のため下肢の麻痺やしびれ，直腸膀胱障害が出る可能性がある．注入中に患者に声を掛けながら症状の出現に注意している．

その他の合併症として治療後の痙攣や意識障害などの報告がある．

治療成績について

当院では同意が得られた114名に対しブラッドパッチ療法を施行．施術後の評価が可能であった103症例では症状軽快44例42.7%，症状改善58例56.3%，不変1例1%であった．低圧の11症例は1〜2回のブラッドパッチ療法で症状軽快した．そのうちの1例は症状の軽快は認めたものの髄液漏出所見は残存し，低圧の状態が継続する無頭痛症例となった．症状は改善するものの残存する症例もあり，その原因としては残存症状が髄液漏出によるものではなく，椎間関節痛や頸性頭痛，心因性やうつ，ストレスによるものなど他の原因が混在しているためと考えている．特にうつ傾向を示す症例が多く，当科の治療と並行して精神科や心療内科受診を勧め，総合的な改善を期待している．

むすび

ブラッドパッチの実際について当院での方法を中心に紹介した．ブラッドパッチは髄液漏れの閉鎖による症状の改善が期待できるが，その診断には微妙な画像所見を呈する場合もよく経験し診断に苦慮する場合もある．今後も継続してできるだけ低侵襲で確実な診断技術の向上に努めていかなければならない．

また，前述の厚労省研究班の研究分担施設では，発表した診断基準で診断した患者に対してのブラッドパッチの第2項先進医療の申請を準備している（平成23年11月現在）．国会答弁でも取り上げられており，近く先進医療として認可されればその後に健康保険収載手技への道が開かれることとなり，患者の金銭面での負担軽減となる．一刻も早い認可が待たれるところである．

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Original Research

Headache prevalence and long working hours: The role of physical inactivity

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SUMMARY

Objectives: Headaches and long working hours are important issues for workers. This study investigated the association between hours worked and the prevalence of headaches, and how that association varies with physical activity.
Study design: Cross-sectional study with two-stage cluster sampling.
Methods: Using data from a nationally representative sample of households in Japan, people aged 20–65 years who worked ≥35 h/week were studied, and the cross-sectional association between the number of hours worked per week (35–45, 46–55 and >55 h/week) and the prevalence rates of headaches of different severity was evaluated.
Results: Of 721 workers, 307 reported experiencing at least one headache per month. Compared with working 35–45 h/week, the prevalence ratios of severe or disabling headaches among individuals working >55 h/week were 1.38 [95% confidence interval (CI) 1.06–1.78] and 1.63 (95% CI 1.09–2.43), respectively. After stratification by the level of physical activity, the prevalence ratios were greater in the low-physical-activity group: 1.56 (95% CI 1.11–2.19) for severe headaches and 2.20 (95% CI 1.31–3.68) for disabling headaches. The number of hours worked was not associated with headaches in the high-physical-activity group.
Conclusions: Among workers in the general population, long working hours were associated with the prevalence of headaches, and the association may depend on a lack of physical activity.

Introduction

Headache is one of the most prevalent symptoms in the general population.[1–6] A population-based survey in Japan indicated that the prevalence rates of migraine and tension-type headaches that met the International Headache Society criteria were 8.4% and 22.4%, respectively.[1] A telephone survey conducted in the USA revealed that the 1-year

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prevalence of episodic tension-type headaches was 38.3%, and 1-year prevalence of chronic tension-type headaches with an attack frequency of ≥15 attacks per month for at least 6 months was 2.2%.[2]

The prevalence of headaches is high in middle age,[1–3] and thus the economic burden of headaches experienced at work is substantial.[3,7,8]

Previous literature has suggested that long working hours are associated with various health outcomes.[9–14] Several mechanisms have been suggested to explain why long working hours may affect health.[15–17] Long working hours reduce the amount of time for sleep, and lack of sleep results in insufficient recovery from fatigue. This may affect physiological processes such as regulation of blood pressure, hormone secretion and sympathetic nervous system activity, and may result in psychological and physical health complaints. In addition, long working hours may be associated with unhealthy lifestyle factors such as smoking, unhealthy diet, alcohol consumption and sedentary behaviour.[18–20] The unhealthy lifestyles of people who work long hours often include risk factors for headaches, but, until now, no study has evaluated the association between long working hours and headaches.

This study therefore examined the association between hours worked and the prevalence of headaches among full-time workers in a representative sample of households in Japan. The relationship between that association and physical activity was also studied, because physical activity can be altered by interventions.

Methods

Study population

Data were collected from a cross-sectional study in Japan that was conducted between November and December 2007. In this cross-sectional study, 4600 people aged 20–80 years were selected from the entire population of Japan by two-stage cluster sampling: the first cluster was the district of residence (Japan was divided into nine districts for this survey) and the second cluster was the population of the city of residence (five classifications according to population: metropolitan areas, city with a population of >150,000 people, city with a population of 50,000–150,000 people, city with a population of <50,000 people, rural areas). In this survey, a visit was made to the residence of each potential respondent to collect the self-administered questionnaires. Written informed consent was obtained from all participants, and the study was approved by the Institutional Review Board of Fukushima Medical University.

Japanese workers generally start work at approximately 20 years of age and retire at 65 years of age, so data from participants aged 20–65 years old were included in the analyses. Data from individuals who did not complete questions regarding the number of hours worked or headaches were excluded from the analyses. Data from those who worked <35 h/week were also excluded because it was considered more likely that they had serious health conditions. Data were collected using a self-administered questionnaire. The questionnaire included questions covering hours worked per week, age, sex, occupation, presence of comorbid conditions, physical activity and headaches.

Hours worked

Hours worked were evaluated by the following question: 'How many hours did you work in the average week in the past month?' The total hours worked per week were divided into three groups: 35–45, 46–55 and >55 h/week.

In Japan, as statutory working hours are 40 h/week, participants who worked 35–45 h per week were designated as the reference group. In addition, all analyses were undertaken using the exact number of hours worked per week as a continuous variable.

Headaches

The questionnaire asked participants about headaches they experienced. All participants were asked: 'Did you have any headaches during the past month? If so, what was your headache like?' The possible answers were: (1) pressing/tightening; (2) pulsating; (3) severe pain around the eye; and (4) other. Participants who experienced headaches in the past month used a five-point Likert scale to rate the frequency of severe or disabling headaches in the past month, separately, as present 'none of the time', 'little of the time', 'some of the time', 'most of the time' or 'all of the time'. These responses were dichotomized into absence of severe or disabling headaches, which was indicated by responses of 'none of the time' or 'little of the time', and presence of severe or disabling headaches.

Statistical methods

First, the association between hours worked and the occurrence of headaches was evaluated among all participants using a multivariable generalized linear model. Three separate multiple regression analyses were undertaken: one for any headaches, one for severe headaches and one for disabling headaches. The adjusted prevalence ratios (APR) and their 95% confidence intervals (95% CI) were estimated after adjusting for age, sex, occupation and the presence of comorbidities. As headaches are most prevalent in people aged 30–49 years,[1–3] age was divided into three categories: 20–29, 30–49 and 50–65 years. Occupation was categorized as: office clerk; manager or employer; specialist or engineer; or other (sales, service, agriculture, forestry, fisheries, metal mining, transport, communications, etc.). The number of comorbid conditions was included as a categorical variable: none or at least one.

Second, the amount of physical activity per week was studied because it was the only factor that could realistically be improved by an intervention among those used in the first analysis (the others being age, sex, hours worked, occupation and presence of comorbidities). Participants were asked about three categories of exercise: light (e.g. walking, light exercise, etc.), moderate (e.g. walking fast, dancing, golfing, playing tennis, etc.) and vigorous (e.g. jogging, playing basketball, playing football, etc.) with reference to metabolic equivalents

(METS).[21,22] The intensity of exercise was weighted as follows: light = 1, moderate = 3 and vigorous = 5. Additionally, participants were asked the frequency and the amount of time spent in each physical activity per week. The amount of physical activity per week was calculated by multiplying the intensity of exercise or activity, frequency and the time spent in each activity per week, and then all the weekly activities were summed. With the median of the amount of physical activity per week as the criterion, each participant was then put either in the low-physical-activity group or the high-physical-activity group. Subgroup analyses were undertaken using those two groups. The APRs between hours worked and headaches for each type of headache and their 95% CI were estimated for any headaches, severe headaches and disabling headaches by controlling for the same covariates as in the first analysis by subgroups.

In the above analyses, the association between hours worked per week and the prevalence of headaches was examined for each level of headache severity. To examine the association between hours worked per week and the occurrence of headaches using all levels of severity at the same time, the proportional odds model was used. In that model, the categorized severity of headaches was used as the dependent variable, and estimated odds ratios and their 95% CI were adjusted for age, sex, occupation and the presence of comorbidities. The categories for headache severity were, in descending order: severe and disabling, severe but not disabling, mild to moderate, and no headaches (Fig. 1). This analysis was replicated in the low-physical-activity group and in the high-physical-activity group. The data were prepared and analysed with SAS Version 9.1 (SAS Institute Inc, Cary, NC, USA), and two-tailed P-values of 0.05 were regarded as statistically significant.

Results

The survey targeted 4600 people, and 2308 responded to the questionnaire (50.2% response rate). Among the 2308 respondents, 1358 were workers and 991 were full-time workers (710 men and 281 women). Of the 991 working participants, individuals aged >65 years ($n = 60$), those who worked <35 h/week ($n = 185$) and those who did not complete the questions regarding the number of hours worked or headaches ($n = 25$) were excluded, leaving data from 721 individuals (525 men and 196 women) available for analysis.

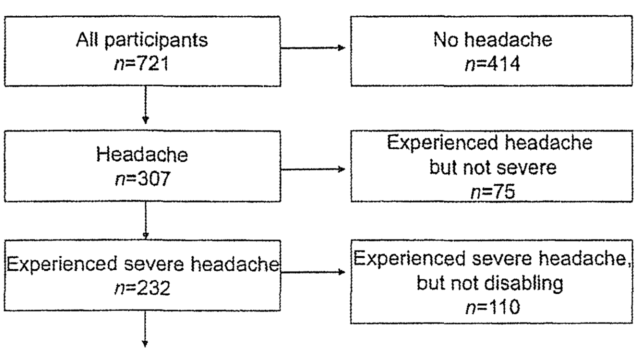

Fig. 1 – Severity of headache in participants (men and women aged 20–65 years in 2007).

Table 1 shows the characteristics of the participants according to hours worked per week. The most commonly reported number of hours worked per week was 40. The mean number of hours worked per week was 49.9 [standard deviation (SD) 11.5] and the median was 48.0 (range 35–100). Among the 721 participants, the number and percentage of types of headaches were as follows: pressing/tightening, $n = 23$ individuals (3%); pulsating, 216 individuals (30%); severe pain around the eye, 34 individuals (5%); and other, 31 individuals (4%).

The numbers of participants and severity of headaches experienced are shown in Fig. 1: severe and disabling, 122 (17%); severe but not disabling, 110 (15%); mild to moderate, 75 (10%); and no headache, 414 (58%). In total, 197 male workers and 110 female workers reported experiencing at least one headache per month. Among them, 149 male workers and 86 female workers reported experiencing severe headaches. A further 76 male workers and 46 female workers reported experiencing disabling headaches. Table 2 shows the associations between hours worked and prevalence ratios of headaches of different severity. The prevalence of any headaches, severe headaches and disabling headaches was higher in women than in men [adjusted prevalence ratio (APR) 1.34 (95% CI 1.12–1.60), APR 1.42 (95% CI 1.13–1.79) and APR 1.65 (95% CI 1.16–2.33), respectively]. There was no significant difference in the prevalence of any headaches between the working-hour groups. A trend test showed a significant trend (P for trend = 0.047) when hours worked was analysed as a continuous variable. Compared with the reference group, the prevalence of severe headaches was

Table 1 – Characteristics of the participants by hours worked at baseline (men and women aged 20–65 years in 2007).

	All ($n = 721$)		Hours worked per week					
			35–45 ($n = 312$)		46–55 ($n = 234$)		>55 ($n = 175$)	
	n	(%)	n	(%)	n	(%)	n	(%)
Sex								
Male	525	(73)	196	(63)	175	(75)	154	(88)
Age (years)								
20–29	95	(13)	40	(13)	30	(13)	25	(14)
30–49	359	(50)	134	(43)	133	(57)	92	(53)
50–65	267	(37)	138	(44)	71	(30)	58	(33)
Occupation								
Office clerk	131	(18)	80	(26)	36	(15)	15	(9)
Employer, manager	74	(10)	31	(10)	23	(10)	20	(11)
Specialist, engineer	220	(31)	90	(29)	81	(35)	49	(28)
Sales, service etc.	296	(41)	111	(36)	94	(40)	91	(52)
Presence of disease under treatment								
Yes	459	(64)	213	(68)	137	(59)	109	(62)
Level of physical activity								
Low	361	(50)	135	(43)	112	(48)	114	(65)
High	360	(50)	177	(57)	122	(52)	61	(35)

Table 2 – Associations between hours worked and prevalence ratios of headaches of different severity (men and women aged 20–65 years in 2007).

	Number of participants who experienced headaches	Prevalence of headaches (%)	Crude prevalence ratio (95% CI)	Adjusted[a] prevalence ratio (95% CI)
All headaches				
Hours worked per week				
35–45	135	43	(ref)	(ref)
46–55	92	39	0.85 (0.60–1.20)	0.93 (0.77–1.12)
>55	80	46	1.10 (0.76–1.60)	1.17 (0.95–1.43)
Test for linear trend[b]			P = 0.283	P = 0.064
Severe headaches				
Hours worked per week				
35–45	94	30	(ref)	(ref)
46–55	70	30	0.99 (0.68–1.43)	1.00 (0.78–1.27)
>55	68	39	1.47 (1.00–2.17)	1.38 (1.06–1.78)
Test for linear trend[b]			P = 0.034	P = 0.032
Disabling headache				
Hours worked per week				
35–45	47	15	(ref)	(ref)
46–55	39	17	1.13 (0.71–1.79)	1.05 (0.72–1.54)
>55	40	23	1.67 (1.04–2.67)	1.63 (1.09–2.43)
Test for linear trend[b]			P = 0.025	P = 0.007

CI, confidence interval.
a Adjusted for age, sex, occupation, physical activity and presence of comorbid disease.
b Total working hours entered into the model as a continuous variable.

significantly higher in the long-working-hours group (APR 1.38, 95% CI 1.06–1.78). Compared with the reference group, the prevalence of disabling headaches was also significantly higher in the long-working-hours group (APR 1.63, 95% CI 1.09–2.43).

Table 3 shows the results for the low-physical-activity group (n = 361) and the high-physical-activity group (n = 360). The median physical activity scores in those two groups were 0.33 METS (range 0.00–1.00) and 5.36 METS (range 1.17–360), respectively. Among the respondents with a low

Table 3 – Stratified analysis of the associations between hours worked and prevalence ratios of headaches (men and women aged 20–65 years in 2007).

	Low physical activity (n = 361)	High physical activity (n = 360)
	Adjusted prevalence ratio[a] (95% CI)	Adjusted prevalence ratio[a] (95% CI)
All headaches		
Hours worked per week		
35–45	(ref)	(ref)
46–55	1.02 (0.77–1.35)	0.86 (0.67–1.12)
>55	1.28 (0.96–1.71)	1.05 (0.74–1.47)
Test for linear trend[b]	P = 0.099	P = 0.746
Severe headaches		
Hours worked per week		
35–45	(ref)	(ref)
46–55	1.09 (0.78–1.51)	0.91 (0.63–1.32)
>55	1.56 (1.11–2.19)	1.16 (0.73–1.84)
Test for linear trend[b]	P = 0.076	P = 0.668
Disabling headaches		
Hours worked per week		
35–45	(ref)	(ref)
46–55	1.09 (0.64–1.88)	1.10 (0.64–1.87)
>55	2.20 (1.31–3.68)	1.04 (0.49–2.20)
Test for linear trend[b]	P = 0.025	P = 0.921

CI, confidence interval.
a Adjusted for age, sex, occupation and presence of comorbid disease.
b Total working hours entered into the model as a continuous variable.

level of physical activity, the prevalence of severe headaches was significantly higher in the long-working-hours group than in the reference group (APR 1.56, 95% CI 1.11–2.19), and the prevalence of disabling headaches was also significantly higher in the long-working-hours group than in the reference group (APR 2.20, 95% CI 1.31–3.68). In the high-physical-activity group, there were no such associations between headaches and the number of hours worked.

In the analysis using the proportional odds model, with the severity of headache as the dependent variable, the adjusted odds ratio (AOR) in the long-working-hours group was significantly higher than that in the reference group (AOR 1.49, 95% CI 1.02–2.18). After stratification by level of physical activity, among those with a low level of physical activity, the AOR was higher in the long-working-hours group than in the reference group (AOR 2.19, 95% CI 1.30–3.69). However, among the respondents with a high level of physical activity, the odds ratio for the long-working-hours group was not significantly different from 1.0.

No significant associations were noticed between either alcohol consumption or smoking status and prevalence of any headaches, severe headaches and disabling headaches (data not shown). Adding smoking status and alcohol consumption to a multivariable model did not attenuate the association between hours worked and the prevalence of headaches. The APRs and the P values for the trend for any headaches, severe headaches and disabling headaches were 1.16 (95% CI 0.95–1.42, P for trend 0.069), 1.36 (95% CI 1.05–1.75, P for trend 0.035), and 1.61 (95% CI 1.08–2.40, P for trend 0.009), respectively.

Discussion

To the authors' knowledge, this is the first study to examine the association between hours worked and headaches experienced, and the first study to examine how that association is related to physical activity. In this study, working for >55 h/week was associated with a higher prevalence of severe or disabling headaches. The strength of that association was greater for more severe headaches. Other studies have examined the association between hours worked and health outcomes such as hypertension,[9,10] diabetes,[11] myocardial infarction,[12] depression,[13] neck/shoulder pain[23] and cognitive function.[14] In addition to the above associations, the present study adds a new dimension to the known effects of working hours on health outcomes.

Several mechanisms may explain the association between working hours and headaches. First, long working hours could cause the contraction of neck and shoulder muscles, especially among office workers. Office work, such as computer use and extended writing or reading, continuously require static contraction of neck and shoulder muscles.[24] As headaches and neck stiffness are frequently associated,[25] long working hours may elevate the risk of experiencing headaches. The results of a recent study[26] that tested the prevalence of self-reported head/neck symptoms among office workers support the present findings. Second, long working hours are related to a lack of sleep[15,17] and a higher prevalence of sleep problems,[16] both of which are associated with headaches.[27,28] Third, long working hours are also associated with high levels of anxiety and depression.[13] Migraines and other severe headaches have been shown to be associated with both depression and anxiety disorders.[28,29] A population-based study in Norway revealed an association between depression and anxiety disorders and several types of headache.[29]

Although an association between long working hours and a high prevalence of headaches was found, it is not clear whether reducing working hours would lower the risk of headaches. Two studies have tested the effect of reducing working hours on health outcomes.[23,32] A study in Sweden compared two interventions, physical exercise or reducing weekly working hours from 40 to 37.5 h, with a reference group among female employees from a public dental healthcare organization.[32] The results suggested that reducing work hours seemed to be more effective if those hours are used for physical exercise. Another interventional study in Norway showed that shortening regular workdays from 7.5 to 6 h reduced the prevalence of neck/shoulder pain among care workers.[25] Although the hours worked at baseline in those studies were shorter than those in the present study, reducing work hours had a distinct effect on health outcomes. However, those studies did not focus on headaches, so the effectiveness of reducing working hours on the risk of headaches should be further explored. People who worked <35 h/week were excluded under the assumption that preexisting chronic health problems may have prevented them from working more hours per week. The association between shorter working hours and the prevalence of headaches in a healthy population should be assessed in future studies.

The results of the present study suggest that physical activity could modify the association between working hours and headaches. Analyses of data that had been stratified by the level of physical activity showed that the number of hours worked was associated with the prevalence of severe or disabling headaches in the low-physical-activity group but not in the high-physical-activity group. The prevalence ratios of severe or disabling headaches among subjects in the low-physical-activity group were higher than those before stratification. Several studies have shown the efficacy of exercise in reducing the prevalence of headaches in the workplace.[25,30–32] A cluster-randomized controlled study in Finland showed that a 15-week programme consisting of light resistance training and guidance resulted in a decrease in the intensity of headaches and neck symptoms among municipal employees who engaged in physically light work.[30] A controlled study in Italy showed the long-term benefit of an educational and physical activity programme consisting of relaxation exercise (once or twice per day) and posture exercise (8–10 times every 2–3 h): the programme decreased the number of days per month that symptomatic municipal office workers developed headaches.[25] These findings support the results of the present study. If long working hours increase the risk of headaches because of greater static contraction of neck and shoulder muscles, a physical programme to reduce muscle strain might be effective for those who work long hours.

As this was a cross-sectional study, it was not possible to address causal associations directly. Specifically, severe headaches may have caused some workers to work shorter hours, and may have caused others to reduce their physical activity but not their long working hours.

In previous studies,[25,30] the participants only comprised office workers at a single organization. In contrast, one strength of the present study was its inclusion of people in a wide variety of occupations from a representative sample of the population of Japan.

In conclusion, working long hours is a risk factor for headaches, and physical activity may reduce the prevalence of headaches in those who work long hours. Future studies are needed to determine the effectiveness of physical activity for reducing the risk of headaches in people who work long hours.

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Ethical approval

Research Ethics Committee of Fukushima Medical University School of Medicine, Japan.

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Competing interests

None declared.

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